

EPA Document# EPA-740-D-25-017 May 2025 Office of Chemical Safety and Pollution Prevention

Draft Risk Evaluation for Dibutyl Phthalate (DBP)

CASRN 84-74-2

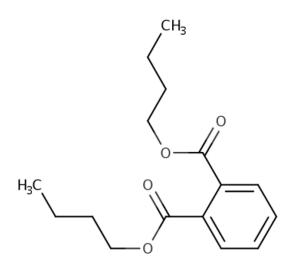




TABLE OF CONTENTS	
ACKNOWLEDGEMENTS	9
EXECUTIVE SUMMARY	. 10
1 INTRODUCTION	16
1.1 Scope of the Risk Evaluation	16
1.1.1 Life Cycle and Production Volume	
1.2 Conditions of Use Included in the Risk Evaluation	20
1.2.1.1 Conceptual Models	
1.2.2 Populations and Durations of Exposure Assessed	
1.2.2.1 Potentially Exposed and Susceptible Subpopulations	
1.3 Organization of the Risk Evaluation	
2 CHEMISTRY AND FATE AND TRANSPORT OF DBP	32
2.1 Summary of Physical and Chemical Properties	
2.2 Summary of Environmental Fate and Transport	33
3 RELEASES AND CONCENTRATIONS OF DBP IN THE ENVIRONMENT	36
3.1 Approach and Methodology	
3.1.1 Manufacturing, Processing, Industrial and Commercial	
3.1.1.1 Crosswalk of Conditions of Use to Occupational Exposure Scenarios	
3.1.1.2 Description of DBP Use for Each OES	
3.1.2 Estimating the Number of Release Days per Year for Facilities in Each OES	
3.1.3 Daily Release Estimation	
3.1.4 Consumer Down-the-Drain and Landfills3.2 Summary of Environmental Releases	
3.2.1 Manufacturing, Processing, Industrial and Commercial	
3.2.2 Weight of Scientific Evidence Conclusions for Environmental Releases from Industrial	44
and Commercial Sources	51
3.2.3 Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for the	
Environmental Release Assessment	62
3.3 Summary of Concentrations of DBP in the Environment	
3.3.1 Weight of Scientific Evidence Conclusions	
3.3.1.1 Surface Water	
3.3.1.2 Ambient Air and Air to Soil Deposition	71
4 HUMAN HEALTH RISK ASSESSMENT	. 73
4.1 Summary of Human Exposures	
4.1.1 Occupational Exposures	
4.1.1.1 Approach and Methodology	
4.1.1.2 Number of Workers and ONUs	
4.1.1.3 Summary of Inhalation Exposure Assessment	
4.1.1.4 Summary of Dermal Exposure Assessment	
4.1.1.5 Weight of Scientific Evidence Conclusions for Occupational Exposure	86
4.1.1.5.1 Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for the	07
Occupational Exposure Assessment	
4.1.2 Consumer Exposures	90

71	4.1.2.1 Summary of Consumer and Indoor Dust Exposure Scenarios and Modeling Approx	
72	and Methodology	
73	4.1.2.2 Modeling Dose Results by COU for Consumer and Indoor Dust	
74	4.1.2.3 Indoor Dust Assessment	
75	4.1.2.4 Weight of Scientific Evidence Conclusions for Consumer Exposure	106
76	4.1.2.5 Strength, Limitations, Assumptions, and Key Sources of Uncertainty for the	
77	Consumer Exposure Assessment	
78	4.1.3 General Population Exposures	
79	4.1.3.1 General Population Screening Level Exposure Assessment Results	117
80	4.1.3.2 Daily Intake Estimates for the U.S. Population Using NHANES Urinary	
81	Biomonitoring Data	
82	4.1.3.3 Overall Confidence in General Population Screening Level Exposure Assessment.	
83	4.1.4 Human Milk Exposures	
84	4.1.5 Aggregate and Sentinel Exposure	
85	4.2 Summary of Human Health Hazard	
86	4.2.1 Background	
87	4.2.2 Non-Cancer Human Health Hazards of DBP	
88	4.2.3 Cancer Human Health Hazards of DBP	
89	4.3 Human Health Risk Characterization	
90	4.3.1 Risk Assessment Approach	
91	4.3.1.1 Estimation of Non-Cancer Risks	
92	4.3.1.2 Estimation of Non-Cancer Aggregate Risks	134
93	4.3.2 Risk Estimates for Workers	134
94	4.3.2.1 Overall Confidence in Worker Risk Estimates for Individual DBP OES	154
95	4.3.2.2 Effect of Duration of Exposure on Dermal Risk Estimates	
96	4.3.2.3 Consideration of Personal Protective Equipment (PPE)	155
97	4.3.2.3.1 Respiratory Protection	155
98	4.3.2.3.2 Glove Protection	156
99	4.3.2.4 Occupational Risk Estimates and Effect of PPE	
100	4.3.3 Risk Estimates for Consumers	166
101	4.3.3.1 Overall Confidence in Consumer Risks	174
102	4.3.4 Risk Estimates for General Population	184
103	4.3.4.1 Overall Confidence in General Population Risk	184
104	4.3.5 Risk Estimates for Potentially Exposed or Susceptible Subpopulations	184
105	4.4 Cumulative Risk Considerations	186
106	4.4.1 Hazard Relative Potency	187
107	4.4.1.1 Relative Potency Factor Approach Overview	188
108	4.4.1.2 Relative Potency Factors	
109	4.4.2 Cumulative Phthalate Exposure: Non-Attributable Cumulative Exposure to DEHP, DE	BP,
110	BBP, DIBP, and DINP Using NHANES Urinary Biomonitoring and Reverse Dosimet	ry 190
111	4.4.2.1 Weight of Scientific Evidence: Non-Attributable Cumulative Exposure to Phthalat	•
112	4.4.3 Estimation of Risk Based on Relative Potency	
113	4.4.4 Risk Estimates for Workers Based on Relative Potency	
114	4.4.4.1 Overall Confidence in Cumulative Worker Risk Estimates	
115	4.4.5 Risk Estimates for Consumers Based on Relative Potency	
116	4.4.5.1 Overall Confidence in Cumulative Consumer Risks	
117	4.4.6 Cumulative Risk Estimates for the General Population	
118	4.5 Comparison of Single Chemical and Cumulative Risk Assessments	

119	5 ENV	IRONMENTAL RISK ASSESSMENT	218
120	5.1 S	ummary of Environmental Exposures	218
121		ummary of Environmental Hazards	
122	5.3 E	nvironmental Risk Characterization	
123	5.3.1	Risk Assessment Approach	
124	5.3.2	Risk Estimates for Aquatic and Terrestrial Species	
125	5.3.3	Environmental Risk Characterization Summary	230
126 127	5.3.4	Overall Confidence and Remaining Uncertainties in Environmental Risk Characterization	236
127	6 UNR	EASONABLE RISK DETERMINATION	
129		uman Health	
130 131	6.1.1 6.1.2	Populations and Exposures EPA Assessed for Human Health Summary of Human Health Effects	
131	6.1.3		
132	6.1.4		
134	6.1.5	Consumers	
135	6.1.6		
136	6.2 E	nvironment	
137	6.2.1	Populations and Exposures EPA Assessed for the Environment	252
138	6.2.2	5	
139	6.2.3		
140	6.3 A	dditional Information Regarding the Basis for the Risk Determination	254
141	REFERE	NCES	270
142	APPEND	ICES	285
143	Appendix	A KEY ABBREVIATIONS AND ACRONYMS	285
144	Appendix	B REGULATORY AND ASSESSMENT HISTORY	288
145	B.1 F	ederal Laws and Regulations	288
146	B.2 St	tate Laws and Regulations	293
147		ternational Laws and Regulations	
148	B.4 A	ssessment History	297
149	Appendix	C LIST OF TECHNICAL SUPPORT DOCUMENTS	299
150	Appendix	D UPDATES TO THE DBP CONDITIONS OF USE TABLE	302
151	Appendix	E CONDITIONS OF USE DESCRIPTIONS	314
152	E.1 M	Ianufacturing – Domestic Manufacturing	314
153	E.2 M	Ianufacturing – Importing	314
154		rocessing – Processing as a Reactant – Intermediate in Plastic Manufacturing	315
155		rocessing – Incorporation into Formulation, Mixture, or Reaction Product – Solvents	
156	(1	Which Become Part of Product Formulation or Mixture) in Chemical and Preparation	
	,	, 1	
157	Ň	Ianufacturing; in Soap, Cleaning Compound, and Toilet Preparation Manufacturing;	215
	N A	, 1	

161	E.6	Processing – Incorporation into Formulation, Mixture, or Reaction Product – Plasticizer in
162		Paint and Coating Manufacturing; Plastic Material and Resin Manufacturing; Rubber
163		Manufacturing; Soap, Cleaning Compound, and Toilet Preparation Manufacturing; Texiles,
164		Apparel, and Leather Manufacturing; in Printing Ink Manufacturing; Basic Organic
165		Chemical Manufacturing; and Adhesive and Sealant Manufacturing
166	E.7	Processing – Incorporation into Article – Plasticizer in Adhesive and Sealant Manufacturing;
167		Building and Construction Materials Manufacturing; Furniture and Related Product
168		Manufacturing; Ceramic Powders; Plastics Product Manufacturing; and Rubber Product
169		Manufacturing
170	E.8	Processing – Repackaging – Laboratory Chemicals in Wholesale and Retail Trade;
171		Plasticizers in Wholesale and Retail Trade; and Plastics Material and Resin Manufacturing 318
172	E.9	Processing – Recycling
173	E.10	Distribution in Commerce
174	E.11	Industrial Use – Non-Incorporative Activities – Solvent, Including in Maleic Anhydride
175		Manufacturing Technology
176	E.12	Industrial Use – Construction, Paint, Electrical, and Metal Products – Adhesives and
177		Sealants
178	E.13	Industrial Use - Construction, Paint, Electrical, and Metal Products - Paints and Coatings 319
179		Industrial Use – Other Uses – Automotive Articles
180		Industrial Use – Other Uses – Lubricants and Lubricant Additives
181		Industrial Use – Other Uses – Propellants
182		Commercial Use – Automotive, Fuel, Agriculture, Outdoor Use Products – Automotive Care
183	2.17	Products
184	E.18	Commercial Use – Construction, Paint, Electrical, and Metal Products – Adhesives and
185	2.10	Sealants
186	E 19	Commercial Use – Construction, Paint, Electrical, and Metal Products – Paints and Coatings 321
187		Commercial Use – Furnishing, Cleaning, Treatment Care Products – Cleaning and
188	L .20	Furnishing Care Products
189	E 21	Commercial Use – Furnishing, Cleaning, Treatment/Care Products – Floor Coverings;
190	1.21	Construction and Building Materials Covering Large Surface Areas Including Stone, Plaster,
191		Cement, Glass, and Ceramic Articles; Fabrics, Textiles, and Apparel
191	F 22	Commercial Use – Furnishing, Cleaning, Treatment Care Products – Furniture and
192	1.22	Furnishings
194	E 23	Commercial Use – Packaging, Paper, Plastic, and Hobby Products – Ink, Toner, and Colorant
195	Ľ.23	Products
196	E 24	Commercial Use – Packaging, Paper, Plastic, and Hobby Products – Packaging (Excluding
197	L.24	Food Packaging), Including Rubber Articles; Plastic Articles (Hard); Plastic Articles (Soft);
197		Other Articles with Routine Direct Contact During Normal Use, Including Ruber Articles;
198		Plastic Articles (Hard)
200	Е 25	Commercial Use – Packaging, Paper, Plastic, and Hobby Products – Toys, Playground, and
	E.23	
201 202	E 26	Sporting Equipment
203		Commercial Use – Other Uses – Laboratory Chemicals
204		Commercial Use – Other Uses – Chemiluminescent Light Sticks
205		Commercial Use – Other Uses – Inspection Penetrant Kit
206		Commercial Use – Other Uses – Lubricants and Lubricant Additives
207	E.31	Consumer Use – Automotive, Fuel, Agriculture, Outdoor Use Products – Automotive Care
208		Products

209	E 32	Consumer Use – Construction, Paint, Electrical, and Metal Products – Adhesives and	
209	E.32	Sealants	. 326
210	Е 22	Consumer Use – Construction, Paint, Electrical, and Metal Products – Paints and Coatings	
211			. 320
	E.34	Consumer Use – Furnishing, Cleaning, Treatment Care Products – Fabric, Textile, and	226
213	E 25	Leather Products	. 326
214	E.35	Consumer Use – Furnishing, Cleaning, Treatment/Care Products – Floor Coverings;	
215		Construction and Building Materials Covering Large Surface Areas Including Stone, Plaste	
216	E A C	Cement, Glass, and Ceramic Articles; Fabrics, Textiles, and Apparel	
217	E.36	Consumer Use – Furnishing, Cleaning, Treatment/Care Products – Cleaning and Furnishing	
218		Care Products	. 327
219	E.37	Consumer Use – Packaging, Paper, Plastic, Hobby Products – Ink, Toner, and Colorant	
220		Products	. 327
221	E.38	Consumer Use – Packaging, Paper, Plastic, Hobby Products – Packaging (Excluding Food	
222		Packaging), Including Rubber Articles; Plastic Articles (Hard); Plastic Articles (Soft); Othe	r
223		Articles with Routine Direct Contact During Normal Use, Including Rubber Articles; Plasti	с
224		Articles (Hard)	. 328
225	E.39	Consumer Use – Packaging, Paper, Plastic, Hobby Products – Toys, Playground, and	
226		Sporting Equipment	. 328
227	E.40	Consumer Use – Other Use – Automotive Articles	. 328
228	E.41	Consumer Use – Other Uses – Chemiluminescent Light Sticks	. 329
229		Consumer Use – Other Uses – Lubricants and Lubricant Additives	
230		Consumer Use – Other – Novelty Articles	
231		Disposal	
232	Appen	dix F DRAFT OCCUPATIONAL EXPOSURE VALUE DERIVATION	. 331
233 234	F.1	Draft Occupational Exposure Value Calculations	. 331

235 LIST OF TABLES

236	Table 1-1. Categories and Subcategories of Use and Corresponding Exposure Scenario in the Risk	
237	Evaluation for DBP	21
238	Table 2-1. Physical and Chemical Properties of DBP	32
239	Table 2-2. Summary of Environmental Fate Information for DBP ^a	34
240	Table 3-1. Crosswalk of Conditions of Use to Assessed Occupational Exposure Scenarios	36
241	Table 3-2. Crosswalk of Assessed Occupational Exposure Scenarios to Conditions of Use	39
242	Table 3-3. Description of the Function of DBP for Each OES	42
243	Table 3-4. Summary of EPA's Annual and Daily Release Estimates for Each OES	45
244	Table 3-5. Summary of Overall Confidence in Environmental Release Estimates by OES	52
245	Table 3-6. Summary of High-End DBP Concentrations in Various Environmental Media from	
246	Environmental Releases	66
247	Table 3-7. Summary of Weight of Scientific Evidence Associated with Each OES	69
248	Table 4-1. Summary of Exposure Monitoring and Modeling Data for Occupational Exposure Scenar	ios
249		76
250	Table 4-2. Summary of Total Number of Workers and ONUs Potentially Exposed to DBP for Each	OES
251		78
252	Table 4-3. Summary of Average Adult Worker Inhalation Exposure Results for Each OES ^a	81
253	Table 4-4. Summary of Average Adult Worker Dermal Exposure Results for Each OES	84
254	Table 4-5. Summary of Assumptions, Uncertainty, and Overall Confidence in Exposure Estimates b	
255	OES	87

256	Table 4-6. Summary of Consumer COUs, Exposure Scenarios, and Exposure Routes	100
257	Table 4-7. Weight of Scientific Evidence Summary Per Consumer COU	
258	Table 4-8. Exposure Scenarios Assessed in General Population Screening Level Analysis	
259	Table 4-9. Summary of the Highest Doses in the General Population through Surface and Drinking	
260	Water Exposure	120
261	Table 4-10. Fish Ingestion for Adults in Tribal Populations Summary	
262	Table 4-11. General Population Ambient Air Inhalation Exposure Summary	
263	Table 4-12. Daily Intake Values and MOEs for DBP Based on Urinary Biomonitoring from the 201'	
264	2018 NHANES Cycle	
265	Table 4-13. Non-Cancer HECs and HEDs Used to Estimate Risks for Acute, Intermediate, and Chro	
266	Exposure Scenarios	
267	Table 4-14. Exposure Scenarios, Populations of Interest, and Hazard Values	
268	Table 4-15. Assigned Protection Factors for Respirators in OSHA Standard 29 CFR 1910.134	
269	Table 4-16. Assigned Protection Factors for Different Dermal Protection Strategies	
270	Table 4-17. Occupational Risk Estimation for Acute Exposure for Female of Reproductive Age	
271	(Benchmark MOE = 30)	158
272	Table 4-18. Occupational Risk Table for DBP	160
273	Table 4-19. Consumer Risk Summary Table	175
274	Table 4-20. Draft Relative Potency Factors Based on Decreased Fetal Testicular Testosterone	189
275	Table 4-21. Cumulative Phthalate Daily Intake (µg/kg-day) Estimates for Women of Reproductive A	sge,
276	Male Children, and Male Teenagers from the 2017–2018 NHANES Cycle	193
277	Table 4-22. Cumulative Phthalate Daily Intake (µg/kg-day) Estimates for Women of Reproductive A	se
278	(16–49 years old) by Race and Socioeconomic Status from the 2017–2018 NHANES	
279	Cycle	195
280	Table 4-23. Risk Summary Table for Female Workers of Reproductive Age Using the RPF Analysis	
281	Table 4-24. Consumer Cumulative Risk Summary Table	212
282	Table 5-1. DBP Concentrations Used in Environmental Risk Characterization	220
283	Table 5-2. Exposure Pathway to Receptors and Corresponding Risk Assessment for the DBP	
284	Environmental Risk Characterization	
285	Table 5-3. Environmental Risk Quotients (RQs) for Aquatic Organisms Associated with Surface Wa	
286	Releases of DBP	227
287	Table 5-4. Environmental Risk Quotients (RQs) for Benthic Organisms Associated with Sediment	
288	Releases of DBP	228
289	Table 5-5. Environmental Risk Quotients (RQs) for Terrestrial Organisms Associated with Air	
290	Deposition to Soil Releases of DBP	
291	Table 5-6. Environmental Risk Summary Table for DBP	231
292	Table 5-7. DBP Evidence Table Summarizing Overall Confidence Derived for Environmental Risk	
293	Characterization	
294	Table 6-1. Supporting Basis for the Unreasonable Risk Determination for Human Health (Occupation	
295	COUs)	
296	Table 6-2. Supporting Basis for the Unreasonable Risk Determination for Human Health (Consumer	
297	COUs)	261
298		

299 LIST OF FIGURES

300	Figure 1-1. TSCA Existing Chemical Risk Evaluation Process	16
	Figure 1-2. Draft Risk Evaluation Document Summary Map	
302	Figure 1-3. DBP Life Cycle Diagram	19

202	
303	Figure 1-4. DBP Conceptual Model for Industrial and Commercial Activities and Uses: Potential
304	Exposure and Hazards
305	Figure 1-5. DBP Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards
306	
307	Figure 1-6. DBP Conceptual Model for Environmental Releases and Wastes: General Population
308	Hazards
309	Figure 1-7. DBP Conceptual Model for Environmental Releases and Wastes: Ecological Exposures and
310	Hazards
311	Figure 3-1. Overview of EPA's Approach to Estimate Daily Releases for Each OES
312	Figure 4-1. Approaches Used for Each Component of the Occupational Assessment for Each OES 75
313	Figure 4-2. Potential Human Exposure Pathways to DBP for the General Population
314	
315	LIST OF APPENDIX TABLES

315 LIST OF AFFENDIA TABLES

316	Table_Apx B-1. Federal Laws and Regulations	288
317	Table_Apx B-2. State Laws and Regulations	293
318	Table_Apx B-3. International Laws and Regulations	
319	Table_Apx B-4. Assessment History of DBP	297
320	Table_Apx D-1. Changes to Categories and Subcategories of Conditions of Use Based on CDR and	
321	Stakeholder Engagement	302
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323 ACKNOWLEDGEMENTS

324 The Assessment Team gratefully acknowledges participation, input, and review comments from U.S. 325 Environmental Protection Agency (EPA or the Agency) Office of Pollution Prevention and Toxics 326 (OPPT) and Office of Chemical Safety and Pollution Prevention (OCSPP) senior managers and science 327 advisors. The Agency is also grateful for assistance from EPA contractors in the preparation of this draft risk evaluation: ERG Inc. (Contract No. 68HERC23D0006, 68HERD20A0002, and GS-00F-079CA); 328 329 General Dynamics Information Technology, Inc. (Contract No. HHSN316201200013W); ICF Inc., LLC 330 (Contract No. 68HERC19D000, 68HERD22A0001, and 68HERC23D0007); SpecPro Professional 331 Services, LLC (Contract No. 68HERC20D0021); and SRC Inc. (Contract No. 68HERH19D0022). 332 333 Docket 334 Supporting information can be found in the public docket, Docket ID (EPA-HQ-OPPT-2018-0503). 335 336 **Disclaimer** 337 Reference herein to any specific commercial products, process, or service by trade name, trademark, 338 manufacturer, or otherwise does not constitute or imply its endorsement, recommendation, or favoring 339 by the United States Government. 340 341 Authors: Mark Myer (Assessment Lead and Environmental Hazard Assessment Co-Lead), Maiko 342 Arashiro and Olivia Wrightwood (General Population Exposure Assessment Co-Leads), Laura Krnavek 343 (Consumer and Indoor Dust Exposure Assessment Lead), Yashfin Mahid (Engineering Assessment 344 Lead), Ryan Sullivan and Juan Bezares Cruz (Physical and Chemical, and Fate Assessment Co-Leads), 345 Ashley Peppriell (Human Health Hazard Assessment Lead), Rachel McAnallen and Carolyn Mottley 346 (Risk Determination Co-Leads), Jennifer Brennan (past Assessment Lead and past Environmental 347 Hazard Assessment Lead), Collin Beachum (Branch Supervisor), Ana Corado (Branch Supervisor), 348 Todd Coleman, Grant Goedjen, Emily Griffin, Bryan Groza, Christelene Horton, Edward Lo, Anthony 349 Luz, Andrew Middleton, Catherine Ngo, Brianne Raccor, Michael Stracka, Nicholas Suek, Dyllan 350 Taylor, and Kevin Vuilleumier. 351 352 Contributors: Yousuf Ahmad, Andrea Amati, Amy Benson, Marcy Card, Nicholas Castaneda, Maggie

Clark, Jone Corrales, Cory Strope, Daniel DePasquale, Lauren Gates, Christina Guthrie, Myles Hodge,
Brandall Ingle-Carlson, Keith Jacobs, June Kang, Grace Kaupas, Yadi Lopez, Kiet Ly, Nerija Orentas,
Andrew Sayer, Shawn Shifflett, Alex Smith, Kelley Stanfield, Cory Strope, Joseph Valdez, Leora

356 Vegosen, Jason P. Wight, and Susanna Wegner.

357

358 **Technical Support:** Mark Gibson and Hillary Hollinger.

359 EXECUTIVE SUMMARY

360 Background

361 EPA has evaluated the health and environmental risks of the chemical dibutyl phthalate (DBP) under the

362 Toxic Substances Control Act (TSCA). In this draft risk evaluation, EPA is preliminarily determining

that DBP presents an unreasonable risk of injury to human health based on identified risk to workers

from 20 conditions of use (COUs) and risk to consumers from 4 COUs, and that DBP presents an

- unreasonable risk to the environment from 1 COU. After considering the risks posed under the COUs,
 EPA did not identify a risk of injury to human health or the environment from the other 19 COUs that
- 367 would drive the unreasonable risk determination for DBP.
- 368

After this draft risk evaluation is informed by public comment and independent, expert peer review,
 EPA will issue a final risk evaluation that includes its determination as to whether DBP presents

- 371 unreasonable risk to human health or the environment based on identified risk of injury from COUs.
- 372

373 DBP is primarily used as a plasticizer in polyvinyl chloride (PVC) in consumer, commercial, and 374 industrial applications-although it is also used in adhesives, sealants, paints, coatings, rubbers, and 375 non-PVC plastics, as well as for other applications. Workers may be exposed to DBP when making 376 these products or otherwise using DBP in the workplace (Section 4.1.1). When it is manufactured or 377 used to make products, DBP can be released into water (Section 3.3.1.1) where because of its properties 378 most will end up in the sediment at the bottom of lakes and rivers. If released into the air (Section 379 3.3.1.2), DBP will attach to dust particles and be deposited on land or into water. Indoors, DBP has the 380 potential over time to be released from products and adhere to dust particles (Section 4.1.2). If it does, 381 people could inhale or ingest dust that contains DBP. 382

Laboratory animal studies have been conducted to study DBP to determine whether it causes a range of non-cancer and cancer health effects on people. After reviewing the available studies, the Agency concludes that there is robust evidence that DBP causes developmental toxicity (a non-cancer human health hazard; Section 4.2.2). The most sensitive adverse developmental effects include effects on the developing male reproductive system consistent with a disruption of androgen action—known as *phthalate syndrome*—which results from decreased fetal testicular testosterone.

388 389

390 EPA is including DBP for cumulative risk assessment (CRA; Section 4.4) along with five other 391 phthalate chemicals that also cause effects on laboratory animals consistent with phthalate syndrome 392 (U.S. EPA, 2023d). Notably, assessments by Health Canada, U.S. Consumer Product Safety 393 Commission (U.S. CPSC), European Chemicals Agency (ECHA), and the Australian National Industrial 394 Chemicals Notification and Assessment Scheme (NICNAS) have reached similar conclusions regarding 395 the developmental effects of DBP. They have also conducted CRAs of phthalates based on these 396 chemicals' shared ability to cause phthalate syndrome. Furthermore, independent, expert peer reviewers 397 endorsed EPA's proposal to conduct a CRA of phthalates under TSCA during the May 2023 meeting of 398 the Science Advisory Committee on Chemicals (SACC) because humans are co-exposed to multiple 399 toxicologically similar phthalates that cause effects on the developing male reproductive system 400 consistent with a disruption of androgen action and phthalate syndrome. In this draft risk evaluation, the 401 Agency has evaluated cumulative exposure to phthalates using human biomonitoring data. Note that 402 these cumulative phthalate exposures cannot be attributed to specific COUs or other sources. This non-403 attributable cumulative exposure and risk, representing the national population, was taken into 404 consideration by EPA in its draft risk evaluation for DBP. By taking into account cumulative risk as 405 other authoritative bodies have done, EPA is confident that it is not underestimating the risk of DBP 406 (Section 4.4).

- In December 2019, EPA designated DBP as a high-priority substance for TSCA risk evaluation and in
- 408 August 2020 released the *Final Scope of the Risk Evaluation for Dibutyl Phthalate (1,2-*
- 409 *benzenedicarboxylic acid, 1,2-dibutyl ester); CASRN 84-74-2* (U.S. EPA, 2020c). This draft risk
- 410 evaluation assesses human health risk to workers, including occupational non-users (ONUs); consumers,
- 411 including bystanders; and the general population exposed to environmental releases. It also assesses risk
- 412 to the environment. Manufacturers report DBP production volumes through the Chemical Data
- 413 Reporting (CDR) rule under the associated CAS Registry Number (CASRN) 84-74-2. The production
- volume for DBP between 2016 and 2019 was between 1 to 10 million pounds (lb) based on the 2020
- 415 CDR data (U.S. EPA, 2020b). EPA describes production volumes as a range to protect confidential
- 416 business information. The Agency has evaluated DBP across its TSCA COUs, ranging from417 manufacture to disposal.
- 417

419 Past assessments of DBP from other government agencies that addressed a broad range of uses, which 420 may have included TSCA and non-TSCA uses, have concluded that DBP can pose risk to human health 421 based on its concentration in products and the environment. Notably, both the U.S. CPSC's and Health 422 Canada's risk assessments included consideration of exposure from children's products as well as from 423 other sources such as personal care products, diet, consumer products, and the environment. However, 424 these past assessments did not specifically consider exposure to workers. In the United States, Canada, 425 and the European Union, the weight fraction of DBP that can be incorporated into children's toys and 426 child care products is limited by regulation (see Appendix B for an overview of existing national and 427 international regulations on DBP). Limits on worker exposure to DBP exist in the United States, 428 Canada, the European Union, Australia, and elsewhere. Additional international regulatory restrictions 429 and labeling requirements for the use of DBP exist.

430

431 In this draft risk evaluation, EPA evaluated risks resulting from exposure to DBP from facilities that 432 manufacture, process, distribute, use or dispose of DBP under industrial and/or commercial COUs 433 subject to TSCA as well as consumer COUs relating to the products resulting from such manufacture 434 and processing. Human or environmental exposure to DBP through uses that are not subject to TSCA 435 (e.g., use in cosmetics, medical devices, food additives) were not specifically evaluated by the Agency 436 in reaching its preliminary determination. This is because these uses are excluded from TSCA's 437 definition of a chemical substance. Thus, conclusions from this evaluation cannot be extrapolated to 438 form conclusions about uses of DBP that are not subject to TSCA and that EPA did not evaluate. 439

440 Determining Unreasonable Risk to Human Health

441 EPA's TSCA existing chemical risk evaluations must determine whether a chemical substance does or 442 does not present unreasonable risk to human health or the environment from its COUs. The 443 unreasonable risk must be informed by the best available science. The Agency, in determining whether 444 DBP presents unreasonable risk to human health, considers risk-related factors as described in its 2024 445 risk evaluation framework rule. Risk-related factors include but are not limited to the type of health 446 effect under consideration; the reversibility of the health effect being evaluated; exposure-related 447 considerations (e.g., duration, magnitude, frequency of exposure); population exposed (including any 448 potentially exposed or susceptible subpopulations); and EPA's confidence in the information used to 449 inform the hazard and exposure values. If an estimate of risk for a specific scenario exceeds the standard 450 risk benchmarks, then the formal determination of whether those risks significantly contribute to the 451 unreasonable risk of DBP under TSCA must be both case-by-case and context-driven.

452

453 EPA evaluated the risks to people from being exposed to DBP at work, indoors, and outdoors. Risks

- 454 were characterized for occupational and consumer exposures to DBP alone as well as in combination
- with the measured cumulative phthalate exposure that is experienced by the U.S. population and that

456 cannot be attributed to a specific use. In its human health evaluation, the Agency used a combination of

- 457 screening level and more refined approaches to assess how people might be exposed to DBP through
 458 breathing or ingesting dust or other particulates, as well as through skin contact. EPA has also authored
- 458 breatning or ingesting dust or other particulates, as well as through skin contact. EPA has also authore 459 a draft cumulative risk technical support document including DBP and five other phthalate chemicals
- 460 that all cause the same health effect—phthalate syndrome (U.S. EPA, 2024k). The CRA takes into
- 461 consideration differences in the ability of each phthalate to cause effects on the developing male
- 462 reproductive system. Use of this "relative potency" across all the phthalates EPA is reviewing that cause
- 463 phthalate syndrome provides a more robust risk assessment of DBP as well as a common basis for
 - 464 adding risk across the six phthalates included in the cumulative assessment.
 - 465

466 In determining whether DBP presents an unreasonable risk of injury to human health, EPA considered 467 the following potentially exposed and susceptible subpopulations (PESS) in its assessment: females of reproductive age; pregnant women; infants; children and adolescents; people who frequently use 468 469 consumer products and/or articles containing high concentrations of DBP; people exposed to DBP in the 470 workplace; people in proximity to releasing facilities, including fenceline communities; and Tribes and 471 subsistence fishers whose diets include large amounts of fish. These subpopulations are PESS because 472 some have greater exposure to DBP per body weight (e.g., infants, children, adolescents) while others 473 may experience exposure from multiple sources or higher exposures than others.

474

475 EPA weighed the scientific evidence in order to determine confidence levels in underlying data sets and 476 risk estimates for human health (see Section 4.3). For the general population, the Agency has robust 477 confidence the risk estimates calculated were conservative and appropriate for a screening level analysis. 478 For workers, EPA has moderate to robust confidence in the risk estimates calculated for inhalation and 479 dermal exposure scenarios and has robust confidence that dermal exposure scenarios represent a 480 conservative upper bound on exposure. For consumers, the Agency has moderate to robust confidence in 481 the risk estimates calculated for inhalation, ingestion, and dermal exposure scenarios and has robust confidence that dermal exposure scenarios represent a conservative upper bound on exposure. 482

483

484 Determining Unreasonable Risk to The Environment

In determining whether DBP presents an unreasonable risk of injury to the environment, EPA considered the following groups of organisms in its assessment: aquatic vertebrates, aquatic invertebrates, benthic invertebrates, aquatic plants and algae, terrestrial mammals, soil invertebrates, and terrestrial plants. The Agency weighed the scientific evidence in order to determine confidence levels in underlying data sets and risk estimates for the environment (see Section 5.3.4). EPA has slight to robust confidence in its environmental data and risk estimates depending on the source of environmental release information for each COU (see Section 5.3.4).

492

493 EPA has preliminarily determined that DBP presents unreasonable risk of injury to the environment 494 based on one COU, Disposal, due to chronic exposure to aquatic vertebrates. These findings are based 495 on wastewater release from treatment plants and is inclusive of wastewater treatment removal of DBP. 496 EPA has robust confidence in the exposure data underlying environmental releases to water for the 497 Disposal COU, as they are based on reported data at plant outfalls from the Discharge Monitoring 498 Report (DMR) database (see Section 3.2). Furthermore, EPA has robust confidence in the hazard data 499 underlying environmental toxicity estimates from DBP exposure in aquatic vertebrates as they are based 500 on high quality toxicity studies (see Section 5.2). EPA has robust overall confidence in the environmental risk characterization for the Disposal COU, and EPA is preliminarily determining that the 501 Disposal COU may contribute significantly to unreasonable risk to the environment for DBP due to 502

- 502 Disposar COO may contribute significantly to unreasonable fisk to the v 503 chronic exposures to aquatic vertebrates from wastewater discharge.
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505 Summary, Considerations, and Next Steps

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506 EPA has preliminarily determined that the following 24 COUs may significantly contribute to unreasonable risk to human health:

- Manufacturing domestic manufacturing (dermal and inhalation)
- Manufacturing importing (dermal and inhalation)
- Processing processing as a reactant intermediate in plastic manufacturing (dermal and inhalation)
- Processing incorporation into formulation, mixture, or reaction product solvents (which become part of product formulation or mixture) in chemical product and preparation
 manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and printing ink manufacturing (dermal and inhalation)
 - Processing incorporation into formulation, mixture, or reaction product pre-catalyst manufacturing (dermal and inhalation)
- Processing incorporation into formulation, mixture, or reaction product plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic organic chemical manufacturing; and adhesive and sealant manufacturing (dermal)
- Processing incorporation into article plasticizer in adhesive and sealant manufacturing;
 building and construction materials manufacturing; furniture and related product manufacturing;
 ceramic powders; plastics product manufacturing; and rubber product manufacturing (dermal)
 - Processing repackaging laboratory chemicals in wholesale and retail trade; plasticizers in wholesale and retail trade; and plastics material and resin manufacturing (dermal and inhalation)
 - Industrial use non-incorporative activities solvent, including in maleic anhydride manufacturing technology (dermal and inhalation)
- Industrial use construction, paint, electrical, and metal products adhesives and sealants (dermal)
- Industrial use construction, paint, electrical, and metal products paints and coatings (dermal and inhalation)
 - Industrial use other uses lubricants and lubricant additives (dermal)
 - Commercial use automotive, fuel, agriculture, outdoor use products automotive care products (dermal)
 - Commercial use construction, paint, electrical, and metal products adhesives and sealants (dermal)
- Commercial use construction, paint, electrical, and metal products paints and coatings (dermal and inhalation)
- Commercial use furnishing, cleaning, treatment care products cleaning and furnishing care products (dermal)
- Commercial use packaging, paper, plastic, toys, hobby products ink, toner, and colorant products (dermal and inhalation)
- Commercial use other uses laboratory chemicals (dermal)
- Commercial use other uses inspection penetrant kit (dermal and inhalation)
- Commercial use other uses lubricants and lubricant additives (dermal)
- Consumer use automotive, fuel, outdoor use products automotive care products (dermal)
- Consumer use construction, paint, electrical and metal products adhesives and sealants (dermal)
- Consumer use construction, paint, electrical and metal products paints and coatings (dermal)

- Consumer use furnishing, cleaning, treatment/care products cleaning and furnishing care products (dermal)
- 554 EPA has preliminarily determined that one COU may significantly contribute to unreasonable risk to the 555 environment:
- Disposal (aquatic vertebrates)
- 557 EPA did not preliminarily identify an unreasonable risk of injury to human health and the environment 558 from the following 19 COUs:
- Processing recycling
- Distribution in commerce
- Industrial use other uses automotive articles
- Industrial use other uses propellants
- Commercial use furnishing, cleaning, treatment care products floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
- Commercial use furnishing, cleaning, treatment care products furniture and furnishings
- Commercial use packaging, paper, plastic, toys, hobby products packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)
- Commercial use packaging, paper, plastic, toys, hobby products toys, playground, and sporting equipment
- Commercial use other uses automotive articles
- Commercial use other uses chemiluminescent light sticks
- Consumer use furnishing, cleaning, treatment/care products fabric, textile, and leather
 products
- Consumer use furnishing, cleaning, treatment/care products floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
- Consumer use packaging, paper, plastic, hobby products ink, toner, and colorant products
- Consumer use packaging, paper, plastic, hobby products packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)
- Consumer use packaging, paper, plastic, hobby products toys, playground, and sporting equipment
- Consumer use other uses automotive articles

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- Consumer use other uses chemiluminescent light sticks
 - Consumer use other uses lubricants and lubricant additives
 - Consumer use other uses novelty articles
- 589 This draft risk evaluation has been released for public comment and will undergo independent, expert
- 590 scientific peer review. EPA seeks public comment on all aspects of this draft risk evaluation. In
- 591 particular, the Agency seeks comment on whether and how exposure controls and personal protective
- equipment (PPE; *e.g.*, respirators, gloves) are used for each of the COUs. EPA also seeks information
- that could be used to replace upper-bound or screening level assumptions, particularly for COUs that
- may significantly contribute to unreasonable risk for DBP. EPA will issue a final DBP risk evaluation
- after considering input from the public and peer reviewers. If in the final risk evaluation the Agency

- determines that DBP presents unreasonable risk to human health or the environment, EPA will initiate regulatory action to the extent necessary so that DBP no longer presents such risk. 596
- 597

598 **1 INTRODUCTION**

EPA has evaluated dibutyl phthalate (DBP) pursuant to section 6(b) of the Toxic Substances Control Act
 (TSCA). DBP is primarily used as a plasticizer in polyvinyl chloride (PVC) in consumer, commercial,

and industrial applications—although it is also used in adhesives, sealants, paints, coatings, rubbers, and

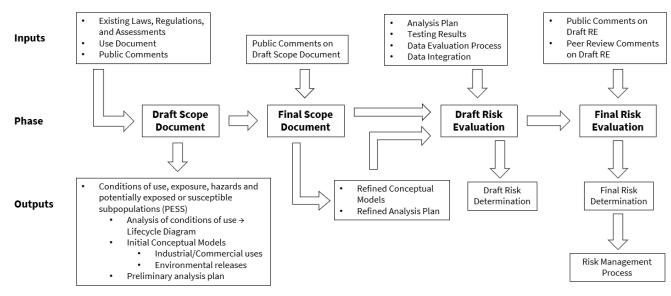
non-PVC plastics, as well as for other applications. Section 1.1 summarizes the scope of this draft DBP
 risk evaluation and provides information on production volume, a life cycle diagram (LCD), TSCA

604 conditions of use (COUs), and conceptual models used for DBP. Section 1.3 presents the organization of

- 605 this draft risk evaluation.
- 606

Figure 1-1 describes the major inputs, phases, and outputs/components of the TSCA risk evaluation
 process, from scoping to releasing the final risk evaluation.





610

611 Figure 1-1. TSCA Existing Chemical Risk Evaluation Process

612 **1.1 Scope of the Risk Evaluation**

613 EPA evaluated risk to human and environmental populations for DBP. Specifically for human 614 populations, the Agency evaluated risk to workers including occupational non-users (ONUs) via 615 inhalation routes; risk to workers including ONUs via dermal routes; risk to consumers via inhalation, dermal, and oral routes; and risk to bystanders via the inhalation route. Additionally, EPA incorporated 616 617 the following potentially exposed and susceptible populations (PESS) into its assessment—females of reproductive age, pregnant women, infants, children and adolescents, people who frequently use 618 consumer products and/or articles containing high-concentrations of DBP, people exposed to DBP in the 619 620 workplace, and tribes whose diets include large amounts of fish. As described further in Section 4.1.3, EPA assessed risks to the general population, which considered risk from exposure to DBP via oral 621 622 ingestion of surface water, drinking water, fish, and soil from air to soil deposition. For environmental 623 populations, the Agency evaluated risk to aquatic species via water and sediment as well as risk to 624 terrestrial species via soil and, qualitatively, through trophic transfer.

625

626 Consistent with EPA's Draft Proposed Approach for Cumulative Risk Assessment (CRA) of High-

627 Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act

628 (U.S. EPA, 2023d), EPA has also authored a draft cumulative risk technical support document (TSD) of

629 DBP and five other toxicologically similar phthalates (*i.e.*, diethylhexyl phthalate [DEHP], dicyclohexyl

630 phthalate [DCHP], diisobutyl phthalate [DIBP], butyl benzyl phthalate [BBP], and diisononyl phthalate [DINP]) that are also being evaluated under TSCA based on a common toxicological endpoint (*i.e.*, 631 phthalate syndrome, which results from decreased fetal testicular testosterone) (U.S. EPA, 2025x). This 632 633 TSD is also referred to as the "revised draft CRA TSD" in this draft risk evaluation. The cumulative 634 analysis takes into consideration differences in phthalate potency to cause effects on the developing 635 male reproductive system. Use of relative potency across the phthalates provides a more robust risk assessment of DBP and a common basis for adding risk across the cumulative chemicals. Numerous 636 637 other regulatory agencies—Health Canada, U.S. Consumer Product Safety Commission (U.S. CPSC), 638 European Chemicals Agency (ECHA), and the Australian National Industrial Chemicals Notification 639 and Assessment Scheme (NICNAS)-have assessed phthalates for cumulative risk. Further, EPA's 640 proposal to conduct a cumulative risk assessment (CRA) of phthalates under TSCA was endorsed by the 641 Science Advisory Committee on Chemicals (SACC) as the best available science because humans are 642 co-exposed to multiple toxicologically similar phthalates that cause effects on the developing male 643 reproductive system consistent with a disruption of androgen action and phthalate syndrome. As described further in Section 4.4, cumulative risk considerations focus on acute duration exposures to the 644 most susceptible subpopulations: female workers and consumers of reproductive age (16-49 years) as 645 646 well as male infants and male children (3-15 years) exposed to consumer products and articles.

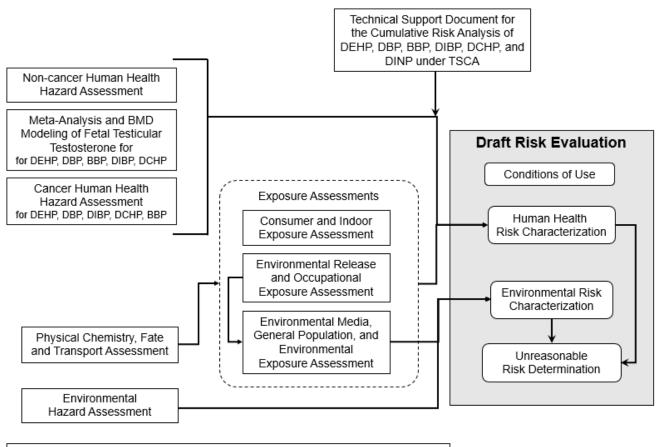
647

The draft DBP risk evaluation comprises a series of technical support documents. Each technical support document contains sub-assessments that inform adjacent, "downstream" TSDs. A basic diagram showing the layout and relationship of these assessments is provided below in Figure 1-2. High-level summaries of each relevant TSD are presented throughout this draft risk evaluation. Detailed information for each TSD can be found in the corresponding documents, which are listed with citations along with supplemental files in Appendix C.

654
655 These TSDs leveraged the data and information sources already identified in the *Final Scope of the Risk*656 *Evaluation for Dibutyl Phthalate (1,2-benzenedicarboxylic acid, 1,2-dibutyl ester); CASRN 84-74-2*657 (also called the "final scope for DBP" or "final scope document") (U.S. EPA, 2020c). OPPT conducted

a comprehensive search for "reasonably available information" to identify relevant DBP data for use in
 the risk evaluation. The approach used to identify specific relevant risk assessment information was
 discipline-specific and is detailed in the *Draft Systematic Review Protocol for Dibutyl Phthalate (DBP)*

661 (U.S. EPA, 2025w), or as otherwise noted in the relevant TSDs.



Chemical-specific systematic review protocol and data extraction files

663 Figure 1-2. Draft Risk Evaluation Document Summary Map

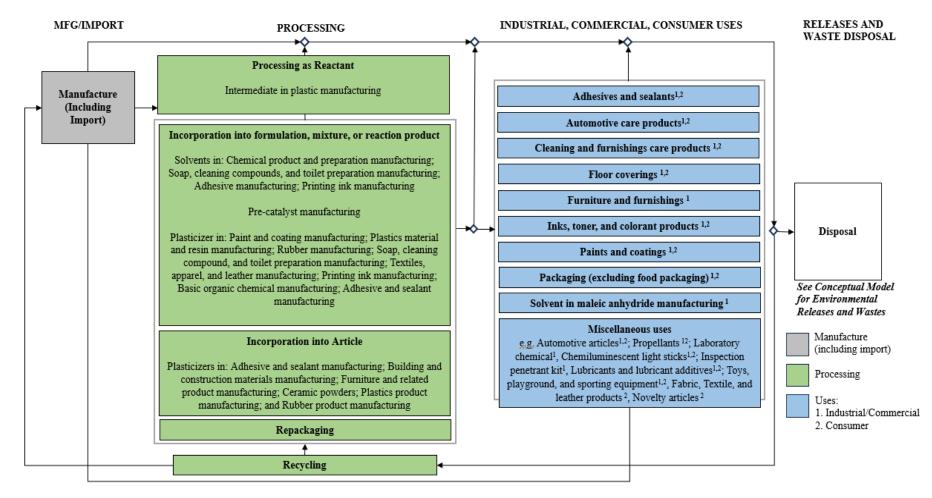
1.1.1 Life Cycle and Production Volume

665 The LCD shown in Figure 1-3 depicts the COUs that are within the scope of the risk evaluation, during various life cycle stages, including manufacturing, processing, distribution, use (industrial, commercial, 666 consumer), and disposal. The information in the LCD is grouped according to the Chemical Data 667 668 Reporting (CDR) processing codes and use categories (including functional use codes for industrial uses 669 and product categories for industrial and commercial uses). The CDR Rule under TSCA section 8(a) 670 (see 40 CFR Part 711) requires certain U.S. manufacturers (including importers) to provide EPA with information on the chemicals they manufacture or import into the United States. EPA collects CDR data 671 672 approximately every four years.

673

664

- 674 EPA included descriptions of the industrial, commercial, and consumer use categories identified from
- 675 the 2020 CDR in the LCD (Figure 1-3) (U.S. EPA, 2020b). The descriptions provide a brief overview of
- 676 the use category; the *Draft Environmental Release and Occupational Exposure Assessment for Dibutyl*
- 677 *Phthalate* (U.S. EPA, 2025q) contains more detailed descriptions (*e.g.*, process descriptions, worker
- activities, process flow diagrams, equipment illustrations) for each manufacturing, processing, use, and
- 679 disposal category.



680

681 Figure 1-3. DBP Life Cycle Diagram

- 682 See Table 1-1 for categories and subcategories of conditions of use. Activities related to distribution (*e.g.*, loading, unloading) will be considered
- throughout the DBP life cycle, as well as qualitatively through a single distribution scenario.

The production volume for DBP between 2016 and 2019 was between 1 to 10 million pounds (lb) based on the latest 2020 CDR data (U.S. EPA, 2020b). EPA described production volumes as a range to

686 protect production volume data claimed as confidential business information (CBI). For the 2016 and

- 687 2020 CDR cycle, collected data included the company name, volume of each chemical
- 688 manufactured/imported, the number of workers at each site, and information on whether the chemical 689 was used in the commercial, industrial, and/or consumer sector(s).
- 690

In the 2020 CDR, one site, Dystar LP in Reidsville, North Carolina, reported a production volume of

51,852 lb for domestic manufacturing of DBP for the 2019 CDR reporting year (U.S. EPA, 2020b).

They had previously reported between 0 and 25,021 lb DBP manufactured between 2016 to 2018.

Polymer Additives, Inc. in Bridgeport, NJ reported manufacture of DBP but claimed their PV as CBI.

- An additional three sites (4 sites total) reported their site activities as CBI; EPA assumed that these sites may manufacture DBP. This resulted in a total of five potential DBP manufacturing sites, two sites with known manufacturing activities and three sites with CBI activities.
- 698

699 EPA calculated the production volume for the four sites with CBI production volumes using a uniform 700 distribution set within the national PV range for DBP. EPA calculated the bounds of the range by taking 701 the national aggregate PV range reported in CDR (1-10 million lb) and subtracting out the PVs that 702 belonged to sites with known volumes (both manufacturing and import). Then, for each bound of the PV 703 range, EPA divided the value by the number of sites with CBI PVs for DBP. Based on the known PVs 704 from importers and manufacturers, the total calculated PV associated with the four sites with CBI PVs is 705 109,546 to 5,252,403 lb/year. Based on this (and after converting lb to kg), EPA set a uniform 706 distribution for the PV for the four sites with CBI PVs with lower bound of 49,689 kg/year, and an 707 upper-bound of 2,382,450 kg/year. For more information regarding DBP's PV for CDR reporters, refer

to Section 3.1 of the *Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025q).

710 **1.2 Conditions of Use Included in the Risk Evaluation**

The final scope for DBP (U.S. EPA, 2020c) identified and described the life cycle stages, categories,
and subcategories that comprise TSCA COUs that EPA planned to consider in the risk evaluation. All
COUs for DBP included in this draft risk evaluation are reflected in the LCD (Figure 1-3) and
conceptual models (Section 1.2.1.1). Table 1-1 below presents all COUs for DBP.

715

716 In this draft risk evaluation, EPA made updates to the COUs listed in the final scope document (U.S. 717 EPA, 2020c). These updates reflect EPA's improved understanding of the COUs based on further 718 outreach, public comments, and updated industry code names under the CDR for 2020. Updates include 719 (1) additions and clarification of COUs based on new reporting in CDR for 2020 or information received 720 from stakeholders; (2) consolidation of redundant COUs from the processing life stage based on 721 inconsistencies found in CDR reporting for DBP processing and uses, and communications with 722 stakeholders about the use of DBP in industry; and (3) correction of typos or edits for consistency. Appendix C provides a complete list of updates to the COUs between the final scope document and the 723 724 draft risk evaluation and an explanation of these updates. EPA may further refine the COU descriptions 725 for DBP that are included in the draft risk evaluation when the final risk evaluation for DBP is 726 published, based upon further outreach, peer-review comments, and public comments. Table 1-1 727 presents the revised COUs that were included and evaluated in this draft risk evaluation for DBP.

Table 1-1. Categories and Subcategories of Use and Corresponding Exposure Scenario in the Risk Evaluation for DBP

Life-Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Manufacturing	Domestic manufacturing	Domestic manufacturing	(<u>U.S. EPA, 2020a, 2019b</u>)
8	Importing	Importing	(<u>U.S. EPA, 2019b</u>)
	Processing as a reactant	Intermediate in plastic manufacturing	(<u>W.R. Grace, 2024</u>)
	Incorporation into formulation, mixture, or reaction product	Solvents (which become part of product formulation or mixture) in chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and printing ink manufacturing	(<u>NLM, 2024; U.S. EPA, 2019b;</u> <u>Kosaric, 2011; Ash and Ash, 2009</u>)
		Pre-catalyst manufacturing	(<u>W.R. Grace, 2024</u>)
Processing		Plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic organic chemical manufacturing; and adhesive and sealant manufacturing	
	Incorporation into article	Plasticizer in adhesive and sealant manufacturing; building and construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing	(<u>NLM, 2024; NASA, 2020; U.S.</u> <u>EPA, 2020a; AIA, 2019; U.S. EPA,</u> <u>2019b; SpecialChem, 2018</u>)
	Repackaging	Laboratory chemicals in wholesale and retail trade; plasticizers in wholesale and retail trade; and plastics material and resin manufacturing	(<u>U.S. EPA, 2020a</u> , <u>2019b</u>)
	Recycling	Recycling	(<u>U.S. EPA, 2019b</u>)
Distribution in Commerce	Distribution in commerce		
Industrial Use	Non-incorporative activities	Solvent, including in maleic anhydride manufacturing technology	(<u>Huntsman, 2024;</u> <u>U.S. EPA, 2020a,</u> <u>2019b</u>)

Life-Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
	Construction, Paint, Electrical, and Metal Products	Adhesives and sealants	(<u>NASA, 2020; MEMA, 2019;</u> <u>Sendesi et al., 2017; Whelton et al.,</u> <u>2017; Ford Motor Company, 2015a</u>)
Industrial Use		Paints and coatings	(<u>Carboline, 2021; NASA, 2020</u>)
industrial Ose	Other uses	Automotive articles	(MEMA, 2019)
		Lubricants and lubricant additives	(<u>MEMA, 2019</u>)
		Propellants	(<u>Liang et al., 2021;</u> <u>U.S. EPA,</u> 2020a; <u>AIA, 2019</u>)
	Automotive, fuel, agriculture, outdoor use products	Automotive care products	(<u>U.S. EPA, 2020a</u>)
	Construction, paint, electrical, and metal products	Adhesives and sealants	(<u>U.S. EPA, 2020a; MEMA, 2019;</u> <u>U.S. EPA, 2019b; Sendesi et al.,</u> <u>2017; Whelton et al., 2017</u>)
		Paints and coatings	(<u>NLM, 2024; U.S. EPA, 2020a</u> , 2019b; <u>GoodGuide, 2011;</u> <u>Streitberger et al., 2011</u>)
	Furnishing, cleaning, treatment care products	Cleaning and furnishing care products	(<u>NLM, 2024; U.S. EPA, 2019b;</u> <u>GoodGuide, 2011</u>)
Commercial Use		Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel	(<u>U.S. EPA, 2020a</u> , <u>2019b</u> ; <u>Sendesi et</u> al., 2017; <u>Whelton et al., 2017</u>)
		Furniture and furnishings	(<u>U.S. EPA, 2019b</u>)
	Packaging, paper, plastic, toys, hobby	Ink, toner, and colorant products	(<u>NLM, 2024; U.S. EPA, 2019b</u>)
	products	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)	(<u>NLM, 2024;</u> <u>U.S. EPA, 2020a</u> , <u>2019b</u>)
		Toys, playground, and sporting equipment	(<u>U.S. EPA, 2019a</u> , <u>f</u>)
	Other uses	Automotive articles	(<u>MEMA, 2019</u>)
		Chemiluminescent light sticks	(<u>U.S. EPA, 2020d</u>)

Life-Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Commercial Use	Other uses	Laboratory chemicals	(<u>NASA, 2020;</u> <u>U.S. EPA, 2020d</u> , <u>2019b</u>)
		Inspection penetrant kit	(<u>U.S. EPA, 2020d; AIA, 2019</u>)
		Lubricants and lubricant additives	(<u>NASA, 2020; U.S. EPA, 2020d;</u> <u>MEMA, 2019</u>)
	Automotive, fuel, agriculture, outdoor use products	Automotive care products	(<u>U.S. EPA, 2020a</u>)
	Construction point	Adhesives and sealants	(<u>MEMA, 2019;</u> <u>U.S. EPA, 2019b</u>)
	Construction, paint, electrical, and metal products	Paints and coatings	(NLM, 2024; U.S. EPA, 2020a, 2019b; GoodGuide, 2011; Streitberger et al., 2011)
	Furnishing, cleaning, treatment care products	Fabric, textile, and leather products	(<u>WSDE, 2023</u> ; <u>U.S. EPA, 2020e</u> , <u>2019b</u>)
		Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel	(<u>U.S. EPA, 2020a</u> , <u>2019b</u>)
Consumer Use		Cleaning and furnishing care products	(<u>NLM, 2024; U.S. EPA, 2019b;</u> <u>GoodGuide, 2011</u>)
	Packaging, paper, plastic, toys, hobby products	Ink, toner, and colorant products	(<u>U.S. EPA, 2019b</u>)
		Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)	(<u>NLM, 2024;</u> <u>U.S. EPA, 2019b</u>)
		Toys, playground and sporting equipment	(<u>U.S. EPA, 2019a</u> , <u>f</u>)
	Other Uses	Automotive articles	(<u>MEMA, 2019</u>)
		Chemiluminescent light sticks	(<u>U.S. EPA, 2020d</u>)
		Lubricants and lubricant additives	(<u>MEMA, 2019</u>)
		Novelty articles	(<u>Sipe et al., 2023; Stabile, 2013</u>)
Disposal	Disposal	Disposal	(<u>U.S. EPA, 2019b</u>)

Life-Cycle Stage ^a	Category ^b	Subcategory ^c	Reference (s)
 "Industrial imported) "Commerce a commerce as furniture Although I this document 	or processed. cial use" means the use of cial enterprise providing s r use" means the use of a c e or clothing) when sold t EPA has identified both in	t which one or more chemicals or mixtur a chemical or a mixture containing a che	emical (including as part of an article) in ical (including as part of an article, such ir use. urposes of distinguishing scenarios in
² These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent COUs of DBP in industrial and/or commercial settings.			
These subcategories represent more specific activities within the life cycle stage and category of the COUs of DBP.			

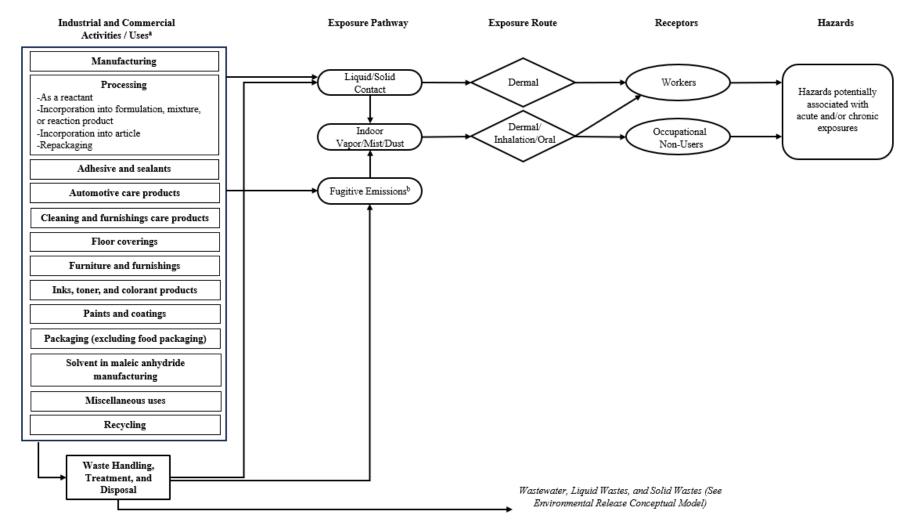
The conceptual model in Figure 1-4 presents the exposure pathways, exposure routes, and hazards to human populations from industrial and commercial activities and uses of DBP. There is potential for exposures to workers and/or ONUs via inhalation and via dermal contact. The conceptual model also includes potential ONU dermal exposure to DBP from mists and dusts deposited on surfaces. EPA

evaluated activities resulting in exposure associated with distribution in commerce (*e.g.*, loading,

unloading) throughout the various life cycle stages and COUs (*e.g.*, manufacturing, processing,

737 industrial use, commercial use, and disposal).

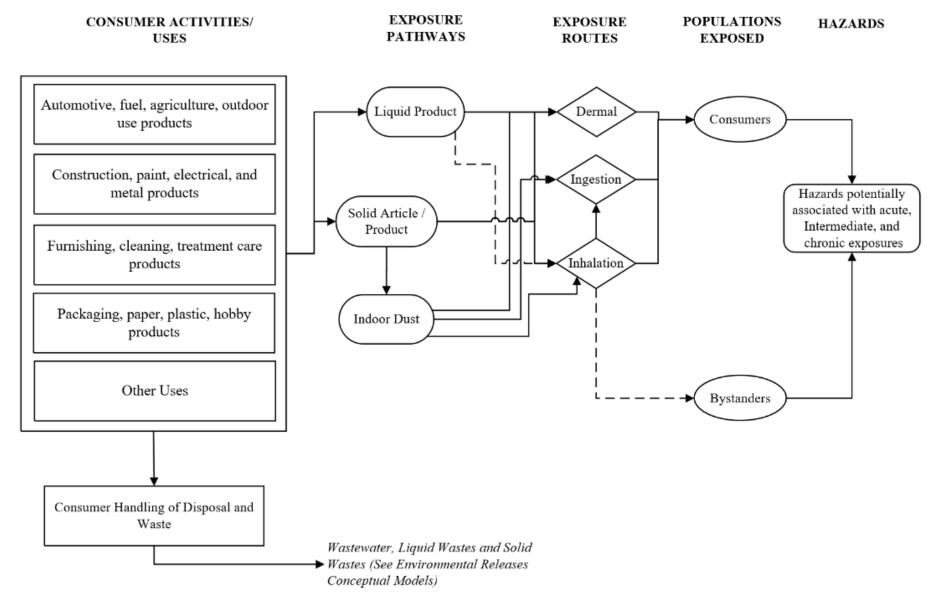
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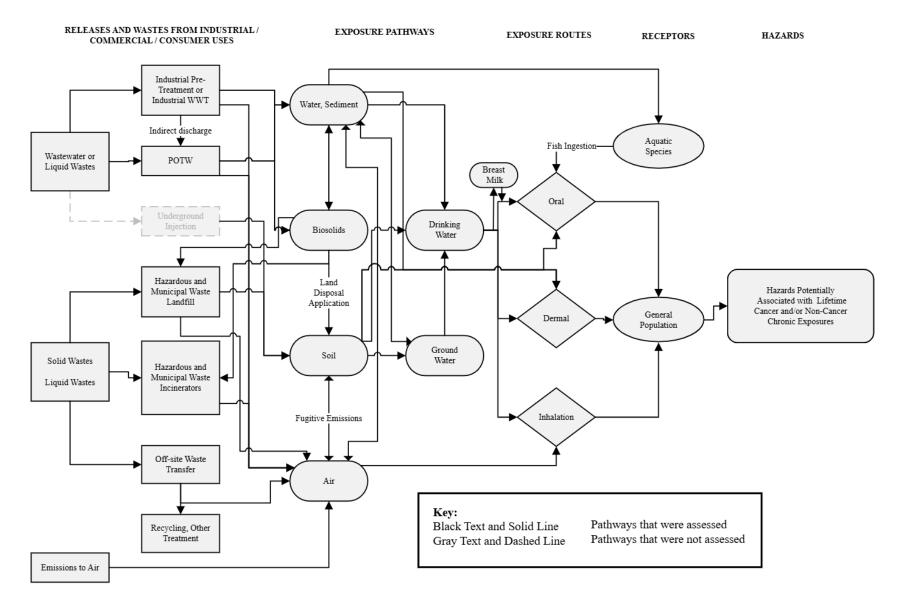
739 Figure 1-4. DBP Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposure and Hazards

- ^{*a*} Some products are used in both commercial and consumer applications. See Table 1-1 for categories and subcategories of conditions of use.
- ⁷⁴¹ ^b Fugitive air emissions are emissions that are not routed through a stack and include fugitive equipment leaks from valves, pump seals, flanges,
- rd2 compressors, sampling connections and open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation
- 743 systems.





- 745 Figure 1-5. DBP Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards
- 746 The conceptual model presents the exposure pathways, exposure routes, and hazards to human populations from consumer activities and uses of DBP.

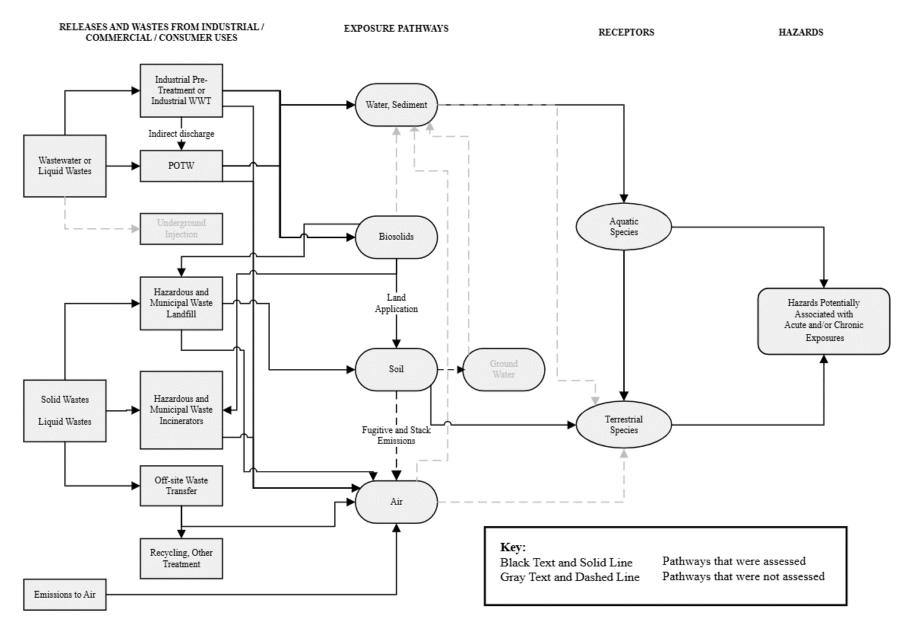


747

748 Figure 1-6. DBP Conceptual Model for Environmental Releases and Wastes: General Population Hazards

749 The conceptual model presents the exposure pathways, exposure routes, and hazards to human populations from releases and wastes from industrial,

750 commercial, and/or consumer uses of DBP.



751

752 Figure 1-7. DBP Conceptual Model for Environmental Releases and Wastes: Ecological Exposures and Hazards

753 The conceptual model presents the exposure pathways, exposure routes, and hazards to ecological populations from releases and wastes from industrial,

commercial, and/or consumer uses of DBP.

755 **1.2.2 Populations and Durations of Exposure Assessed**

Based on the conceptual models presented in Section 1.2.1.1, EPA evaluated risk to environmental and
 human populations. Environmental risks were evaluated for acute and chronic exposure scenarios for
 aquatic and terrestrial species, as appropriate. Human health risks were evaluated for acute,

759 intermediate, and chronic exposure scenarios, as applicable based on reasonably available exposure and

- hazard data, as well as the relevant populations for each. Human populations assessed include the
- 761 following:
- Workers, including average adults and females of reproductive age;
- ONUs, including average adult workers (individuals of both sexes age 16+ years, including pregnant workers)
- Consumers, including infants (<1 year), toddlers (1–2 years), children (3–5 and 6–10 years), young teens (11–15 years), teenagers (16–20 years), and adults (21+ years);
- Bystanders, including infants (<1 year), toddlers (1–2 years), and children (3–5 and 6–10 years);
 young teens (11–15 years), teenagers (16–20 years), and adults (21+ years); and
- General population, including infants (<1 year), toddlers (1–5 years), children (6–10 years), youth (11–15 and 16–20 years), and adults (21+ years).
- Note that the age groups for consumers, bystanders, and general population are different because each
 life stage used unique exposure factors (*e.g.*, mouthing, drinking water ingestion, fish consumption
 rates). These exposure factors are provided in EPA's *Exposure Factors Handbook: 2011 Edition* (U.S.
 EPA, 2011b).
- 774 <u>1</u> 775

776 Consistent with its Draft Proposed Approach for Cumulative Risk Assessment (CRA) of High-Priority 777 Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act (U.S. 778 EPA, 2023d), EPA is focusing its relative potency factor (RPF) analysis and phthalate CRA on 779 populations most relevant to the common hazard endpoint (*i.e.*, reduced fetal testicular testosterone)— 780 specifically females of reproductive age and male infants and male children. This approach emphasizes 781 a common health effect for sensitive subpopulations; however, additional health endpoints are identified for broader populations and described in the individual non-cancer human health hazard assessments for 782 783 DBP (U.S. EPA, 2024f), DCHP (U.S. EPA, 2024g), DEHP (U.S. EPA, 2024h), BBP (U.S. EPA, 2024e), DIBP (U.S. EPA, 2024i), and DINP (U.S. EPA, 2024n). Additionally, EPA is focusing its RPF and 784 785 CRA on acute duration exposures. This is because—as described further in the Revised Draft Technical 786 Support Document for the CRA of DEHP, DBP, BBP, DIBP, DCHP, and DINP under TSCA (U.S. EPA, 787 2025x)—there is evidence that effects on the developing male reproductive system consistent with a 788 disruption of androgen action can result from a single exposure during the critical window of 789 development.

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1.2.2.1 Potentially Exposed and Susceptible Subpopulations

TSCA section 6(b)(4)(A) requires that risk evaluations "determine whether a chemical substance 791 792 presents an unreasonable risk of injury to health or the environment, without consideration of costs or 793 other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible 794 subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." TSCA section 3(12) states that "the term 'potentially exposed or susceptible subpopulation' 795 796 [PESS] means a group of individuals within the general population identified by the Administrator who, 797 due to either greater susceptibility or greater exposure, may be at greater risk than the general population 798 of adverse health effects from exposure to a chemical substance or mixture, such as infants, children,

799 pregnant women, workers, or the elderly."

800

- 801 This draft risk evaluation considers PESS throughout the human health risk assessment (Section 4),
- 802 including throughout the exposure assessment, hazard identification, and dose-response analysis
- supporting this assessment. EPA incorporated the following PESS into its assessment: females of
- reproductive age, pregnant women, infants, children and adolescents, people who frequently use
 consumer products and/or articles containing high concentrations of DBP, people exposed to DBP in the
- 806 workplace, and tribes whose diets include large amounts of fish. These subpopulations are PESS
- 807 because some have greater exposure to DBP per body weight (*e.g.*, infants, children, adolescents) or due
- 808 to age-specific behaviors (e.g., mouthing of toys, wires, and erasers by infants and children assessed in
- the consumer exposure scenarios), while some experience aggregate or sentinel exposures. EPA also
- evaluated non-attributable exposures and cumulative risk to phthalates (*i.e.*, DEHP, DBP, BBP, DIBP,
- and DINP) using biomonitoring data from National Health and Nutrition Examination Survey
 (NHANES). This non-attributable cumulative risk from exposure to DEHP, DBP, BBP, DIBP,
- (NHANES). This non-attributable cumulative risk from exposure to DEHP, DBP, BBP, DIBP, and
 DINP was taken into consideration as part of EPA's cumulative risk calculations for DBP, presented
- below in Section 4.4 and around exposures to DBP from both occupational and consumer
- 815 COUs/occupational exposure scenarios (OESs).
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- 817 Section 4.3.5 summarizes how PESS were incorporated into the draft risk evaluation through
- 818 consideration of potentially increased exposures and/or potentially increased biological susceptibility
- and summarizes additional sources of uncertainty related to consideration of PESS.

820 **1.3 Organization of the Risk Evaluation**

- This draft risk evaluation for DBP includes five additional major sections, and several appendices, as
 described below:
- Section 2 summarizes basic physical and chemical characteristics as well as the fate and transport of DBP.
 - Section 3 includes an overview of releases and concentrations of DBP in the environment.
- Section 4 presents the human health risk assessment, including the exposure, hazard, and risk characterization based on the COUs. It includes a discussion of PESS based on both greater exposure and/or susceptibility as well as a description of aggregate and sentinel exposures.
 Section 4 also discusses assumptions and uncertainties and how they potentially impact the strength of the evidence of draft risk evaluation. Finally, Section 4 presents cumulative risk estimates from exposure to BBP, DEHP, DBP, DIBP, DCHP, and DINP (Section 4.4), as well as a comparison of the individual BBP risk assessment and the draft CRA (Section 4.5)
- Section 5 provides a discussion and analysis of the environmental risk assessment, including the environmental exposure, hazard, and risk characterization based on the COUs for DBP. It also discusses assumptions and uncertainties and how they potentially impact the strength of the evidence of draft risk evaluation.
 - Section 6 presents EPA's proposed determination of whether DBP presents an unreasonable risk to human health or the environment under the assessed COUs.
 - Appendix A provides a list of key abbreviations and acronyms used throughout this draft risk evaluation.
- Appendix B provides a brief summary of the federal, state, and international regulatory history of DBP.
- Appendix C incudes a list and citations for all TSDs and supplemental files included in the draft risk evaluation for DBP.

- Appendix D provides a summary of updates made to COUs for DBP from the final scope document to this draft risk evaluation.
- Appendix E provides descriptions of the DBP COUs evaluated by EPA.
- Appendix F provides the draft occupational exposure value for DBP that was derived by EPA.

849 2 CHEMISTRY AND FATE AND TRANSPORT OF DBP

850 Physical and chemical properties determine the behavior and characteristics of a chemical that inform its

condition of use, environmental fate and transport, potential toxicity, exposure pathways, routes, and

hazards. Environmental fate and transport includes environmental partitioning, accumulation,
 degradation, and transformation processes. Environmental transport is the movement of the chemical

within and between environmental media, such as air, water, soil, and sediment. Thus, understanding the

environmental fate of DBP informs the specific exposure pathways, and potential human and

- 856 environmental exposed populations that EPA considered in this draft risk evaluation.
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Sections 2.1 and 2.2 summarize the physical and chemical properties, and environmental fate and transport of DBP, respectively. See the *Draft Chemistry, Fate, and Transport Assessment for Dibutyl*

860 *Phthalate (DBP)* (U.S. EPA, 2024j).

2.1 Summary of Physical and Chemical Properties

EPA gathered and evaluated physical and chemical property data and information according to the
process described in the *Draft Systematic Review Protocol for Dibutyl Phthalate (DBP)* (U.S. EPA,
2025w). EPA considered both measured and estimated physical and chemical property data/information
as described in the *Draft Physical Chemistry, Fate, and Transport Assessment for Dibutyl Phthalate*(*DBP*) (U.S. EPA, 2024j). The selected values are summarized in Table 2-1, as applicable. Information
on the full, extracted dataset is available in the *Draft Data Quality Evaluation and Data Extraction Information for Physical and Chemical Properties for Dibutyl Phthalate* (*DBP*) (U.S. EPA, 2025k).

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Table 2-1. Physical and	Chemical Properties of DBP
Lable # 1. Lugsteal and	Chemical I Toperfies of DDI

Property	Selected Value(s)	Reference(s)	Overall Data Quality Rating
Molecular formula	C ₁₆ H ₂₂ O ₄	_	_
Molecular weight	278.35 g/mol	_	_
Physical form	Oily liquid	<u>O'Neil (2013)</u>	High
Melting point	−35 °C	<u>Rumble (2018)</u>	High
Boiling point	340 °C	<u>O'Neil (2013)</u>	High
Density	1.0465 g/cm ³	<u>Rumble (2018)</u>	High
Vapor pressure	2.01E-05 mm Hg	<u>U.S. EPA (2019c)</u>	High
Vapor density	9.58	<u>NLM (2024)</u>	High
Water solubility	11.2 mg/L	Howard et al. (1985)	High
Organic carbon:water (Log K _{OC})	3.69 (average of 7 values ranging between 3.14– 3.94)	Xiang et al. (2019); Russell and Mcduffie (1986)	High
Octanol:water partition coefficient (log K _{OW})	4.5	<u>NLM (2024)</u>	High
Octanol:air partition coefficient (log K _{OA})	8.63 (EPI Suite [™])	<u>U.S. EPA (2017)</u>	High

Property	Selected Value(s)	Reference(s)	Overall Data Quality Rating
Air:water partition coefficient (log K _{AW})	-4.131 (EPI Suite [™])	<u>U.S. EPA (2017)</u>	High
Henry's Law constant	1.81E–06 atm⋅m³/mol at 25 °C	<u>NLM (2024)</u>	High
Flash point	157 °C	<u>NLM (2024)</u>	High
Autoflammability	402 °C	NLM (2024)	High
Viscosity	20.3 cP	<u>NLM (2024)</u>	High

871 **2.2 Summary of Environmental Fate and Transport**

872 Reasonably available environmental fate data—including biotic and abiotic biodegradation rates, 873 removal during wastewater treatment, volatilization from water sources, and organic carbon:water 874 partition coefficient (log K_{OC})—are parameters used in the current risk evaluation. In assessing the 875 environmental fate and transport of DBP, EPA considered the full range of results from the available highest quality data sources obtained during systematic review. Information on the full extracted dataset 876 877 is available in the Draft Data Quality Evaluation and Data Extraction Information for Environmental 878 Fate and Transport for Dibutyl Phthalate (DBP) (U.S. EPA, 2025i). Other fate estimates were based on modeling results from EPI Suite[™] (U.S. EPA, 2012b), a predictive tool for physical and chemical 879 properties and environmental fate estimation. Information regarding the model inputs is available in the 880 Draft Physical Chemistry and Fate and Transport Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 881 882 2024j). 883

EPA evaluated the reasonably available information to characterize the environmental fate and transport of DBP, the key points of the fate assessment for DBP (U.S. EPA, 2024j) are summarized below and listed in Table 2-2.

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Given the consistent results from numerous high-quality studies, there is robust evidence of thefollowing:

- DBP not expected to undergo significant direct photolysis but will undergo indirect
 photodegradation by reacting with hydroxyl radicals in the atmosphere with a half-life of 1.13 to
 1.15 days.
- DBP will partition to organic carbon and particulate matter in air.
- DBP will not hydrolyze under standard environmental conditions, but its hydrolysis rate increases with increased pH and temperature in deep-landfill environments.
- DBP will biodegrade in aerobic surface water, soil, and wastewater treatment processes.
 - DBP will not biodegrade under anoxic conditions and may have high persistence in anaerobic soils and sediment.
- DBP will be removed with wastewater treatment and will sorb significantly to sludge, with a small fraction being present in wastewater treatment plant (WWTP) effluent.
- DBP has low bioaccumulation potential.
- DBP may be persistent in surface water and sediment proximal to continuous points of release.
- DBP is expected to transform to monobutyl phthalate (MBP), butanol, and phthalic acid in the environment.

- As a result of limited studies identified, there is moderate confidence that DBP
- Will be removed in conventional drinking water treatment systems both in the treatment process and via reduction by chlorination and chlorination byproducts in post-treatment storage and drinking water conveyance with a removal efficiency of 31 to 64.5 percent (Kong et al., 2017; Shan et al., 2016).
- 910 Findings that were found to have a robust weight of evidence supporting them had one or more high-
- 911 quality studies that were largely in agreement with each other. Findings that were said to have a
- 912 moderate weight of evidence were based on a mix of high- and medium-quality studies that were largely
- 913 in agreement but varied in sample size and consistency of findings.
- 914

915 **Table 2-2. Summary of Environmental Fate Information for DBP**^a

Parameter	Value	Reference(s)	Overall Data Quality Rating
Aerobic primary biodegradation in water	68.3–100% in 7–28 days	<u>NITE (2019); SRC (1983);</u> <u>Tabak et al. (1981)</u>	High
Aerobic biodegradation in sediment	$t_{1/2} = 2.9$ days in natural river sediment collected from the Zhonggang, Keya, Erren, Gaoping, Donggang, and Danshui Rivers, Taiwan	<u>Yuan et al. (2002)</u>	High
Anaerobic biodegradation in sediment	$t_{1/2} = 14.4$ days in natural river sediment collected from the Zhonggang, Keya, Erren, Gaoping, Donggang, and Danshui Rivers in Taiwan	<u>Yuan et al. (2002)</u>	High
Aerobic biodegradation in soil	88.1–97.2% after 200 days in Chalmers slit loam, Plainfield sand, and Fincastle silt loam soils	<u>Inman et al. (1984)</u>	High
Hydrolysis	$t_{1/2} = approximately 22 \text{ years at pH 7} \\ and 25 \ ^{\circ}\text{C}; \ K_{H} = 1.0 \pm 0.05\text{E}02 \ M^{\text{-}1} \\ \text{sec}^{\text{-}1} \text{ at pH 10-12 and 30 \ ^{\circ}\text{C}} $	<u>ATSDR (1999); Wolfe et al.</u> (1980)	High
Photolysis	Direct: Expected to be susceptible to direct photolysis by sunlight; contains chromophores that absorb at wavelengths >290 nm Indirect: $t_{1/2} = 1.13$ days (•OH rate constant of 9.47E–12 OH/cm ³) and 1.15 days (•OH rate constant of 9.28E–12 OH/cm ³); (estimated based on a 12-hour day with 1.5E06 •OH/cm ³)	Lei et al. (2018); Peterson and Staples (2003)	High
Environmental degradation half-lives	1.15 days (air) 10 days (water) 20 days (soil)	Lei et al. (2018); SRC (1983)	High

Parameter	Value	Reference(s)	Overall Data Quality Rating
(selected values for modeling)	90 days (sediment)		
Wastewater treatment plant (WWTP) removal	65–98%	<u>U.S. EPA (1982)</u>	High
Aquatic bioconcentration factor (BCF)	2.9 ± 0.1 and 30.6 ± 3.4 in brown shrimp (<i>Penaeus aztecus</i>) at 100 and 500 ppb, respectively; 11.7 in sheepshead minnow (<i>Cyprinodon</i> <i>variegate</i>) at 100 ppb; 21.1 ± 9.3 and 41.6 ± 5.1 in American oyster (<i>Crassostrea virginica</i>) at 100 and 500 ppb, respectively	Wofford et al. (1981)	High
Aquatic bioaccumulation factor (BAF)	100, 316, 251 and 1,259 L/kg dry weight (dw) in bluegill, bass, skygager, and crucian carp, respectively.	Lee et al. (2019)	High
Aquatic Trophic Magnification Factor (TMF)	0.70 (Experimental; 18 marine species)	Mackintosh et al. (2004)	High
Plant Concentration Factor (PCF)	0.26–4.78 (Fruit and vegetables)	<u>Sun et al. (2015)</u>	High
Terr. Biota-sediment accumulation factor (BSAF)	0.242–0.460 (Eisenia fetida)	Ji and Deng (2016); Hu et al. (2005)	High
	n on value selection can be found in the <i>I</i> <i>Phthalate (DBP)</i> (<u>U.S. EPA, 2024j</u>).	Draft Physical Chemistry, Fate, an	d Transport

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917 3 RELEASES AND CONCENTRATIONS OF DBP IN THE 918 ENVIRONMENT

EPA estimated environmental releases and concentrations of DBP. Section 3.1 describes the approach
and methodology for estimating releases; Section 3.2 presents estimates of environmental releases; and
Section 3.3 presents the approach and methodology for estimating environmental concentrations as well
as a summary of concentrations of DBP in the environment.

923 **3.1 Approach and Methodology**

This section provides an overview of the approach and methodology for assessing releases to the
 environment from industrial, commercial, and consumer uses. Specifically, Sections 3.1.1 through 3.1.3
 describe the approach and methodology for estimating releases to the environment from industrial and
 commercial uses.

928 **3.1.1**

3.1.1 Manufacturing, Processing, Industrial and Commercial

This subsection describes the grouping of manufacturing, processing, industrial and commercial COUs
into OESs as well as the use of DBP within each OES. Specifically, Section 3.1.1.1 provides a crosswalk
of COUs to OESs and 3.1.1.2 provides descriptions for the use of DBP within each OES.

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3.1.1.1 Crosswalk of Conditions of Use to Occupational Exposure Scenarios

933 EPA categorized the COUs listed in Table 1-1 into OESs. Table 3-1 provides a crosswalk between the 934 COUs and OESs whereas Table 3-2 provides the reverse: a crosswalk of OESs to COUs. Each OES is 935 developed based on a set of occupational activities and conditions such that similar occupational 936 exposures and environmental releases are expected from the use(s) covered under that OES. For each 937 OES, EPA provided occupational exposure and environmental release results, which are expected to be 938 representative of the entire population of workers and sites for the given OES in the United States. In 939 some cases, EPA defined only a single OES for multiple COUs, while in other cases the Agency 940 developed multiple OESs for a single COU. EPA made this determination by considering variability in 941 release and use conditions and whether the variability required discrete scenarios or could be captured as 942 a distribution of exposures. The Draft Environmental Release and Occupational Exposure Assessment 943 for Dibutyl Phthalate (DBP) (U.S. EPA, 2025q) provides further information on specific OESs.

944

945 Table 3-1. Crosswalk of Conditions of Use to Assessed Occupational Exposure Scenarios

COU			OES^d	
Life Cycle Stage ^a	Category ^b	Subcategory ^c	OES	
Manufasturing	Domestic manufacturing	Domestic manufacturing	Manufacturing	
Manufacturing	Importing	Importing	Import and repackaging	
Processing	Repackaging	Laboratory chemicals in wholesale and retail trade; plasticizers in wholesale and retail trade; and plastics material and resin manufacturing	Import and repackaging	
	Processing as a reactant	Intermediate in plastic manufacturing	Incorporation into formulations, mixtures, or reaction product	

	OFS		
Life Cycle Stage ^a	Category ^b	Subcategory ^c	OES^d
		Solvents (which become part of product formulation or mixture) in chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and printing ink manufacturing	Incorporation into formulations, mixtures, or reaction product
Processing	Incorporation into formulation, mixture, or reaction product	Plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic organic chemical manufacturing; and adhesive and sealant manufacturing	Incorporation into formulations, mixtures, or reaction product; PVC plastics compounding; Non-PVC material manufacturing
		Pre-catalyst manufacturing	Incorporation into formulations, mixtures, or reaction product
	Incorporation into articles	Plasticizer in adhesive and sealant manufacturing; building and construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing	PVC plastics converting; Non-PVC material manufacturing;
	Recycling	Recycling	Recycling
Distribution in Commerce	Distribution in commerce		Distribution in commerce
	Non-incorporative activities	Solvent, including in maleic anhydride manufacturing technology	Industrial process solvent use
	Construction, paint,	Adhesives and sealants	Application of adhesives and sealants
Industrial Use	electrical, and metal products	Paints and coatings	Application of paints and coatings
		Automotive articles	Fabrication or use of final product or articles
	Other uses	Lubricants and lubricant additives	Use of lubricants and functional fluids
		Propellants	Fabrication or use of final product or articles

	COU		- OES ^d	
Life Cycle Stage ^a	Category ^b	Subcategory ^c		
	Automotive, fuel, agriculture, outdoor use products	Automotive care products	Use of lubricants and functional fluids	
	Construction, paint,	Adhesives and sealants	Application of adhesives and sealants	
	electrical, and metal products	Paints and coatings	Application of paints and coatings	
		Cleaning and furnishing care products	Use of lubricants and functional fluids	
	Furnishing, cleaning, treatment care products	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel;	Fabrication or use of final product or articles	
		Furniture and furnishings		
~	Packaging, paper, plastic, toys, hobby products	Ink, toner, and colorant products	Application of paints and coatings	
Commercial Use		Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)	Fabrication or use of final product or articles	
		Toys, playground, and sporting equipment	Fabrication or use of final product or articles	
		Laboratory chemicals	Use of laboratory chemicals	
		Automotive articles	Fabrication or use of final product or articles	
	Other uses	Chemiluminescent light sticks	Fabrication or use of final product or articles	
		Inspection penetrant kit	Use of penetrants and inspection fluids	
		Lubricants and lubricant additives	Use of lubricants and functional fluids	
Disposal	Disposal	Disposal	Waste handling, treatment, and disposal	

^{*a*}Life Cycle Stage Use Definitions (40 CFR 711.3)

 "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.

- "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.

- "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.

	OES^d								
Life Cycle Stage ^a	Category ^b	Subcategory ^c	UE5						
– Although EPA	- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios								
in this docum	nent, the Agency interprets t	the authority over "any manner or metho	od of commercial use" under						
TSCA section	n $6(a)(5)$ to reach both.								
^b These categories of	COU appear in the life cycle	e diagram, reflect CDR codes, and broadly	represent COUs of DBP in						
industrial and/or com	nmercial settings.	-	-						
^c These subcategories	s represent more specific acti	vities within the life cycle stage and cates	gory of the COU of DBP.						
^d An OES is based or	^d An OES is based on a set of facts, assumptions, and inferences that describe how releases and exposures take place within								
an occupational COU. The occurrence of releases/exposures may be similar across multiple conditions of use (multiple									
	COUs mapped to single OES), or there may be several ways in which releases/exposures take place for a given condition								
	of use (single COU mapped to multiple OESs).								

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Table 3-2. Crosswalk of Assessed Occupational Exposure Scenarios to Conditions of Use

OES ^a	COU								
UES	Life Cycle Stage ^b	Category ^c	Subcategory ^d						
Manufacturing	Manufacturing	Domestic manufacturing	Domestic manufacturing						
Import and	Manufacturing	Importing	Importing						
repackaging	Processing	Repackaging	Laboratory chemicals in wholesale and retail trade; plasticizers in wholesale and retail trade; and plastics material and resin manufacturing						
	Processing	Processing as a reactant	Intermediate in plastic manufacturing						
Incorporation	Processing	Incorporation into formulation, mixture, or reaction product	Solvents (which become part of product formulation or mixture) in chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and printing ink manufacturing						
into formulations, mixtures, or reaction product	Processing	Incorporation into formulation, mixture, or reaction product	Plasticizer in paint and coating manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic organic chemical manufacturing; and adhesive and sealant manufacturing						
	Processing	Incorporation into formulation, mixture, or reaction product	Pre-catalyst manufacturing						
PVC plastics compounding	Processing	Incorporation into formulation, mixture, or reaction product	Plasticizer in plastic material and resin manufacturing						
PVC plastics converting	Processing	Incorporation into articles	Plasticizer in adhesive and sealant manufacturing; building and construction materials manufacturing; furniture and related						

0.5.6%	COU								
OES ^a	Life Cycle Stage ^b	Category ^c	Subcategory ^d						
			product manufacturing; ceramic powders; plastics product manufacturing						
Non-PVC	Processing	Incorporation into formulation, mixture, or reaction product	Plasticizer in plastic material and resin manufacturing; rubber manufacturing						
non-PVC materials manufacturing	Processing	Incorporation into articles	Plasticizer in adhesive and sealant manufacturing; building and construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing						
Application of adhesives and	Commercial Use	Construction, paint, electrical, and metal products	Application of adhesives and sealants						
sealants	Industrial Use	Construction, paint, electrical, and metal products	Application of adhesives and sealants						
	Commercial Use	Packaging, paper, plastic, toys, hobby products	Ink, toner, and colorant products						
Application of paints and coatings	Commercial Use	Construction, paint, electrical, and metal products	Paints and coatings						
	Industrial Use	Construction, paint, electrical, and metal products	Paints and coatings						
Industrial process solvent use	Industrial Use	Non- incorporative activities	Solvent, including in maleic anhydride manufacturing technology						
Use of laboratory chemicals (solid)	Commercial Use	Other uses	Laboratory chemicals						
Use of laboratory chemicals (liquid)	Commercial Use	Other uses	Laboratory chemicals						
	Commercial Use	Other uses	Lubricants and lubricant additives						
	Industrial Use	Other uses	Lubricants and lubricant additives						
Use of lubricants and functional fluids	Commercial Use	Automotive, fuel, agriculture, outdoor use products	Automotive care products						
i u u u	Commercial Use	Furnishing, cleaning, treatment care products	Cleaning and furnishing care products						
Use of penetrants and inspection fluids	Commercial Use	Other uses	Inspection penetrant kit						

OFS/	COU							
OES ^a	Life Cycle Stage ^b	Category ^c	Subcategory ^d					
	Commercial Use	Furnishing, cleaning, treatment care products	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel					
	Commercial Use	Furnishing, cleaning, treatment care products	Furniture and furnishings					
	Commercial Use	Other uses	Automotive articles					
Fabrication or use	Commercial Use	Other uses	Chemiluminescent light sticks					
of final product	Industrial Use	Other uses	Automotive articles					
or articles	Industrial Use	Other uses	Propellants					
	Commercial Use	Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)					
	Commercial Use	Packaging, paper, plastic, toys, hobby products	Toys, playground, and sporting equipment					
Recycling	Processing	Recycling	Recycling					
Waste handling, treatment, and disposal	Disposal	Disposal	Disposal					

^{*a*} An OES is based on a set of facts, assumptions, and inferences that describe how releases and exposures take place within an occupational condition of use. The occurrence of releases/exposures may be similar across multiple conditions of use (multiple COUs mapped to single OES), or there may be several ways in which releases/exposures take place for a given condition of use (single COU mapped to multiple OESs).

^b Life Cycle Stage Use Definitions (40 CFR 711.3)

- "Industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.
- "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
- "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA Section 6(a)(5) to reach both.

^c These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of DPB in industrial and/or commercial settings.

^{*d*} These subcategories represent more specific activities within the life cycle stage and category of the conditions of use of DBP.

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950 3.1

3.1.1.2 Description of DBP Use for Each OES

After EPA characterized the OESs for the occupational exposure assessment of DBP, the occupational

uses of DBP for all OESs were summarized. Brief summaries of the uses of DBP for all OESs arepresented in Table 3-3.

954

955 **Table 3-3. Description of the Function of DBP for Each OES**

OES	Role/Function of DBP
Manufacturing	DBP is typically produced through the esterification of the carboxyl groups phthalic anhydride with n-butyl alcohol in the presence of sulfuric acid as a catalyst.
Import and repackaging	DBP is imported domestically for use and/or may be repackaged before shipment to formulation sites.
Incorporation into formulation, mixture, or reaction product	DBP is used primarily as a plasticizer in the formulation of paints and coatings. DBP is also incorporated into other products such as adhesives, sealants, inks, toners, and colorant products.
PVC plastics compounding	DBP is used in PVC plastics to increase flexibility.
PVC plastics converting	DBP is used in PVC plastics to increase flexibility.
Non-PVC materials compounding and converting	DBP is used in non-PVC polymers, such as resins, and as an intermediate in rubber product manufacturing.
Application of adhesives and sealants	DBP is used as an additive in adhesives and sealants for industrial and commercial use.
Application of paints and coatings	DBP is used in paint and coating products for industrial and commercial use.
Industrial process solvent use	DBP is used as a solvent for industrial use, primarily for the formulation of maleic anhydride.
Use of laboratory chemicals	DBP is a laboratory chemical used for laboratory analyses in liquid and solid forms.
Use of lubricants and functional fluids	DBP is used as a functional fluid for processes in printing and related support activities and is also used as a lubricant such as textile fiber lubricant in industrial processes.
Use of penetrants and inspection fluids	DBP is used in inspection penetrant kits for commercial use.
Fabrication of final product from articles	DBP is found in a wide array of different final articles not found in other OES including building and construction materials, flooring materials, furniture, and furnishings.
Recycling	Some PVC plastics that contain DBP may be recycled either in- house or at PVC recycling facilities to manufacture new PVC material.
Waste handling, treatment, and disposal	Upon fabrication or use of DBP-containing products, residual chemicals are disposed and released to air, wastewater, or disposal facilities.
Distribution in commerce	Distribution in commerce consists of the transportation associated with the moving of DBP-containing products and/or articles between sites manufacturing, processing, and use COUs, or the transportation of DBP containing wastes to recycling sites or for final disposal.

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3.1.2 Estimating the Number of Release Days per Year for Facilities in Each OES

957 The number of release days associated with the releases is included in the release tables for different OES in section 3 of the Draft Environmental Release and Occupational Exposure Assessment for 958 Dibutyl Phthalate (DBP) (U.S. EPA, 2025q). Unless EPA identified conflicting information, EPA 959 assumed that the number of release days per year for a given release source equals the number of 960 961 operating days at the facility. EPA used information from National Emissions Inventory (NEI), generic scenarios (GSs), emission scenario documents (ESDs), and other literature sources obtained through 962 systematic review to assess the number of operating days for releases. When monte carlo modeling was 963 performed to estimate releases, a discrete value or a range of input for the number of release days was 964

input to the monte carlo simulation. The model generated the 50th and 95th percentiles of operating days
which was associated with the central tendency and high-end estimates of releases respectively. The
number of release days used in the assessment is expected to be reasonable since EPA used information
directly reported by facilities or information from sources which through EPA's systematic review
process.

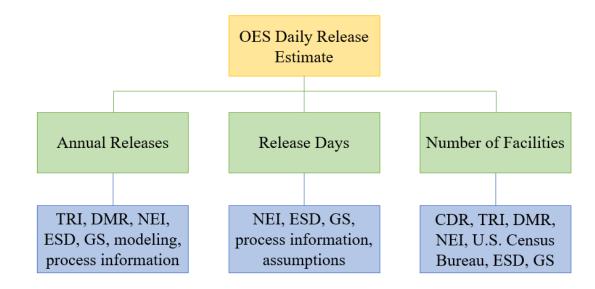
3.1.3 Daily Release Estimation

For each OES, EPA estimated releases to each media of release using Toxics Release Inventory (TRI) 971 972 data (2017–2022), Discharge Monitoring Report (DMR) data (2017–2022), and NEI data (2017–2020) 973 or modeling as shown in Figure 3-1. Where available, EPA used NEI, GSs, or ESDs to estimate number 974 of release days, which EPA used to convert between annual release estimates and daily release 975 estimates. EPA used 2020 CDR, TRI, DMR, NEI, and Monte Carlo modeling data to estimate the 976 number of sites using DBP within an OES. The Draft Environmental Release and Occupational 977 Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025q) describes EPA's approach and 978 methodology for estimating daily releases and provides detailed facility level results for each OES.

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- 980 For each OES, EPA estimated DBP releases per facility to each release media applicable to that OES.
- 981 For DBP, EPA assessed releases to water, air, or land (*i.e.*, disposal to land).



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983 Figure 3-1. Overview of EPA's Approach to Estimate Daily Releases for Each OES

- 984 TRI = Toxics Release Inventory; DMR = Discharge Monitoring Report; NEI = National Emissions Inventory;
- 985 CDR = Chemical Data Reporting; ESD = Emission Scenario Document; GS = Generic Scenario

3.1.4 Consumer Down-the-Drain and Landfills

EPA evaluated down-the-drain releases of DBP for consumer COUs qualitatively. Although EPA
acknowledges that there may be DBP releases to the environment via the cleaning and disposal of
adhesives, sealants, paints, coatings, cleaners, waxes, and polishes, the Agency did not quantitatively
assess down-the-drain and disposal scenarios of consumer products due to limited information from
monitoring data or modeling tools. EPA instead conducted a qualitative screening level assessment
using physical and chemical properties. See the *Draft Consumer and Indoor Dust Exposure Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025c) for further details.

995 Adhesives, sealants, paints, coatings, cleaners, waxes, and polishes can be disposed down-the-drain 996 while users wash their hands, brushes, sponges, and other product applying tools. In addition, these 997 products can be disposed of when users no longer have use for them or have reached the product shelf 998 life and taken to landfills. All other solid products and articles listed in Table 4-5 of the Draft Consumer and Indoor Dust Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025c) can be removed 999 1000 and disposed in landfills, or other waste handling locations that properly manage the disposal of 1001 products like adhesives, sealants, paints, lacquers, and coatings. Section 3.2 in the Draft Environmental 1002 Media and General Population and Environmental Exposure for Dibutyl Phthalate (DBP) (U.S. EPA, 1003 2025p) summarizes DBP monitoring data identified for landfills. Briefly, no studies were identified 1004 which reported the concentration of DBP in landfills or in the surrounding areas in the U.S., but DBP was identified in sludge in wastewater plants in China, Canada, and the U.S. DBP is expected to have a 1005 1006 high affinity to particulate (log $K_{OC} = 3.14 - 3.94$) and organic media (log $K_{OW} = 4.5$), which would limit 1007 leaching to groundwater. Because of its high hydrophobicity and high affinity for soil sorption, it is 1008 unlikely that DBP will migrate from landfills via groundwater infiltration.

1009 **3.2 Summary of Environmental Releases**

1010 **3.2.1 Manufacturing, Processing, Industrial and Commercial**

1011 EPA combined its estimates for annual releases, release days, number of facilities, and hours of release 1012 per day to estimate a range of daily releases for each OES. Table 3-4 presents a summary of these ranges 1013 across facilities. See the Draft Environmental Release and Occupational Exposure Assessment for 1014 Dibutyl Phthalate (DBP) (U.S. EPA, 2025q) for additional detail on deriving the overall confidence 1015 score for each OES. EPA was not able to estimate site-specific releases for the final use of products or 1016 articles OES. Disposal sites handling post-consumer, end-use DBP were not quantifiable due to the wide 1017 and dispersed use of DBP in PVC and other products. Pre-consumer waste handling, treatment, and 1018 disposal are assumed to be captured in upstream OES.

1019 Table 3-4. Summary of EPA's Annual and Daily Release Estimates for Each OES

OES	Type of Discharge, ^{a} Air Emission, ^{b} or Transfer	Rele	Estimated Annual Release (kg/site-year) ^d		Estimated Daily Release (kg/site-day) ^e		Source(s)
	for Disposal ^c	Central Tendency ^g	High-End	Central Tendency ^g	High-End	- Facilities ^f	
	Stack air	0.24	0.24	7.8E-04	7.8E-04		
	Fugitive air	9.9E-04	1.7E-03	3.3E-06	5.5E-06	1-Dystar LP,	CDR, peer-reviewed literature
Manafaataainaa	Wastewater, incineration, or landfill	558	585	1.9	2.0	Reidsville, NC	(GS/ESD)
Manufacturing	Stack air	3.0	5.7	1.0E-02	1.9E-02		
	Fugitive air	7.8E-04	1.6E-03	2.6E-06	5.4E-06	_4	Environmental release modeling
	Wastewater, incineration, or landfill	6,942	1.3E04	23	43		
	Stack air	0	0	0	0	4	NEI
	Stack air	0	227	0	0.87	10	TRI
Import and	Fugitive air	35	113	9.5E-02	0.31	4	NEI
repackaging	Fugitive air	0	227	0	0.87	10	TRI
	Wastewater	227	227	0.87	0.87	5	TRI/DMR
	Land	5,994	3.7E04	16	103	2	TRI
	Stack air	0	8.4	0	3.4E-02	32	NEI
Incorporation into	Stack air	0	311	0	1.2	18	TRI
mixture,	Fugitive air	4.6	51	1.1E-02	0.18	32	NEI
formulation, or	Fugitive air	0	238	0	0.95	18	TRI
reaction product	Wastewater	227	227	0.91	0.91	11	TRI/DMR
	Land	510	1.0E04	2.0	40	3	TRI

OES	Type of Discharge, ^a Air Emission, ^b or Transfer	Estimated Annual Release (kg/site-year) ^d		Estimated Daily Release (kg/site-day) ^e		Number of	Source(s)
	for Disposal ^c	Central Tendency ^g	High-End	Central Tendency ^g	High-End	- Facilities ^f	
	Stack air	N/A	N/A	N/A	N/A	1	NEI (one site provided fugitive air emissions but stated that stack air releases were not applicable)
	Stack air	10	13	4.2E-02	8.0E-02	1	TRI
PVC plastic	Fugitive air	6.7	6.7	1.9E-02	1.9E-02	1	NEI
compounding	Fugitive air	1.4	1.4	5.5E-03	5.5E-03	1	TRI
	Wastewater	0.28	43	1.1E-03	0.12	14	DMR
	Land	2.7	566	9.5E-03	2.0	3	Surrogate data – Non-PVC material manufacturing
	Stack air	53	58	0.21	0.23	7	NEI
	Stack air	0	0	0	0	1	TRI
	Fugitive air	3.5E-02	1.8	6.8E-05	6.6E–03	7	NEI
PVC plastics	Fugitive air	0.45	0.45	1.8E-03	1.8E-03	1	TRI
converting	Wastewater	0.28	43	1.1E-03	0.12	14	Surrogate data – PVC plastics compounding.
	Land	2.7	566	9.5E-03	2.0	3	Surrogate data – Non-PVC material manufacturing
	Stack air	9.0E-02	177	7.8E-05	0.61	49	NEI
Non-PVC	Stack air	4.3	34	1.7E-02	0.26	4	TRI
material	Fugitive air	1.4	117	5.2E-03	0.44	49	NEI
manufacturing (compounding	Fugitive air	0.24	59	9.5E-04	0.45	4	TRI
and converting)	Wastewater	4.5E-03	4.5E-03	1.8E-05	1.8E-05	1	TRI
	Land	2.7	566	9.5E-03	2.0	3	TRI

OES	Type of Discharge, ^a Air Emission, ^b or Transfer	Estimated Annual Release (kg/site-year) ^d		Estimated Daily Release (kg/site-day) ^e		Number of	Source(s)
	for Disposal ^c	Central Tendency ^g	High-End	Central Tendency ^g	High-End	Facilities ^f	
	Stack air	4.4E06	99	1.7E-08	0.39	164	NEI
	Stack air	0	0	0	0	1	TRI
Application of	Fugitive air	1.2	97	4.9E-03	0.39	164	NEI
adhesives and	Fugitive air	0	0	0	0	1	TRI
sealants ^h	Incineration or landfill	291	1,357	1.4	7.1	04.072	
	Wastewater, incineration, or landfill	209	860	0.97	4.5	94–973 generic sites	Modeled environmental release
	Stack air	4.4E-06	99	1.7E-08	0.39	164	NEI
	Stack air	0	0	0	0	1	TRI
	Fugitive air	1.2	97	4.9E-03	0.39	164	NEI
Application of	Fugitive air	0	0	0	0	1	TRI
paints and	Wastewater	0	0	0	0		Modeled environmental release
coatings (no spray control) ^h	Incineration or landfill	92	368	0.36	1.4		
spray control)	Wastewater, incineration or landfill	72	206	0.28	0.80	219–2,624 generic sites	
	Unknown (air, wastewater, incineration, or landfill)	1,957	8,655	7.6	34		
	Stack air	4.4E06	99	1.7E-08	0.39	164	NEI
	Stack air	0	0	0	0	1	TRI
	Fugitive air	1.2	97	4.9E-03	0.39	164	NEI
Application of	Fugitive air	0	0	0	0	1	TRI
paints and	Wastewater	0	0	0	0		
coatings (spray control) ^{<i>h</i>}	Incineration or landfill	1,858	8,170	7.2	32		
	Wastewater, incineration or landfill	72	206	0.28	0.80	219–2,660 generic sites	Modeled environmental release
	Unknown (air, wastewater, incineration, or landfill)	0	0	0	0]	

OES	Type of Discharge, ^{<i>a</i>} Air Emission, ^{<i>b</i>} or Transfer	Estimated Annual Release (kg/site-year) ^d		Estimated Daily Release (kg/site-day) ^e		Number of	Source(s)
	for Disposal ^c	Central Tendency ^g	High-End	Central Tendency ^g	High-End	Facilities ^f	
	Stack air	96	192	0.38	0.77	2	NEI
	Stack air	74	122	0.66	1.1	1	TRI
	Fugitive air	181	182	0.72	0.73	2	NEI
Industrial process	Fugitive air	180	180	0.72	1.6	1	TRI
solvent use	Wastewater	No data identi to water for th		DES; EPA assum	ed no releases	N/A	N/A
	Land	510	1.0E04	2.0	40	3	Surrogate data – Incorporation into formulation, mixture, or reaction product.
	Fugitive air	1.4	2.7	3.8E-03	7.5E-03	2	NEI
Use of laboratory	Stack air	N/A	N/A	N/A	N/A	2	NEI
chemicals (liquid)	Wastewater, incineration, or landfill	17	80	4.8E-02	0.22	5,587–36,873 generic sites	Modeled environmental release
	Fugitive air	1.4	2.7	3.8E-03	7.5E-03	2	NEI
	Stack air	N/A	N/A	N/A	N/A	2	NEI
Use of laboratory chemicals (solid)	Wastewater, incineration, or landfill	4.3	19	1.2E-02	5.2E-02		
chemicals (solid)	Unknown (air, wastewater, incineration, or landfill)	1.5E-02	0.11	4.0E-05	2.9E-04	31,477–36,873 generic sites	Modeled environmental release
	Incineration or landfill	1.9E-02	0.13	5.3E-05	3.5E-04	1	
	Landfill	6.4	35	3.0	13	1	
Use of lubricants	Wastewater	15	74	6.8	26		
and functional	Recycling	0.22	1.7	0.11	0.62	-3,337-39,808 generic sites	Modeled environmental release
fluids	Fuel blending (incineration)	5.0	37	2.3	14	-generic sites	

OES	Type of Discharge, ^{<i>a</i>} Air Emission, ^{<i>b</i>} or Transfer		d Annual ease -year) ^d	Estimated Daily Release (kg/site-day) ^e		Number of	Source(s)
	for Disposal ^c	Central Tendency ^g	High-End	Central Tendency ^g	High-End	- Facilities ^f	
Use of penetrants	Fugitive air	1.6E-05	3.0E-05	6.4E08	1.2E-07		
and inspection fluids (non- aerosol)	Wastewater, incineration, or landfill	6.7	8.7	2.7E-02	3.5E-02	14,538–20,770 generic sites	Modeled environmental release
Use of penetrants	Fugitive air	0.99	1.3	4.0E-03	5.2E-03	14 541 00 767	
and inspection fluids (aerosol)	Wastewater, incineration, or landfill	5.7	7.4	2.3E-02	3.0E-02	- 14,541–20,767 generic sites	
Fabrication and final use of products or articles	No data was available to est described qualitatively.	timate releases	for this OES a	and there were n	o suitable surrog	gate release data c	or models. This release is
	Stack air	9.0E-02	177	7.8E-05	0.61	49	
	Stack air	4.3	34	1.7E-02	0.26	4	Surrogate data – Non-PVC
	Fugitive air	1.4	117	5.2E-03	0.44	49	material manufacturing
Recycling	Fugitive air	0.24	59	9.5E-04	0.45	4	
j •g	Wastewater	0.28	43	1.1E-03	0.12	14	Surrogate data – PVC plastics compounding
	Land	2.7	566	9.5E-03	2.0	3	Surrogate data – Non-PVC material manufacturing
	Stack air	0	105	0	0.37	147	NEI
	Stack air	0	190	0	1.5	20	TRI
Waste handling,	Fugitive air	6.4E-05	19	2.0E-07	5.8E-02	147	NEI
treatment, and disposal	Fugitive air	0	2.8	0	2.2E-02	20	TRI
and a sour	Wastewater	1.1	78	3.9E-03	0.27	70	TRI/DMR
	Land	4,762	7.1E04	17	247	12	TRI

^a Direct discharge to surface water; indirect discharge to non-POTW; indirect discharge to POTW

^b Emissions via fugitive air; stack air; or treatment via incineration

^c Transfer to surface impoundment, land application, or landfills

^d For modeled results, the presented central tendency and high-end are the 50th and 95th percentile values of the modeled distribution. For programmatic data, the presented central tendency is calculated from the median reported release amounts and high-end from the reported maximum release amounts. The specific

OES	Type of Discharge, ^a Air Emission, ^b or Transfer for Disposal ^c	Estimated Annual Release (kg/site-year) ^d		Estimated Daily Release (kg/site-day) ^e		Number of	Source(s)
		Central Tendency ^g	High-End	Central Tendency ^g	High-End	Facilities^f	
central tendency and high-end values presented depends on the number of sites with programmatic data. For databases with six or more reporting facilities, EPA estimated central tendency and high-end releases using the 50th and 95th percentile values, respectively. For three to five facilities, EPA estimated the central tendency and high-end releases using the 50th percentile and maximum values, respectively. For two sites, EPA presented the midpoint and the maximum value. Finally, EPA presented sites with only one data point as-is from the programmatic database.							
COU). ^{<i>f</i>} Where available, EPA used the 2020 CDR (U.S. EPA, 2020b), NEI (U.S. EPA, 2023a), DMR (U.S. EPA, 2024a), and TRI databases (U.S. EPA, 2024o), 2020 U.S. County Business Practices (U.S. Census Bureau, 2022), and Monte Carlo models to estimate the number of sites that use DBP for each condition of use. Some modeled OES calculated the number of facilities/sites, presented as 50th and 95th percentiles. Other modeled OES set the number of facilities deterministically, presented as one value. ^{<i>g</i>} The central tendency values for NEI air were calculated using the median of the reported releases at each site.							

^{*g*} The central tendency values for NEI air were calculated using the median of the reported releases at each site. ^{*h*} Data for the Application of adhesives and sealants OES and Application of paints and coatings OES were assessed together as the release estimate details provided by the database sources were insufficient to characterize between the two OESs. Data presented are expected to be representative for both OESs.

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3.2.2 Weight of Scientific Evidence Conclusions for Environmental Releases from Industrial and Commercial Sources

For each OES, EPA considered the assessment approach, the quality of the data and models, and the
uncertainties in the assessment results to determine a level of confidence for the environmental release
estimates. Table 3-5 provides EPA's weight of scientific evidence rating for each OES.

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EPA integrated numerous evidence streams across systematic review sources to develop environmental
release estimates for DBP. The Agency made a judgment on the weight of scientific evidence supporting
the release estimates based on the strengths, limitations, and uncertainties associated with the release
estimates. EPA described this judgment using the following confidence descriptors: robust, moderate,
slight, or indeterminate.

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1033 In determining the strength of the overall weight of scientific evidence, EPA considered factors that increase or decrease the strength of the evidence supporting the release estimate (whether measured or 1034 1035 estimated), including quality of the data/information, relevance of the data to the release scenario 1036 (including considerations of temporal and spatial relevance), and the use of surrogate data when 1037 appropriate. In general, higher rated studies (as determined through data evaluation) increase the weight 1038 of scientific evidence when compared to lower rated studies, and EPA gave preference to chemical- and 1039 scenario-specific data over surrogate data (e.g., data from a similar chemical or scenario). For example, 1040 a conclusion of moderate weight of scientific evidence is appropriate where there is measured release 1041 data from a limited number of sources, such that there is a limited number of data points that may not 1042 cover most or all the sites within the OES. A conclusion of slight weight of scientific evidence is 1043 appropriate where there is limited information that does not sufficiently cover all sites within the COU, 1044 and the assumptions and uncertainties are not fully known or documented. See EPA's Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances, Version 1.0: A Generic 1045 1046 TSCA Systematic Review Protocol with Chemical-Specific Methodologies (also called the "Draft Systematic Review Protocol") (U.S. EPA, 2021a) for additional information on weight of scientific 1047 1048 evidence conclusions. 1049

Table 3-5 summarizes EPA's overall weight of scientific evidence conclusions for its release estimates
for each OES. NEI obtained a high data quality rating and TRI and DMR obtained a medium quality
rating from EPA's systematic review process. In general, modeled data had data quality ratings of
medium. As a result, for releases that used GSs/ESDs, the weight of scientific conclusion was moderate
when used in tandem with Monte Carlo modeling.

1055 Table 3-5. Summary of Overall Confidence in Environmental Release Estimates by OES

OES	Weight of Scientific Evidence Conclusion in Release Estimates
Manufacturing	EPA found limited chemical specific data for the Manufacturing OES and assessed environmental releases using models and model parameters derived from CDR, the 2023 Methodology for Estimating Environmental Releases from Sampling Wastes (<u>U.S. EPA</u> , 2023f), and sources identified through systematic review (including surrogate—DINP and DIDP—industry-supplied data). EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment, with media of release assessed using appropriate default input parameters from EPA/OPPT models and industry-supplied data. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allow for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Additionally, Monte Carlo modeling uses a large number of data points (simulation runs) and considers the full distributions of input parameters. EPA used facility-specific DBP manufacturing volumes for all facilities that reported this information to CDR. For facilities that did not report DBP manufacturing volumes to CDR, operating parameters were derived using data from a current U.S. manufacturing site for DIDP and DINP that is assumed to operate using similar operating parameters as DBP manufacturing. This information was used to provide more accurate estimates than the generic values provided by the EPA/OPPT models. These strengths increase the weight of evidence.
	The primary limitation of EPA's approach is the uncertainty in the representativeness of release estimates toward the true distribution of potential releases. In addition, 1 DBP manufacturing site and 2 manufacturing and/or import sites claimed their DBP production volume as CBI for the purpose of CDR reporting; therefore, DBP throughput estimates for these sites are based on the national aggregate PV and reported import volumes from other sites. Additional limitations include uncertainties in the representativeness of the surrogate industry-provided operating parameters from DIDP and DINP and the generic EPA/OPPT models used to calculate environmental releases for DBP manufacturing sites. These limitations decrease the weight of evidence.
	As discussed above, the strength of the analysis includes using Monte Carlo modeling, which can use a range as an input, increases confidence in the analysis. However, several uncertainties discussed above, such as using surrogate parameters, reduced the confidence of the analysis. Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate, considering the strengths and limitations of the reasonably available data.
Import and repackaging	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2024o), and 2017 and 2020 NEI (U.S. EPA, 2023a, 2019e). NEI captures additional sources that are not included in TRI due to reporting thresholds. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites. The air releases assessment is based on 10 reporting sites in NEI and 4 reporting sites in TRI. Based on the NAICS and SIC codes used to map data from the reporting databases (CDR, DMR, etc.), there may be 14 additional repackaging sites that we do not have reported releases for this media in this assessment.
	Land releases are assessed using reported releases from 2017–2022 TRI. The primary limitation is that the land releases assessment is based on 2 reporting sites (2 sites only reported air releases), and EPA did not have additional sources to estimate land releases from this OES. Based on the NAICS and SIC codes used to map data from the reporting databases (CDR, DMR, NEI, etc.), there may be 26 additional repackaging sites that do not have reported releases for this media in this assessment.

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	Water releases are assessed using reported releases from 2017–2022 TRI and DMR. The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. The primary limitation is that the water release assessment is based on 1 reporting site under DMR and 4 reporting sites in TRI (2 sites only reported air releases), and EPA did not have additional sources to estimate water releases from this OES. Based on the NAICS and SIC codes used to map data from the reporting databases (CDR, NEI, etc.), there may be 23 additional repackaging sites that do not have reported releases for this media in this assessment.
	As discussed above, the strength of the analysis includes using industry reported release data to various EPA databases. However, several uncertainties discussed above, such as not capturing all release sources, slightly reduced the confidence of the analysis. Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust, considering the strengths and limitations of reasonably available data.
Incorporation into formulations, mixtures, or reaction products	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2024o), and 2017 and 2020 NEI (U.S. EPA, 2023a, 2019e). The primary strength of TRI data is that TRI compiles the data reported directly by facilities that manufacture, process, and/or use DBP. NEI captures additional sources that are not included in TRI due to reporting thresholds. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites. The air releases assessment is based on 32 reporting sites under NEI and 18 reporting sites in TRI (2 sites reported under both TRI and NEI). Based on the NAICS and SIC codes used to map data from the reporting databases (CDR, DMR, etc.), there may be 2 additional incorporation into formulation, mixture, or reaction product sites that do not have reported releases for this media in this assessment. The relatively large number of reporting sites is a strength for these release estimates as they add variability to the assessment and as a result are more likely to be representative of the industry as a whole.
	Land releases are assessed using reported releases from 2017–2022 TRI. The primary limitation is that the land releases assessment is based on three reporting sites, and EPA did not have additional sources to estimate land releases from this OES. Based on the NAICS and SIC codes used to map data from the reporting databases (CDR, DMR, NEI, etc.), there may be 47 additional incorporation into formulation, mixture, or reaction product sites that do not have reported releases for this media in this assessment.
	Water releases are assessed using reported releases from 2017–2022 TRI. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness to all sites because TRI may not capture all relevant sites, and EPA did not have additional sources to estimate water releases from this OES. The water releases assessment is based on 11 reporting sites in TRI. Based on the NAICS and SIC codes used to map data from the reporting databases (CDR, NEI, etc.), there may be 39 additional incorporation into formulation, mixture, or reaction product sites that do not have reported releases for this media in this assessment.
	As discussed above, the strength of the analysis includes using industry reported release data to various EPA databases. However, several uncertainties discussed above, such as not capturing all release sources, slightly reduced the confidence of the analysis.

OES	Weight of Scientific Evidence Conclusion in Release Estimates				
	Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust, considering the strengths and limitations of reasonably available data.				
PVC plastics compounding	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2024o), and 2017 and 2020 NEI (U.S. EPA, 2023a, 2019e). The primary strength of TRI data is that TRI compiles the data reported directly by facilities that manufacture, process, and/or use DBP. NEI captures additional sources that are not included in TRI due to reporting thresholds. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites. The air releases assessment is based on 1 reporting site under NEI and 1 reporting site in TRI. Based on the NAICS and SIC codes used to map data from the reporting databases (CDR, DMR, etc.), there may be 15 additional PVC plastics compounding sites that do not have reported releases for this media in this assessment.				
	TRI reporters identified for this OES reported 0 releases for land; however, it is uncertain if that is representative for PVC compounding sites as a whole. Because of this, EPA assessed land releases using surrogate data from sites that were identified under the OES for non-PVC materials manufacturing. Releases were estimated using reported releases from 2017–2022 TRI. The primary limitation is that the land releases assessment is based on 3 reporting sites, and EPA did not have additional sources to estimate land releases from this OES.				
	Water releases are assessed using reported releases from to DMR (<u>U.S. EPA, 2024a</u>). The primary strength of DMR data is that it may capture additional sources that are not included in TRI due to reporting thresholds. A factor that decreases the overall confidence for this OES include the uncertainty in the accuracy of reported releases. The water releases assessment is based on 14 reporting sites. Based on the NAICS and SIC codes used to map data from the reporting databases (CDR, NEI, etc.), there may be 3 PVC plastics compounding sites that do not have reported releases for this media in this assessment.				
	As discussed above, the strength of the analysis includes using industry reported release data to various EPA databases. However, several uncertainties discussed above, such as not capturing all release sources, slightly reduced the confidence of the analysis. Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust, considering the strengths and limitations of reasonably available data.				
PVC plastics converting	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2024o), and 2017 and 2020 NEI (U.S. EPA, 2023a, 2019e). The primary strength of TRI data is that TRI compiles the data reported directly by facilities that manufacture, process, and/or use DBP. NEI captures additional sources that are not included in TRI due to reporting thresholds. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites. The air releases assessment is based on 7 reporting sites under NEI and 1 reporting site in TRI. Based on the NAICS and SIC codes used to map data from the reporting databases (CDR, DMR, etc.), there may be 2 additional PVC plastics converting sites that do not have reported releases for this media in this assessment.				
	EPA did not identify land release data from TRI reporters for this OES. These releases were assessed using surrogate data from sites that were identified under the OES for non-PVC materials manufacturing due to expected similarities in the processes that occur at the				

OES	Weight of Scientific Evidence Conclusion in Release Estimates					
	sites. Releases were estimated using reported releases from 2017–2022 TRI. The primary limitation is that the land releases assessment is based on 3 reporting sites, and EPA did not have additional sources to estimate land releases from this OES.					
	EPA did not identify water release data from TRI and DMR reporters for this OES. These releases are assessed using surrogate da from sites that were identified under the OES for PVC plastics compounding due to expected similarities in the processes that occ the sites. Water releases are assessed using reported releases from to DMR (U.S. EPA, 2024a). The primary strength of DMR data that it may capture additional sources that are not included in TRI due to reporting thresholds. A factor that decreases the overall confidence for this OES include the uncertainty in the accuracy of reported releases. The water releases assessment is based on 14 reporting sites.					
	As discussed above, the strength of the analysis includes using industry reported release data to various EPA databases. However, several uncertainties discussed above, such as not capturing all release sources, slightly reduced the confidence of the analysis. Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust, considering the strengths and limitations of reasonably available data.					
Non-PVC material manufacturing	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2024o), and 2017 and 2020 NEI (U.S. EPA, 2023a, 2019e). NEI captures additional sources that are not included in TRI due to reporting thresholds. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites. The air releases assessment is based on 49 reporting sites under NEI and 4 reporting sites in TRI (one site reported under both TRI and NEI). The relatively large number of reporting sites is a strength for these release estimates as they add variability to the assessment and as a result are more likely to be representative of the industry as a whole.					
	Land releases are assessed using reported releases from 2017–2022 TRI. The primary limitation is that the land releases assessment is based on 3 reporting sites, and EPA did not have additional sources to estimate land releases from this OES. Based on the NAICS and SIC codes used to map data from the reporting databases (CDR, DMR, NEI, etc.), there may be 49 additional non PVC-material manufacturing sites that do not have reported releases for this media in this assessment.					
	Water releases are assessed using reported releases from 2017–2022 TRI. The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the limitations in representativeness to all sites because TRI may not capture all relevant sites, and EPA did not have additional sources to estimate water releases from this OES. The water releases assessment is based on 1 reporting site in TRI. Based on the NAICS and SIC codes used to map data from the reporting databases (CDR, NEI, etc.), there may be 51 additional sites that do not have reported releases for this media in this assessment.					
	As discussed above, the strength of the analysis includes using industry reported release data to various EPA databases. However, several uncertainties discussed above, such as not capturing all release sources, slightly reduced the confidence of the analysis.					

OES	Weight of Scientific Evidence Conclusion in Release Estimates				
	Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust, considering the strengths and limitations of reasonably available data.				
Application of adhesives and sealants	Air releases are assessed using reported releases from 2017 and 2020 NEI (U.S. EPA, 2023a, 2019e). NEI captures additional sources that are not included in TRI due to reporting thresholds. Another factor that increases the strength of the data is that air release data was provided by 166 reporting sites, which adds variability to the assessment. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the fact that the type of end-use product is uncertain between adhesives/sealants and paint/coatings, and the limitations in representativeness to all sites because NEI may not capture all relevant sites.				
	EPA was unable to identify chemical and site-specific releases to land and water and assessed these releases using the ESD on the Use of Adhesives (OECD, 2015). EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment and media of release using appropriate default input parameters from the ESD and EPA/OPPT models. The Agency believes a strength of the Monte Carlo modeling approach is that variation in model input values allow for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. Additionally, EPA used DBP-specific data on concentration and application methods for different DBP-containing adhesives and sealant products in the analysis. These data provide more accurate estimates than the generic values provided by the ESD. These strengths increase the weight of evidence.				
	The primary limitation of EPA's approach to land and water releases is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, the generic default values in the ESD may not represent releases from real-world sites that incorporate DBP into adhesives and sealants. Based on the number of formulated products identified, the overall production volume of DBP for this OES was estimated by assuming that the portion of DBP with uncertain end-use will be split between adhesives/sealants and paint/coating products. EPA lacks data on DBP-specific facility use volume and number of use sites; therefore, the Agency based facility throughput estimates and number of sites on industry-specific default facility throughputs from the ESD, DBP product concentrations, and the overall production volume range from CDR data which has a reporting threshold of 25,000 lb. These limitations decrease the weight of evidence.				
	As discussed above, the strength of the analysis includes using industry reported release data to various EPA databases. However, several uncertainties discussed above, such as not capturing all release sources, slightly reduced the confidence of the analysis. Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust, considering the strengths and limitations of reasonably available data.				
Application of paints and coatings	Air releases are assessed using reported releases from 2017 and 2020 NEI (U.S. EPA, 2023a, 2019e). NEI captures additional sources that are not included in TRI due to reporting thresholds. Another factor that increases the strength of the data is that air release data was provided by 166 reporting sites, which adds variability to the assessment. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, the fact that the type of end-use product is uncertain between adhesives/sealants and paint/coatings, and the limitations in representativeness to all sites because NEI may not capture all relevant sites.				

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	EPA was unable to identify chemical and site-specific releases to land and water and assessed these releases using the ESD on the Application of Radiation Curable Coatings, Inks and Adhesives and the GS on Coating Application via Spray Painting in the Automotive Refinishing Industry (OECD, 2011a, b). EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment. EPA assessed media of release using appropriate default input parameters from the ESD, GS, and EPA/OPPT models and a default assumption that all paints and coatings are applied via spray application. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allow for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. Additionally, EPA used DBP-specific data on concentration for different DBP-containing paints and coatings in the analysis. These data provide more accurate estimates than the generic values provided by the GS and ESD. These strengths increase the weight of evidence. The primary limitation of EPA's approach to land and water releases is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, the generic default values in the GS and ESD may not represent releases from real-world sites that incorporate DBP into paints and coatings. Additionally, EPA assumes spray applications of the coatings, which may not be representative of other coating application methods. In addition, the Agency lacks data on DBP-specific facility use volume and number of use sites; therefore, EPA based throughput estimates on values from ESD, GS, and CDR data which has a reporting threshold of 25,000 lb and an annual DBP production volume range. Finally, EPA estimated the overall producti
	that can use range as an input. However, several uncertainties discussed above, such as the unavailability of reported releases for land and water, slightly reduced the confidence of the analysis. Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust, considering of the strengths and limitations of reasonably available data.
Industrial process solvent use	Air releases are assessed using reported releases from 2017–2022 TRI (U.S. EPA, 2024o), and 2017 and 2020 NEI (U.S. EPA, 2023a, 2019e). NEI captures additional sources that are not included in TRI due to reporting thresholds. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites. The air releases assessment is based on 2 reporting sites under NEI and 1 reporting site in TRI (site reported under both TRI and NEI). Based on the NAICS and SIC codes used to map data from the reporting databases (CDR, DMR, etc.), there may be 1 additional industrial process solvent use site that is not accounted for in this assessment.
	EPA was unable to identify land release data from TRI reporters for this OES. These releases were assessed using surrogate data from sites that were identified under the OES for incorporation into formulation, mixtures, or reaction products due to expected similarities in the processes that occur at the sites. Land releases were estimated using reported releases from 2017–2022 TRI. The primary limitation is that the land releases assessment is based on 3 reporting sites, and EPA did not have additional sources to estimate land releases from this OES.

OES	Weight of Scientific Evidence Conclusion in Release Estimates				
	EPA was unable to identify water release data from TRI and DMR reporters for this OES; however, based on the specifics of DBP's use in the process, the Agency does not expect water releases for this OES. This is based on process information provided by Huntsman Corporation, which was rated high in systematic review (Huntsman, 2015).				
	As discussed above, the strength of the analysis includes using industry reported release data to various EPA databases. However, several uncertainties discussed above, such as not capturing all release sources or using surrogate reported releases, slightly reduced the confidence of the analysis. Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust, considering of the strengths and limitations of reasonably available data.				
Use of laboratory chemicals	Air releases are assessed using reported releases from 2017 and 2020 NEI (U.S. EPA, 2023a, 2019e). NEI captures additional sources that are not included in TRI due to reporting thresholds. NEI data was collected from 2 reporting sites. Factors that decrease the overall confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites because NEI may not capture all relevant sites.				
	EPA were unable to identify chemical and site-specific releases to land and water and assessed these releases using the Draft GS on the Use of laboratory chemicals (U.S. EPA, 2023h). EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment, and media of release using appropriate default input parameters from the GS and EPA/OPPT models for solid and liquid DBP materials. EPA believes a strength of the Monte Carlo modeling approach is that variation in model input values allow for estimation of a range of potential release values that are more likely to capture actual releases than a discrete value. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. EPA used SDSs from identified laboratory DBP products to inform product concentration and material states. These strengths increase the weight of evidence.				
	EPA believes the primary limitation of the land and water release assessments to be the uncertainty in the representativeness of values toward the true distribution of potential releases. In addition, the Agency lacks data on DBP-specific laboratory chemical throughput and number of laboratories; therefore, EPA based the number of laboratories and throughput estimates on stock solution throughputs from the Draft GS on the Use of Laboratory Chemicals and on CDR Reporting Thresholds. Additionally, because no entries in CDR indicate a laboratory use and there were no other sources to estimate the volume of DBP used in this OES, EPA developed a high-end bounding estimate based on the CDR reporting threshold of 25,000 lb or 5% of total product volume for a given use, which by definition is expected to over-estimate the average release case. These limitations decrease the weight of evidence.				
	As discussed above, the strength of the analysis includes using industry reported release data to NEI and using Monte Carlo modeling that can use range as an input. However, several uncertainties discussed above, such as the unavailability of reported releases for land and water, slightly reduced the confidence of the analysis. Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust, considering of the strengths and limitations of reasonably available data.				
Use of lubricants and functional fluids	EPA found limited chemical-specific data for the Use of lubricants and functional fluids OES and assessed releases to the environment using the ESD on the Lubricant and Lubricant Additives. EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment and media of release using appropriate default input parameters from the ESD and				

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	EPA/OPPT models. The Agency believes the strength of the Monte Carlo modeling approach is that variation in model input values and a range of potential release values are more likely to capture actual releases than discrete values. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. EPA did not identify a lubricant or functional fluid product that contained DBP but identified 1 DINP-containing functional fluid for use in Monte Carlo analysis for the risk evaluation for that chemical. Therefore, EPA used products containing DINP as surrogate for concentration and use data in the analysis. This data provides more accurate estimates than the generic values provided by the ESD.
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, the generic default values in the ESD may not represent releases from real-world sites using DBP-containing lubricants and functional fluids. In addition, EPA lacks information on the specific facility use rate of DBP-containing products and number of use sites; therefore, EPA estimated the number of sites and throughputs based on CDR, which has a reporting threshold of 25,000 lb (<i>i.e.</i> , not all potential sites represented), and an annual DBP production volume range that spans an order of magnitude. The respective share of DBP use for each OES presented in the EU Risk Assessment Report may differ from actual conditions adding some uncertainty to estimated releases. Furthermore, EPA lacks chemical-specific information on concentrations of DBP in lubricants and functional fluids and primarily relied on surrogate data. Actual concentrations may differ adding some uncertainty to estimated releases.
	As discussed above, the strength of the analysis includes using Monte Carlo modeling, which can use a range as an input, increases confidence in the analysis. However, several uncertainties discussed above, such as the lack of availability of reported releases, reduced the confidence of the analysis. Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate, considering the strengths and limitations of the reasonably available data.
Use of penetrants and inspection fluids	EPA found limited chemical specific data for the Use of penetrants and inspection fluids OES and assessed releases to the environment using the ESD on the Use of Metalworking Fluids (OECD, 2011c). EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate releases to the environment, media of release using appropriate default input parameters from the ESD, and EPA/OPPT models. The Agency believes the strength of the Monte Carlo modeling approach is that variation in model input values and a range of potential release values are more likely to capture actual releases than discrete values. Monte Carlo modeling also consider a large number of data points (simulation runs) and the full distributions of input parameters. EPA assessed an aerosol and non-aerosol application method based on surrogate DINP-specific penetrant data that also provided DINP concentration. The safety and product data sheets that EPA used to obtain these values provide more accurate estimates than the generic values provided by the ESD.
	The primary limitation of EPA's approach is the uncertainty in the representativeness of estimated release values toward the true distribution of potential releases at all sites in this OES. Specifically, the generic default values in the ESD and the surrogate material parameters may not be representative of releases from real-world sites that use DBP-containing inspection fluids and penetrants. Additionally, because no entries in CDR indicate this OES use case and there were no other sources to estimate the volume of DBP used in this OES, EPA developed a high-end bounding estimate based on CDR reporting threshold, which by definition is expected to overestimate the average release case.

OES	Weight of Scientific Evidence Conclusion in Release Estimates
	As discussed above, the strength of the analysis includes using Monte Carlo modeling, which can use a range as an input, increases confidence in the analysis. However, several uncertainties discussed above, such as the lack of availability of reported releases, reduced the confidence of the analysis. Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate, considering the strengths and limitations of the reasonably available data.
Fabrication or use of final product or articles	No data were available to estimate releases for this OES and there were no suitable surrogate release data or models. This release is described qualitatively.
Recycling	EPA found limited chemical specific data for the Recycling OES. EPA assessed releases to the environment from recycling activities using the Revised Draft GS for the Use of Additives in Plastic Compounding (U.S. EPA, 2021e) as surrogate for the recycling process. EPA/OPPT models were combined with Monte Carlo modeling to estimate releases to the environment. EPA believes the strength of the Monte Carlo modeling approach is that variation in model input values and a range of potential release values are more likely to capture actual releases than discrete values. Monte Carlo modeling also considers a large number of data points (simulation runs) and the full distributions of input parameters. EPA referenced the Quantification and evaluation of plastic waste in the United States (Milbrandt et al., 2022), to estimate the rate of PVC recycling in the United States. EPA estimated the DBP PVC market share (based on the surrogate market shares from DINP and DIDP) to define an approximate recycling volume of PVC containing DBP. These strengths increase the weight of evidence.
	volume. DBP may also be present in non-PVC plastics that are recycled; however, EPA was unable to identify information on these recycling practices. These limitations decrease the weight of evidence. As discussed above, the strength of the analysis includes using Monte Carlo modeling, which can use a range as an input, increases confidence in the analysis. However, several uncertainties discussed above, such as the lack of availability of reported releases,
	reduced the confidence of the analysis. Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate, considering the strengths and limitations of the reasonably available data.
Waste handling, treatment, and disposal	<i>General Waste Handling, Treatment, and Disposal</i> Air releases for non-POTW sites are assessed using reported releases from 2017–2022 TRI, and 2017 and 2020 NEI. NEI captures additional sources that are not included in TRI due to reporting thresholds. Factors that decrease the confidence for this OES include the uncertainty in the accuracy of reported releases, and the limitations in representativeness to all sites because TRI and NEI may not capture all relevant sites. The air release assessment is based on 147 sites under NEI and 20 sites in TRI (with 9 sites reporting under

OES	Weight of Scientific Evidence Conclusion in Release Estimates			
	both NEI and TRI). Based on other reporting databases (CDR, DMR, etc), there are 12 additional non-POTW sites that do not have reported releases for this media in this assessment.			
	Land releases for non-POTW are assessed using reported releases from 2017–2022 TRI. The primary limitation is that the land releases assessment is based on 12 reporting sites, and EPA did not have additional sources to estimate land releases from this OES. Based on the reporting databases (CDR, DMR, NEI, etc.), there are 214 additional waste handling, treatment, and disposal sites that do not have reported releases for this media in this assessment.			
	Water releases for non-POTW sites are assessed using reported releases from 2017 to 2022 TRI and DMR. The primary strength of TRI data is that TRI compiles the best readily available release data for all reporting facilities. For non-POTW sites, the primary limitation is that the water release assessment is based on 13 reporting sites under DMR and one reporting site in TRI, and EPA did not have additional sources to estimate water releases from this OES. Based on other reporting databases (CDR, NEI, etc), there are 156 additional sites that do not have reported releases for this media in this assessment.			
	As discussed above, the strength of the analysis includes using industry reported release data to various EPA databases. However, several uncertainties discussed above, such as not capturing all release sources, slightly reduced the confidence of the analysis. Therefore, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust, considering the strengths and limitations of reasonably available data.			
	<i>Waste Handling, Treatment, and Disposal (POTW and Remediation)</i> Water releases for POTW and remediation sites are assessed using reported releases from 2017–2022 DMR, which has a high overall data quality determination from the systematic review process. A strength of using DMR data and the Pollutant Loading Tool used to pull the DMR data is that the tool calculates an annual pollutant load by integrating monitoring period release reports provided to the EPA and extrapolating over the course of the year. However, this approach assumes average quantities, concentrations, and hydrologic flows for a given period are representative of other times of the year. A total of 57 POTW/remediation sites reported releases of DBP to DMR. Based on this information, for POTW releases, EPA has concluded that the weight of scientific evidence for this assessment is moderate to robust, considering the strengths and limitations of reasonably available data.			

10573.2.3Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for the1058Environmental Release Assessment

1059 Strengths

1060 EPA compiled release information using reported releases from the 2017 through 2022 TRI (U.S. EPA, 2024o), 2017 through 2022 DMR (U.S. EPA, 2024a), and 2017 through 2020 NEI (U.S. EPA, 2023a, 1061 1062 2019e). NEI obtained a high data quality rating and TRI and DMR obtained a medium quality rating 1063 from EPA's systematic review process. Furthermore, TRI-reporting facilities are required to submit their "best available data" to EPA for TRI reporting purposes. Some facilities are required to measure or 1064 1065 monitor emission or other waste management quantities due to regulations unrelated to the TRI Program 1066 (e.g., permitting requirements), or due to company policies. These existing, reasonably available data are often used by facilities for TRI reporting purposes, as they represent the best available data (e.g., stack 1067 1068 releases can be directly measured by stack testing using EPA reference methods providing a directly 1069 measured emission rate which can then be used to calculate annual emissions). DMR-reporting facilities are required to monitor, measure, and report effluent at regular intervals, thus generating many site-1070 1071 specific water release datapoints. Though NEI does not require stack testing or continuous emissions 1072 monitoring and reporting agencies may use different emission estimation methods, reasonable estimates 1073 may be obtained through mass-balance calculations, the use of emission factors, and engineering 1074 calculations.

1075

1076 Limitations

1077 Facilities are only required to report to TRI if the facility has 10 or more full-time employees, is 1078 included in an applicable NAICS code, and manufactures, processes, or uses the chemical in quantities 1079 greater than a certain threshold (25,000 lb for manufacturers and processors and 10,000 lb for users). For 1080 NEI, the Air Emissions Reporting Requirements (AERR) only requires Criteria Air Pollutants (CAP) data reporting, Hazardous Air Pollutants (HAP) data reporting is voluntary. As a result, EPA augments 1081 1082 SLT-provided HAP data with other information to better estimate point, nonpoint, and mobile source 1083 HAP emissions. For point sources, HAP augmentation is performed on each emissions source using the 1084 WebFIRE database or data from TRI. DMR data are submitted by NPDES permit holders to states or directly to the EPA according to the monitoring requirements of the facility's permit. States are only 1085 1086 required to load major discharger data into DMR and may or may not load minor discharger data. The 1087 definition of major vs. minor discharger is set by each state and could be based on discharge volume or 1088 facility size. Due to these limitations across programs, some sites may release DBP but are not included 1089 in TRI, NEI, or DMR. It is uncertain, the extent to which, sites not captured in these databases release 1090 DBP into the environment or whether releases from sites not in the databases are to water, air, or 1091 landfill.

1092

Manufacturers and importers of DBP submit CDR data to EPA if they meet reporting threshold requirements. Sites are only required to report production data to CDR if their yearly production volume exceeds 25,000 lb. Sites can claim their production volume as CBI, further limiting the production volume information in CDR. As a result, some sites that produce or use DBP may not be included in the CDR dataset and the total production volume for a given OES may be underestimated. The extent to which sites that are not captured in the CDR release DBP into the environment is unknown. The media of release for these sites is also unknown.

1100

1101 Assumptions and Uncertainties

1102 There is some uncertainty in the DMR data pulled using the ECHO Pollutant Loading Tool Advanced

1103 Search option. For facilities that reported having zero pollutant loads to DMR, the EZ Search Load

Module uses a combination of setting non-detects equal to zero and as one-half the detection limit to calculate the annual pollutant loadings. This method could cause overestimation or underestimation of annual and daily pollutant loads. A strength of using DMR data and the Pollutant Loading Tool is that the tool calculates an annual pollutant load by integrating monitoring period release reports provided to the EPA and extrapolating over the course of the year. However, this approach assumes average quantities, concentrations, and hydrologic flows for a given period are representative of other times of the year.

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1112 When monitoring or direct measurement data are not reasonably available or are known to be non-

1113 representative for TRI reporting purposes, the TRI regulations require that facilities determine release

and other waste management quantities of TRI-listed chemicals by making reasonable estimates.
There is additional uncertainty in daily release estimates for air emissions. Facilities reporting to TRI
report annual air emissions while NEI reports annual air emissions and the estimated number of release
days. To assess daily air emissions for TRI, EPA used relevant data from relevant ESDs or GSs to

- 1118 estimate the expected number of release days.
- 1119

1120 CDR information on the downstream processing and use of DBP at facilities is also limited; therefore, 1121 there is some uncertainty as to the production volume attributed to a given OES. For OES with limited 1122 CDR data, EPA developed potential production volume ranges given reported CDR data, known 1123 reporting thresholds, and the national aggregate production volume of 1,000,000 to 10,000,000 lb for 1124 DBP in 2019. To handle an OES without programmatic data, EPA used the potential production volume 1125 ranges as uniform distributions in Monte Carlo modeling when assessing releases for each OES. Due to 1126 the wide range of potential production volumes attributable to certain OES, the overall releases may be 1127 over or underestimated. DBP releases at each site may vary from day to day, such that on any given day 1128 the actual daily release rate may be higher or lower than the estimated average daily release rate. 1129

1130 The EPA has further identified the following additional uncertainties that contribute to the overall1131 uncertainty in the environmental release assessment:

- 1132
- Use of Census Bureau for Number of Facilities: In some cases, EPA estimated the maximum number of facilities for a given OES using data from the U.S. Census. In such cases, the Agency determined the maximum number of sites for use in Monte Carlo modeling from industry data from the U.S. Census Bureau, County and Business Patterns dataset (U.S. BLS, 2023).
- Uncertainties Associated with Facility Throughputs: EPA estimated facility throughputs of DBP or DBP-containing products using various methods, including using generic industry data presented in the relevant GS or ESD or by calculation based on estimated number of facilities and overall production volume of DBP from CDR for the given OES. In either case, the values used for facility throughputs may encompass a wide range of possible values. Due to these uncertainties, the facility throughputs may be under or overestimated.
- Uncertainties Associated with Number of Release Days Estimate: For most OESs, EPA
 estimated the number of release days using programmatic data where available, or from GSs,
 ESDs, or SpERC factsheets when no programmatic data were found. In such cases, EPA used
 applicable sources to estimate a range of release days over the course of an operating year. Due
 to uncertainty in DBP-specific facility operations, release days may be under or overestimated.
- Uncertainties Associated with DBP-Containing Product Concentrations: In most cases, the number of identified products for a given OES were limited. In such cases, EPA estimated a range of possible DBP concentrations for products in the OES. However, the extent to which

1151these products represent all DBP-containing products within the OES is uncertain. For OESs1152with little-to-no reasonably available product data, EPA estimated DBP concentrations from GSs1152EED

- 1153 or ESDs. Due to these uncertainties, the average product concentrations may be under or 1154 overestimated.
- overestimate

3.3 Summary of Concentrations of DBP in the Environment

1156 Based on the environmental release assessment summarized in Section 3.2 and presented in EPA's Draft 1157 Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025q), DBP is expected to be released to the environment via air, water, biosolids, and disposal to 1158 landfills. Environmental media concentrations were quantified in ambient air, soil from ambient air 1159 1160 deposition, surface water, and sediment. Additional analysis of surface water used as drinking water was 1161 conducted for the Human Health Risk Assessment (Section 4). Given limited available information on 1162 DBP in soil and groundwater from releases to biosolids and landfills, along with the availability of high-1163 quality physical and chemical and fate data (Section 2), concentrations of DBP in soil and groundwater 1164 from releases to biosolids and landfills were not quantified (discussed further below. Air releases of 1165 DBP from fugitive and stack emissions with deposition to soil were estimated using the Integrated Indoor/Outdoor Air Calculator (IIOAC) Model, as described in Section 8.1.3 of the Draft Environmental 1166 Media, General Population, and Environmental Exposure Assessment for Dibutyl Phthalate (DBP) 1167 1168 (U.S. EPA, 2025p).

1169

1170 EPA relied on its fate assessment to determine which environmental pathways to consider for its 1171 screening level analysis of environmental exposure and general population exposure. Details on the 1172 environmental partitioning and media assessment can be found in Draft Chemistry, Fate, and Transport 1173 Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2024i). Briefly, based on DBP's fate parameters 1174 and behavior (e.g., Henry's Law constant, $\log K_{OC}$, water solubility, fugacity modeling), EPA 1175 anticipates DBP to be predominantly in water and soil, though DBP may also exist in air and sediments. 1176 Therefore, EPA quantitatively assessed concentrations of DBP in surface water, sediment, ambient air, 1177 and soil from air to soil deposition. Soil concentrations of DBP from land application of biosolids were 1178 not quantitatively assessed due to limited available information as well as the expectation that DBP is to have limited persistence potential and mobility in soils receiving biosolids. Thus, they present limited 1179 1180 exposure potential. In contrast, EPA has greater confidence in quantifying DBP concentrations in soil resulting from air to soil deposition since it is direct deposition into soil rather than mobility from air to 1181 1182 soil (as with biosolids). Therefore, EPA quantified air to soil deposition with a screening level approach 1183 for the purpose of the environmental exposure assessment.

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1185 Further detail on the screening level assessment of each environmental pathway can be found in the 1186 Draft Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl 1187 *Phthalate (DBP)* (U.S. EPA, 2025p). EPA began its environmental and general population exposure 1188 assessment with a screening level approach using the highest modeled environmental media 1189 concentrations for the environmental pathways expected to be of greatest concern. The highest 1190 environmental media concentrations were estimated using the release estimates for an OES associated 1191 with a COU that, paired with conservative assumptions of environmental conditions, resulted in the greatest modeled concentration of DBP in a given environmental medium type. Therefore, EPA did not 1192 1193 estimate environmental concentrations of DBP resulting from all OESs presented in Table 3-1. Details 1194 on the use of screening level analyses in exposure assessment can be found in EPA's Guidelines for 1195 Human Exposure Assessment (U.S. EPA, 2019d).

1196

1197For the water pathway, different hydrological flow rates were used for the different screening level1198exposure scenarios. The 30Q5¹ flows (lowest 30-day average flow that occurs in a 5-year period) are

1199 used to estimate acute, incidental human exposure through swimming or recreational contact. The

- harmonic mean² flows provide a more conservative estimate as compared to annual average flows and are therefore preferred for assessing potential chronic human exposure via drinking water. The harmonic
- 1202 mean is also used for estimating human exposure through fish ingestion because it takes time for
- 1203 chemical concentrations to accumulate in fish. Lastly, for aquatic or ecological exposure, a $7Q10^3$ flow
- 1204 (lowest 7-day average flow that occurs in a 10-year period) is used to estimate exceedances of
- 1205 concentrations of concern for aquatic life (U.S. EPA, 2007b).
- 1206

1207 For the screening level assessment, the OES(s) resulting in the highest environmental concentration of 1208 DBP to be used for subsequent exposure screening varied by environmental media, as shown in Table 1209 3-6. Releases to surface water were sorted by comparing daily release estimates with receiving water 1210 body flow rates to determine the order of release concentrations prior to modeling. Manufacturing yielded the highest water concentration using a 7Q10 flow, a 30Q5 flow, and harmonic mean flow. The 1211 combined release estimates from the Waste handling, treatment, and disposal (stack; corresponding to 1212 1213 the Disposal COU) and Application of paints, coatings, adhesives, and sealants (fugitive; corresponding 1214 to the Industrial/commercial use; Construction, paint, electrical, and metal products; and Adhesives and sealants/paints and coatings COUs) OESs yielded the highest ambient air concentration. The summary 1215 1216 table also indicates whether the high-end estimate was used for environmental or general population 1217 exposure assessment as well as which flow statistics were selected to screen for risks to human or 1218 environmental health. For the screening level analysis, if the high-end environmental media 1219 concentrations did not result in potential environmental or human health risk, no further OESs were 1220 assessed, and no further refinements were pursued. For the surface water and ambient air pathways, only 1221 the OESs resulting in the highest estimated water column or ambient air concentrations were carried 1222 forward to the human health risk assessment (*i.e.*, Manufacturing for water; Waste handling, treatment, 1223 and disposal [stack]; Application of paints, coatings, adhesives, and sealants; and Application of paints, 1224 coatings, adhesives, and sealants [fugitive] for ambient air). For aquatic ecological exposure, the OES 1225 resulting in the highest estimated water column or sediment concentrations (Manufacturing) was used as 1226 the starting point to determine the reference concentration for the screening assessment; see Sections 5.1 1227 and 5.3.1 for details of how the ecological screening assessment was performed. 1228

² Harmonic mean is defined as the inverse mean of reciprocal daily arithmetic mean flow values. These flows represent a long-term average and are used to generate estimates of chronic human exposures via drinking water and fish ingestion.

¹ 30Q5 is defined as 30 consecutive days of lowest flow over a 5-year period. These flows are used to determine acute human exposures via drinking water (U.S. EPA, 2007b).

³ 7Q10 is defined as 7 consecutive days of lowest flow over a 10-year period. These flows are used to calculate estimates of chronic surface water concentrations to compare with the COCs for aquatic life.

Table 3-6. Summary of High-End DBP Concentrations in Various Environmental Media from Environmental Releases

OES ^a	Release Media	Environmental Media	DBP Concentration	Environmental or General Population
		Total water column (7Q10) ^{<i>b</i>} , P50 flow ^{<i>c</i>}	1,160 μg/L (286-day average)	
Manufacturing	Water	P75 flow	67.80 μg/L (286-day average)	Environmental
		P90 flow	4.00 μg/L (286-day average)	
		Benthic sediment (7Q10), P50 flow	27 mg/kg (7-day average)	
Manufacturing	Sediment	P75 flow	1.57 mg/kg (7-day average)	Environmental
		P90 flow	0.093 mg/kg (7-day average)	
Fugitive: application of paints, coatings, adhesives, and sealants stack: waste handling, treatment, and disposal	Air deposition to soil	Annual deposition rate to soil	0.00178 mg/kg/yr (365-day release)	Environmental and General Population
	Water	Total water column (30Q5) ^{<i>d</i>} , P50 flow ^{<i>c</i>}	885 μg/L	General Population
Manufacturing		P75 flow	46.6 µg/L	
		P90 flow	3.0 µg/L	
		Surface water (30Q5) ^d	14.5 μg/L	
Waste handling, treatment, and disposal	Water	Surface water (harmonic mean) ^{<i>e</i>}	14.5 µg/L	General Population
Waste handling, treatment, and disposal (stack)		Daily-averaged total (fugitive and stack, 100 m)	17.26 μg/m ³	General Population
Application of paints, coatings, adhesives, and sealants Application of paints, coatings, adhesives, and sealants (fugitive)	Ambient air	Annual-averaged total (fugitive and stack, 100 m)	11.82 µg/m ³	General Population

^{*a*} Table 3-1 provides the crosswalk of OES to COUs.

^b 7Q10 is the 7 consecutive days of lowest flow over a 10-year period.

^c The P50, P75, and P90 flows refer to the 50th, 75th, and 90th percentiles of the distribution of water body flow rates in generic release scenarios; see Appendix B of the *Draft Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025p).

^{*d*} 30Q5 is defined as 30 consecutive days of lowest flow over a 5-year period.

^{*e*} Harmonic mean is defined as the inverse mean of reciprocal daily arithmetic mean flow values. These flows represent a long-term average.

1231**3.3.1** Weight of Scientific Evidence Conclusions

Detailed discussion of the strengths, limitations, and sources of uncertainty for presented environmental
media concentrations leading to a weight of scientific evidence conclusion can be found in the *Draft Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025p). However, the weight of scientific evidence conclusion is
summarized below for the modeled concentrations for surface water and ambient air.

For the screening level assessment, EPA used the release estimates presented in Table 3-4 to model DBP concentrations in different environmental media. The Agency assessed additional variables when considering the weight of scientific evidence for its estimation of environmental media concentrations. Some additional considerations include the use of an additional model (Point Source Calculator of the Variable Volume Water Model [VVWM-PSC], IIOAC, etc.) using the release as an input, the applicability of the release data to the environmental media being considered, likelihood of an

1244 occurrence of a release to the specific environmental compartment, and available monitoring data.

1245 **3.3.1.1 Surface Water**

For the screening level human health assessment, EPA utilized releases associated with the Manufacturing OES as it resulted in the highest surface water concentrations. EPA determined the surface water concentration associated with this OES represented a conservative high-end exposure scenario (approximately 20× higher than concentrations indicated by monitoring data) and was appropriate to use in its screening level assessment to assess all other OESs and their associated COUs.

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1252 EPA utilized daily release information as an input to the Variable Volume Water Model with Point 1253 Source Calculator Tool (VVWM-PSC) Model to estimate surface water concentrations for use in 1254 general population and environmental exposure assessments. As mentioned in Section 3.2, the Agency 1255 estimated a range for daily releases for each OES when possible. EPA was not able to estimate site-1256 specific releases for the Final use of products or articles OES. Disposal sites handling post-consumer, end-use DBP were not quantifiable due to the wide and dispersed use of DBP in PVC and other 1257 products. Pre-consumer waste handling, treatment, and disposal are assumed to be captured in upstream 1258 1259 OES. Several OESs had releases estimated using programmatic data. EPA compiled programmatic 1260 release information using reported releases from TRI, DMR, and NEI. NEI obtained a high-quality 1261 rating whereas TRI and DMR obtained a medium-quality rating from EPA's systematic review process, 1262 as discussed in Table 3-5. One limitation was that the extent to which sites not captured in these 1263 databases release DBP into the environment is uncertain. Additionally, not all OESs are represented in 1264 these databases.

1265 For OESs that did not have reported release data, releases were estimated using GSs/ESDs. For releases 1266 that use GSs/ESDs, EPA concluded the weight of scientific conclusion was moderate. Five OESs 1267 (Manufacturing, Application of adhesives and sealants, Application of paints and coatings, Use of 1268 laboratory chemicals, and Use of penetrants and inspection fluids) had modeled releases from generic 1269 scenarios for multimedia discharges to combinations of multiple of the following: water, wastewater 1270 (POTW), incineration, landfill, and air. For these generic scenario OESs, there was insufficient 1271 information to determine the fraction of the release going to each of the reported media types, including 1272 to surface water. For these OESs, surface water, pore water, and sediment concentrations of DBP were 1273 estimated using VVWM-PSC, assuming a conservative scenario in which all of the multimedia releases 1274 were to surface water. Based on comparison with reported scenarios for DBP wastewater release, EPA 1275 has less confidence in the unlikely combination of high-end releases of DBP to the lowest-flow generic 1276 condition (P50) water bodies. Where EPA had sufficient data to produce estimates of releases to surface 1277 water from generic scenarios (such as with the Use of lubricants and functional fluids OES), EPA

estimated release concentrations, but these estimates had greater uncertainty in the modeled exposureresults relative to those releases for which EPA obtained programmatic release data.

1280 Table 3-7 below identifies the data available for use in modeling surface water concentrations for each 1281 OES and EPA's confidence in the estimated surface water concentrations used for exposure assessment. 1282 For the screening level general population assessment, the Agency identified the OES (Manufacturing) that resulted in the highest surface water concentrations to assess exposure (Table 3-6). EPA prioritized 1283 1284 use of programmatic data with actual release data from reporting facilities where overall confidence in 1285 the estimates would be higher. For estimating surface water concentrations from releases, the Agency 1286 prioritized the use of TRI annual release reports over DMR monitoring data, reviewing DMR period 1287 data as supporting information for the releases reported to TRI. Releases from facilities reporting via 1288 TRI Form A, which represents undefined releases to unspecified media types, less than 500 lb per year, 1289 were not directly modeled. Because of this, and for the purpose of the tiered approach taken for the 1290 general population analysis, environmental concentrations from potential releases to surface water from 1291 facilities reporting via TRI Form A were expected to be lower than the high-end concentrations applied 1292 for screening.

For facilities reporting releases to TRI and DMR, relevant flow data from the associated receiving water body were collected by querying multiple EPA databases and permit IDs under the National Pollutant Discharge Elimination System (NPDES). The flow data include self-reported hydrologic reach codes on NPDES permits and the best available flow estimates from EPA and U.S. Geological Survey (USGS) databases. Other model inputs were derived from reasonably available literature collected and evaluated through EPA's systematic review process for TSCA risk evaluations. All monitoring and experimental data included in this analysis were from articles rated medium or high quality from this process.

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1302 The weight of scientific evidence conclusions regarding confidence in the release estimates from 1303 facilities and the associated receiving water body and hydrologic flow information described in the 1304 preceding paragraphs, for the estimated surface water concentrations associated with each OES and water release data type are presented in Table 3-7. EPA proceeded with the use of TRI data for modeling 1305 1306 surface water concentrations as a screening step for exposure pathways requiring screening level 1307 refinement beyond the first tier employing release estimates from the Manufacturing OES. EPA 1308 identified the Waste handling, treatment, and disposal OES as appropriate as it resulted in a high-end 1309 surface water concentration based on reporting data for actual facilities. Additionally, release 1310 concentrations were estimated at the point of release in the receiving water body, as a conservative 1311 assumption to evaluate the upper-end of potential exposure concentrations for a given release. Overall, 1312 EPA has robust confidence that the high-end estimated surface water concentration modeled using the Manufacturing OES is appropriate to use in its high-end, screening level assessment to assess all OESs 1313 1314 and their associated COUs—including those with releases that were unable to be quantified—if no risk 1315 is found beyond the benchmark. Releases from all other OESs and their associated COUs (including 1316 OESs and COUs with releases that could not be quantified and those with releases modeled from generic 1317 scenarios) are expected to result in lower environmental concentrations in surface water. Where risks in 1318 subsequent analyses are found in excess of the appropriate benchmark, further analysis of other OES is 1319 conducted. General population and environmental risk estimates from surface water can be found in 1320 Sections 4.3.4 and 5.3.2, respectively. 1321

1322 Table 3-7. Summary of Weight of Scientific Evidence Associated with Each OES

OES^a	Water Release Data Type(s)	WOSE Surface Water Concentrations
Manufacturing ^b	Generic Scenario (multimedia)	No facilities reported releases for this OES, so EPA modeled releases using generic scenarios. Because EPA was unable to determine the fraction of multimedia releases to surface water, the Agency estimated a conservative scenario assuming that all multimedia releases went to surface water. EPA has slight confidence in the precision of the high-end of these estimates and resulting determinations of risk, due to compounding conservative assumptions creating an unlikely release scenario. However, the Agency has moderate to robust confidence in these estimates representing a theoretical upper-bound of potential release concentrations, which can effectively be applied in a screening exercise to screen for risk.
Import and repackaging	TRI, DMR	All reported releases to TRI within this OES were via Form A. Due to EPA's high confidence that such releases to surface water, if present, would not exceed the high-end releases applied for screening, no quantitative estimate of surface water release concentrations was conducted for this OES for TRI releases. One facility reporting to DMR listed DBP monitoring but reported no discharge in the last decade.
Incorporation into formulation, mixture, or reaction product	TRI	All reported releases to TRI within this OES were via Form A. Due to EPA's high confidence that such releases to surface water, if present, would not exceed the high-end releases applied for screening, no quantitative estimate of surface water release concentrations was conducted for this OES.
PVC plastics compounding	TRI, DMR	EPA conducted modeling using the PSC tool to estimate surface water and sediment concentrations of DBP. PSC inputs include physical and chemical properties of DBP which received a high confidence rating and a reported DBP release from TRI which received a moderate to robust rating. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust.
Non-PVC material compounding	TRI, DMR	EPA conducted modeling using the SC tool to estimate surface water and sediment concentrations of DBP. PSC inputs include physical and chemical properties of DBP, which received a high confidence rating and a reported DBP release from TRI, which received a moderate to robust rating. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust.
Incorporation into adhesives and sealants	Generic Scenario (multimedia)	No facilities reported releases for this OES, so EPA modeled releases using generic scenarios. Because the Agency was unable to determine the fraction of multimedia releases to surface water, EPA estimated a conservative scenario assuming that all multimedia releases went to surface water. EPA has slight confidence in the precision of the high-end of these estimates and resulting determinations of risk, due to compounding conservative assumptions creating an unlikely release scenario. However, EPA has moderate to robust confidence in these estimates representing a theoretical upper-bound of potential release

OES ^a	Water Release Data Type(s)	WOSE Surface Water Concentrations
		concentrations, which can effectively be applied in a screening exercise to screen out risk.
PVC plastics converting (surrogate release data from PVC plastics compounding)	TRI	EPA conducted modeling using the PSC tool to estimate surface water and sediment concentrations of DBP. PSC inputs include physical and chemical properties of DBP, which received a high confidence rating and reported DBP releases from TRI, which received a moderate to robust rating. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate.
Non-PVC material converting	TRI	EPA conducted modeling using the PSC tool to estimate surface water and sediment concentrations of DBP. PSC inputs include physical and chemical properties of DBP, which received a high confidence rating and reported DBP releases from TRI, which received a moderate to robust rating. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust.
Recycling (surrogate release data from PVC plastics compounding)	DMR	EPA conducted modeling using the PSC tool to estimate surface water and sediment concentrations of DBP. PSC inputs include physical and chemical properties of DBP, which received a high confidence rating and reported DBP releases from TRI, which received a moderate to robust rating. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate.
Industrial process solvent use	No water releases	EPA was unable to identify water release data from TRI and DMR reporters for this OES; however, based on the specifics of DBP's use in the process, EPA does not expect water releases for this OES.
Application of adhesives and sealants	Generic Scenario (multimedia)	No facilities reported releases for this OES, so EPA modeled releases using generic scenarios. Because the Agency was unable to determine the fraction of multimedia releases to surface water, EPA estimated a conservative scenario assuming that all multimedia releases went to surface water. EPA has slight confidence in the precision of the high-end of these estimates and resulting determinations of risk, due to compounding conservative assumptions creating an unlikely release scenario. However, EPA has moderate to robust confidence in these estimates representing a theoretical upper bound of potential release concentrations, which can effectively be applied in a screening exercise to screen out risk.
Application of paints and coatings	Generic Scenario (multimedia)	No facilities reported releases for this OES, so EPA modeled releases using generic scenarios. Because EPA was unable to determine the fraction of multimedia releases to surface water, EPA estimated a conservative scenario assuming that all multimedia releases went to surface water. EPA has slight confidence in the precision of the high-end of these estimates and resulting determinations of risk, due to compounding conservative assumptions creating an unlikely release scenario. However, EPA has moderate to robust confidence in these estimates representing a theoretical upper bound of potential release concentrations, which can effectively be applied in a screening exercise to screen out risk.

OES ^a	Water Release Data Type(s)	WOSE Surface Water Concentrations
Use of laboratory chemicals	Generic Scenario (multimedia)	No facilities reported releases for this OES, so EPA modeled releases using generic scenarios. Because the Agency was unable to model releases to just surface water, EPA concluded that there was insufficient precision in release data to calculate a surface water concentration based on the release data.
Use of lubricants and functional fluids	Generic Scenario (water-specific)	No facilities reported releases for this OES, so EPA modeled releases using generic scenarios. Sufficient release data were available to model a surface water-specific release, and the resulting range of estimated concentrations were below the high-end releases applied for general population screening.
Use of penetrants and inspection fluids	Generic Scenario (water-specific)	No facilities reported releases for this OES, so EPA modeled releases using generic scenarios. Sufficient release data were available to model a surface water-specific release, and the resulting range of estimated concentrations were below the high-end releases applied for general population screening.
Waste handling, treatment, and disposal	TRI, DMR	EPA conducted modeling using the PSC tool to estimate surface water and sediment concentrations of DBP. PSC inputs include physical and chemical properties of DBP, which received a high confidence rating and reported DBP releases from TRI, which received a moderate to robust rating. Based on this information, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust.

DMR = Discharge Monitoring Report; OES = occupational exposure scenario; PSC = point source calculator (tool); TRI = Toxics Release Inventory

^{*a*} Table 3-1 provides a crosswalk of industrial and commercial COUs to OES.

^b The Manufacturing OES is highlighted as this scenario was used for screening level assessments.

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3.3.1.2 Ambient Air and Air to Soil Deposition

1324 EPA used the IIOAC Model, previously peer-reviewed methodology for fenceline communities (U.S. 1325 EPA, 2022b), and integrated recommendations from that and other peer reviews to evaluate exposures 1326 and deposition rates via the ambient air pathway for this assessment. The IIOAC Model was developed 1327 based on a series of pre-run scenarios within American Meteorological Society/EPA Regulatory Model 1328 (AERMOD; the Agency's regulatory model), which gives EPA greater confidence in the IIOAC Model 1329 results. However, since results from IIOAC are based on the pre-run AERMOD scenarios, IIOAC modeling is limited to the parameters (e.g., stack parameters, meteorological data, and other factors) 1330 1331 used as inputs to those pre-run AERMOD scenarios; thus limiting the flexibility of the IIOAC results for 1332 highly site-specific or date specific modeling needs (e.g., if refined analyses are needed). The screening 1333 level analyses presented in this assessment, IIOAC provides reliable and reproduceable results which 1334 can be used to characterize upper-bound exposures and derive screening level risk estimates, giving 1335 EPA moderate confidence in the results and findings.

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1337 The Agency considered three different datasets for DBP releases for this assessment. Those datasets

1338 include EPA estimated releases based on production volumes of DBP from facilities that manufacture,

- 1339 process, repackage, or dispose of DBP (<u>U.S. EPA, 2025q</u>); releases reported to TRI by industry (2017–
- 1340 2022 reporting years); and releases reported to NEI (U.S. EPA, 2025q) (2017 and 2020 reporting years).
- 1341 This gives the Agency moderate confidence that release data utilized is representative and high-end

1342 releases are not missed. EPA uses the maximum daily releases of DBP across all OES/COUs as direct 1343 inputs to the IIOAC Model, giving the Agency high confidence that the releases used are health protective for a screening level analysis. However, the use of estimated or reported annual release data 1344 1345 and number of operating days to calculate daily average releases assumes operations are continuous and 1346 releases are the same for each day of operation. This can underestimate short-term or daily exposure and 1347 deposition rates because results may miss actual peak releases (and associated exposures) if higher and lower releases occur on different days. The uncertainties associated with the release data are detailed in 1348 1349 the Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (U.S. 1350 EPA, 2025q).

1351 1352 The maximum daily fugitive release value used in this assessment was reported to the 2017 NEI dataset 1353 and is associated with the Application of paints, coatings adhesives, and sealants OES. The maximum 1354 daily stack release value used in this assessment was reported to the TRI dataset and is associated with 1355 the Waste handling, treatment, and disposal OES. Both maximum daily release values represent the maximum daily release reported across all facilities and COUs and are used as direct inputs to the 1356 IIOAC Model to estimate concentrations and deposition rates. Additionally, these releases were reported 1357 1358 by two different facilities in two different locations. Therefore, these two releases do not align either 1359 spatially or temporally. For this screening level ambient air assessment, EPA modeled these two releases 1360 assuming they occurred from the same location, at the same time, during the same reporting year, and 1361 under the same OES to determine a "total exposure" to DBP from both release types. These assumptions 1362 provide a conservative estimate of total exposure, ensure possible exposure from either release type are 1363 not missed, and retain health protective estimates of exposure and associated risk estimates. The lack of 1364 spatial or temporal alignment gives the Agency low confidence in the exposure scenario modeled (cannot occur at same time under assumptions modeled) and overestimates ambient concentrations and 1365 1366 deposition rates at the evaluated distances. Due to the conservative assumptions made along with the use 1367 of the highest release estimates, EPA has robust confidence the modeled ambient air concentrations and 1368 deposition rates are highly conservative estimates appropriate for a screening level analysis for all OESs 1369 and associated COUs. Based on the risk findings described in Section 4.1.3.1-even with the 1370 conservative assumptions and exposure scenario modeled—results indicate the total exposure or 1371 deposition rate under this scenario still does not indicate an exposure or risk concern. Therefore, EPA 1372 has robust confidence that exposure to and deposition rates of DBP via the ambient air pathway do not 1373 pose an exposure or risk concern and no further, refined analysis is pursued. If new information becomes available and after EPA's consideration of such information and results, under the same scenario and 1374 1375 assumptions, indicate an exposure or risk concern, then the Agency would have low confidence in the results and refine the analysis to be more representative of a real exposure scenario (e.g., only determine 1376 1377 exposures and derive risk estimates based on a single facility reporting both release types).

1378 4 HUMAN HEALTH RISK ASSESSMENT

DBP – Human Health Risk Assessment (Section 4): Key Points

EPA evaluated all reasonably available information to support human health risk characterization of DBP for workers, ONUs, consumers, bystanders, and the general population. Exposures to workers, ONUs, consumers, bystanders, and the general population are described in Section 4.1. Human health hazards are described in Section 4.2. Human health risk characterization is described in Section 4.3. The following bullets summarize the key points.

Exposure Key Points

- EPA assessed inhalation and dermal exposures for workers and ONUs, as appropriate, for each OES (Section 4.1.1). Both dermal and inhalation were primary routes of exposure, depending on the OES.
- EPA assessed inhalation, dermal, and oral exposures for consumers and bystanders, as appropriate, for each TSCA COU (Section 4.1.2) in scenarios that represent a range of use patterns and behaviors. The primary route of exposure was dermal for most products, followed by inhalation.
- EPA assessed inhalation, oral, and dermal exposures for the general population via ambient air, surface water, drinking water, and fish ingestion for Tribal populations (Sections 4.1.3 and 4.3.4).
- EPA assessed non-attributable cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP for the U.S. civilian population using NHANES urinary biomonitoring data and reverse dosimetry (Section 4.4.2).

Hazard Key Points

- EPA identified adverse effects on the developing male reproductive system consistent with a disruption of androgen action, leading to phthalate syndrome, as the most sensitive and robust non-cancer hazard associated with oral exposure to DBP in experimental animal models (Section 4.2).
- A non-cancer POD of 2.1 mg/kg-day (derived from a $BMDL_5 = 9 mg/kg$ -day) was selected to characterize non-cancer risks for acute, intermediate, and chronic durations of exposure. A total uncertainty factor of 30 was selected for use as the benchmark margin of exposure.
- Under the *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005), EPA has preliminarily determined that there is *Suggestive Evidence of Carcinogenic Potential* of DBP in rats based on pancreatic cancer. Consistent with the guidelines, the Agency did not quantitatively evaluate DBP for cancer risk.
- EPA derived draft relative potency factors (RPFs) based on a common hazard endpoint (*i.e.*, reduced fetal testicular testosterone). Draft RPFs were derived via meta-analysis and benchmark dose (BMD) modeling.

Risk Assessment Key Points

- Dermal exposures drive acute non-cancer risks to workers in occupational settings (Section 4.3.2).
- Dermal exposures drive acute non-cancer risks to consumers (Section 4.3.3).
- For the general population, exposures to DBP through biosolids, landfills, surface water, drinking water, fish ingestion, and ambient air were not determined to be pathways of concern. (Sections 4.1.3 and 4.3.4).
- EPA considered PESS throughout the exposure assessment, hazard identification, and dose-response analysis supporting this draft risk evaluation (Section 4.3.4.1).
- EPA considered cumulative risk to workers and consumers through exposure to DBP from individual COUs in combination with cumulative non-attributable national exposure to DEHP, DBP, BBP, DIBP, and DINP as estimated from NHANES biomonitoring data (Sections 4.4.4 and 4.4.5).

1379 **4.1 Summary of Human Exposures**

1380 4.1.1 Occupational Exposures

The following subsections briefly describe EPA's approach to assessing occupational exposures and 1381 1382 provide exposure assessment results for each OES. As stated in the final scope for DBP (U.S. EPA, 1383 2020c), the Agency evaluated exposures to workers and occupational non-users (ONUs) via the 1384 inhalation route, and exposures to workers via the dermal route associated with the manufacturing, 1385 processing, use, and disposal of DBP. Also, EPA assessed dermal exposure to workers and ONUs from mist and dust deposited on surfaces. The Draft Environmental Release and Occupational Exposure 1386 1387 Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025q) provides additional details on the 1388 development of approaches and the exposure assessment results.

1389 4.1.1.1 Approach and Methodology

As described in the final scope document (<u>U.S. EPA, 2020c</u>), EPA distinguished exposure levels among
 potentially exposed employees for workers and ONUs. In general, the primary difference between

1392 workers and ONUs is that workers may handle DBP and have direct contact with the DBP, while ONUs

- 1393 work in the general vicinity of DBP but do not handle DBP. Where possible, for each condition of use
- 1394 (COU), EPA identified job types and categories for workers and ONUs.

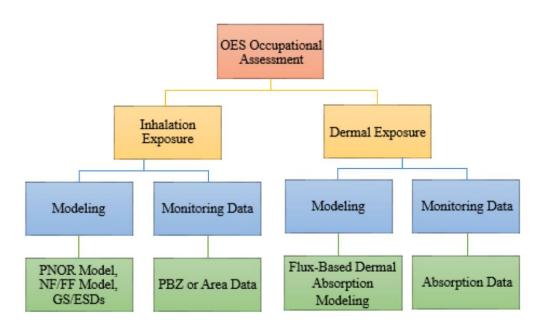
1395 As discussed in Section 3.1.1.1, EPA established OESs to assess the exposure scenarios within each 1396 COU; Table 3-1 provides a crosswalk between COUs and OESs. For occupational inhalation exposures, 1397 EPA primarily used chemical-specific inhalation exposure monitoring data for the OESs. In the absence 1398 of inhalation monitoring data, the Agency used inhalation exposure models to estimate central tendency 1399 and high-end exposures. For cases where occupational dermal exposure to liquid DBP was assessed, 1400 EPA used a flux-limited dermal absorption value derived from a study conducted by Doan et al. (2010) 1401 to estimate high-end and central tendency dermal exposures. For occupational dermal exposure to solid 1402 DBP, EPA used a flux-limited dermal absorption model to estimate high-end and central tendency 1403 dermal exposures for workers in each OES. For occupational dermal exposure assessment, EPA 1404 assumed a standard 8-hour workday and the chemical is contacted at least once per day. Because DBP 1405 has low volatility and relatively low absorption, it is possible that the chemical remains on the surface of 1406 the skin after dermal contact until the skin is washed. Therefore, in absence of exposure duration data, 1407 EPA has assumed that absorption of DBP from occupational dermal contact with materials containing 1408 DBP may extend up to 8 hours per day (U.S. EPA, 1991). However, dermal exposure may be eliminated if a worker uses proper personal protective equipment (PPE; e.g., respirators, gloves) or washes their 1409 1410 hands after contact with DBP or DBP-containing material. Therefore, the assumption of an 8-hour 1411 exposure duration for DBP may lead to overestimation of dermal exposure. For average adult workers, 1412 the surface area of contact was assumed equal to the area of one hand (*i.e.*, 535 cm²) or two hands (*i.e.*, 1413 1,070 cm²) for central tendency or high-end exposures, respectively (U.S. EPA, 2011a). The dermal

1414 methods are described in the *Draft Environmental Release and Occupational Exposure Assessment for* 1415 *Dibutyl Phthalate (DBP)* (U.S. EPA, 2025q).

1415 1416

EPA evaluated the quality of data sources using the data quality review evaluation metrics and rating
criteria described in the Draft Systematic Review Protocol (U.S. EPA, 2021a). The Agency assigned an
overall quality level of high, medium, or low to the relevant data. In addition, EPA established an
overall confidence level for the data when integrated into the occupational exposure assessment. The
Agency considered the assessment approach, quality of the data and models, and uncertainties in

- 1422 assessment results to assign an overall weight of scientific evidence rating of robust, moderate, or slight.
- 1423



1424

Figure 4-1. Approaches Used for Each Component of the Occupational Assessment for Each OES
 PBZ = personal breathing zone; PNOR = particulates not otherwise regulated

1427

1428 For the inhalation and dermal exposure routes, EPA provided occupational exposure results that are 1429 representative of central tendency and high-end exposure conditions. The central tendency is expected to represent occupational exposures in the center of the exposure distribution for a given COU. For risk 1430 1431 evaluation, EPA used the 50th percentile (median), mean (arithmetic or geometric), mode, or midpoint 1432 value of a distribution to represent the central tendency scenario. The Agency preferred to provide the 1433 50th percentile of the distribution. However, if the full distribution was unknown, EPA used either the 1434 mean, mode, or midpoint of the distribution to represent the central tendency, depending on the statistics 1435 available for the distribution. The high-end exposure is expected to represent occupational exposures 1436 that occur at probabilities above the 90th percentile but below the highest exposure for any individual 1437 (U.S. EPA, 1992). For this draft risk evaluation, EPA provided high-end results at the 95th percentile. If 1438 the 95th percentile was not reasonably available, the Agency used a different percentile greater than or 1439 equal to the 90th percentile but less than or equal to the 99th percentile, depending on the statistics 1440 available for the distribution. If the full distribution is not known and the preferred statistics are not 1441 reasonably available, EPA estimated a maximum or bounding estimate in lieu of the high-end. Table 4-1 1442 provides a summary of the approach used to assess worker and ONU exposures and the Agency's 1443 weight of scientific evidence rating for the given exposure assessments.

1444 Table 4-1. Summary of Exposure Monitoring and Modeling Data for Occupational Exposure Scenarios

					In	halation	Exposure	e					De	rmal Exp	osure
		DBP N			Surrogate Monitoring						Emp	irical	Modeling		
OES	Worker	# Data Points / # Data Sources	ONU		Data Quality Ratings	Worker	# Data Points / # Data Sources	ONU	# Data Point	Data Quality Ratings	Worker	ONU	Worker	Data Quality Rating	Worker
Manufacturing	✓	3 data sources ^a	×	N/A	М	×	N/A	x	N/A	N/A	×	×	√	М	×
Import and repackaging	×	N/A	×	N/A	N/A	~	3 data sources ^a	x	N/A	М	×	×	~	М	x
Incorporation into formulations, mixtures, or reaction products	×	N/A	×	N/A	N/A	~	3 data sources ^{<i>a</i>}	×	N/A	М	×	x	~	М	x
PVC plastics compounding	×	N/A	×	N/A	N/A	√	4 data points ^b	×	N/A	М	~	×	~	М	√
PVC plastics converting	~	4 data points ^b	x	N/A	М	x	N/A	x	N/A	N/A	~	x	x	N/A	~
Non-PVC materials manufacturing (compounding and converting)	×	N/A	x	N/A	N/A	~	4 data points ^b	x	N/A	М	~	x	~	М	~
Application of paints and coatings	~	14 data points	x	N/A	M/H	×	N/A	x	N/A	N/A	×	x	~	М	x
Application of adhesives and sealants	~	19 data points ^c	x	N/A	М	×	N/A	x	N/A	N/A	×	x	~	М	x
Use of laboratory chemicals	×	N/A	x	N/A	N/A	~	19 data points ^c	×	N/A	М	~	x	~	М	~
Use of industrial process solvents	x	N/A	x	N/A	N/A	~	3 data source ^a	x	N/A	М	x	x	~	М	x
Use of lubricants and functional fluids	×	N/A	x	N/A	N/A	~	19 data points ^c	×	N/A	М	×	x	~	М	x
Use of penetrants and inspection fluids	×	N/A	x	N/A	N/A	x	N/A	×	N/A	N/A	~	x	~	М	x
Fabrication of final product from articles	~	3 data points	×	N/A	М	×	N/A	x	N/A	N/A	~	×	×	N/A	√
Recycling	×	N/A	x	N/A	N/A	x	N/A	x	N/A	N/A	✓	x	x	N/A	\checkmark
Waste handling, treatment, and disposal	×	N/A	×	N/A	N/A	×	N/A	×	N/A	N/A	~	×	×	N/A	✓

		Inhalation Exposure												Dermal Exposure		
		DBP M			Surrogate Monitoring					Modeling		Empirical				
OES	Worker	# Data Points / # Data Sources			Data Quality Ratings		# Data Points / # Data Sources	ONU	# Data Point	Data Quality Ratings	Worker	ONU	Worker	Data Quality Rating	Worker	

ONU = occupational non-user

Where EPA was not able to estimate ONU inhalation exposure from monitoring data or models, this was assumed equivalent to the central tendency experienced by workers for the corresponding OES.

Surrogate monitoring data means monitoring data from another similar OES was used.

M: Medium and H: High from EPA's systematic review process (U.S. EPA, 2021a)

Data quality ratings for reported data are based on EPA systematic review and include ratings Low (L), Medium (M), and High (H)

× No data available

✓ Data available

^{*a*} For the Manufacturing, Import and repackaging, Incorporation into formulations, mixtures, or reaction products, and Use of industrial process solvents OESs, the same inhalation monitoring data were used. The monitoring data were obtained from three risk evaluations, each study presented a single exposure concentration during manufacturing of DBP. However, these exposure values were estimated from multiple data points measured during DBP manufacturing. For more information, see Section 3.1.4.2 of the *Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025q).

^b For PVC plastics compounding, PVC plastics converting, and Non-PVC materials manufacturing OESs, the same inhalation monitoring data from PVC plastics converting were used.

^c For Application of adhesives and sealants, Use of laboratory chemicals, and Use of lubricants and functional fluids OESs, the same monitoring data from application of adhesives and sealants were used.

1445

1446 **4.1.1.2 Number of Workers and ONUs**

Table 4-2 summarizes the number of facilities and total number of exposed workers for all OESs. For
scenarios in which the results are expressed as a range, the low end of the range is based on the 50th
percentile estimate of the number of sites and the upper end of the range is based on the 95th percentile
estimate of the number of sites. For some OESs, the estimated number of facilities is based on the
number of reporting sites to the 2020 CDR (U.S. EPA, 2020b), NEI (U.S. EPA, 2023a), DMR (U.S.
EPA, 2024a), and TRI databases (U.S. EPA, 2024o).

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Table 4-2. Summary of Total Number of Workers and ONUs Potentially Exposed to DBP for Each
 OES

OES ^a	Total Exposed Workers	Total Exposed ONUs ^b	Number of Facilities	Notes
Manufacturing	195	90	5	Number of workers and ONU estimates based on the Bureau of Labor Statistics (BLS) and U.S. Census Bureau data (<u>U.S. BLS, 2023</u> ; <u>U.S. Census Bureau</u> , <u>2015</u>). Number of facilities estimated based on identified sites from CDR.
Import and Repackaging	560	252	28	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S. BLS, 2023;</u> <u>U.S. Census Bureau, 2015</u>). Number of facilities estimated based on identified sites from CDR, TRI, NEI, and DMR.
Incorporation into formulations, mixtures, or reaction products	1,700	750	50	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2023; U.S. Census Bureau, 2015). Number of facilities estimated based on identified sites from CDR, TRI, NEI, and DMR.
PVC plastics compounding	459	204	17	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2023; U.S. Census Bureau, 2015). Number of facilities estimated based on identified sites from CDR, TRI, NEI, and DMR.
PVC plastics converting	180	50	10	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2023; U.S. Census Bureau, 2015). Number of facilities estimated based on identified sites from CDR, TRI, NEI, and DMR.
Non-PVC material manufacturing	1,196	312	52	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2023; U.S. Census Bureau, 2015). Number of facilities estimated based on identified sites from CDR, TRI, NEI, and DMR.
Application of adhesives and sealants	5,264-44,408	1,692–14,274	94–793	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S. BLS, 2023;</u> <u>U.S. Census Bureau, 2015</u>). Number of facilities estimated using modeled data.

OES ^a	Total Exposed Workers	Total Exposed ONUs ^b	Number of Facilities	Notes
Application of paints and coatings	2,628-31,488	1,314–15,744	219–2,624	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S. BLS, 2023;</u> <u>U.S. Census Bureau, 2015</u>). Number of facilities estimated using modeled data.
Industrial process solvent use	117	54	3	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2023; U.S. Census Bureau, 2015). Number of facilities estimated based on identified sites from CDR, TRI, NEI, and DMR.
Use of laboratory chemicals	36,873	331,857	36,873	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S. BLS, 2023;</u> <u>U.S. Census Bureau, 2015</u>). Number of facilities estimated using data from BLS.
Use of lubricants and functional fluids	293,656– 3,503,104	73,414– 875,776	3,337– 39,808	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S. BLS, 2023;</u> <u>U.S. Census Bureau, 2015</u>). Number of facilities estimated using modeled data.
Use of penetrants and inspection fluids	188,994– 270,010	87,228– 124,620	14,538– 20,770	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S. BLS, 2023;</u> <u>U.S. Census Bureau, 2015</u>). Number of facilities estimated using modeled data.
Fabrication or use of final products or articles		N/A		Number of sites data was unavailable for this OES. Based on the BLS and U.S. Census Bureau data (U.S. BLS, 2023; U.S. Census Bureau, 2015).
Recycling	754	406	58	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (U.S. BLS, 2023; U.S. Census Bureau, 2015). Number of facilities estimated based on identified recycling sites.
Waste handling, treatment, and disposal	2,951	1,589	227	Number of workers and ONU estimates based on the BLS and U.S. Census Bureau data (<u>U.S. BLS, 2023;</u> <u>U.S. Census Bureau, 2015</u>). Number of facilities estimated based on identified sites from CDR, TRI, NEI, and DMR.

^a An OES is based on a set of facts, assumptions, and inferences that describe how releases and exposures take place within an occupational COU. The occurrence of releases/exposures may be similar across multiple COUs (multiple COUs mapped to single OES), or there may be several ways in which releases/exposures take place for a given COU (single COU mapped to multiple OESs).

^b ONUs do not directly handle DBP, but may be exposed to dust, vapors. or mists that enter their personal breathing zone while working in locations near where DBP is handled by workers.

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4.1.1.3 Summary of Inhalation Exposure Assessment

1458 Table 4-3 presents a summary of inhalation exposure results based on reasonably available monitoring 1459 data and exposure modeling for each OES. This tables provides a summary of the 8-hour time weighted 1460

average (8-hour TWA) inhalation exposure estimates, as well as the acute dose (AD), the intermediate 1461 average daily dose (IADD), and the chronic average daily dose (ADD). The Draft Environmental

- 1463 provides exposure results for females of reproductive age and ONUs—including additional details
- regarding AD, IADD, and ADD calculations along with EPA's approach and methodology forestimating inhalation exposures.

1466 Table 4-3. Summary of Average Adult Worker Inhalation Exposure Results for Each OES^a

OES	All Rou 8-Hour (mg/r	TWA	A (mg/kg			DD sg/day)		DD (g/day)		Method Used	
	СТ	HE	СТ	HE	СТ	HE	СТ	HE	Data Type(s)	Monitorin	g Data
	CI	пе	CI	пе	CI	HE		пе	Data Type(s)	Source(s)	Rating(s) ^b
Manufacturing	0.50	1.0	6.3E–02	0.13	4.6E–02	9.2E–02	4.3E-02	8.6E–02	Monitoring data	(<u>ECB, 2008; ECJRC,</u> 2004; <u>SRC, 2001</u>)	All three sources received a rating of medium
Import and repackaging	0.50	1.0	6.3E–02	0.13	4.6E–02	9.2E–02	4.3E-02	8.6E–02	Surrogate monitoring data	(ECB, 2008; ECJRC, 2004; SRC, 2001)	All three sources received a rating of medium
Incorporation into formulations, mixtures, or reaction products	0.50	1.0	6.3E–02	0.13	4.6E–02	9.2E-02	4.3E-02	8.6E–02	Surrogate monitoring data	(<u>ECB, 2008; ECJRC, 2004; SRC, 2001</u>)	All three sources received a rating of medium
PVC plastics compounding	0.34	2.9	4.3E–02	0.36	3.1E-02	0.26	2.9E-02	0.25	Surrogate monitoring data, PNOR Model ^c for dust	(<u>ECJRC, 2004</u>)	Source received a rating of medium
PVC plastics converting	0.34	2.9	4.3E-02	0.36	3.1E-02	0.26	2.9E-02	0.25	Monitoring data, PNOR Model for dust	(ECJRC, 2004)	Source received a rating of medium
Non-PVC materials manufacturing (compounding and converting)	0.29	1.7	3.6E-02	0.21	2.6E-02	0.15	2.4E-02	0.14	Surrogate monitoring data, PNOR Model for dust	(<u>ECJRC, 2004</u>)	Source received a rating of medium
Application of adhesives and sealants	5.0E-02	0.10	6.3E–03	1.3E-02	4.6E–03	9.2E–03	4.0E-03	8.6E–03	Monitoring data	(<u>NIOSH, 1977</u>)	Source received a rating of medium
Application of paints and coatings	0.83	5.2	0.10	0.66	7.6E–02	0.48	7.1E-02	0.45	Monitoring data	(<u>OSHA, 2019; Rohm</u> <u>& Haas, 1990</u>)	OSHA CEHD received a rating of high; the Rohm & Haas

OES	All Rou 8-Hour (mg/r	TWA	A (mg/k			IADD (mg/kg/day)		DD (g/day)	Method Used		
	СТ НІ		СТ	HE	СТ	ПЕ	СТ	HE	Data Type(s)	Monitorir	ng Data
	CI	HE	CI	пе	CI	HE	CI	пе	Data Type(s)	Source(s)	Rating(s) ^b
											source received a rating of low
Use of industrial process solvents	0.50	1.0	6.3E–02	0.13	4.6E-02	9.2E-02	4.3E-02	8.6E-02	Surrogate monitoring data	(ECB, 2008; ECJRC, 2004; SRC, 2001)	All three sources received a rating of medium
Use of laboratory chemicals (solid)	3.8E-02	0.54	4.8E–03	6.8E–02	3.5E-03	5.0E-02	3.3E-03	4.6E–02	PNOR Model for dust	No monitoring data source	N/A
Use of laboratory chemicals (liquid)	5.0E-02	0.10	6.3E–03	1.3E-02	4.6E–03	9.2E–03	4.3E–03	8.6E–03	Surrogate monitoring data	(<u>NIOSH, 1977</u>)	Source received a rating of medium
Use of lubricants and functional fluids	5.0E-02	0.10	6.3E–03	1.3E-02	4.2E-04	1.7E-03	3.4E-05	1.4E-04	Surrogate monitoring data	(<u>NIOSH, 1977</u>)	Source received a rating of medium
Use of penetrants and inspection fluids	1.5	5.6	0.19	0.70	0.14	0.51	0.13	0.48	Near-field/far- field approach	No monitoring data source	N/A
Fabrication or use of final products from articles	0.10	0.84	1.3E-02	0.11	9.2E–03	7.7E–02	8.6E-03	7.2E–02	Monitoring data	(ECJRC, 2004; Rudel et al., 2001)	Both sources received a rating of medium
Recycling	0.11	1.6	1.4E-02	0.20	9.9E–03	0.14	9.2E-03	0.13	PNOR Model for dust	No monitoring data source	N/A
Waste handling, treatment, and disposal	0.11	1.6	1.4E-02	0.20	9.9E–03	0.14	9.2E–03	0.13	PNOR Model for dust	No monitoring data source	N/A

 a AD = acute dose; ADD = chronic average daily dose; CT = central tendency; HE = high-end; IADD = intermediate average daily dose; OES = occupational exposure scenario; TWA = time-weighted average

^b The ratings included in this table reflect the rating of the data source as determined by the systematic review process. The rating of the data source per the systematic review process is not reflective of the confidence in the risk estimates for the OES.

^c Generic Model for Central Tendency and High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated ("PNOR Model") (U.S. EPA, 2021d)

1468 4.1.1.4 Summary of Dermal Exposure Assessment

- 1469 Table 4-4 presents a summary of dermal exposure results, which are based on reasonably available
- empirical dermal absorption data and dermal absorption modeling. Flux-based dermal approaches wereconsidered more appropriate because DBP has relatively low absorption and low volatility. This table
- 1472 provides a summary of the acute potential dose rate (APDR) for occupational dermal exposure
- 1473 estimates, as well as the AD, the IADD, and the chronic ADD. The *Draft Environmental Release and*
- 1474 Occupational Exposure Assessment for Dibutyl Phthalate (U.S. EPA, 2025q) provides exposure results
- 1475 for females of reproductive age and ONUs. The *Draft Environmental Release and Occupational*
- 1476 *Exposure Assessment for Dibutyl Phthalate* also provides additional details regarding AD, IADD, and
- 1477 ADD calculations along with EPA's approach and methodology for estimating dermal exposures.

1478 Table 4-4. Summary of Average Adult Worker Dermal Exposure Results for Each OES

Dermal Estimates (Average Adult Worker)										
OES	Exposu	re Type	APDR ^{a b}	(mg/day)	AD ^a (n	ng/kg/day)	IADD ^a ((mg/kg/day)	ADD ^a (1	ng/kg/day)
UES	Liquid ^c	Solid ^c	CT ^d	\mathbf{HE}^{d}	\mathbf{CT}^{d}	\mathbf{HE}^{d}	CT ^d	\mathbf{HE}^{d}	CT ^d	\mathbf{HE}^{d}
Manufacturing	Х		100	201	1.3	2.5	0.92	1.8	0.86	1.7
Import and repackaging	Х		100	201	1.3	2.5	0.92	1.8	0.86	1.7
Incorporation into formulation, mixture, or reaction product	Х		100	201	1.3	2.5	0.92	1.8	0.86	1.7
PVC plastics compounding	Х	X	102	204	1.3	2.5	0.93	1.9	0.87	1.7
PVC plastics converting		Х	1.4	2.7	1.7E-02	3.4E-02	1.2E-02	2.5E-02	1.2E-02	2.3E-02
Non-PVC material manufacturing	Х		102	204	1.3	2.5	0.93	1.9	0.87	1.7
Application of adhesives and sealants	Х		100	201	1.3	2.5	0.92	1.8	0.80	1.7
Application of paints and coatings	Х		100	201	1.3	2.5	0.92	1.8	0.86	1.7
Use of laboratory chemicals (liquid)	Х		75	201	0.94	2.5	0.69	1.8	0.64	1.7
Use of laboratory chemicals (solid)		X	1.4	2.7	1.7E-02	3.4E-02	1.2E-02	2.5E-02	1.2E-02	2.3E-02
Industrial process solvent use	Х		100	201	1.3	2.5	0.92	1.8	0.86	1.7
Use of lubricants and functional fluids	Х		56	169	0.70	2.1	4.7E-02	0.28	3.8E-03	2.3E-02
Use of penetrants and inspection fluids	Х		100	201	1.3	2.5	0.92	1.8	0.85	1.7
Fabrication or use of final products and articles		Х	1.4	2.7	1.7E-02	3.4E-02	1.2E-02	2.5E-02	1.2E-02	2.3E-02

	Dermal Estimates (Average Adult Worker)										
OFS	Exposu	re Type	APDR ^{a b} (mg/day)		AD^{a} (mg	g/kg/day)	IADD ^a (n	ng/kg/day)	ADD ^a (mg/kg/day)		
OES	Liquid ^c	Solid ^c	\mathbf{CT}^{d}	\mathbf{HE}^{d}	\mathbf{CT}^d	\mathbf{HE}^{d}	\mathbf{CT}^d	\mathbf{HE}^{d}	\mathbf{CT}^d	\mathbf{HE}^{d}	
Recycling		Х	1.4	2.7	1.7E-02	3.4E-02	1.2E-02	2.5E-02	1.2E-02	2.3E-02	
Waste handling, treatment, and disposal		Х	1.4	2.7	1.7E-02	3.4E-02	1.2E-02	2.5E-02	1.2E-02	2.3E-02	

^{*a*} AD = acute dose; ADD = average daily dose; APDR = acute potential dose rate; IADD = intermediate average daily dose

^b APDR values are reported for either liquid or solid exposure types as indicated by the "Exposure Type" column

^{*c*} EPA used dermal absorption data for 7% oil-in-water DBP formulations to estimate occupational dermal exposures for liquid (<u>Doan et al., 2010</u>). The study received a rating of medium from EPA's systematic review process. EPA used an aqueous absorption model to estimate occupational dermal exposures for solid (<u>U.S. EPA, 2023c, 2004b</u>).

^{*d*} For average adult workers, central tendency means the surface area of contact was assumed equal to the area of one hand (*i.e.*, 535 cm²) and high-end means the surface area of contact was assumed equal to the area of two hands (*i.e.*, 1,070 cm²) (U.S. EPA, 2011a).

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1480	4.1.1.5 Weight of Scientific Evidence Conclusions for Occupational Exposure
1481	Judgment on the weight of scientific evidence is based on the strengths, limitations, and uncertainties
1482	associated with the exposure estimates. EPA considers factors that increase or decrease the strength of
1483	the evidence supporting the exposure estimate—including quality of the data/information, applicability
1484	of the exposure data to the COU (including considerations of temporal and locational relevance) and the
1485	representativeness of the estimate for the whole industry. The best professional judgment is summarized
1486	using the descriptors of robust, moderate, slight, or indeterminant, in accordance with the Draft
1487	Systematic Review Protocol (U.S. EPA, 2021a). For example, a conclusion of moderate is appropriate
1488	where exposure data is generated from a generic model with high data quality and some chemical-
1489	specific or industry-specific inputs, such that the exposure estimate is a reasonable representation of
1490	potential sites within the OES. A conclusion of slight is appropriate where there is limited information
1491	that does not sufficiently cover all potential exposures within the COU, and the assumptions and
1492	uncertainties are not fully known or documented. See the Draft Systematic Review Protocol (U.S. EPA,
1493	2021a) for additional information on weight of scientific evidence conclusions. Table 4-5 provides a
1494	summary of EPA's overall confidence in its occupational exposure estimates for each of the OESs
1495	assessed.

1496 Table 4-5. Summary of Assumptions, Uncertainty, and Overall Confidence in Exposure Estimates by OES

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
Manufacturing	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the full-shift TWA inhalation exposure estimates for the Manufacturing OES. The primary strength of this approach is the use of directly applicable monitoring data, which is preferrable to other assessment approaches, such as modeling or the use of occupational exposure limits (OELs). EPA used personal breathing zone (PBZ) air concentration data pulled from 3 sources to assess inhalation exposures (ECB, 2008; ECJRC, 2004; SRC, 2001). All 3 data sources received a rating of medium from EPA's systematic review process. These data were DBP-specific, though it is uncertain whether the measured concentrations accurately represent the entire industry.
	The primary limitations of these data include the uncertainty of the representativeness of these data toward the true distribution of inhalation concentrations for this scenario. Additionally, the dataset is only built on limited data points (3 data source) with a significant spread of measurements. The SRC source cites an ACC study that provides a datapoint as a worst-case scenario, the ECJRC, 2008 source only provides a single datapoint with uncertain statistics and the ECJRC, 2004 source provided a dataset with an uncertain range and number of samples. EPA also assumed 8 exposure hours per day and 250 exposure days per year based on continuous DBP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures.
	Although the use of monitoring data specific to this OES increases the strength of the analysis, the few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust.
Import and repackaging	EPA used surrogate monitoring data from DBP manufacturing facilities to estimate worker inhalation exposures, due to no relevant OES-specific data availability for import and repackaging inhalation exposures. The primary strength of this approach is the use of monitoring data, which is preferrable to other assessment approaches, such as modeling or the use of OELs. EPA used PBZ air concentration data pulled from 3 sources to assess inhalation exposures (ECB, 2008; ECJRC, 2004; SRC, 2001). All 3 data sources received a rating of medium from EPA's systematic review process. These data were DBP-specific, though it is uncertain whether the measured concentrations accurately represent the entire industry. The primary limitations of these data include uncertainty in the representativeness of these data for this OES and true distribution of inhalation concentrations in this scenario. Additionally, the dataset is only built on limited data points (3 data sources) with a significant spread of measurements. The SRC source cites an ACC study that provides a datapoint as a worst-case scenario, the ECJRC, 2008 source only provides a single datapoint with uncertain statistics and the ECJRC, 2004 source provided a dataset with an uncertain range and number of samples. EPA also assumed 8 exposure hours per day and 250 exposure days per year based on continuous DBP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures.
	Although the use of surrogate monitoring data increases the strength of the analysis, the few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA concluded that the weight of scientific evidence for this assessment is moderate.

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
Incorporation into formulations, mixtures, or reaction products	EPA used surrogate monitoring data from DBP manufacturing facilities to estimate worker inhalation exposures, due to no data availability for Incorporation into formulations, mixtures, or reaction products (adhesives, coatings, and other) inhalation exposures. The primary strength of this approach is the use of monitoring data, which is preferrable to other assessment approaches, such as modeling or the use of OELs. EPA used PBZ air concentration data pulled from 3 sources to assess inhalation exposures (ECB, 2008; ECJRC, 2004; SRC, 2001). All 3 data sources received a rating of medium from EPA's systematic review process. These data were DBP-specific, though it is uncertain whether the measured concentrations accurately represent the entire industry.
	The primary limitations of these data include uncertainty in the representativeness of these data for this OES and the true distribution of inhalation concentrations in this scenario. Additionally, the dataset is only built on limited data points (3 data sources) with a significant spread of measurements. The SRC source cites an ACC study that provides a datapoint as a worst-case scenario, the ECJRC, 2008 source only provides a single datapoint with uncertain statistics and the ECJRC, 2004 source provided a dataset with an uncertain range and number of samples. EPA also assumed 8 exposure hours per day and 250 exposure days per year based on continuous DBP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures.
	Although the use of surrogate monitoring data increases the strength of the analysis, the few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA concluded that the weight of scientific evidence for this assessment is moderate.
PVC plastics compounding	EPA considered the assessment approach, the quality of the data, and the uncertainties in the assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for PVC plastics compounding. EPA used surrogate monitoring data from a PVC converting facility to estimate worker inhalation exposures due to no relevant OES-specific data. The primary strength of this approach is the use of monitoring data, which is preferrable to other assessment approaches, such as modeling or the use of OELs. EPA used PBZ air concentration data pulled from 1 source to assess inhalation exposures to vapor. This source provided worker exposures from 2 different studies (ECJRC, 2004) and received a rating of medium from EPA's systematic review process.
	EPA also expects compounding activities to generate dust from solid PVC plastic products; therefore, the Agency incorporated the PNOR Model (U.S. EPA, 2021d) into the assessment to estimate worker inhalation exposures to solid particulate. A strength of the model is that the respirable PNOR range was refined using OSHA CEHD datasets, which EPA tailored to the Plastics and Rubber Manufacturing NAICS code (NAICS 326), and the resulting dataset contains 237 discrete sample data points (OSHA, 2019). EPA estimated the highest expected concentration of DBP based on the Generic Scenario for the Use of Additives in Plastic Compounding (U.S. EPA, 2021e).
	The primary limitations of these data include uncertainty in the representativeness of the vapor monitoring data and the PNOR Model in capturing the true distribution of inhalation concentrations for this OES. Additionally, the vapor monitoring dataset consisted of just 4 datapoints for workers, none of the datapoints indicate the worker tasks, and 2 of the data points are for an unspecified sector of the "polymer industry." Furthermore, the OSHA CEHD dataset used in the PNOR Model is not specific to DBP. Finally, EPA

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates
	assumed 8 exposure hours per day and 250 exposure days per year based on continuous DBP exposure during each working day for a typical worker schedule. It is uncertain whether this assumption captures actual worker schedules and exposures.
	Although the use of surrogate monitoring data increases the strength of the analysis, the few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA concluded that the weight of scientific evidence for this assessment is moderate.
PVC plastics converting	EPA considered the assessment approach, the quality of the data, and the uncertainties in the assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for PVC plastics converting. EPA used PBZ air concentration data pulled from1 source to assess inhalation exposures to vapor. The primary strength of this approach is the use of directly applicable monitoring data, which is preferrable to other assessment approaches such as modeling or the use of OELs. This source provided worker exposures from 2 different studies (ECJRC, 2004) and received a rating of medium from EPA's systematic review process.
	EPA also expects converting activities to generate dust from solid PVC plastic products; therefore, the Agency incorporated the PNOR Model (U.S. EPA, 2021d) into the assessment to estimate worker inhalation exposures to solid particulate. A strength of the model is that the respirable PNOR range was refined using OSHA CEHD datasets, which EPA tailored to the Plastics and Rubber Manufacturing NAICS code (NAICS 326) and the resulting dataset contains 237 discrete sample data points (OSHA, 2019). EPA estimated the highest expected concentration of DBP based on the Generic Scenario for the Use of Additives in Plastic Compounding (U.S. EPA, 2021e).
	The primary limitations of these data include uncertainty in the representativeness of the vapor monitoring data and the PNOR Model in capturing the true distribution of inhalation concentrations for this OES. Additionally, the vapor monitoring dataset consisted of just four datapoints for workers, none of the datapoints indicate the worker tasks, and 2 of the data points are for an unspecified sector of the "polymer industry." Further, the OSHA CEHD dataset used in the PNOR Model is not specific to DBP. Finally, EPA assumed 8 exposure hours per day and 250 exposure days per year based on continuous DBP exposure during each working day for a typical worker schedule. It is uncertain whether this assumption captures actual worker schedules and exposures.
	Although the use of monitoring data specific to this OES increases the strength of the analysis, the few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust.
Non-PVC materials compounding and converting	EPA considered the assessment approach, the quality of the data, and the uncertainties in the assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for non-PVC materials compounding and converting. The Agency used surrogate monitoring data from a PVC converting facility to estimate worker inhalation exposures due to no relevant OES-specific data. The primary strength of this approach is the use of monitoring data, which is preferrable to other assessment approaches such as modeling or the use of OELs. EPA used PBZ air concentration data pulled from 1 source to assess inhalation exposures to vapor. This source provided worker exposures from 2 different studies (ECJRC, 2004) and received a rating of medium from EPA's systematic review process.

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates					
	EPA also expects compounding activities to generate dust from solid PVC plastic products; therefore, the Agency incorporated the PNOR Model (U.S. EPA, 2021d) into the assessment to estimate worker inhalation exposures to solid particulate. A strength of the model is that the respirable PNOR range was refined using OSHA CEHD datasets, which EPA tailored to the Plastics and Rubber Manufacturing NAICS code (NAICS 326) and the resulting dataset contains 237 discrete sample data points (OSHA, 2019). EPA estimated the highest expected concentration of DBP based on the Emission Scenario Document on Additives in Rubber Industry (OECD, 2004a).					
	The primary limitations of these data include uncertainty in the representativeness of the vapor monitoring data and the PNOR Model in capturing the true distribution of inhalation concentrations for this OES. Additionally, the vapor monitoring dataset consisted of just 4 datapoints for workers, none of the datapoints indicate the worker tasks, and 2 of the data points are for an unspecified sector of the "polymer industry." Further, the OSHA CEHD dataset used in the PNOR Model is not specific to DBP. Finally, EPA assumed 8 exposure hours per day and 250 exposure days per year based on continuous DBP exposure during each working day for a typical worker schedule. It is uncertain whether this assumption captures actual worker schedules and exposures.					
	Although the use of surrogate monitoring data increases the strength of the analysis, the few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA concluded that the weight of scientific evidence for this assessment is moderate.					
Application of adhesives and sealants	EPA considered the assessment approach, the quality of the data, and the uncertainties in the assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the application of adhesives and sealants. The Agency used monitoring data from a NIOSH HHE that documented exposures at a single furniture assembly site to estimate worker inhalation exposures to vapor. The primary strength of this approach is the use of directly applicable monitoring data, which is preferrable to other assessment approaches such as modeling or the use of OELs. EPA used PBZ air concentration data from this source to assess inhalation exposures (<u>NIOSH, 1977</u>). The source received a rating of medium from EPA's systematic review process.					
	The primary limitations of these data include uncertainty in the representativeness of the vapor monitoring data in capturing the true distribution of inhalation concentrations for this OES. Only 1 use site type, furniture manufacturing, is represented by the data and this may not represent the entire adhesive and sealant industry. Additionally, 100% of the vapor monitoring datapoints were below the LOD and therefore the actual exposure concentration is unknown with the LOD used as an upper limit of exposure. Finally, EPA assumed 8 exposure hours per day and 232–250 exposure days per year based on continuous DBP exposure during each working day for a typical worker schedule with the exposure days representing the 50–95th percentile of the exposure day distribution. It is uncertain whether this assumption captures actual worker schedules and exposures.					
	Although the use of monitoring data specific to this OES increases the strength of the analysis, the few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust and provides an upper-bound estimate of exposures.					

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates					
Application of paints and coatings	EPA considered the assessment approach, the quality of the data, and the uncertainties in the assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the application of paints and coatings. EPA identified 2 full-shift PBZ monitoring samples in OSHA's CEHD and a monitoring dataset from an industry sponsored study found through EPA's literature search. The primary strength of this approach is the use of directly applicable monitoring data, which is preferrable to other assessment approaches such as modeling or the use of OELs. EPA used PBZ air concentration data from the 2 sources, which represent 3 different use facilities, to assess inhalation exposures (OSHA, 2019; Rohm & Haas, 1990). The OSHA CEHD source received a rating of high and the Rohm & Haas source received a rating of low from EPA's systematic review process.					
	The primary limitations of these data include uncertainty in the representativeness of the monitoring data in capturing the true distribution of inhalation concentrations for this OES. Three different use sites are represented by the data but these may not represent the overall DBP-containing paint and coating industry. Finally, EPA assumed 8 exposure hours per day and 250 exposure days per year based on continuous DBP exposure during each working day for a typical worker schedule. It is uncertain whether this assumption captures actual worker schedules and exposures.					
	Although the use of monitoring data specific to this OES increases the strength of the analysis, the few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA concluded that the weight of scientific evidence for this assessment is moderate to robust.					
Use of industrial process solvents	EPA considered the assessment approach, the quality of the data, and the uncertainties in the assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the Use of industrial process solvents. Due to no relevant OES-specific data, EPA used surrogate monitoring data from DBP manufacturing facilities to estimate worker inhalation exposures. The primary strength of this approach is the use of monitoring data, which is preferrable to other assessment approaches such as modeling or the use of OELs. EPA used PBZ air concentration data pulled from 3 sources to assess inhalation exposures (ECB, 2008; ECJRC, 2004; SRC, 2001). All 3 data sources received a rating of medium from EPA's systematic review process. These data were DBP-specific, though it is uncertain whether the measured concentrations accurately represent the entire industry.					
	The primary limitations of these data include uncertainty in the representativeness of these data for this OES and the true distribution of inhalation concentrations in this scenario. Additionally, the dataset is only built on limited data points (3 data sources) with a significant spread of measurements. The SRC source sites an ACC conversation that provides a datapoint as a worst-case scenario, the ECJRC, 2008 source only provides a single datapoint with uncertain statistics and the ECJRC, 2004 source provided a dataset with an uncertain range and number of samples. EPA also assumed 8 exposure hours per day and 250 exposure days per year based on continuous DBP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. DBP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures.					

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates						
	Although the use of surrogate monitoring data increases the strength of the analysis, the few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA concluded that the weight of scientific evidence for this assessment is moderate.						
Use of laboratory chemicals	EPA considered the assessment approach, the quality of the data, and the uncertainties in the assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the Use of laboratory chemicals. Due to no relevant OES-specific data, the Agency used surrogate monitoring data from a NIOSH HHE for Application of adhesives and sealants OES to estimate worker vapor inhalation exposures as well as the PNOR Model (<u>U.S. EPA, 2021d</u>) to characterize worker particulate inhalation exposures. The primary strength of this approach is the use of monitoring data, which are preferrable to other assessment approaches such as modeling or the use of OELs. EPA used PBZ air concentration data from the NIOSH HHE to assess inhalation exposures (<u>NIOSH, 1977</u>). The source received a rating of medium from EPA's systematic review process.						
	EPA also used the PNOR Model (U.S. EPA, 2021d) to estimate worker inhalation exposure to solid particulate. The model data is based on OSHA CEHD data (OSHA, 2019). EPA used a subset of the respirable particulate data from the generic model identified with the Professional, Scientific, and Technical Services NAICS code (NAICS code 54) to assess this OES, which the Agency expects to be the most representative subset of the particulate data for use of laboratory chemicals in the absence of DBP-specific data. EPA estimated the highest expected concentration of DBP in identified DBP-containing products applicable to this OES.						
	The primary limitation of this approach is uncertainty in the representativeness of the vapor monitoring data and the PNOR Model in capturing the true distribution of inhalation concentrations for this OES. Additionally, the vapor monitoring data come from 1 source where the identified samples were below the LOD and therefore the actual exposure concentration is unknown with the LOD used as an upper limit of exposure. Further, the OSHA CEHD dataset used in the PNOR Model is not specific to DBP. EPA also assumed 8 exposure hours per day and 250 exposure days per year based on continuous DBP exposure each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures.						
	Although the use of surrogate monitoring data increases the strength of the analysis, teh few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA concluded that the weight of scientific evidence for this assessment is moderate and provides an upper-bound estimate of exposures.						
Use of lubricants and functional fluids	EPA considered the assessment approach, the quality of the data, and the uncertainties in the assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates for the Use of lubricants and functional fluids. Due to no relevant OES-specific data, the Agency used surrogate monitoring data from the OES for application of adhesives containing DBP to estimate worker vapor inhalation exposures. The primary strength of this approach is the use of monitoring data, which are preferrable to other assessment approaches, such as modeling or the use of OELs. EPA used PBZ air concentration data from this source to assess inhalation exposures (NIOSH, 1977). The source received a rating of medium from EPA's systematic review process.						
	The primary limitation of this approach is uncertainty in the representativeness of the vapor monitoring data in capturing the true distribution of inhalation concentrations for this OES. Additionally, the vapor monitoring data come from 1 source and 100% of the						

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates						
	data were below the LOD. EPA also assumed 8 exposure hours per day and 2 to 4 exposure days per year based on a typical equipment maintenance schedule; it is uncertain whether this captures actual worker schedules and exposures.						
	Although the use of surrogate monitoring data increases the strength of the analysis, teh few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA concluded that the weight of scientific evidence for this assessment is moderate and provides an upper-bound estimate of exposures						
Use of penetrants and inspection fluids	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the 8-hour TWA inhalation exposure estimates. EPA developed a Penetrant and Inspection Fluid Near-Field/Far-Field Inhalation Exposure Model which uses a near-field/far-field approach and the inputs to the model were derived from references that received ratings of medium-to-high for data quality in the systematic review process. EPA combined this model with Monte Carlo modeling to estimate occupational exposures in the near-field (worker) and far-field (ONU) inhalation exposures. A strength of the Monte Carlo modeling approach is that variation in model input values and a range of potential exposure values is more likely than a discrete value to capture actual exposure at sites, the high number of data points (simulation runs), and the full distributions of input parameters. EPA identified and used a DINP-containing penetrant/inspection fluid product as surrogate to estimate concentrations, application methods, and use rate.						
	exposures. EPA lacks facility and DBP-specific product use rates, concentrations, and application methods, therefore, estimates are made based on surrogate DINP-containing product. The Agency only found 1 product to represent this use scenario; however, and its representativeness of all DBP-containing penetrants and inspection fluids is not known. Also, EPA based exposure days and operating days as specified in the ESD on the Use of Metalworking Fluids (OECD, 2011c), which may not be representative of all facilities and workers that use these products.						
	above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate.						
Fabrication or Use of Final Product and Articles	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the full-shift TWA inhalation exposure estimates for the fabrication or use of final products or articles OES. EPA used monitoring data from a facility melting, shaping, and gluing plastics and a facility welding plastic roofing components (ECJRC, 2004; Rudel et al., 2001) to assess worker inhalation exposures to vapor. Both sources received a rating of medium from EPA's systematic review process. EPA also utilized the PNOR Model (U.S. EPA, 2021d) to estimate worker inhalation exposure to solid particulate. The primary strength of this approach is the use of monitoring data, which is preferrable to other assessment approaches such as modeling or the use of OELs. For the vapor exposure, EPA used workplace DBP air concentration data found from 2 sources to assess inhalation exposures to vapor. This data was DBP-specific and from facilities manipulating finished DBP-containing articles.						

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates						
	The respirable particulate concentrations used by the generic model is based on OSHA CEHD data (<u>OSHA, 2019</u>). EPA used a subset of the respirable particulate data from the generic model identified with the Furniture and Related Product Manufacturing NAICS code (NAICS code 337) to assess this OES, which EPA expects to be the most representative subset of the particulate data for this OES. EPA estimated the highest expected concentration of DBP in particulates during product fabrication using plasticizer additive concentration information from the Use of Additives in Plastic Converting Generic Scenario (<u>U.S. EPA, 2004a</u>). These strengths increase the weight of evidence.						
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DBP is uncertain. Further, the model lacks metadata on worker activities. EPA assumed 8 exposure hours per day based on continuous DBP particulate exposure while handling DBP-containing products on site each working day for a typical worker schedule; it is uncertain whether this captures actual worker schedules and exposures. The Agency set the number of exposure days for both central-tendency and high-end exposure estimates at 250 days per year based on EPA default assumptions. Vapor exposures are not expected to significantly contribute to overall inhalation exposure compared to particulate exposures. These limitations decrease the weight of evidence.						
	Although the use of monitoring data specific to this OES increases the strength of the analysis, the few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides an upper-bound estimate of exposures.						
Recycling	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the full-shift TWA inhalation exposure estimates for the recycling OES. EPA utilized the PNOR Model (U.S. EPA, 2021d) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model are based on OSHA CEHD data (OSHA, 2019). EPA used a subset of the respirable particulate data from the generic model identified with the Administrative and Support and Waste Management and Remediation Services NAICS code (NAICS code 56) to assess this OES, which EPA expects to be the most representative subset of the particulate data for this OES. EPA estimated the highest expected concentration of DBP in plastic using plasticizer additive concentration information from the Use of Additives in Plastic Converting Generic Scenario (U.S. EPA, 2004a). These strengths increase the weight of evidence.						
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DBP is uncertain. Further, the model lacks metadata on worker activities. The Agency set the number of exposure days for both central-tendency and high-end exposure estimates at 250 days per year based on EPA default assumptions. Also, it was assumed that each worker is potentially exposed for 8 hours per workday; however, it is uncertain whether this captures actual worker schedules and exposures. These limitations decrease the weight of evidence.						
	Although the use of PNOR Model which is based on OSHA CEHD monitoring data increases the strength of the analysis, the few uncertainties discussed in the paragraph above reduces confidence of the analysis. Therefore, based on these strengths and						

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates						
	limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides an upper-bound estimate of exposures.						
Waste handling, treatment, and disposal	EPA considered the assessment approach, the quality of the data, and uncertainties in assessment results to determine a weight of scientific evidence conclusion for the full-shift TWA inhalation exposure estimates for the waste handling, treatment, and disposal OES. EPA utilized the PNOR Model (U.S. EPA, 2021d) to estimate worker inhalation exposure to solid particulate. The respirable particulate concentrations used by the generic model are based on OSHA CEHD data (OSHA, 2019). EPA used a subset of the respirable particulate data from the generic model identified with the Administrative and Support and Waste Management and Remediation Services NAICS code (NAICS code 56) to assess this OES, which EPA expects to be the most representative subset of the particulate data for this OES. EPA estimated the highest expected concentration of DBP in plastic using plasticizer additive concentration information from the Generic Scenario for the Use of Additives in Plastic Compounding (U.S. EPA, 2021e). These strengths increase the weight of evidence.						
	The primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. Specifically, EPA lacks facility-specific particulate concentrations in air, and the representativeness of the data set used in the model towards sites that actually handle DBP is uncertain. Furthermore, the model lacks metadata on worker activities. The Agency set the number of exposure days for both central-tendency and high-end exposure estimates at 250 days per year based on EPA default assumptions. Also, it was assumed that each worker is potentially exposed for 8 hours per workday; however, it is uncertain whether this captures actual worker schedules and exposures. These limitations decrease the weight of evidence.						
	Although the use of PNOR Model, which is based on OSHA CEHD monitoring data, increases the strength of the analysis, few uncertainties discussed in the paragraph above reduce confidence of the analysis. Therefore, based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is moderate and provides an upper-bound estimate of exposures.						
Dermal – Liquids	EPA used dermal absorption data for 7% oil-in-water DBP formulations to estimate occupational dermal exposures for liquid (<u>Doan</u> et al., 2010). The tests were performed on guinea pigs, which have more permeable skin than humans (<u>OECD</u> , 2004b), meaning the dermal absorption value is likely protective for human skin. However, it is acknowledged that variations in chemical concentration and co-formulant components affect the rate of dermal absorption. Additionally, it is unclear how representative the data from Doan et al. (2010) are for neat DBP. Because EPA assumed absorptive flux of DBP measured from guinea pig experiments serves as an upper bound of potential absorptive flux of chemical into and through the skin for dermal contact with all liquid products. EPA is confident that the dermal absorption data using guinea pigs provides an upper bound of dermal absorption of DBP.						
	For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the chemical is contacted at least once per day. Because DBP has low volatility and relatively low absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until the skin is washed. Therefore, in absence of exposure duration data, EPA has assumed that absorption of DBP from occupational dermal contact with materials containing DBP may extend up to 8 hours per day (U.S. EPA, 1991). However, if a worker uses proper PPE or washes their hands after contact with DBP or DBP-containing materials dermal exposure may be eliminated. Therefore, the assumption of an 8-hour exposure duration for DBP may lead to overestimation of dermal						

OES	Weight of Scientific Evidence Conclusion in Exposure Estimates						
	exposure. For average adult workers, the surface area of contact was assumed equal to the area of 1 hand (<i>i.e.</i> , 535 cm ²), or 2 hands (<i>i.e.</i> , 1,070 cm ²), for central tendency exposures, or high-end exposures, respectively (U.S. EPA, 2011a). Other parameters such as frequency and duration of use, and surface area in contact, are well understood and representative. Despite moderate confidence in the estimated values themselves, EPA has robust confidence that the dermal liquid exposure estimates are upper bound of potential exposure scenarios.						
Dermal – Solids	It is expected that dermal exposure to solid matrices would result in far less absorption, but there are no studies that report dermal absorption of DBP from a solid matrix. For cases of dermal absorption of DBP from a solid matrix, EPA assumed that DBP will first migrate from the solid matrix to a thin layer of moisture on the skin surface. Therefore, absorption of DBP from solid matrices is considered limited by aqueous solubility and is estimated using an aqueous absorption model (U.S. EPA, 2023c, 2004b). Nevertheless, it is assumed that absorption of the aqueous material serves as a reasonable upper bound for contact with solid materials. Also, EPA acknowledges that variations in chemical concentration and co-formulant components affect the rate of dermal absorption. For OES with lower concentrations of DBP in the solid, it is possible that the estimated amount absorbed using the modeled flux value would exceed the amount of DBP available in the dermal load. In these cases, EPA capped the amount absorbed to the maximum amount of DBP in the solid (<i>i.e.</i> , the product of the dermal load and the weight fraction of DBP). For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the chemical is contacted at least once per day. Because DBP has low volatility and relatively low absorption, it is possible that the chemical absorption of DBP from occupational dermal contact with materials containing DBP may extend up to 8 hours per day (U.S. EPA, 1991). However, if a worker uses proper PPE or washes their hands after contact with DBP or DBP-containing materials dermal exposure may be eliminated. Therefore, the assumption of an 8-hour exposure assessment is limited in that it does not consider the uniqueness of each material potentially contacted; however, the dermal exposure assessment is limited in that it does not consider the uniqueness of each material potentially contacted; however, the dermal exposure estimates are expected to be representative of materials potentially encountered						
	Therefore, the dermal absorption estimates assume that dermal absorption of DBP from solid objects would be limited by the aqueous solubility of DBP. EPA has moderate confidence in the aspects of the exposure estimate for solid articles because of the high uncertainty in the assumption of partitioning from solid to liquid, and because subsequent dermal absorption is not well characterized. Additionally, there are uncertainties associated to the flux-limited approach which likely results in overestimations due to the assumption about excess DBP in contact with skin for the entire work duration. Other parameters such as frequency and duration of use, and surface area in contact have unknown uncertainties due to lack of information about use patterns. Despite moderate confidence in the estimated values themselves, EPA has robust confidence that the exposure estimates are upper bound of potential exposure scenarios.						

14984.1.1.5.1 Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for
the Occupational Exposure Assessment1500EPA assigned overall confidence descriptions of high, medium, or low to the exposure assessments1501based on the strength of the underlying scientific evidence. When the assessment is supported by robust1502evidence, EPA's overall confidence in the exposure assessment is high; when supported by moderate1503evidence, EPA's overall confidence is medium; when supported by slight evidence, EPA's overall

1504 confidence is low.

1505 1506 *Strengths*

1507 The exposure scenarios and exposure factors underlying the inhalation and dermal assessment are 1508 supported by moderate to robust evidence. Occupational inhalation exposure estimates were informed 1509 by moderate or robust sources of directly applicable and surrogate monitoring data or modeling was 1510 used to estimate the inhalation exposure estimates. Exposure factors for occupational inhalation

- 1511 exposure include duration of exposure, body weight, and breathing rate, which were informed by
- 1512 moderate to robust data sources.
- 1513

1514 Limitations

1515 The principal limitation of the exposure assessments is uncertainty in the representativeness of the data

and models used as there is limited direct exposure monitoring data for DBP in the literature from

1517 systematic review. A limitation of the modeling methodologies is that most of the model input data from

GSs/ESDs, such as air speed or loss factors, are generic for the OESs and not specific to the use of DBP within the OESs. Additionally, the selected generic models and data may not be representative of all

chemical- or site-specific work practices and engineering controls. Limitations associated with dermal
 exposure assessment are described in Table 4-5.

1523 Assumptions

When determining the appropriate model for assessing exposures to DBP, the Agency considered the physical form of DBP during different OESs. DBP may be present in various physical forms such as a powder, mist, paste, or in solution during the various OESs. EPA assessed each respective OES assuming the physical form of DBP based on available product data, CDR data, and information from applicable GSs/ESDs. Because the physical form of DBP can influence exposures substantially, EPA assumed DBP is present in the physical form that is most prevalent and/or most protective for the given OES when assessing the exposures.

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EPA calculated chronic ADD values assuming workers and ONUs are exposed at the same level for their entire working lifetime, which may result in an overestimate. Individuals may change jobs during the course of their career such that they are no longer exposed to DBP and the actual ADD values become lower than the estimates presented. EPA collected tenure data to estimate central tendency and high-end working years of exposure that is assumed to inherently take into account workers changing

1537 jobs. Assumptions associated with dermal exposure assessment are described in Table 4-5.

1538

1539 Uncertainties

1540 EPA addressed variability in inhalation models by identifying key model parameters and applying

1541 statistical distributions that mathematically define the parameter's variability. The Agency defined

- 1542 statistical distributions for parameters using documented statistical variations where available. Where
- the statistical variation was unknown, EPA made assumptions to estimate the parameter distribution
- using available literature data, such as GSs and ESDs. However, there is uncertainty as to the
- 1545 representativeness of the parameter distributions because these data are often not specific to sites that

1546 1547 1548 1549	use DBP. In general, the effects of these uncertainties on the exposure estimates are unknown as the uncertainties may result in either overestimation or underestimation of exposures, depending on the actual distributions of each of the model input parameters. Uncertainties associated with dermal exposure assessment are described in Table 4-5.
1550	4.1.2 Consumer Exposures
1551	The following subsections briefly describe EPA's approach to assessing consumer exposures and
1552	provide exposure assessment results for each COU. The Draft Consumer and Indoor Dust Exposure
1553	Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025c) provides additional details on the
1554	development of approaches and the exposure assessment results. The consumer exposure assessment
1555	evaluated exposures from individual COUs whereas the indoor dust assessment uses a subset of
1556	consumer articles with large surface area and presence in indoor environments to garner COU specific
1557	contributions to the total exposures from dust.
1558 1559	4.1.2.1 Summary of Consumer and Indoor Dust Exposure Scenarios and Modeling Approach and Methodology
1560	The major steps in performing a consumer exposure assessment are summarized below:
1561 1562	• identification and mapping of product and article examples following the consumer COU table (Table 4-6), product, and article identification;
1563 1564	 compilation of products' and articles' manufacturing use instructions to determine patterns of use;

- selection of exposure routes and exposed populations according to product/article use 1566 descriptions;
- 1567 identification of data gaps and further search to fill gaps with studies, chemical surrogates or ٠ product and article proxies, or professional judgement; 1568
- selection of appropriate modeling tools based on available information and chemical properties; 1569 •
 - gathering of input parameters per exposure scenario; and
 - parameterization of selected modeling tools.

1572 Consumer products or articles containing DBP were matched with the identified consumer COUs. Table 4-6 summarizes the consumer exposure scenarios by COU for each product example(s), the exposure 1573 1574 routes, which scenarios are also used in the indoor dust assessment, and whether the analysis was 1575 conducted qualitatively or quantitatively, see Sections 2.2.1 and 2.2.2 in (U.S. EPA, 2025c) for detailed descriptions, explanations, and rationale. The indoor dust assessment uses consumer product and article 1576 1577 information for selected items with the goal of recreating the indoor environment. The subset of consumer products and articles that are used in the indoor dust assessment are selected for their potential 1578 1579 to have large surface area for dust collection, roughly larger than 1 m^2 .

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1571

1581 When a quantitative analysis of reasonably available information was conducted, exposure from the 1582 consumer COUs was estimated by modeling. Exposure via inhalation and ingestion routes were modeled 1583 using EPA's CEM, Version 3.2 (U.S. EPA, 2023c). Dermal exposures for both liquid products and solid 1584 articles were calculated outside of CEM, see Draft Consumer Exposure Analysis for Dibutyl Phthalate 1585 (DBP) (U.S. EPA, 2025d) for calculations and inputs. CEM dermal modeling uses a dermal model approach that assumes infinite DBP migration from product to skin without considering saturation 1586 which result in overestimations of dose and subsequent risk, see Section 2.3 in U.S. EPA (2025c) for a 1587 1588 detailed explanation. Dermal exposures were estimated using a computational framework implemented within a spreadsheet environment using a flux-limited, dermal absorption approach for liquid and solid 1589

1590 products (U.S. EPA, 2025d). For each exposure route, EPA used the 10th percentile, average, and 95th

percentile value of an input parameter (*e.g.*, weight fraction, surface area) where possible to characterize low, medium, and high exposure scenarios for a given COU. If only a range was reported, EPA used the

- 1592 now, medium, and mgn exposure scenarios for a given COC. If only a range was reported, Ef A used the 1593 minimum and maximum of the range as the low and high values, respectively. The average of the
- reported low and high values from the reported range was used for the medium exposure scenario. See
- 1595 Draft Consumer and Indoor Dust Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025c)
- 1596 for details about the consumer modeling approaches, sources of data, model parameterization, and
- assumptions. High-, medium-, and low-intensity use exposure scenarios serve as a two-pronged
- approach. First, it provides a sensitivity analysis with insight on the impact of the main modeling input parameters (*e.g.*, skin contact area, duration of contact, and frequency of contact) in the doses and risk
- 1600 estimates. And second, the high-intensity use exposure scenarios are used first to screen for potential
- 1601 risks at the upper bound of possible exposures and then, if needed, to refine.
- 1602

1603 Exposure via the inhalation route occurs from inhalation of DBP gas-phase emissions or when DBP 1604 partitions to suspended particulate from direct use or application of products. However, DBP's low volatility is expected to result in negligible gas-phase inhalation exposures. Sorption to suspended and 1605 settled dust is likely to occur based on monitoring data (see indoor dust monitoring data in Section 1606 1607 4.1.2.1) and its affinity for organic matter that is typically present in household dust). Thus, inhalation 1608 and ingestion of suspended and settled dust is considered in this draft assessment. Exposure via the 1609 dermal route can occur from direct contact with products and articles. Exposure via ingestion depends 1610 on the product or article use patterns. Exposure can occur via direct mouthing (i.e., directly putting 1611 product in mouth) in which the person can ingest settled dust with DBP or directly ingesting DBP from

1612 migration to saliva. Additionally, ingestion of suspended dust can occur when DBP migrates from article

- 1613 to dust or partitions from gas-phase to suspended dust.
- 1614

EPA made some adjustments to match CEM's lifestages to those listed in the U.S. Centers for Disease
Control and Prevention (CDC) guidelines (CDC, 2021) and EPA's *A Framework for Assessing Health Risks of Exposures to Children* (U.S. EPA, 2006). CEM lifestages are re-labeled from this point forward
as follows:

- 1619 Adult $(21 + years) \rightarrow Adult$
- 1620 Youth 2 (16–20 years) \rightarrow Teenager
- 1621 Youth 1 (11–15 years) \rightarrow Young teen
- 1622 Child 2 (6–10 years) \rightarrow Middle childhood
- 1623 Child 1 (3–5 years) \rightarrow Preschooler
- Infant 2 (1–2 years) \rightarrow Toddler
- 1625 Infant 1 (<1 year) \rightarrow Infant

1626 EPA assessed acute, intermediate, and chronic exposures to DBP from consumer COUs. For the acute 1627 dose rate calculations, an averaging time of 1 day is used representing the maximum time-integrated 1628 dose over a 24-hour period during the exposure event. The chronic dose rate is calculated iteratively at a 1629 30-second interval during the first 24 hours and every subsequent hour for 60 days and averaged over 1 year. Intermediate dose is the exposure to continuous or intermittent (depending on product) use during 1630 1631 a 30-day period, which is roughly 1 month. See Sections 2.2.1 and 2.2.2 and Appendix A in (U.S. EPA, 2025c) for details about acute, chronic, and intermediate dose calculations. Professional judgment and 1632 product use descriptions were used to estimate events per day and per month/year for the calculation of 1633 1634 the intermediate/chronic dose.

1635 **Table 4-6. Summary of Consumer COUs, Exposure Scenarios, and Exposure Routes**

Consumer Condition of Use Category	Consumer Condition of Use Subcategory	Product/Article	Exposure Scenario and Route ^a	Evaluated Routes						
						Ingestion		n		
				Inhalation ^b	Dermal	Suspended Dust	Settled Dust	Mouthing		
Automotive, fuel, agriculture, outdoor use products	Automotive care products	See automotive adhesives	Use of product in DIY small-scale auto repair and hobby activities. Direct contact during use; inhalation of emissions during use	~	~	×	×	×		
Construction, paint, electrical, and metal products	Adhesives and sealants	Adhesive for small repairs	Direct contact during use	×	√	×	×	×		
Construction, paint, electrical, and metal products	Adhesives and sealants	Automotive adhesives	Use of product in DIY small-scale auto repair and hobby activities. Direct contact during use; inhalation of emissions during use	~	~	×	×	×		
Construction, paint, electrical, and metal products	Adhesives and sealants	Construction adhesives	Direct contact during use	×	√	×	×	×		
Construction, paint, electrical, and metal products	Paints and coatings	Metal coatings	Use of product in DIY home repair and hobby activities. Direct contact during use; inhalation of emissions during use	~	√	×	×	×		
Construction, paint, electrical, and metal products	Paints and coatings	Sealing and refinishing sprays (indoor use)	Application of product in house via spray. Direct contact during use; inhalation of emissions during use	~	~	×	×	×		
Construction, paint, electrical, and metal products	Paints and coatings	Sealing and refinishing sprays (outdoor use)	Application of product outdoors via spray. Direct contact during use; inhalation of emissions during use	~	√	×	×	×		
Furnishing, cleaning, treatment care products	Fabric, textile, and leather products	Synthetic leather clothing	Direct contact during use	×	\checkmark	×	×	×		
Furnishing, cleaning, treatment care products	Fabric, textile, and leather products	Synthetic leather furniture	Direct contact during use; inhalation of emissions / ingestion of airborne particulate; ingestion by mouthing	√ c	\checkmark	√ c	√ c	\checkmark		
Furnishing, cleaning, treatment/care products	Cleaning and furnishing care products	Spray cleaner	Application of product in house via spray. Direct contact during use; inhalation of emissions during use	~	√	×	×	×		

	Consumer Condition of Use Subcategory				Evalu	uated Ro	outes	
~		Product/Article	Exposure Scenario and Route ^a			Ι	ngestio	1
Consumer Condition of Use Category				Inhalation ^b	Dermal	Suspended Dust	Settled Dust	Mouthing
Furnishing, cleaning, treatment/care products	Cleaning and furnishing care products	Waxes and polishes	Application of product in house via spray. Direct contact during use; inhalation of emissions during use	~	~	×	×	×
Furnishing, cleaning, treatment/care products	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel	Vinyl flooring	Direct contact, inhalation of emissions / ingestion of dust adsorbed chemical	√ c	~	√ c	√ c	×
Furnishing, cleaning, treatment/care products	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel	Wallpaper	Direct contact during installation (teenagers and adults) and while in place; inhalation of emissions / ingestion of dust adsorbed chemical	√ c	~	√ c	√ c	×
Other uses	Novelty articles	Adult toys	Direct contact during use; ingestion by mouthing	×	\checkmark	×	×	\checkmark
Other uses	Automotive articles	Synthetic leather seats. see synthetic leather furniture	Direct contact during use; inhalation of emissions / ingestion of airborne particulate; ingestion by mouthing	√ c	✓	√ c	√ c	×
Other uses	Automotive articles	Car mats	Direct contact during use; inhalation of emissions / ingestion of airborne particulate; ingestion by mouthing	√ c	✓	√ c	√ c	×
Other uses	Chemiluminescent light sticks	Small articles with semi routine contact; glow sticks	Direct contact during use	×	√	×	×	×
Other uses	Lubricants and lubricant additives	No consumer products identified. See adhesives for small repairs	Current products were not identified. Foreseeable uses were matched with the adhesives for small repairs because similar use patterns are expected.	×	\checkmark	×	×	×
Packaging, paper, plastic, hobby products	Ink, toner, and colorant products	No consumer products identified. See adhesives for small repairs	Current products were not identified. Foreseeable uses were matched with the	×	√	×	×	×

					Evalu	ated Ro	outes	
~	Consumer Condition of Use Subcategory	Product/Article				Ingestion		
Consumer Condition of Use Category			Exposure Scenario and Route ^a	Inhalation ^b	Dermal	Suspended Dust	Settled Dust	Mouthing
			adhesives for small repairs because similar use patterns are expected.					
Packaging, paper, plastic, hobby products	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)	Footwear	Direct contact during use	×	~	×	×	×
Packaging, paper, plastic, hobby products	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)	Shower curtains	Direct contact during use; inhalation of emissions / ingestion of dust adsorbed chemical while hanging in place	√ c	~	√ c	√ c	×
Packaging, paper, plastic, hobby products	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)	Small articles with semi routine contact; miscellaneous items including a pen, pencil case, hobby cutting board, costume jewelry, tape, garden hose, disposable gloves, and plastic bags/pouches	Direct contact during use	×	~	×	×	×
Packaging, paper, plastic, hobby products	Toys, playground, and sporting equipment	Children's toys (legacy). produced before cpsia statutory and regulatory limitations, 0.1%.	Collection of toys. Direct contact during use; inhalation of emissions / ingestion of airborne PM; ingestion by mouthing	√ c	\checkmark	√ c	√ c	~
Packaging, paper, plastic, hobby products	Toys, playground, and sporting equipment	Children's toys (new). produced after cpsia statutory and regulatory limitations, 0.1%.	Collection of toys. Direct contact during use; inhalation of emissions / ingestion of airborne particulate; ingestion by mouthing	√ c	√	√ c	√ c	√

				Evaluated Routes						
						Ingestion				
Consumer Condition of Use Category	Consumer Condition of Use Subcategory	Product/Article	Exposure Scenario and Route ^a	Inhalation ^b	Dermal	Suspended Dust	Settled Dust	Mouthing		
Packaging, paper, plastic, hobby products	Toys, playground, and sporting equipment	Small Articles with Semi Routine contact; miscellaneous items including a football, balance ball, and pet toy	Direct contact during use	×	√	×	×	×		
Packaging, paper, plastic, hobby products	Toys, playground, and sporting equipment	Tire crumb and artificial turf	Direct contact during use (particle ingestion via hand-to-mouth)	~	~		🗸 d			
Disposal	Disposal	Down the drain products and articles	Down the drain and releases to environmental media	×	×	×	×	×		
Disposal	Disposal	Residential end-of-life disposal, product demolition for disposal	Product and article end-of-life disposal and product demolition for disposal	×	×	×	×	×		

DIY-do-it-yourself

CPSIA – Consumer Product Safety Improvement Act of 2008 (CPSIA section 108(a), 15 U.S.C. § 2057c(a);16 CFR. 1307.3(a)), Congress permanently prohibited the sale of children's toys or childcare articles containing concentrations of more than 0.1 percent DBP.

^{*a*} See Sections 2.2.1 and 2.2.2 in (U.S. EPA, 2025c) for details about exposure scenarios per COU and product example and exposure routes assessed quantitatively and qualitatively.

^b Inhalation scenarios considered suspended dust and gas-phase emissions.

^c Scenario used in Indoor Dust Exposure Assessment in Section 4 in (U.S. EPA, 2025c). These indoor dust articles scenarios consider the surface area from multiple articles such as toys, while furniture and flooring already have large surface areas. For these articles dust can deposit and contribute to significantly larger concentration of dust than single small articles

^d The tire crumb and artificial turf ingestion route assessment considers all 3 types of ingestions, settled dust, suspended dust, and mouthing altogether, but results cannot be provided separately has it was done for all other articles and products.

✓ Quantitative consideration

× Qualitative Consideration

1636

1637 Inhalation and Ingestion Exposure Routes Modeling Approaches

1638 Key parameters for articles modeled in CEM 3.2 2 (U.S. EPA, 2023c) are summarized in detail in

1639 Section 2 in Draft Consumer and Indoor Dust Exposure Assessment for Dibutyl Phthalate (DBP) (U.S.

1640 EPA, 2025c). Calculations, sources, input parameters, and results are also available in *Draft Consumer*

1641 *Exposure Analysis for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025d). Generally, and when possible,

1642 model parameters were determined based on specific articles identified in this assessment and CEM

1643 defaults were only used where specific information was not available. A list of some of the most

important in developing representative scenarios for the selected modeling tools and approaches inputparameters for exposure from articles and products is included below:

- weight fraction (articles and products);
- density (articles and products);
- duration of use (products);
- frequency of use for chronic, acute, and intermediate (products);
- product mass used (products);
- article surface area (articles);
- chemical migration rate to saliva (articles);
- area mouthed (articles); and
- use environment volume (articles and products).

Of these, the chemical migration rate from articles to saliva and area mouthed are most important to
 mouthing exposure scenarios. According to a sensitivity analysis conducted for CEM input parameters,
 duration, frequency, and amount used are key determinants of estimated exposure concentrations.

1659 For each scenario, high-, medium-, and low-intensity use exposure scenarios were developed in which 1660 values for duration of use, frequency of use, and surface area were determined based on reasonably 1661 available information or professional judgment. Each input parameter listed above was parameterized 1662 according to the article-specific data found via systematic review. If article-specific data were not 1663 available, CEM default parameters were used, or if CEM default parameters were not applicable, an 1664 assumption based on article use descriptions by manufacturers was used, always leaning on the health protective values. For example, for all scenarios, the near-field modeling option was selected to account 1665 1666 for a small personal breathing zone around the user during product use in which concentrations are higher, rather than employing a single well-mixed room. This represents a conservative modeling 1667 assumption in the absence of article-specific emission data. A near-field volume of 1 m³ was selected. 1668 1669 See Section 2.1 for weight fraction selection and Section 2.2.3 for parameterization details in the Draft Consumer and Indoor Dust Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025c). 1670

1671

1672 Dermal Exposure Routes Modeling Approaches

1673 Dermal modeling was conducted outside of CEM. The use of CEM for dermal absorption, which relies 1674 on total concentration rather than aqueous saturation concentration, would greatly overestimate exposure 1675 to DBP in liquid and solid products and articles. See U.S. EPA (2025c) for details. The dermal dose of 1676 DBP associated with use of both liquid products and solid articles was calculated in a spreadsheet, see 1677 Draft Consumer Exposure Analysis for Dibutyl Phthalate (DBP) (U.S. EPA, 2025d). EPA used a dermal exposure modeling approach with a range of conservative and plausible input parameters for contact 1678 1679 surface area as well as duration and frequency of contact. The flux-limited, screening dermal absorption approaches for liquid and solid products and articles assume an excess of DBP in contact with the skin 1680 1681 independent of concentration in the article/product. Dermal flux values for liquid products was from 1682 Doan et al. (2010), and solid products flux values were calculated and applied in the corresponding 1683 scenario. The flux-limited screening approach provides an upper bound of dermal absorption of DBP

and likely results in some overestimations, see Section 4.1.2.4 for a discussion on limitations, strengths,
and confidence. For each product or article, high-, medium-, and low-intensity use exposure scenarios
were developed. Values for duration of dermal contact and area of exposed skin were determined based
on the reasonably expected use for each item. Key parameters for the dermal model are shown in
Section 2.3 in (U.S. EPA, 2025c).

1689

4.1.2.2 Modeling Dose Results by COU for Consumer and Indoor Dust

This section summarizes the dose estimates from inhalation, ingestion, and dermal exposure to DBP in
consumer products and articles. Detailed tables of the dose results for acute, intermediate, and chronic
exposures are available in the *Draft Consumer Risk Calculator for Dibutyl Phthalate (DBP)* (U.S. EPA,
2025e). Modeling dose results for acute, intermediate, and chronic exposures as well as data patterns are
described in Section 3 in the *Draft Consumer and Indoor Exposure Assessment for Dibutyl Phthalate*(*DBP*) (U.S. EPA, 2025c). The remainder of this section provides a brief summary of the main dose
results patterns for visualizations.

1697

1698 For young teens, teenagers, and young adults (11–20 years) and adults (21+ years), dermal contact was a 1699 strong driver of exposure to DBP across all routes, with the dose received being generally higher than or 1700 similar to the dose received from exposure via inhalation or ingestion. The largest acute dose estimated 1701 was for dermal exposure to adhesives, sealers, coatings, and waxes for young teens to adults. The largest 1702 chronic dose estimated was for dermal and inhalation exposure to metal coatings for young teens to 1703 adults, followed by dermal exposure to adhesives, footwear, and waxes. It is noteworthy that the dermal 1704 analysis used a flux-limited approach, which has larger uncertainties than inhalation dose results-see 1705 Section 4.1.2.4 for a detailed discussion of uncertainties within approaches, inputs, and overall estimate 1706 confidence.

1707

Among the younger lifestages, infant to 10 years, the pattern was less clear as these ages were not
designated as product users and therefore not modeled for dermal contact with any of the liquid products
assessed that resulted in larger dermal doses for the older lifestages. Key differences in exposures among
lifestages include designation as a product user or bystander; behavioral differences such as hand to
mouth contact times and time spent on the floor; and dermal contact expected from touching specific

1713 articles that may not be appropriate for some lifestages.

1714 4.1.2.3 Indoor Dust Assessment

1715 Products and articles that contain DBP are ubiquitous in modern indoor environments and DBP can 1716 partition, migrate, or evaporate (to a lesser extent based on physical and chemical properties) into indoor 1717 air and concentrate in household dust. See Sections 4.1 and 4.2 of the Draft Consumer and Indoor 1718 Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025c) for a summary of indoor dust 1719 monitoring data that EPA used to establish the presence of DBP in indoor dust in the residential 1720 environment. Exposure to DBP through dust ingestion, dust inhalation, and dermal absorption is a 1721 particular concern for young children between the ages of 6 months and 2 years. This is because 1722 crawling on the ground and pulling up on ledges increases hand-to-dust contact as does placing their 1723 hands and objects in their mouths. Specifically, exposure to DBP via ingestion of dust was assessed for all articles expected to contribute significantly to dust concentrations due to high surface area (exceeding 1724 $\sim 1 \text{ m}^2$) for either a single article or collection of similar articles, as appropriate. In a screening 1725 1726 assessment, EPA considered the aggregation of chronic dust ingestion doses, see Section 4.3 in in the Draft Consumer and Indoor Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025c). The 1727 1728 highest dose was for preschoolers aged 3 to 5 years.

- 1730 Articles included in the indoor assessment included the following:
- synthetic leather furniture,
- vinyl flooring,
- in-place wallpaper,
- 1734 car mats,
- shower curtains,
- children's toys, both legacy and new, and
- tire crumb.

4.1.2.4 Weight of Scientific Evidence Conclusions for Consumer Exposure

Key sources of uncertainty for evaluating exposure to DBP in consumer goods and strategies to address 1739 1740 those uncertainties are described in detail in Section 5.1 of the Draft Consumer and Indoor Dust Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025c). Generally, designation of robust 1741 1742 confidence suggests that the supporting scientific evidence weighed against the uncertainties is adequate 1743 to characterize exposure assessments. The supporting weight of scientific evidence outweighs the 1744 uncertainties to the point where it is unlikely that the uncertainties could have a significant effect on the 1745 exposure estimate. The designation of moderate confidence suggests that the supporting scientific 1746 evidence weighed against the uncertainties is reasonably adequate to characterize exposure assessments. 1747 The designation of slight confidence is assigned when the weight of scientific evidence may not be 1748 adequate to characterize the scenario, when the assessor is making the best scientific assessment 1749 possible in the absence of complete information, and when there are additional uncertainties that may 1750 need to be considered. The DBP consumer exposure overall confidence to use the results for risk 1751 characterization ranges from moderate to robust, depending on COU scenario. The basis for the 1752 moderate to robust confidence in the overall exposure estimates is a balance between using parameters 1753 that will represent various populations' use patterns and leaning on conservative assumptions that are 1754 deemed not excessive or unreasonable and are well characterized.

1755 1756

1738

4.1.2.5 Strength, Limitations, Assumptions, and Key Sources of Uncertainty for the Consumer Exposure Assessment

1757 The exposure assessment of chemicals from consumer products and articles has inherent challenges due 1758 to many sources of uncertainty in the analysis, including variations in product formulation, patterns of 1759 consumer use, frequency, duration, and application methods. Variability in environmental conditions 1760 may also alter physical and/or chemical behavior of the product or article. Table 4-7 summarizes the 1761 overall confidence per COU and discusses the rationale used to assign the overall certainty. The 1762 subsections preceding Table 4-7 describe sources of uncertainty for several parameters used in consumer 1763 exposure modeling that apply across COUs and provide an in depth understanding of sources of 1764 uncertainty and limitations and strengths within the analysis. The confidence to use the results for risk 1765 characterization ranges from moderate to robust.

1766

1767 **Product Formulation and Composition**

1768 Variability in the formulation of consumer products, including changes in ingredients, concentrations,

and chemical forms, can introduce uncertainty in exposure assessments. In addition, data were
sometimes limited for weight fractions of DBP in consumer goods. EPA obtained DBP weight fractions

1771 in various products and articles from material safety data sheets, databases, and existing literature. A

1772 significant number of DBP concentration in consumer goods data values were published across several

- 1773 studies published by the Danish EPA (Danish EPA, 2020). EPA used the Danish EPA information under
- 1774 the assumption that the weight fractions reported are representative of DBP content that could be present
- 1775 in items sold in the United States. Where possible, EPA obtained multiple values for weight fractions for

- 1776 similar products or articles. The lowest value was used in the low exposure scenario, the highest value in
- 1777 the high exposure scenario, and the average of all values in the medium exposure scenario. EPA
- 1778 decreased uncertainty in exposure and subsequent risk estimates in the high-, medium-, and low-
- 1779 intensity use scenarios by capturing the weight fraction variability and obtaining a better
- 1780 characterization of the varying composition of products and articles within one COU. Overall weight
- 1781 fraction confidence is *moderate* for products/articles with multiple sources but insufficient description
- on how the concentrations were obtained, *robust* for products/articles with more than one source, and
- *slight* for articles with only one source with unconfirmed content or little understanding on how the information was produced.
- 1784 information was proc1785

1786 Product Use Patterns

- 1787 Consumer use patterns such as frequency of use, duration of use, method of application, and skin contact 1788 area are supported to differ. Where possible, high medium, and law default values from CEM 2.2's
- area are expected to differ. Where possible, high, medium, and low default values from CEM 3.2's
 prepopulated scenarios were selected for mass of product used, duration of use, and frequency of use. In
- instances where no prepopulated scenario was appropriate for a specific product, low, medium, and high
- values for each of these parameters were estimated based on the manufacturers' product descriptions.
- 1792 EPA decreased uncertainty by selecting use pattern inputs that represent product and article use
- descriptions and furthermore capture the range of possible use patterns in the high to low intensity use
- 1794 scenarios. Exposure and risk estimates are considered representative of product use patterns and well
- 1795 characterized. The overall confidence for most use patterns is rated *robust*.
- 1796

1797 Article Use Patterns

- For articles inhalation and ingestion exposures, the high-, medium-, and low-intensity use scenarios default values from CEM 3.2's prepopulated scenarios were selected for indoor use environment/room volume, interzone ventilation, and surface layer thickness. For articles' dermal exposures use patterns such as duration and frequency of use and skin contact area are expected to have a range of low to high use intensities. For articles that do not use duration of use as an input in CEM, professional judgment was used to select the duration of use/article contact duration for the low, medium, and high exposure
- 1804 scenario levels for most articles except carpet tiles and vinyl flooring. Carpet tiles and vinyl flooring
- 1805 contact duration values were taken from EPA's *Standard Operating Procedures for Residential* 1806 *Pesticide Exposure Assessment* for the high exposure level (2 hours; time spent on floor surfaces) (U.S.
- 1807 EPA, 2012c). ConsExpo (U.S. EPA, 2012c) for the medium exposure level (1 hour; time a child spends
- 1808 crawling on treated floor), and professional judgment for the low exposure level (0.5 hour). There are
- 1809 more uncertainties in the assumptions and professional judgment for contact duration inputs for articles;
- 1810 thus, EPA has *moderate* confidence in those inputs.
- 1811

1812 Article Surface Area

- The surface area of an article directly affects the potential for DBP emissions to the environment. For each article modeled for inhalation exposure, low, medium, and high estimates for surface area were calculated in Section 2 in U.S. EPA (2025c). This approach relied on manufacturer-provided dimensions where possible equalities from EPA's Functions for the environment of the set of the environment. For
- 1816 where possible, or values from EPA's *Exposure Factors Handbook* for floor and wall coverings. For 1817 small items that might be expected to be present in a home in significant quantities, such as children's
- 1817 sinal items that high be expected to be present in a nome in significant quantities, such as children s 1818 toys, aggregate values were calculated for the cumulative surface area for each type of article in the
- 1819 indoor environment. Overall confidence in surface area is *robust* for articles like furniture, wall
- 1820 coverings, flooring, toys, and shower curtains because there is a good understanding of the presence and
- 1821 dimensions of these articles in indoor environments.
- 1822

1823 Human Behavior

1824 CEM 3.2 has three different activity patterns: stay-at-home; part-time out-of-the home (daycare, school,

- 1825 or work); and full-time out-of-the-home. The activity patterns were developed based on the
- 1826 Consolidated Human Activity Database (CHAD). For all products and articles modeled, the stay-at 1827 home activity pattern was chosen as it is the most protective assumption.
- 1828

1829 Mouthing durations are a source of uncertainty in human behavior. The data used in this assessment are 1830 based on a study in which parents observed children (n = 236) ages 1 month to 5 years of age for 15 1831 minutes each session and 20 sessions in total (Smith and Norris, 2003). There was considerable 1832 variability in the data due to behavioral differences among children of the same lifestage. For instance, 1833 while children aged 6 to 9 months had the highest average mouthing duration for toys at 39 minutes per 1834 day, the minimum duration was 0 minutes and the maximum was 227 minutes per day. The observers noted that the items mouthed were made of plastic roughly 50 percent of the mouthing time, but this was 1835 1836 not limited to soft plastic items likely to contain significant plasticizer content. In another study, 169 1837 children aged 3 months to 3 years were monitored by trained observers for 12 sessions at 12 minutes 1838 each (Greene, 2002). They reported mean mouthing durations ranging from 0.8 to 1.3 minutes per day 1839 for soft plastic toys and 3.8 to 4.4 minutes per day for other soft plastic objects (except pacifiers). Thus, 1840 it is likely that the mouthing durations used in this assessment provide a health protective estimate for 1841 mouthing of soft plastic items likely to contain DBP. EPA assigned a *moderate* confidence associated 1842 with the duration of activity for mouthing because the magnitude of the overestimation is not well 1843 characterized. All other human behavior parameters are well understood or the ranges used capture use 1844 patterns representative of various lifestages, which results in a *robust* confidence in use patterns.

1845

1846 Inhalation and Ingestion Modeling Tool

Confidence in the model used considers whether the model has been peer reviewed, as well as whether it is being applied in a manner appropriate to its design and objective. The model used, CEM 3.2, has been peer reviewed (ERG, 2016), is publicly available, and has been applied in the manner intended by estimating exposures associated with uses of household products and/or articles. This also considers the default values data source(s) such as building and room volumes, interzonal ventilation rates, and air exchange rates. Overall confidence in the proper use of CEM for consumer exposure modeling is *robust*.

1853

1854 Dermal Modeling of DBP Exposure for Liquids

Experimental dermal data was identified via the systematic review process to characterize consumer dermal exposures to liquids or mixtures and formulations containing DBP. Section 2.3.1 in U.S. EPA (2025c) provides a description of the selected study and rationale to use (Doan et al., 2010) whereas Section 2.3.2 summarizes the approach and dermal absorption values used. The confidence in the dermal exposure to liquid products model used in this assessment is *moderate*.

1860

1861 EPA selected Doan et al. (2010) as a representative study for dermal absorption to liquids. Doan et al. 1862 (2010) is a study in guinea pigs and uses a formulation consisting of 7 percent oil-in-water, which is 1863 preferred over studies that use neat chemicals. In addition, Doan et al. (2010) conducted both in vivo and 1864 *in vitro* experiments in female, hairless guinea pigs to compare absorption measurements using the same dose of DBP, which increases confidence in the data used. Although there is uncertainty regarding the 1865 magnitude of the difference between dermal absorption through guinea pigs' skin vs. human skin for 1866 1867 DBP, based on DBP physical and chemical properties (size, solubility), EPA is confident that the dermal absorption data using guinea pigs for (Doan et al., 2010) provides an upper-bound estimate of dermal 1868 1869 absorption of DBP.

1870

1871 Another source of uncertainty regarding the dermal absorption of DBP from products or formulations

- 1872 stems from the varying concentrations and co-formulants that exist in products or formulations
- 1873 containing DBP. Dermal contact with products or formulations that have lower concentrations of DBP

- 1874 may exhibit lower rates of flux since there is less material available for absorption. Conversely, co-
- 1875 formulants or materials within the products or formulations may lead to enhanced dermal absorption-
- 1876 even at lower concentrations—but EPA is unclear of the magnitude of the enhanced dermal absorption.
- 1877 Therefore, it is uncertain whether the products or formulations containing DBP would result in 1878 decreased or increased dermal absorption.
- 1878 1879
- In summary, for the purposes of this draft risk evaluation, EPA assumes that the absorptive flux of DBP
 measured from *in vitro* guinea pig experiments serves as an upper bound of potential absorptive flux of
 chemical into and through the skin for dermal contact with all liquid products or formulations.
- 1883

1884 Dermal Modeling of DBP Exposure for Solids

1885 Because experimental dermal data were not identified via the systematic review process to estimate dermal exposures to solid products or articles containing DBP, a modeling approach was used to 1886 1887 estimate exposures (see Section 2.3.3 in U.S. EPA (2025c)). EPA notes that there is uncertainty with respect to the modeling of dermal absorption of DBP from solid matrices or articles. Similarly, since 1888 1889 there were no available data related to the dermal absorption of DBP from solid matrices or articles, 1890 EPA has assumed that dermal absorption of DBP from solid objects would be limited by aqueous 1891 solubility of DBP. During direct dermal contact, DBP can migrate to the aqueous phase available in the 1892 skin surface or be weakly bound to the polymer. The fraction of DBP associated with polymer chains is 1893 less likely to contribute to dermal exposure as compared to the aqueous fraction of DBP because the 1894 chemical is strongly hydrophobic. To determine the maximum steady-state aqueous flux of DBP, EPA 1895 utilized CEM (U.S. EPA, 2023c) to first estimate the steady-state aqueous permeability coefficient of 1896 DBP. The estimation of the steady-state aqueous permeability coefficient within CEM (U.S. EPA, 1897 2023c) is based on a quantitative structure-activity relationship (QSAR) model presented by ten Berge 1898 (2009), which considers chemicals with $log(K_{ow})$ ranging from -3.70 to 5.49 and molecular weights 1899 ranging from 18 to 584.6. The molecular weight and log(K_{ow}) of DBP falls within the range suggested 1900 by ten Berge (2009). Therefore, there is low to medium uncertainty regarding the accuracy of the OSAR 1901 model used to predict the steady-state aqueous permeability coefficient for DBP. There are some 1902 uncertainties on the assumption of migration from solid to aqueous media to skin, which assumes the 1903 aqueous dermal exposure model assumes that DBP absorbs as a saturated aqueous solution (*i.e.*, 1904 concentration of absorption is equal to water solubility), which would be the maximum concentration of 1905 absorption of DBP expected from a solid material. EPA has moderate confidence in the dermal exposure to solid products or articles modeling approach 1906

1907

1908 Ingestion via Mouthing

The chemical migration rate of DBP was estimated based on data compiled in a review published by the Danish EPA in 2016 (Danish EPA, 2016), see Section 2.2.3.1 in U.S. EPA (2025c). For chemical migration rates to saliva, existing data were highly variable both within and between studies; for example, the mild mouthing intensity range from 0.04 to 5.8 μ g/cm²-h with an average of 0.17 μ g/cm²-h and a standard deviation of 1.4 μ g/cm²-h. As such, based on available data for chemical migration rates of DBP to saliva, the range of values used in this assessment (0.17, 24.3, and 48.5 μ g/cm²-h for the mild,

- 1915 medium, and harsh intensity respectively) are considered likely to capture the true value of the
- 1916 parameter depending on article expected uses. For example, EPA assumes children mouthing practices
- 1917 can be mild, medium, or harsh for children's toys. Although adults' mouthing practices for adult toys are
- 1918 not expected to be harsh. Harsh mouthing of adult toys can likely result in the breakage or destruction of
- 1919 the article and adults tend to control the harshness of their mouthing better than infants and toddlers.
- 1920 EPA calculated a high-intensity use of adult toys using harsh mouthing approaches as part of the
- screening approach and recognized that this highly conservative result is very unlikely behavior. The

- Agency did not identify use pattern information regarding adult toys and most inputs are based onprofessional judgment assumptions.
- 1924
- 1925 A major limitation of all existing data is that DBP weight fractions for products tested in mouthing
- studies skew heavily towards relatively high weight fractions (30–60%) whereas measurements for
 weight fractions less than 15 percent are rarely represented in the dataset. Thus, it is unclear whether the
 migration rate values are applicable to consumer goods with low (<15%) weight fractions of DBP,
 where rates might be lower than represented by typical or worst-case values determined by existing data
- 1930

sets.

1931

EPA has a *moderate* confidence in mouthing estimates due to uncertainties about professional judgment inputs regarding mouthing durations for adult toys and synthetic leather furniture for children. In general, the chemical migration rate input parameter has a moderate confidence due to the large variability in the empirical data used in this assessment and unknown correlation between chemical migration rate and DBP concentration in articles.

1937

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
Construction, paint, electrical, and metal products; Adhesives and	Three different scenarios were assessed under this COU for three product types with differing use patterns: Adhesives for small repairs, automotive adhesives, and construction adhesives. Adhesives for small repairs and construction	Inhalation– Robust
sealants	adhesives were assessed for dermal exposures only, due to the small product amount and surface area used in each application, inhalation and ingestion would have low exposure potential for these two scenarios. Automotive adhesives were assessed for dermal and inhalation exposures. The overall confidence in this COU's inhalation exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use. See Section 2.1.2 in U.S. EPA (2025c) for number of products, product examples, and weight fraction data.	Dermal – Moderate
	For dermal exposure EPA used a dermal flux-limited approach, which was estimated based on DBP dermal absorption in guinea pigs. The flux-limited approach likely results in overestimations due to the assumption about excess DBP in contact with skin. An overall moderate confidence in dermal assessment of adhesives was assigned. Uncertainties about the difference between human and guinea pig skin absorption increase uncertainty and due to increased permeability of guinea pig skin as compared to human skin dermal absorption estimates likely overestimate exposures. Other parameters such as frequency and duration of use, and surface area in contact, are well understood and representative, resulting in a moderate overall confidence.	
Construction, paint, electrical, and metal products; Paints and coatings	Three different scenarios were assessed under this COU for 3 product types with differing use patterns: metal coatings, indoor sealing and refinishing sprays, and outdoor sealing and refinishing sprays. All 3 scenarios were assessed for dermal and inhalation exposures. The overall confidence in this COU inhalation exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use. See Section 2.1.2 in U.S. EPA (2025c) for number of products, product examples, and weight fraction data.	Inhalation– Robust Dermal – Moderate
	For dermal exposure EPA used a dermal flux-limited approach, which was estimated based on DBP dermal absorption in guinea pigs. The flux-limited approach likely results in overestimations due to the assumption about excess DBP in contact with skin. An overall moderate confidence in dermal	

1938 Table 4-7. Weight of Scientific Evidence Summary Per Consumer COU

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	assessment of adhesives was assigned. Uncertainties about the difference between human and guinea pigs skin absorption increase uncertainty and due to increased permeability of guinea pig skin as compared to human skin dermal absorption estimates likely overestimate exposures. Other parameters such as frequency and duration of use, and surface area in contact, are well understood and representative, resulting in an overall confidence of moderate.	
Furnishing, cleaning, treatment care products; Fabric, textile, and leather products	Two different scenarios were assessed under this COU for articles with differing use patterns: synthetic leather clothing and synthetic leather furniture. Indoor synthetic furniture articles were assessed for all exposure routes as part of the indoor exposure assessment (<i>i.e.</i> , inhalation, ingestion (suspended and settled dust, and mouthing), and dermal), while synthetic clothing was only assessed for dermal contact since the articles were too small to result in significant inhalation and ingestion exposures. The overall confidence in the synthetic leather furniture and clothing COU inhalation exposure estimate is robust because the CEM default parameters are representative of typical use patterns and location of use. The stay-at-home activity use input parameter is considered a conservative input that although representative of actual uses for some populations is also believed to result in an upper-bound exposure. See Section 2.1.1 in U.S. EPA (2025c) for article examples and weight fraction data.	Inhalation – Robust
	The indoor furniture ingestion via mouthing exposure estimate overall confidence is moderate due to uncertainties in the parameters used for chemical migration to saliva, such as large variability in empirical migration rate data for harsh, medium, and mild mouthing approaches. Additionally, there are uncertainties from the unknown correlation between chemical concentration in articles and chemical migration rates, and no reasonably available data were available to compare and confirm selected rate parameters to better understand uncertainties.	Ingestion – Moderate Dermal – Moderate
	The dermal absorption estimate assumes that dermal absorption of DBP from solid objects would be limited by the aqueous solubility of DBP. EPA has moderate confidence in the aspects of the exposure estimate for solid articles because of the high uncertainty in the assumption of partitioning from solid to liquid, and because subsequent dermal absorption is not well characterized. Additionally, there are uncertainties associated to the flux-limited approach which likely results in overestimations due to the assumption about excess DBP in contact with skin. Other parameters such as frequency and duration of use, and surface area in contact have unknown uncertainties due to lack of information about use patterns, resulting in an overall confidence of moderate.	
Furnishing, cleaning, treatment/care products; Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles, and apparel	Two different scenarios were assessed under this COU for articles with differing use patterns: vinyl flooring and wallpaper. Both scenarios were part of the indoor assessment and evaluated for all exposure routes except mouthing. The scenarios capture the variability from varying manufacturing formulations in the high-, medium-, and low-intensity use estimates and the weight fraction ranges reported. The overall confidence in the vinyl flooring and wallpaper COU inhalation exposure estimate is moderate because the CEM input parameters are representative, but there are uncertainties in the surface area used and location of use. The stay-at-home activity use input parameter is considered a conservative input that although representative of actual uses for some populations is also believed to result in an upper-bound exposure. See Section 2.1.1 in U.S. EPA (2025c) for article examples and weight fraction data.	Inhalation – Moderate Ingestion – Moderate Dermal – Moderate

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	The dermal absorption estimate assumes that dermal absorption of DBP from solid objects would be limited by the aqueous solubility of DBP. EPA has moderate confidence in the aspects of the exposure estimate for solid articles because of the high uncertainty in the assumption of partitioning from solid to liquid, and because subsequent dermal absorption is not well characterized. Additionally, there are uncertainties associated to the flux-limited approach which likely results in overestimations due to the assumption about excess DBP in contact with skin. Other parameters such as frequency and duration of use, and surface area in contact, have unknown uncertainties due to lack of information about use patterns, resulting in an overall confidence of moderate.	
Other uses; Novelty articles	for dermal contact and ingestion via mouthing exposures. Inhalation exposures were determined to be minimal due to small surface area to release DBP. The adult toys ingestion exposure estimate overall confidence is moderate due to uncertainties in the parameters used for chemical migration to saliva such as large variability in empirical migration rate data for harsh, medium, and mild mouthing approaches. Additionally, there are uncertainties from the unknown correlation between chemical concentration in articles and chemical migration rates, and no data were reasonably available to compare and confirm selected rate parameters to better understand uncertainties. In addition, there are unknown uncertainties in the use duration input parameters which were assumed based on professional judgment. EPA calculated a high-intensity use of adult toys using harsh mouthing approaches as part of the screening approach, however recognizing that this highly conservative use pattern is very unlikely behavior, it is not to be used to estimate risk. EPA did not identify use pattern information regarding adult toys. The dermal absorption estimate assumes that dermal absorption of DBP from solid objects would be limited by the aqueous solubility of DBP. EPA has moderate confidence in the aspects of the exposure estimate for solid articles because of the high uncertainty in the assumption of partitioning from solid to liquid, and because subsequent dermal absorption is not well characterized. Additionally, there are uncertainties associated to the flux-limited approach which likely results in overestimations due to the assumption about excess DBP in contact with skin. Other parameters such as frequency and duration of	Ingestion – Moderate Dermal – Moderate
Other uses; Automotive articles	use, and surface area in contact have unknown uncertainties due to lack of information about use patterns, resulting in an overall confidence of moderate. Two different scenarios were assessed under this COU for articles with differing use patterns: car mats and synthetic leather seats. Both scenarios were part of the indoor assessment and evaluated for all exposure routes except mouthing. The overall confidence in the inhalation exposure estimate for the car mats and synthetic leather seats COU is robust because the CEM input parameters are representative. The stay-at-home activity use input parameter is considered a conservative input that although representative of actual uses for some populations is also believed to result in an upper-bound exposure. See Section 2.1.1 in U.S. EPA (2025c) for article examples and weight fraction data. The dermal absorption estimate assumes that dermal absorption of DBP from solid objects would be limited by the aqueous solubility of DBP. EPA has moderate confidence in the aspects of the exposure estimate for solid articles because of the high uncertainty in the assumption of partitioning from solid to liquid, and because subsequent dermal absorption is not well characterized. Additionally, there are uncertainties associated to the flux-limited approach	Inhalation and Dust Ingestion – Robust Dermal – Moderate

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	which likely results in overestimations due to the assumption about excess DBP in contact with skin. Other parameters such as frequency and duration of use, and surface area in contact have unknown uncertainties due to lack of information about use patterns, resulting in an overall confidence of moderate.	
Other uses; Chemiluminescent light sticks	One scenario was assessed for this COU, chemiluminescent light sticks. The scenario was assessed for dermal exposures. Inhalation and ingestion exposures were determined to be minimal due to small surface area to release DBP. The dermal absorption estimate assumes that dermal absorption of DBP from solid objects would be limited by the aqueous solubility of DBP. EPA has moderate confidence in the aspects of the exposure estimate for solid articles because of the high uncertainty in the assumption of partitioning from solid to liquid, and because subsequent dermal absorption is not well characterized. Additionally, there are uncertainties associated to the flux-limited approach which likely results in overestimations due to the assumption about excess DBP in contact with skin. Other parameters such as frequency and duration of use, and surface area in contact, have unknown uncertainties due to lack of information about use patterns, resulting in an overall confidence of moderate.	Dermal – Moderate
Packaging, paper, plastic, hobby products; Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)	Three different scenarios were assessed under this COU for 3 article types with differing use patterns: footwear, shower curtains, and small articles with semi routine contact (<i>e.g.</i> , miscellaneous items including a pen, pencil case, hobby cutting board, costume jewelry, tape, garden hose, disposable gloves, and plastic bags/pouches). Footwear and small articles with semi routine contact scenarios were assessed for dermal exposures only. Shower curtains were assessed for dermal and also part of the indoor assessment and evaluated for all exposure routes except mouthing. The overall confidence in this COU inhalation exposure estimate is robust because the CEM input parameters are representative. The stay-at-home activity use input parameter is considered a conservative input that although representative of actual uses for some populations is also believed to result in an upper-bound exposure. See Section 2.1.1 in U.S. EPA (2025c) for article examples and weight fraction data. The dermal absorption estimate assumes that dermal absorption of DBP from solid objects would be limited by the aqueous solubility of DBP. EPA has moderate confidence in the aspects of the exposure estimate for solid articles because of the high uncertainty in the assumption of partitioning from solid to liquid, and because subsequent dermal absorption is not well characterized. Additionally, there are uncertainties associated to the flux-limited approach which likely results in overestimations due to the assumption about excess DBP in contact with skin. Other parameters such as frequency and duration of use, and surface area in contact, have unknown uncertainties due to lack of information about use patterns, resulting in an overall confidence of moderate.	Inhalation and Dust Ingestion – Robust Dermal – Moderate
Packaging, paper, plastic, hobby products; Toys, playground, and sporting equipment Packaging, paper, plastic,	Four different scenarios were assessed under this COU for various articles with differing use patterns: legacy children's toys, and new children's toys, tire crumb and artificial turf, and a variety of PVC articles with potential for routine contact. Toys scenarios were included in the indoor assessment for all exposure routes (inhalation, dust ingestion, mouthing, and dermal) with varying use patterns and inputs. Tire crumb was also part of the indoor assessment for all exposure routes except mouthing, while articles of routine contact were only assessed for dermal exposures since they are too small to result in impactful	CEM Inhalation – Robust Ingestion, Tire crumb Inhalation, and Dermal
hobby products; Toys, playground, and sporting equipment	inhalation or ingestion exposures. The high-, medium-, and low-intensity scenarios capture variability and provide a range of representative use patterns. The overall confidence in this COU inhalation exposure estimate is robust because a good understanding of the CEM model parameter inputs and representativeness of actual use patterns and location of use. The stay-at-home	– Moderate

Consumer COU Category and Subcategory	Weight of Scientific Evidence	Overall Confidence
	activity use input parameter is considered a conservative input that although representative of actual uses for some populations is also believed to result in an upper-bound exposure. See Section 2.1.1 in U.S. EPA (2025c) for article examples and weight fraction data. Tire crumb inhalation confidence is moderate due to higher uncertainty in using surrogate chemical air concentrations, while all other parameters are well understood and representative of use patterns by the various age groups. The overall confidence in this COU's mouthing and dermal exposure assessment is moderate.	
	The mouthing parameters used like duration and surface area for infants to children are very well understood, while older groups have less specific information because mouthing behavior is not expected. The chemical migration value is DBP specific, and the only sources of uncertainty are related to a large variability in empirical migration rate data for harsh, medium, and mild mouthing approaches. Additionally, there are uncertainties from the unknown correlation between chemical concentration in articles and chemical migration rates, and no data were reasonably available to compare and confirm selected rate parameters to better understand uncertainties.	
	Dermal absorption estimates are based on the assumption that dermal absorption of DBP from solid objects will be limited by aqueous solubility of DBP. EPA has moderate confidence for solid objects because the high uncertainty in the assumption of partitioning from solid to liquid and subsequent dermal absorption is not well characterized. Additionally, there are uncertainties associated to the flux-limited approach which likely results in overestimations due to the assumption about excess DBP in contact with skin. Other parameters like frequency and duration of use, and surface area in contact have unknown uncertainties due to lack of information about use patterns, making the overall confidence of moderate.	

1939

1940

4.1.3 General Population Exposures

General population exposures occur when DBP is released into the environment and the environmental
media is then a pathway for exposure. As described in the *Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025q), releases of DBP
are expected in air, water, and disposal to landfills. Figure 4-2 provides a graphic representation of
where and in which media DBP is estimated to be found due to environmental releases and the
corresponding route of exposure for the general population.

1947
1948 EPA began its DBP exposure assessment using a screening level approach that relies on conservative
1949 assumptions. Conservative assumptions, including default input parameters for modeling environmental

1950 media concentrations, help characterize exposure resulting from the high-end of the expected

distribution. Several of the OESs presented in Table 1-1 report facility location data and releases in the
 Toxics Release Inventory (TRI) and Discharge Monitoring Report (DMR) databases. When facility

1953 location- or scenario-specific information were unavailable, EPA used generic EPA models and default

1954 input parameter values as described in the *Draft Environmental Release and Occupational Exposure*

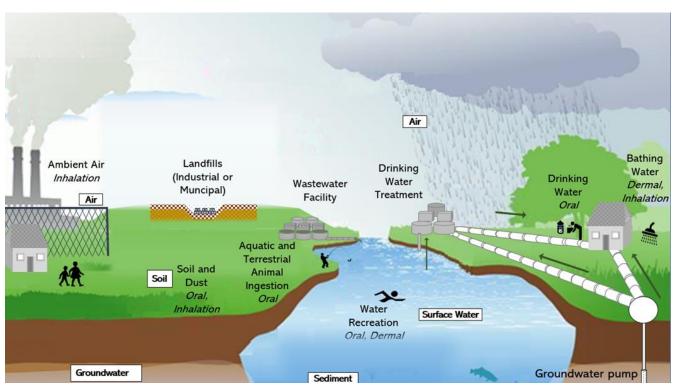
1955 Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025q). Details on the use of screening level analyses

in exposure assessment can be found in EPA's *Guidelines for Human Exposure Assessment* (U.S. EPA,
 2019d).

1958 EPA considered a subset of the general population living near facilities releasing DBP to the ambient air

1959 (which includes fenceline communities) as part of the ambient air exposure assessment. EPA utilized a

- pre-screening methodology described in EPA's *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities (Version 1.0)* (U.S. EPA, 2022b) for the
 ambient air exposure risk assessment. For other exposure pathways, EPA's screening method assessing
 high-end exposure scenarios used release data that reflect exposures expected to occur in proximity to
 releasing facilities, which would include fenceline populations.
- 1965
- 1966 EPA evaluated the reasonably available information for releases of DBP from facilities that use, 1967 manufacture, or process DBP under industrial and/or commercial COUs subject to TSCA regulations 1968 detailed in the Draft Environmental Release and Occupational Exposure Assessment for Dibutyl 1969 Phthalate (DBP) (U.S. EPA, 2025q). As described in Section 3.3, using the release data, EPA modeled 1970 predicted concentrations of DBP in surface water, sediment, drinking water, and ambient air in the 1971 United States. Table 3-6 summarizes the high-end DBP concentrations in environmental media from 1972 environmental releases. The reasoning for assessing different pathways qualitatively or quantitatively is 1973 discussed briefly in Section 3.3 and additional detail can be found in the Draft Environmental Media, 1974 General Population, and Environmental Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 1975 2025p).
- 1976



- 1977
- Figure 4-2. Potential Human Exposure Pathways to DBP for the General Population
 Potential routes of exposure are shown in italics under each potential pathway of exposure.
- 1980
- 1981 High-end estimates of DBP concentration in the various environmental media presented in the *Draft*
- 1982 Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl
- 1983 *Phthalate (DBP)* (U.S. EPA, 2025p) were used for screening level purposes in the general population
- 1984 exposure assessment. EPA's Guidelines for Human Exposure Assessment (U.S. EPA, 2019d) defines
- 1985 high-end exposure estimates as a "plausible estimate of individual exposure for those individuals at the
- 1986 upper end of an exposure distribution, the intent of which is to convey an estimate of exposure in the
- 1987 upper range of the distribution while avoiding estimates that are beyond the true distribution." If risk is
- 1988 not found for these individuals with high-end exposure, no risk is anticipated for central tendency

exposures, which is defined as "an estimate of individuals in the middle of the distribution." Therefore, if there is no risk for an individual identified as having the potential for the highest exposure associated with a COU for a given pathway of exposure, that pathway was determined not to be a pathway of concern and not pursued further. If any pathways were identified as a pathway of concern for the general population, further exposure assessments for that pathway would be conducted to include higher tiers of modeling when available, refinement of exposure estimates, and exposure estimates for additional subpopulations and OES/COUs.

1996

1997 Identifying individuals at the upper end of an exposure distribution included consideration of high-end 1998 exposure scenarios defined as those associated with the industrial and commercial releases from a COU 1999 and OES that resulted in the highest environmental media concentrations. As described in Section 3.3, 2000 EPA focused on estimating high-end concentrations of DBP from the largest estimated releases for the 2001 purpose of its screening level assessment for environmental and general population exposures. This 2002 means that EPA considered the environmental concentration of DBP in a given environmental media 2003 resulting from the OES that had the highest release compared to any other OES for the same releasing media. Release estimates from OES resulting in lower environmental media concentrations were not 2004 2005 considered for this screening level assessment. Additionally, individuals with the greatest intake rate of 2006 DBP per body weight were considered to be those at the upper end of the exposure.

2007

2008 Table 4-8 summarizes the high-end exposure scenarios that were considered in the screening level 2009 analysis, including the lifestage assessed as the most potentially exposed population based on intake rate 2010 and body weight. Table 4-8 also indicates which pathways were evaluated quantitatively or 2011 qualitatively. Exposure was assessed quantitatively only when environmental media concentrations were 2012 quantified for the appropriate exposure scenario. For example, exposure from soil or groundwater 2013 resulting from DBP release to the environment via biosolids or landfills was not quantitatively assessed 2014 because DBP concentrations to the environment from biosolids and landfills were not quantified. Due to 2015 the high confidence in the biodegradation rates and physical and chemical data, there is robust 2016 confidence that DBP will not be mobile and will have low persistence potential in receiving soils. 2017 Similarly, there is robust confidence that DBP is unlikely to be present in landfill leachates. However, 2018 exposure was still assessed qualitatively for exposures potentially resulting from biosolids and landfills. 2019 Further details on the screening level approach and exposure scenarios evaluated by EPA for the general 2020 population are provided in the Draft Environmental Media, General Population, and Environmental

Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025p). OESs resulting in the highest

modeled environmental media concentrations were selected for the purpose of screening level analyses.

- 2021 2022
- 2023

2024	Table 4-8. Exp	posure Scena	arios Assess	ed in Gene	eral Popul	lation Scr	eening I	Level Ar	alysis

OES	Exposure Pathway	Exposure Route	Exposure Scenario	Lifestage	Analysis (Quantitative or Qualitative)
All	Biosolids	Al	All scenarios assessed qualitatively		
All	Landfills	Al	l scenarios assessed qual	itatively	Qualitative
Manufacturing	Surface	Dermal	Dermal exposure to DBP in surface water during swimming	All	Quantitative
Waste handling, treatment, and disposal	water	Oral	Incidental ingestion of DBP in surface water during swimming	All	Quantitative

OES	Exposure Pathway	Exposure Route	Exposure Scenario	Lifestage	Analysis (Quantitative or Qualitative)	
Manufacturing Waste handling, treatment, and disposal	Drinking water	Oral	Ingestion of drinking water	All	Quantitative	
			Ingestion of fish for general population	Adults and young toddlers (1–2 years old)	Quantitative	
Manufacturing	Fish ingestion	Oral	Oral	Ingestion of fish for subsistence fishers	Adults (16 to <70 years old)	Quantitative
			Ingestion of fish for Tribal populations	Adults (16 to <70 years old)	Quantitative	
Waste handling, treatment, disposal (stack)		Inhalation	Inhalation of DBP in ambient air from industrial releases	All	Quantitative	
Application of paints, coatings, adhesives, and sealants (fugitive)	Ambient air	Oral	Ingestion of DBP in soil from air to soil deposition resulting from industrial releases	Infant and Children (6 month to 12 years)	Quantitative	

2025

2026 EPA also considered biomonitoring data, specifically urinary biomonitoring data from CDC's

2027 NHANES, to estimate exposure using reverse dosimetry (see Section 10.2 of the *Draft Environmental*

2028 Media, General Population, and Environmental Exposure Assessment for Dibutyl Phthalate (DBP)

2029 (U.S. EPA, 2025p)). Reverse dosimetry is a powerful tool for estimating exposure, but reverse

dosimetry modeling does not distinguish between routes or pathways of exposure and does not allow for source apportionment (*i.e.*, exposure from TSCA COUs cannot be isolated from uses that are not subject to TSCA). Instead, reverse dosimetry provides an estimate of the total dose (or aggregate exposure) responsible for the measured biomarker. Therefore, intake doses estimated using reverse dosimetry are not directly comparable to the exposure estimates from the various environmental media presented in this document. However, the total intake dose estimated from reverse dosimetry can help contextualize

2036 the exposure estimates from exposure pathways outlined in Table 4-8 as being potentially under- or

2037 overestimated.

4.1.3.1 General Population Screening Level Exposure Assessment Results

2039 Land Pathway

2040 EPA evaluated general population exposures via the land pathway (*i.e.*, application of biosolids, 2041 landfills) qualitatively. Due to hydrophobicity (log $K_{OW} = 4.5$) and affinity for sorption to soil and 2042 organic constituents in soil (log $K_{OC} = 3.14 - 3.94$), DBP is unlikely to migrate to groundwater via runoff 2043 after land application of biosolids. Additionally, the half-life of less than 1 day to 19 days in aerobic soils (U.S. EPA, 2024) indicates that DBP will have low persistence potential in the aerobic 2044 2045 environments associated with freshly applied biosolids. Because the physical and chemical properties of 2046 DBP indicate that it is unlikely to migrate from land applied biosolids to groundwater via runoff, EPA 2047 did not model groundwater concentrations resulting from land application of biosolids.

2048

2038

Although there are limited measured data on DBP in landfill leachates, DBP may leach from landfill material but is expected to have limited mobility beyond the landfill. DBP in leachate is unlikely to

infiltrate groundwater due to the high affinity to organic matter and sediment. Interpretation of the high quality physical and chemical property data also suggest that DBP is unlikely to be present in landfill
 leachate. Therefore, EPA concludes that further assessment of DBP in landfill leachate is not needed.

2055 Surface Water Pathway – Incidental Ingestion and Dermal Contact from Swimming

2056 As described in Section 3.3, EPA conducted modeling of reported releases, when available, to surface water at the point of release (*i.e.*, in the immediate water body receiving the effluent) to assess the 2057 2058 expected resulting environmental media concentrations from TSCA COUs. When reported releases were unavailable for an OES, EPA estimated releases to surface water using generic scenarios as explained in 2059 2060 Section 3.2. EPA conducted modeling with VVWM-PSC to estimate concentrations of DBP within 2061 surface water and to estimate settled sediment in the benthic region of streams. Releases associated with 2062 the Manufacturing OES resulted in the highest total water column concentrations among reported 2063 releases, with water concentrations of 885 µg/L using 30Q5 flow (Table 4-9). Because of relevance to 2064 the exposure route, acute incidental surface water exposures and acute drinking water exposures were derived from the 3005 flow concentrations, and chronic drinking water exposures were derived from the 2065 harmonic mean (HM) flow concentrations. COUs mapped to the Manufacturing OES are shown in 2066 2067 Table 3-1. As described in Section 3.3.1.1, Manufacturing OES was chosen as an appropriate OES for a 2068 screening level assessment based on it resulting in a conservatively high surface water concentration 2069 based on high volumes of releases associated with low flow metrics (P50). Additionally, the generic 2070 release scenario for the Manufacturing OES estimates a combined release to wastewater, incineration, or 2071 landfill. Because the proportion of the release from Manufacturing OES to just surface water could not 2072 be determined from reasonably available information, for screening purposes, EPA assumed that all of 2073 the release would be to wastewater to represent an upper bound of surface water concentrations. 2074

These water column concentrations from the Manufacturing OES were used to estimate the (1) acute dose rate (ADR) and average daily dose (ADD) from dermal exposure, and (2) incidental ingestion of DBP while swimming for adults (21+ years), youths (11–15 years), and children (6–10 years). Detailed results for all exposures can be found in *Draft Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025p). In this section, exposure scenarios leading to the highest modeled dose are shown in Table 4-9.

2082 For the purpose of a screening level assessment, EPA used a MOE approach using high-end exposure 2083 estimates to determine if exposure pathways were pathways of concern for potential non-cancer risks. MOEs for general population exposure through dermal exposure and incidental ingestion during 2084 2085 swimming ranged from 203 to 403 (compared to a benchmark of 30) for surface water concentrations 2086 estimated using releases from Manufacturing OES (P50). Because all estimated MOEs exceeded the 2087 benchmark, no additional scenarios were assessed. Thus, based on a screening level assessment, risks for 2088 non-cancer health effects are not expected for the incidental ingestion or incidental dermal contact to 2089 surface water during swimming.

2090

2054

2091 Surface Water Pathway – Drinking Water

2092 Similar to the assessment of incidental ingestion and dermal contact from swimming described above, 2093 for screening level purposes, EPA assessed the OES resulting in the highest modeled surface water 2094 concentrations in the drinking water exposure analysis. Manufacturing OES resulted in the highest total 2095 water column concentrations among reported releases, with water concentrations of 885 µg/L using 2096 3005 flow (Table 4-9). Because of relevance to the exposure route, acute drinking water exposures were 2097 derived from the 30Q5 flow concentrations whereas chronic drinking water exposures were derived 2098 from the harmonic mean flow concentrations. As described above and in Section 3.3, surface water 2099 concentrations modeled using releases associated with the Manufacturing OES represent an upper-

2100 bound based on many conservative assumptions—including all of the estimated total release going to

surface water, high releases paired with low flow assumptions (P50), and no treatment of wastewater
before release to the environment.

ADR and ADD values from drinking water exposure to DBP were calculated for various age groups but the most exposed lifestage, infants (birth to <1 year), is shown below. Detailed results for all exposures can be found in *Draft Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025p). Exposure scenarios leading to the highest modeled dose are shown in Table 4-9; note that acute doses are presented here as they are greater than chronic doses.

2110

2111 MOE for general population exposure through drinking water were 17 for the drinking water scenario 2112 based on surface water concentrations estimated from releases associated with Manufacturing OES 2113 paired with a low flow (P50) for the lifestage with the highest exposure (compared to a benchmark of 2114 30) (Table 4-9). While there is moderate to robust confidence in the use of Manufacturing releases as an 2115 upper-bounding condition to screen for risk (see Section 3.3), there is only slight confidence in the 2116 precision of the estimated concentrations. This is particularly true in the case of the lowest flow (P50) 2117 condition as EPA does not expect large releasers to discharge to a body of water consistent with the low 2118 flow rate. Therefore, there is greater confidence that the medium (P75) and high flow (P90) scenarios 2119 are representative of real-world practices. Because of this, EPA assessed additional scenarios including 2120 drinking water exposures from the Manufacturing OES paired with a medium (P75) and high (P90) flow 2121 as refinements to the most conservative scenario (*i.e.*, Manufacturing releases to P50 flow). For the 2122 refined scenarios the MOEs for the highest exposed lifestage were 319 and 4,958 for medium (P75) and 2123 high flow (P90), respectively.

2124

EPA also assessed the Waste handling, treatment, and disposal OES, which had the highest reported
release to surface water based on DMR. The Agency has higher confidence in the surface water
concentrations estimated from this release due to direct reporting of the release amounts and receiving
water bodies from the facilities within the OES. For the drinking water scenario for Waste handling,
treatment, and disposal OES, the MOE for the lifestage with the highest exposure (infants) was 1,026.

2130 2131 Based on the screening level assessment, EPA estimates low potential exposure to DBP via drinking 2132 water—even under high-end release scenarios and without considering expected treatment removal 2133 efficiencies from drinking water treatment. These exposure estimates also assume that the drinking 2134 water intake location is very close (within a few km) to the point of discharge and do not incorporate 2135 any dilution beyond the point of discharge. Actual concentrations in raw and finished water are likely to 2136 be lower than these conservative estimates as applying dilution factors will decrease the exposure for all 2137 scenarios, while additional distances downstream would allow further partitioning and degradation. 2138 Based on screening level analysis, risks for non-cancer health effects are not expected for the drinking 2139 water pathway; therefore, the drinking water pathway is not considered to be a pathway of concern to 2140 DBP for the general population.

2141

Table 4-9. Summary of the Highest Doses in the General Population through Surface and Drinking Water Exposure

Water Column Concentration		_	Incidental Ingestion Surface Water ^c		Drinking Water ^d		
30Q5 Conc. (μg/L)	ADR (mg/kg- day)	Acute MOE (Benchmark MOE = 30)	ADR (mg/kg-day)	Acute MOE (Benchmark MOE = 30)	ADR (mg/kg- day)	Acute MOE (Benchmark MOE = 30)	
885.0	1.04E-02	203	4.74E-03	443	1.25E-01	17	
46.6	Not assessed ^e	Not assessed ^e	Not assessed ^e	Not assessed ^e	6.58E-03	319	
3.0	Not assessed ^e	Not assessed ^e	Not assessed ^e	Not assessed ^e	4.24E-04	4,958	
14.5	Not assessed ^e	Not assessed ^e	Not assessed ^e	Not assessed ^e	2.05E-03	1,026	
	Concentration 30Q5 Conc. (µg/L) 885.0 46.6 3.0 14.5	ConcentrationSurfa30Q5 Conc. (µg/L)ADR (mg/kg- day)885.01.04E-0246.6Not assessed ^e 3.0Not assessed ^e	ConcentrationSurface Water b 30Q5 Conc. (µg/L)ADR (mg/kg- day)Acute MOE (Benchmark MOE = 30)885.0 $1.04E-02$ 203 46.6Not assessed e Not assessed e 3.0Not assessed e Not assessed e 14.5NotNot assessed e	ConcentrationSurface Water b Surface30Q5 Conc. (µg/L)ADR (mg/kg- day)Acute MOE (Benchmark MOE = 30)ADR (mg/kg-day)885.0 $1.04E-02$ 203 $4.74E-03$ 46.6Not assessed ^e Not assessed ^e Not assessed ^e 3.0Not assessed ^e Not assessed ^e Not assessed ^e 14.5NotNot assessed ^e Not assessed ^e	ConcentrationSurface Water b Surface Water c 30Q5 Conc. (µg/L)ADR (mg/kg- day)Acute MOE (Benchmark MOE = 30)ADR (mg/kg-day)Acute MOE (Benchmark MOE = 30)885.0 $1.04E-02$ 203 $4.74E-03$ 443 46.6Not assessed e Not assessed e Not assessed e Not assessed e 3.0Not 	ConcentrationSurface Water b Surface Water c Drinking30Q5 Conc. (µg/L)ADR (mg/kg- day)Acute MOE (Benchmark MOE = 30)ADR (mg/kg-day)Acute MOE (Benchmark MOE = 30)ADR (mg/kg- day)885.0 $1.04E-02$ 203 $4.74E-03$ 443 $1.25E-01$ 46.6Not assessed e Not assessed e Not assessed e Not assessed e 802×203 3.0Not assessed e Not assessed e Not assessed e Not assessed e 802×203 14.5NotNot assessed e Not assessed e Not assessed e 802×203	

^a Table 3-1 provides a crosswalk of industrial and commercial COUs to OES.

^b Most exposed age group: Adults (21+ years)

^c Most exposed age group: Youth (11–15 years)

^d Most exposed age group: Infant (birth to <1 year)

^e These scenarios were not assessed because the MOE exceeded the benchmark of 30 in the prior scenario used for screening

2144

2145 Fish Ingestion

2146 The key parameters to estimate human exposure to DBP via fish ingestion are the surface water 2147 concentration, bioaccumulation factor (BAF), and fish ingestion rate. Surface water concentrations for DBP associated with a particular COU were modeled using VVWM-PSC as described in Section 2148 3.3.1.1. The harmonic mean flow and resulting estimated concentrations in surface water and fish tissue 2149 2150 were applied to calculate exposure via fish ingestion because the harmonic mean flow is considered 2151 representative of long-term DBP concentrations that would enter fish tissue over time. The details on the 2152 BAF, which considers the animal's uptake of a chemical from both diet and the water column, can be 2153 found in the Draft Environmental Media, General Population, and Environmental Exposure Assessment 2154 for Dibutyl Phthalate (DBP) (U.S. EPA, 2025p).

2155

EPA evaluated exposure and potential risk to DBP through fish ingestion for populations and age groups
that had the highest fish ingestion rate per kg of body weight—including for adults and young toddlers
in the general population, adult subsistence fishers, and adult Tribal populations. Children were not

2159 considered for reasons explained in Sections 7.2 and 7.3 of the *Draft Environmental Media, General*

2160 Population, and Environmental Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025p).

2161 Only the fish ingestion rate changes across the different populations; the surface water concentration and

2162 BAF remain the same. ADR and ADD values from fish ingestion exposure to DBP were calculated for

2163 various populations and age groups and can be found in Section 7 of the *Draft Environmental Media*,

2164 General Population, and Environmental Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA,

2165 <u>2025p</u>), but Table 4-10 shows only results for the Tribal populations as they represent the highest

- 2166 exposure because of their elevated fish ingestion rates compared to both the general population and
- 2167 subsistence fisher population. Exposure to Tribal populations were estimated based on current mean

- (U.S. EPA, 2011a) and current 95th percentile (Polissar et al., 2016) fish ingestion rate. Current
 ingestion rate refers to the present-day consumption levels that are suppressed by contamination,
 degradation, or loss of access. Heritage rates existed prior to non-indigenous settlement on Tribal
 fishers' resources and changes to culture and lifeways. Therefore, current ingestion rates are considered
 more representative of contemporary rates of fish consumption and are presented below. Heritage rates
 are discussed in further detail in *Draft Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025p).
- 2175

2176 EPA used the solubility limit for DBP in water (11.2 mg/L; see Table 2-1) as the initial tier of the 2177 screening level analysis, and screening level risk estimates were below the benchmark MOE for all 2178 populations (U.S. EPA, 2025p). The next highest-tier refinement used the Manufacturing OES (high-end 2179 releases) that resulted in the highest modeled DBP concentrations in surface water. As discussed in 2180 Section 3.3, surface water concentrations for the Manufacturing OES were estimated for various flows 2181 (i.e., P50, P75, and P90). EPA expects larger releases to occur to water bodies with higher flow rates 2182 consistent with the P75 and P90 rather than lower flow rates represented by the P50. As such, DBP exposure via fish ingestion for the Manufacturing OES based on the P50 flow rates was not evaluated. 2183 2184 Table 4-10 presents only risk estimates for Tribal populations as the most highly exposed populations. 2185 Risk estimates using the Manufacturing OES (high-end releases, P75 flow rate) were above the 2186 benchmark MOE for all populations except Tribal populations at the current 95th percentile ingestion rate (MOE = 19 and 25). Risk estimates using the P90 flow rate were above the benchmark MOE for all 2187 2188 populations.

2189

2190 While risk estimates for the Manufacturing OES at the P75 flow rate were below the benchmark MOE 2191 for Tribal populations at the current 95th percentile ingestion rate, EPA has only slight confidence in the 2192 results. That is because the Manufacturing OES had modeled releases from generic scenarios 2193 discharging to multiple environmental media and there is insufficient information to determine the 2194 fraction of release going to each of the media types (Section 3.3.1.1). EPA instead relied on reported 2195 releases from TRI and DMR to evaluate the fish ingestion pathway. The Waste handling, treatment, and 2196 disposal OES had the highest reported release to surface water based on DMR. No risk estimates were 2197 below the benchmark MOE for this OES. EPA has moderate-to-robust confidence in these risk 2198 estimates. Overall, the exposure to DBP via fish ingestion is not expected to be a pathway of concern.

2199

Based on screening level analysis, risks for non-cancer health effects are not expected for Tribal
 populations via the fish ingestion pathway; therefore, the fish ingestion pathway is not considered to be

2201 populations via the fish ingestion pathway, therefore, the fish ingestion pathway is not considered to be 2202 a pathway of concern to DBP for Tribal populations, subsistence fishers, and the general population.

2203 Further discussion on the resulting risk estimates from higher-tier refinements and conclusions is

2204 provided in Section 4.3.4.

2205

2206 Table 4-10. Fish Ingestion for Adults in Tribal Populations Summary

Calculation Method ^c	Current Mean (Benchmark	8	Current Tribal Ingestion Rate ^b , 95th Percentile ^b		
Calculation Method	ADR/ADD (mg/kg-day)	Chronic and Acute MOE ^a	ADR/ADD (mg/kg-day)	Chronic and Acute MOE ^a	
Water solubility limit (11.2 mg/L)	12.4 (tilapia) 9.50 (common carp)	0.2 (tilapia) 0.2 (common carp)	50.1 (tilapia) 38.3 (common carp)	0.0 (tilapia) 0.1 (common carp)	
Manufacturing (HE, P75, 0.02 mg/L)	2.70E–02 (tilapia) 2.07E–02 (common carp)	78 (tilapia) 102 (common carp)	1.09E–01 (tilapia) 8.35E–05 (common carp)	19 (tilapia) 25 (common carp)	
Manufacturing (HE, P90, 0.002 mg/L)	1.88E–03 (tilapia) 1.44E–03 (common carp)	1,116 (tilapia) 1,457 (common carp)	7.60E–03 (tilapia) 5.82E–03 (common carp)	276 (tilapia) 361 (common carp)	
Waste handling, treatment, disposal – POTW (4.60E–05 mg/L)	1.61E–02 (tilapia) 1.23E–02 (common carp)	131 (tilapia) 171 (common carp)	6.48E–02 (tilapia) 4.96E–02 (common carp)	32 (tilapia) 42 (common carp)	

ADR = acute dose rate; ADD = average daily dose; CT = central tendency; HE = high-end, 95th percentile; MOE = margin of exposure

^{*a*} The acute and chronic MOEs are identical because the exposure estimates and the POD do not change between acute and chronic.

^b Current ingestion rate (mean at 2.7 g/kg-day and 95th percentile at 10.9 g/kg-day used in this assessment) refers to the present-day consumption levels that are suppressed by contamination, degradation, or loss of access. ^c Screening level assessment started with the water solubility limit and using the OES with highest surface water

concentrations (Plastic compounding). 2207

2208 Ambient Air Pathway

2209 As part of the ambient air exposure assessment, EPA considered exposures to the general population in 2210 proximity to releasing facilities, including fenceline communities, by utilizing a previously peer-2211 reviewed, pre-screening methodology described in EPA's Draft TSCA Screening Level Approach for 2212 Assessing Ambient Air and Water Exposures to Fenceline Communities (Version 1.0) (U.S. EPA, 2213 2022b). EPA used the IIOAC model to estimate ambient air concentrations and deposition rates using 2214 pre-run results from a suite of dispersion scenarios in a variety of meteorological and land-use settings within American Meteorological Society/EPA Regulatory Model (AERMOD). The maximum fugitive 2215 2216 release value used in this assessment was reported to the 2017 NEI dataset and is associated with the 2217 Application of paints, coatings, adhesives, and sealants OES. The maximum stack release value used in 2218 this assessment was reported to the TRI dataset and is associated with the Waste handling, treatment, 2219 and disposal OES. Both maximum release values represent the maximum release reported across all 2220 facilities and COUs and are used as direct inputs to the IIOAC model to estimate concentrations and 2221 deposition rates. EPA used the maximum 95th percentile modeled concentrations and deposition rates across a series of exposure scenarios considering particle size and urban/rural topography to characterize 2222 2223 exposures and derive risk estimates. Calculations for general population exposure to ambient air via 2224 inhalation and ingestion from air to soil deposition for lifestages expected to be highly exposed based on exposure factors can be found in Draft Ambient Air IIOAC Exposure Results and Risk Calculations 2225 2226 Dibutyl Phthalate (DBP) (U.S. EPA, 2025a). Inhalation exposure to DBP from ambient air is expected 2227 to be much higher than exposure to DBP via soil ingestion resulting from air to soil deposition and is, therefore, presented below for the screening level analysis. 2228 2229

2230 For a screening level assessment, EPA utilized the highest ambient air concentrations modeled from 2231 release data from actual release facilities using conservative assumptions. The highest 95th percentile 2232 modeled daily average concentration used to derive acute risk estimates for fugitive releases was 16.73 2233 $\mu g/m^3$ and for stack releases was 0.53 $\mu g/m^3$. These concentrations occurred at 100 m from the releasing facility and together result in a total exposure from facility releases of $17.26 \,\mu g/m^3$. They are attributable 2234 to two separate OESs: fugitive releases from Application of paints, coatings adhesives, and sealants 2235 2236 (corresponding to the Industrial/commercial use; Construction, paint, electrical, and metal products; and 2237 Adhesives and sealants/paints and coatings COUs) and stack releases from Waste handling, treatment, 2238 and disposal (corresponding to the Disposal COU). The highest 95th percentile modeled annual average 2239 concentration used to derive chronic risk estimates for fugitive releases was 11.46 μ g/m³ and 0.37 μ g/m³ for stack releases. These concentrations occurred at 100 m from the releasing facility, together result in a 2240 total exposure from facility releases of $11.82 \,\mu g/m^3$ and are attributable to two separate OESs (fugitive 2241 2242 releases from Application of paints, coatings adhesives, and sealants and stack releases from Waste 2243 handling, treatment, and disposal). Table 3-1 shows COUs mapped to each OES

2244

2245 Table 4-11 summarizes the total exposures and the associated MOE calculated using the inhalation 2246 human equivalent concentration (HEC). The HEC is derived in the Draft Non-cancer Human Health 2247 Hazard Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2024f) and based on an 80 kg adult. Using 2248 the highest modeled 95th percentile air concentration, MOEs for general population exposure through 2249 inhalation of ambient air are 695 for acute and 1,015 for chronic (compared to a benchmark of 30) for an 2250 adult. Because the HEC was derived for adults, MOEs for other lifestages were not calculated. However, 2251 considering similar or smaller inhalation rates for younger lifestages and greatest body weight difference 2252 of a factor of 16.7 between an adult (80 kg) and newborn (4.8 kg) based on EPA's Exposure Factors 2253 Handbook: 2011 Edition (U.S. EPA, 2011b), MOEs for all lifestages will still exceed the benchmark 2254 based on the estimates for adults.

2255

Because these derived risk estimates based on the conservative screening analysis are well above relative benchmarks for non-cancer health effects, EPA concludes inhalation of DBP via the ambient air pathway is not a pathway of concern for the general population. Additionally, because exposure via soil ingestion resulting from air to soil deposition is less than exposure from inhalation via ambient air, the Agency concludes that soil ingestion resulting from air to soil deposition is not a pathway of concern for the general population.

2262

Table 4-11. General Population Ambient Air Inhalation Exposure Summary

	Acute (Daily Aver	rage) ^b	Chronic (Annual Average) ^b	
OES ^a	Air Concentration ^c (µg/m ³)	MOE	Air Concentration ^c (µg/m ³)	MOE
Application of paints, coatings, adhesives, and sealants (fugitive)	17.26	695	11.82	1,015
Waste handling, treatment, and disposal (stack)				

^{*a*} Table 3-1 provides a crosswalk of industrial and commercial COUs to OES.

^b EPA assumes the general population is continuously exposed (*i.e.*, 24 hours per day, 365 days per year) to outdoor ambient air concentrations. Therefore, daily average modeled ambient air concentrations are equivalent to acute exposure concentrations, and annual average modeled ambient air concentrations are equivalent to chronic exposure concentrations.

^c Air concentrations are reported for the high-end (95th percentile) modeled value at 100 m from the emitting facility and stack plus fugitive releases combined.

2264

4.1.3.2 Daily Intake Estimates for the U.S. Population Using NHANES Urinary Biomonitoring Data

2267 EPA used a screening level approach to calculate sentinel exposures to the general population from 2268 TSCA releases. EPA also analyzed urinary biomonitoring data from the CDC's NHANES dataset to 2269 provide context for aggregate exposures in the U.S. non-institutionalized, civilian population. The 2270 NHANES dataset reports urinary concentrations for 15 phthalate metabolites specific to individual 2271 phthalate diesters. EPA analyzed data for two metabolites of DBP; mono-3-hydroxybutyl phthalate 2272 (MHBP) (measured in the 2015–2018 NHANES cycles) and mono-n-butyl phthalate (MnBP) (measured 2273 in the 1999–2018 NHANES cycles). Urinary metabolite levels reported in the most recent NHANES 2274 survey (*i.e.*, 2017–2018) were used to calculate daily intake for various demographic groups reported 2275 within NHANES (Table 4-12). Median daily intake estimates across demographic groups ranged from 2276 0.21 to 0.56 μ g/kg-day, while 95th percentile daily intake estimates ranged from 0.59 to 2.02 μ g/kg-day. The highest daily intake value estimated was for male toddlers (3 to <6 years old) and was 2.02 µg/kg-2277 2278 day at the 95th exposure percentile. Detailed results of the NHANES analysis can be found in Section 2279 11.1 of Draft Environmental Media, General Population, and Environmental Exposure Assessment for 2280 Dibutyl Phthalate (DBP) (U.S. EPA, 2025p).

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2266

Using 50th and 95th percentile daily intake values calculated from reverse dosimetry, EPA calculated MOEs ranging from 4,100 to 10,000 at the 50th percentile and 1,000 to 3,600 at the 95th percentile across demographic groups using the acute/intermediate/chronic POD (*i.e.*, an HED of 2,100 μ g/kg-day) based on reduced fetal testicular testosterone (Table 4-13). The lowest calculated MOE of 1,000 was for male toddlers (3 to <6 years old), based on the 95th percentile exposure estimate. All calculated MOEs at the 50th and 95th percentiles were above the benchmark of 30, indicating that aggregate exposure to DBP alone does not pose a risk to the non-institutionalized, U.S. civilian population.

2290 General population exposure estimates calculated from exposure to ambient air, surface water, fish 2291 ingestion, and soil from TSCA releases are not directly analogous to daily intake values estimated via 2292 reverse dosimetry from NHANES. While NHANES may be used to provide context for aggregate 2293 exposures in the U.S. population, NHANES is not expected to capture exposures from specific TSCA 2294 COUs that may result in high-dose exposure scenarios (e.g., occupational exposures to workers)—as 2295 compared to EPA's general population exposure assessment which evaluates sentinel exposures for 2296 specific exposure scenarios corresponding to TSCA releases. However, as a screening level analysis, 2297 media-specific general population exposure estimates calculated were compared to daily intake values 2298 calculated using reverse dosimetry of NHANES biomonitoring data. Comparison of the values showed 2299 that many of the exposure estimates resulting from incidental dermal contact or ingestion of surface water (assuming no wastewater treatment) (Table 4-9) and ingestion of fish for adults in Tribal 2300 2301 populations (assuming heritage ingestion rate; see the Draft Environmental Media, General Population, 2302 and Environmental Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025p)) exceeded the 2303 total daily intake values estimated using NHANES (Table 4-12).

Exposure estimates for the general population via ambient air, surface water, and drinking water
resulting from TSCA releases quantified in this document are likely overestimates. This is because
exposure estimates from individual pathways exceed the total intake values calculated from NHANES
measured even at the 95th percentile of the U.S. population for all ages. Further, this is consistent with
the U.S. CPSC's conclusion that DBP exposure comes primarily from diet for women, infants, toddlers,
and children and that the outdoor environment is not a major source of exposure to DBP (CPSC, 2014).

Table 4-12. Daily Intake Values and MOEs for DBP Based on Urinary Biomonitoring from the 2017 to 2018 NHANES Cycle

Demographic	50th percentile Daily Intake (95% CI) (µg/kg-day)	95th percentile Daily Intake (95% CI) (µg/kg-day)	50th Percentile MOE (Benchmark = 30)	95th Percentile MOE (Benchmark = 30)	
All	0.33 (0.3–0.36)	1.16 (0.96–1.35)	6,400	1,800	
Females	0.31 (0.27–0.35)	1.02 (0.93–1.11)	6,800	2,100	
Males	0.34 (0.31–0.37)	1.33 (0.93–1.72)	6,200	1,600	
White non-Hispanic	0.33 (0.29–0.38)	0.97 (0.7–1.24)	6,400	2,200	
Black non-Hispanic	0.32 (0.28–0.37)	1.18 (0.84–1.52)	6,600	1,800	
Mexican-American	0.29 (0.24–0.33)	0.91 (0.68–1.13)	7,200	2,300	
Other	0.38 (0.31–0.44)	1.8 (-0.29-3.88)	5,500	1,200	
Above poverty level	0.38 (0.33-0.43)	1.26 (0.91–1.62)	5,500	1,700	
Below poverty level	0.31 (0.27–0.34)	1.04 (0.84–1.24)	6,800	2,000	
Toddlers (3 to <6 years old)	0.55 (0.5–0.6)	1.54 (1.07–2)	3,800	1,400	
Children (6 to <11 years old)	0.36 (0.31-0.41)	1.37 (0.88–1.86)	5,800	1,500	
Adolescents (12 to <16 years old)	0.28 (0.21–0.34)	0.62 (0.37–0.88)	7,500	3,400	
Adults (16+ years old)	0.21 (0.17-0.25)	0.61 (0.39–0.84)	10,000	3,400	
Male toddlers (3 to <6 years old)	0.56 (0.49–0.63)	2.02 (1.31-2.74)	3,800	1,000	
Male children (6 to <11 years old)	0.38 (0.32–0.44)	1.41 (-0.01 to 2.83)	5,500	1,500	
Male adolescents (12 to <16 years old)	0.33 (0.26–0.4)	0.62 (-1.03 to 2.27)	6,400	3,400	
Male adults (16+ years old)	0.21 (0.15–0.28)	0.59 (0.35–0.83)	10,000	3,600	
Female toddlers (3 to <6 years old)	0.51 (0.44–0.57)	1.44 (1.04–1.84)	4,100	1,500	
Female children (6 to <11 years old)	0.34 (0.28–0.41)	0.95 (0.62–1.29)	6,200	2,200	
Female adolescents (12 to <16 years old)	0.26 (0.17–0.34)	0.61 (0.29–0.94)	8,100	3,400	
Women of reproductive age (16–49 years old)	0.21 (0.16–0.26)	0.61 ^{<i>a</i>}	10,000	3,400	
Female adults (16+ years old)	0.21 (0.16–0.26)	0.61 ^{<i>a</i>}	10,000	3,400	
^a 95% confidence intervals (CI) con	uld not be calculated d	ue to small sample size	e or a standard error of	zero.	

2314 2315

4.1.3.3 Overall Confidence in General Population Screening Level Exposure Assessment

2316 The weight of scientific evidence supporting the general population exposure estimate is decided based

2317 on the strengths, limitations, and uncertainties associated with the exposure estimates. These are

discussed in detail for ambient air, surface water, drinking water, and fish ingestion in the *Draft*

2319 Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl

Phthalate (DBP) (U.S. EPA, 2025p). EPA summarized its weight of scientific evidence using
 confidence descriptors: robust, moderate, slight, or indeterminate. The Agency used general
 considerations (*i.e.*, relevance, data quality, representativeness, consistency, variability, uncertainties) as
 well as chemical-specific considerations for its weight of scientific evidence conclusions.

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2325 EPA determined robust confidence in its qualitative assessment of biosolids and landfills. For its 2326 quantitative assessment for surface water, drinking water, ambient air, and fish ingestion, the Agency 2327 modeled exposure due to various general population exposure scenarios resulting from different 2328 pathways of exposure. Exposure estimates utilized high-end inputs for the purpose of risk screening. 2329 When available, monitoring data was compared to modeled estimates to evaluate overlap, magnitude, 2330 and trends. EPA has robust confidence that modeled releases used are appropriately conservative for a 2331 screening level analysis. Therefore, the Agency has robust confidence that no exposure scenarios will 2332 lead to greater doses than presented in this evaluation. Despite slight and moderate confidence in the 2333 estimated values themselves, confidence in exposure estimates capturing high-end exposure scenarios 2334 was robust given that many of the modeled values exceeded those of monitored values and exceeded 2335 total daily intake values calculated from NHANES biomonitoring data. This adds to confidence that 2336 exposure estimates captured high-end exposure scenarios.

4.1.4 Human Milk Exposures

Infants are potentially more susceptible than older children, teens, and adults for various reasons including their higher exposure per body weight, immature metabolic systems, and the potential for chemical toxicants to disrupt sensitive developmental processes. Reasonably available information from studies of experimental animal models also indicates that DBP is a developmental and reproductive toxicant (U.S. EPA, 2024f). EPA considered exposure and hazard information, as well as pharmacokinetic models, to determine the most scientifically supportable appropriate approach to evaluate infant exposure to DBP from human milk ingestion (U.S. EPA, 2025p).

2346 EPA identified 13 biomonitoring studies, one of which is from the United States, from reasonably 2347 available information that investigated if DBP or its metabolites were present in human milk. None of the studies characterized if any of the study participants may be occupationally exposed to DBP. 2348 2349 Nonetheless, DBP or its metabolites were consistently detected in human milk. However, it is important 2350 to note that biomonitoring data do not distinguish between exposure routes or pathways and do not allow 2351 for source apportionment. In other words, biomonitoring data reflect total infant exposure through 2352 human milk ingestion and the contribution of specific TSCA COUs to overall exposure cannot be 2353 determined.

2354

2355 Furthermore, no human health studies have evaluated only lactational exposure from quantified levels of 2356 DBP in milk. While EPA explored the potential to model milk concentrations and concluded that there 2357 is insufficient information (e.g., sensitive and specific half-life data) available to support modeling of the 2358 milk pathway, the Agency also concluded that modeling is not needed to adequately evaluate risks 2359 associated with exposure through milk. This is because the POD used in this assessment is based on 2360 male reproductive effects resulting from maternal exposures throughout sensitive phases of development 2361 in multigenerational studies. EPA therefore has confidence that the risk estimates calculated based on 2362 maternal exposures are protective of a nursing infant's greater susceptibility during this unique lifestage 2363 whether due to sensitivity or greater exposure per body weight. Further discussion of the human milk 2364 pathway is provided in the Draft Environmental Media, General Population, and Environmental

2365 *Exposure for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025p).

2366 4.1.5 Aggregate and Sentinel Exposure

TSCA section 6(b)(4)(F)(ii) (15 USC 2605(b)(4)(F)(ii)) requires EPA, in conducting a risk evaluation,
to describe whether aggregate and sentinel exposures under the COUs were considered and the basis for
their consideration.

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EPA defines aggregate exposure as "the combined exposures to an individual from a chemical substance
across multiple routes and across multiple pathways (40 CFR § 702.33)." For the draft DBP risk
evaluation, the Agency considered aggregate risk across all routes of exposure for each individual
consumer and occupational COU evaluated for acute, intermediate, and chronic exposure durations.
EPA did not consider aggregate exposure for the general population. As described in Section 4.1.3, a
risk screening approach was used for the general population exposure assessment.

EPA did not consider aggregate exposure scenarios across COUs because the Agency did not find any evidence to support such an aggregate analysis based on the reasonably available information, such as statistics of populations using certain products represented across COUs, or workers performing tasks across COUs. However, EPA considered combined exposure across all routes of exposure for each individual occupational and consumer COU to calculate aggregate risks (Sections 4.3.2 and 4.3.3).

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EPA defines sentinel exposure as "the exposure to a chemical substance that represents the plausible 2384 2385 upper-bound of exposure relative to all other exposures within a broad category of similar or related 2386 exposures (40 CFR 702.33)." In terms of this draft risk evaluation, the Agency considered sentinel 2387 exposures by considering risks to populations who may have upper-bound exposures; for example, 2388 workers and ONUs who perform activities with higher exposure potential or consumers who have higher 2389 exposure potential or certain physical factors like body weight or skin surface area exposed. EPA 2390 characterized high-end exposures in evaluating exposure using both monitoring data and modeling 2391 approaches. Where statistical data are available, the Agency typically uses the 95th percentile value of 2392 the available dataset to characterize high-end exposure for a given condition of use. For general 2393 population and consumer exposures, EPA occasionally characterized sentinel exposure through a "high-2394 intensity use" category based on elevated consumption rates, breathing rates, or user-specific factors.

2395 4.2 Summary of Human Health Hazard

4.2.1 Background

This section briefly summarizes the non-cancer and cancer human health hazards of DBP (Sections 4.2.2
and 4.2.3, respectively). Additional information on the non-cancer and cancer human health hazards of
DBP are provided in the *Draft Non-cancer Human Health Hazard Assessment for Dibutyl Phthalate*(*DBP*) (U.S. EPA, 2024f) and the *Draft Cancer Human Health Hazard Assessment for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate*(*DIBP), and Dicyclohexyl Phthalate (DCHP)* (U.S. EPA, 2025b).

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4.2.2 Non-Cancer Human Health Hazards of DBP

The majority of toxicokinetic data for DBP is derived from oral exposure studies. Although reasonably available data on other routes of exposure are sparse, there is some indication that DBP can be expected to be readily absorbed through the lung (U.S. EPA, 2024f). Following oral exposure, DBP is hydrolyzed in the gastrointestinal tract to MBP, which is then absorbed, systemically distributed, and can undergo further metabolism (*e.g.*, oxidation, glucuronidation) in the liver. Metabolites of DBP—not the parent phthalate—are associated with the adverse effects of DBP. Most (67–97%) of the administered dose of MBP is excreted in urine within 24 hours while a small proportion is also eliminated in the feces. DBP

- and its metabolites can cross the placenta to the developing fetus. As stated in the Draft Non-Cancer
- 2412 Human Health Hazard Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2024f), the Agency
- assumed an oral absorption of 100 percent and an inhalation absorption of 100 percent. EPA is
- 2414 proposing to use DBP dermal absorption data from an study by Doan et al. (2010) to estimate the dermal
- flux of DBP, as described previously in the Summary of Occupational Exposures (Sections 4.1.1) and Summary of Consumer Exposures (Section 4.1.2).
- 2416 2417
- EPA identified effects on the developing male reproductive system as the most sensitive and robust noncancer hazard associated with oral exposure to DBP in experimental animal models. Effects on the
 developing male reproductive system were also identified as the most sensitive and robust non-cancer
 effect following oral exposure to DBP by existing assessments of DBP, including those by the U.S.
 Consumer Product Safety Commission (CPSC, 2014), Health Canada (Health Canada, 2020), European
- 2423 Chemicals Bureau (ECJRC, 2004), European Chemicals Agency (ECHA, 2017a, b, 2010), The
- European Food Safety Authority (<u>EFSA, 2019, 2005</u>), the Australian National Industrial Chemicals
- Notification and Assessment Scheme (<u>NICNAS, 2013</u>), the National Toxicology Program Center for the
- Evaluation of Risks to Human Reproduction (<u>NTP, 2003</u>), the California Office of Environmental
 Health Hazard Assessment (OEHHA, 2007), and in other assessments (NASEM, 2017). EPA also
- Health Hazard Assessment (<u>OEHHA, 2007</u>), and in other assessments (<u>NASEM, 2017</u>). EPA also considered epidemiologic evidence qualitatively as part of hazard identification and characterization.
- 2429 However, the Agency did not use epidemiology studies quantitatively for dose-response assessment—
- primarily due to uncertainty associated with exposure characterization that is further discussed in the
- 2431 Draft Non-cancer Human Health Hazard Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2024f).
- 2432 Use of epidemiologic evidence qualitatively is consistent with phthalates assessment by Health Canada
- 2433 (<u>Health Canada, 2020</u>) and the U.S. CPSC (2014).
- 2434

2435 EPA identified 37 oral exposure studies (35 of rats, 2 of mice) that investigated the developmental and 2436 reproductive effects of DBP following gestational and/or perinatal exposure to DBP, including multi-2437 generational studies of reproduction (Wine et al., 1997; NTP, 1995). However, there are limited data that evaluate the effects of DBP following inhalation or dermal exposures. Data that evaluate chronic 2438 2439 exposures via any route are limited to one study (NTP, 2021). Across available studies, the most 2440 sensitive developmental effects identified by EPA include effects on the developing male reproductive 2441 system consistent with a disruption of androgen action and development of phthalate syndrome. The 2442 Agency has previously concluded in the Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control 2443 Act (U.S. EPA, 2023d) that oral exposure to DBP can induce effects on the developing male 2444 2445 reproductive system consistent with a disruption of androgen action and described a mode of action (MOA) for phthalate syndrome. 2446

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2448 EPA is proposing a point of departure (POD) of 9 mg/kg-day (derived from a BMDL₅; human 2449 equivalent dose [HED] of 2.1 mg/kg-day) based on phthalate syndrome-related effects on the developing 2450 male reproductive system (*i.e.*, decreased fetal testicular testosterone) to estimate non-cancer risks from 2451 oral exposure to DBP for acute, intermediate, and chronic durations of exposure in this draft risk 2452 evaluation of DBP. The proposed POD was derived from EPA's updated meta-analysis originally 2453 conducted by the National Academies of Sciences, Engineering, and Medicine (NASEM, 2017) and 2454 subsequent benchmark dose (BMD) modeling of decreased fetal testicular testosterone (ex vivo testicular 2455 testosterone production or testicular testosterone content) in eight studies of rats exposed to DBP during gestation (Gray et al., 2021; Furr et al., 2014; Johnson et al., 2011; Struve et al., 2009; Howdeshell et al., 2456 2457 2008; Martino-Andrade et al., 2008; Johnson et al., 2007; Kuhl et al., 2007). The 95 percent lower 2458 confidence limit of the BMD associated with a five percent response (*i.e.*, BMDL₅) is 9 mg/kg-day

2459 (HED 2.1 mg/kg-day) and is within the range of candidate PODs (*i.e.*, 1–10 mg/kg-day) identified from

other studies based on antiandrogenic effects on the developing male reproductive system (Furr et al., 2461 2014; Moody et al., 2013; Boekelheide et al., 2009; Lee et al., 2004). These studies support the selection 2462 of the BMDL₅ of 9 mg/kg-day for the acute, intermediate, and chronic duration POD. The sole chronic 2463 study identified by EPA does not offer a more sensitive candidate chronic POD (*i.e.*, the 2-year NTP 2464 (2021) study of rats supports a LOAEL of 510 mg/kg-day (HED = 130 mg/kg-day).

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2466 EPA performed ³/₄-body weight scaling to yield the HED and is applying the animal-to-human 2467 uncertainty factor (*i.e.*, interspecies uncertainty factor; UF_A) of $3 \times$ and the within human variability 2468 uncertainty factor (*i.e.*, intraspecies uncertainty factor; UF_H) of 10×. Thus, a total UF of 30× is applied 2469 for use as the benchmark MOE. Overall, based on the strengths, limitations, and uncertainties discussed 2470 in the Draft Non-cancer Human Health Hazard Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2471 2024f), EPA has robust overall confidence in the proposed POD based on effects on the developing 2472 male reproductive system. This POD will be used to characterize risk from exposure to DBP for acute, 2473 intermediate, and chronic exposure scenarios. The applicability and relevance of this POD for all 2474 exposure durations (acute, intermediate, and chronic) is described in the Draft Non-cancer Human 2475 Health Hazard Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2024f). Risk estimates based on the 2476 selected POD are relevant for females of reproductive age and males at any lifestage. Decreased fetal 2477 testicular testosterone is the most sensitive endpoint. Additionally, there is (1) epidemiological evidence 2478 that DBP exposure can adversely affect the developing male reproductive system consistent with 2479 phthalate syndrome in males of any age, and (2) that DBP exposure at higher concentrations can cause 2480 other health effects in females as well (see the Draft Non-cancer Human Health Hazard Assessment for 2481 Dibutyl Phthalate (DBP) (U.S. EPA, 2024f)). Therefore, EPA considers the proposed POD to be 2482 relevant across sex, lifestage, and durations of exposure. 2483

2484 No data are available for the dermal or inhalation routes that are suitable for deriving route-specific 2485 PODs. Therefore, EPA is using the proposed acute/intermediate/chronic oral POD to evaluate risks from 2486 dermal exposure to DBP. Differences between oral and dermal absorption are accounted for in dermal 2487 exposure estimates in the draft risk evaluation for DBP. For the inhalation route, EPA is extrapolating 2488 the oral HED to an inhalation human equivalent concentration (HEC) per EPA's Methods for Derivation 2489 of Inhalation Reference Concentrations and Application of Inhalation Dosimetry (U.S. EPA, 1994) 2490 using the updated human body weight and breathing rate relevant to continuous exposure of an 2491 individual at rest provided in EPA's Exposure Factors Handbook: 2011 Edition (U.S. EPA, 2011b). The 2492 oral HED and inhalation HEC values selected by EPA to estimate non-cancer risk from 2493 acute/intermediate/chronic exposure to DBP in the draft risk evaluation of DBP are summarized in Table 2494 4-13.

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4.2.3 Cancer Human Health Hazards of DBP

As discussed in the *Draft Cancer Human Health Hazard Assessment for Di(2-ethylhexyl) Phthalate*(DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), and
Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2025b), available *in vivo* and *in vitro* genotoxicity assays of
DBP and *in vivo* carcinogenicity studies of DBP in rats and mice indicate that DBP is not a direct acting
genotoxicant or mutagen. However, there is some limited evidence that DBP might be weakly genotoxic
in some *in vitro* assays.

DBP has been evaluated for carcinogenicity in two recent chronic oral exposure studies (1 in rats, 1 in mice) conducted by NTP (2021). Across available carcinogenicity studies, DBP showed no carcinogenic activity in male or female B6C3F1 mice exposed to up to 1,306 to 1,393 mg/kg-day DBP through the diet for 2 years, or in female SD rats exposed to up to 600 mg/kg-day DBP through the diet for 2 years (NTP, 2021). In male SD rats, treatment with 510 mg/kg-day DBP caused a significant trend in

2508 increased incidence of pancreatic acinar cell adenomas in male SD rats fed diets containing DBP for 2 2509 years (NTP, 2021). Overall, EPA considers there to be some limited evidence to support the conclusion 2510 that chronic oral exposure to DBP causes pancreatic tumors in rats. As discussed further in the Draft 2511 Cancer Human Health Hazard Assessment for DEHP, DBP, BBP, DIBP, and DCHP (U.S. EPA, 2025b), read-across to other toxicologically similar phthalates such as DEHP and BBP that also induce 2512 2513 pancreatic acinar cell tumors in rats provides additional evidence to support the conclusion that phthalates, including DBP, can cause pancreatic acinar cell adenomas in rats, supporting EPA's 2514 2515 conclusion. 2516 2517 Under the Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005), EPA reviewed the weight of scientific evidence for the carcinogenicity of DBP and has preliminarily determined that there is 2518 2519 Suggestive Evidence of Carcinogenic Potential of DBP in rodents. According to the Guidelines for 2520 Carcinogen Risk Assessment (U.S. EPA, 2005), a descriptor of Suggestive Evidence of Carcinogenic 2521 Potential is appropriate "when the weight of evidence is suggestive of carcinogenicity; a concern for 2522 potential carcinogenic effects in humans is raised, but the data are judged not sufficient for a stronger 2523 conclusion. This descriptor covers a spectrum of evidence associated with varying levels of concern for

2524 carcinogenicity, ranging from a positive cancer result in the only study on an agent to a single positive 2525 cancer result in an extensive database that includes negative studies in other species." EPA's 2526 determination is based on evidence of pancreatic acinar cell adenomas in one study of male SD rats 2527 (NTP, 2021). Pancreatic tumors were not observed in female SD rats or B6C3F1 mice of either sex in 2528 NTP bioassays (NTP, 2021). According to the Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005), when there is Suggestive Evidence, "the Agency generally would not attempt a dose-response 2529 2530 assessment, as the nature of the data generally would not support one." Consistently, EPA is not 2531 conducting a dose-response assessment for DBP or evaluating DBP for carcinogenic risk to humans.

Further information can be found in the Draft Cancer Human Health Hazard Assessment for Di(2ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl
Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2025b).

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Target Organ System	Species	Duration	POD (mg/kg- day)	Effect	HED ^a (mg/kg- day)	HEC (mg/m ³) [ppm]	Benchmark MOE	Reference (TSCA Study Quality Rating)
Developing nale eproductive ystem	Rat	5–14 days throughout gestation	$BMDL_5 = 9$	↓ fetal testicular testosterone	2.1		UF _A = 3 UF _H =10 <i>Total UF=30</i>	(<u>Gray et al., 2021</u>) (High) (<u>Furr et al., 2014</u>) (High) (<u>Johnson et al., 2011</u>) (Medium) (<u>Struve et al., 2009</u>) (Medium) (<u>Howdeshell et al., 2008</u>) (High) (<u>Martino-Andrade et al., 2008</u>) (Medium) (<u>Johnson et al., 2007</u>) (Medium) (<u>Kuhl et al., 2007</u>) (Low)

2536 Table 4-13. Non-Cancer HECs and HEDs Used to Estimate Risks for Acute, Intermediate, and Chronic Exposure Scenarios

 $BMDL_5 = benchmark dose (lower confidence limit) associated with a 5% response level; HEC = human equivalent concentration; HED = human equivalent dose; MOE = margin of exposure; POD = point of departure; UF = uncertainty factor$

^{*a*} EPA used allometric body weight scaling to the ³/₄-power to derive the HED. Consistent with EPA Guidance (U.S. EPA, 2011c), the interspecies uncertainty factor (UF_A), was reduced from 10 to 3 to account for the remaining uncertainty associated with interspecies differences in toxicodynamics. EPA used a default intraspecies (UF_H) of 10 to account for variation in sensitivity within human populations.

^b The BMDL₅ was derived through meta-regression and BMD modeling of fetal testicular testosterone data from eight studies of DBP with rats (<u>Gray et al., 2021</u>; <u>Furr et al., 2014</u>; Johnson et al., 2011; <u>Struve et al., 2009</u>; <u>Howdeshell et al., 2008</u>; <u>Martino-Andrade et al., 2008</u>; Johnson et al., 2007).

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4.3 Human Health Risk Characterization

4.3.1 Risk Assessment Approach

The exposure scenarios, populations of interest, and toxicological endpoints used for evaluating risks
from acute, short-term/intermediate, and chronic/lifetime exposures are summarized below in Table
4-14.

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Table 4-14. Exposure Scenarios, Populations of Interest, and Hazard Values

	Workers					
	Male and female adolescents and adults (16+ years old) and females of reproductive age					
	directly working with DBP under light activity (breathing rate of 1.25 m ³ /h) (for further					
	details see (U.S. EPA, 2025q))					
	Exposure Durations					
	• Acute – 8 hours for a single workday					
	• Intermediate – 8 hours per workday for 22 days per 30-day period					
	• <i>Chronic</i> – 8 hours per workday for 250 days per year for 31 or 40 working years					
	Exposure Routes					
	• Inhalation and dermal					
	Occupational Non-Users					
	Male and female adolescents and adults (16+ years old) indirectly exposed to DBP within					
	the same work area as workers (breathing rate of $1.25 \text{ m}^3/\text{h}$) (for further details see (U.S.					
	EPA, 2025q))					
	Exposure Durations					
	Acute, Intermediate, and Chronic – same as workers					
	Exposure Routes					
Population of Interest	• Inhalation, dermal (for COUs where mist and dust deposited on surfaces)					
and Exposure	Consumers					
Scenario	Male and female infants (<1 year), toddlers (1–2 years), children (3–5 years and 6–10					
	years), young teens (11–15 years), teenagers (16–20 years) and adults (21+ years) exposed					
	to DBP through product or articles use (for further details see (U.S. EPA, 2025c))					
	Exposure Durations					
	• <i>Acute</i> – 1 day exposure					
	• Intermediate – 30 days per year					
	• <i>Chronic</i> – 365 days per year					
	Exposure Routes					
	• Inhalation, dermal, and oral					
	Bystanders					
	Male and female infants (<1 year), toddlers (1–2 years), and children (3–5 years and 6–10					
	years) incidentally exposed to DBP through product use (for further details see (U.S. EPA,					
	<u>2025c</u>))					
	Exposure Durations					
	• <i>Acute</i> – 1 day exposure					
	• Intermediate – 30 days per year					
	• <i>Chronic</i> – 365 days per year					
	Exposure Routes					
	• Inhalation					

	General Population					
	Male and female infants, children, youth, and adults exposed to DBP through drinking					
	water, surface water, soil from air to soil deposition, and fish ingestion (for further details					
	see (<u>U.S. EPA, 2025p</u>))					
	Exposure Durations					
	• Acute – Exposed to DBP continuously for a 24-hour period					
	• <i>Chronic</i> – Exposed to DBP continuously up to 33 years					
	Exposure Routes – Inhalation, dermal, and oral (depending on exposure scenario)					
Population of Interest	Cumulative Exposure Based on NHANES Biomonitoring					
and Exposure	Clindren aged 5–5, 0–11 years, and 11 to <10 years, male and remain adults 10+ years, and					
Scenario	females of reproductive age (16–49 years of age) exposed to DEHP, DBP, BBP, DIBP, and DINP through all exposure pathways and routes as measured through urinary biomonitoring					
	(<i>i.e.</i> , NHANES) (for further details see (U.S. EPA, $2025x$))					
	Exposure Durations					
	Durations not easily characterized in urinary biomonitoring studies					
	 Likely between acute and intermediate as phthalates have elimination half-lives on the 					
	order of several hours and are quickly excreted from the body in urine. Spot urine					
	samples, as collected through NHANES, are representative of relatively recent					
	exposures.					
	Exposure Routes					
	NHANES urinary biomonitoring data provides an estimate of aggregate exposure (<i>i.e.</i> ,					
	exposure through oral, inhalation, and dermal routes)					
	Non-Cancer Acute/Intermediate/Chronic Value					
	Sensitive health effect: Developmental toxicity (<i>i.e.</i> , reduced fetal testicular testosterone					
	content)					
	HEC Daily, continuous (assumes breathing rate of $0.6125 \text{ m}^3/\text{h}$ and 24 hours/day for					
	continuous exposure (U.S. EPA, 2011a)) = 12 mg/m ³ (1.0 ppm) UED Daily 2.1 mg/kg dayy darmal and aral					
	HED Daily = 2.1 mg/kg-day; dermal and oral Total UF (benchmark MOE) = 30 (UF _A = 3; UF _H = 10)					
	10tar OF (0cheminark MOL) = 50 (01 A = 5, 01 H = 10)					
TT 141. T266 4 -	Hazard Relative Potency					
Health Effects, Concentration and	Relative potency factors for DBP, DEHP, BBP, DIBP, DCHP, and DINP were derived					
Time Duration	based on reduced fetal testicular testosterone. DBP was selected as the index chemical (for					
	further details see (U.S. EPA, 2025x)).					
	$RPF_{DBP} = 1$ (index chemical)					
	$\operatorname{RPF}_{\operatorname{DEHP}} = 0.84$					
	$\operatorname{RPF}_{\operatorname{BBP}} = 0.52$					
	$RPF_{DIBP} = 053$					
	$RPF_{DCHP} = 1.66$ $PPE_{} = 0.21$					
	$RPF_{DINP} = 0.21$ Index chemical (DBP) POD = HED daily = 2.1 mg/kg-day					
	Total UF (benchmark MOE) = 30 (UF _A = 3 ; UF _H = 10)					
	10tat OF (conclimate NOE) = 50 (OFA = 5, OFH = 10)					

4.3.1.1 Estimation of Non-Cancer Risks

EPA used a margin of exposure (MOE) approach to identify potential non-cancer risks for individual exposure routes (*i.e.*, oral, dermal, inhalation). The MOE is the ratio of the non-cancer POD divided by a human exposure dose. Acute, short-term, and chronic MOEs for non-cancer inhalation and dermal risks were calculated using Equation 4-1.

2551 Equation 4-1. Margin of Exposure Calculation

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 $MOE = \frac{Non - cancer \ Hazard \ Value \ (POD)}{Human \ Exposure}$

2554	Where:		
2555	MOE	=	Margin of exposure for acute, short-term, or chronic
2556			risk comparison (unitless)
2557	Non-cancer Hazard Value (POD)	=	HEC (mg/m ³) or HED (mg/kg-day)
2558	Human Exposure	=	Exposure estimate (mg/m ³ or mg/kg-day)

2560 MOE risk estimates may be interpreted in relation to benchmark MOEs. Benchmark MOEs are typically 2561 the total UF for each non-cancer POD. The MOE estimate is interpreted as a human health risk of concern if the MOE estimate is less than the benchmark MOE (*i.e.*, the total UF). On the other hand, if 2562 2563 the MOE estimate is equal to or exceeds the benchmark MOE, the risk is not considered to be of concern 2564 and mitigation is not needed. Typically, the larger the MOE, the more unlikely it is that a non-cancer adverse effect occurs relative to the benchmark. When determining whether a chemical substance 2565 presents unreasonable risk to human health or the environment, calculated risk estimates are not "bright-2566 2567 line" indicators of unreasonable risk, and EPA has the discretion to consider other risk-related factors in addition to risks identified in the risk characterization. 2568

4.3.1.2 Estimation of Non-Cancer Aggregate Risks

As described in Section 4.1.5, EPA considered aggregate risk across all routes of exposure for each individual consumer and occupational COU evaluated for acute, intermediate, and chronic exposure durations. To identify potential non-cancer risks for aggregate exposure scenarios for workers (Section 4.3.2) and consumers (Section 4.3.3), EPA used the total MOE approach (U.S. EPA, 2001). For this approach, MOEs for each exposure route of interest in the aggregate scenario must first be calculated. The total MOE for the aggregate scenario can then be calculated using Equation 4-2.

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2577 Equation 4-2. Total Margin of Exposure Calculation

- 2578
- 2579

Total MOE =	1					
TOLULMOE –	1	1	1			
	MOE _{Oral}	MOE _{Dermal}	MOE _{Inhalation}			

2580 2581

X X 71

2581	where:		
2582	Total MOE	=	Margin of exposure for aggregate scenario (unitless)
2583	MOE _{Oral}	=	Margin of exposure for oral route (unitless)
2584	MOE _{Dermal}	=	Margin of exposure for dermal route (unitless)
2585	MOE Inhalation	=	Margin of exposure for inhalation route (unitless)
2586			

- Total MOE risk estimates may be interpreted in relation to benchmark MOEs, similarly as to described in the preceding Section 4.3.1.1.
- 2589 4.3.2 Risk Estimates for Workers
- This section summarizes risk estimates for workers from inhalation and dermal exposures, as well as
 aggregated exposures to DBP from individual DBP OESs and COUs across routes (

Table 4-18). Risks are calculated for all exposed workers based on the DBP-derived PODs described in Section 4.2.2. The occupational exposure values (OEVs) are discussed in Appendix F. This section provides discussion and characterization of risk estimates for workers, including females of reproductive age and ONUs, for the various OESs and COUs.

2598 Manufacturing

2599 For the manufacture of DBP, dermal exposure to liquids is expected to be the dominant route of 2600 exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 15 to 25 for average adult workers and females of reproductive age, while high-end dermal MOEs for the same 2601 2602 populations and exposure scenarios ranged from 0.8 to 1.3 (benchmark = 30). The central tendency MOEs for the same populations and exposure scenarios ranged from 30 to 49 for inhalation exposure 2603 2604 and 1.7 to 2.7 for dermal exposure. Aggregation of inhalation and dermal exposures led to negligible 2605 differences in risk when compared to risk estimates from dermal exposure alone. The MOEs presented 2606 in this paragraph are with no use of PPE. Section 4.3.2.4 and Table 4-17 provides more information on 2607 PPE that could be used to reduce the MOEs above the benchmark MOE. As noted previously, EPA is 2608 interested in public comments that may inform the use of exposure controls and PPE for different COU.

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2610 The high-end and central tendency worker inhalation exposure results for this OES are based on data from three different risk evaluations; each presented a single data point to characterize full-shift 2611 exposure to workers during DBP manufacturing (ECB, 2008; ECJRC, 2004; SRC, 2001). To determine 2612 central tendency and high-end values, EPA used the mid-point and maximum value, respectively, due to 2613 2614 limited data points. There is uncertainty about how well these data represent the true distribution of 2615 actual inhalation concentrations for worker exposures in a specific facility, and the lack of ONU 2616 exposure data, for which EPA used worker data as surrogate data; and that there are only three data 2617 points used for the inhalation assessment.

2618

2619 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the 2620 chemical is contacted at least once per day. Because DBP has low volatility and relatively low 2621 absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until 2622 the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of DBP 2623 from occupational dermal contact with materials containing DBP may extend up to 8 hours per day 2624 (U.S. EPA, 1991). However, if a worker uses proper PPE or washes their hands after contact with DBP or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-2625 2626 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area of occupational dermal exposure, EPA assumed a high-end value of 1,070 cm² for male workers and 890 2627 2628 cm^2 for female workers. These high-end occupational dermal exposure surface area values are based on 2629 the mean two-hand surface area for adults EPA's Exposure Factors Handbook (U.S. EPA, 2011a). For 2630 central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand 2631 (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for male workers and 445 cm^2 for female workers). 2632

2633

2634 High-end and central tendency dermal exposures to liquid were determined using data from Doan et al. (2010). The study estimated a dermal absorption rate from experiments on female hairless guinea pigs 2635 2636 using a formulation of 7 percent oil-in-water emulsion. Using the study's estimate for DBP absorption in skin, 56.3 percent of the 1 mg/cm² dose over 24 hours, EPA estimated the steady-state flux of DBP and 2637 2638 the resultant dose based on exposure area. Although EPA determined that all data were of acceptable 2639 quality without notable deficiencies and integrated all the data into the final exposure assessment, it's 2640 uncertain how representative the use of a 7 percent oil-in-water emulsion formulation is for OESs where 2641 the neat form of DBP is used. There is also uncertainty in the use of guinea pigs over human skin, as

2642 guinea pig tissue is known to be more permeable than human tissue. Therefore, uncertainties about the 2643 difference between human and guinea pigs skin absorption increase uncertainty.

2644

Due to limited inhalation data points, both the central and high-end exposure estimates are expected to be reflective of worker inhalation exposures for this OES. Also, since the dermal exposures are upperbound estimates, it can be conservatively assumed that the central tendency values of exposure estimates are expected to be most reflective of worker dermal exposures. This applies to COUs covered under the "Manufacturing" OES (*i.e.*, Manufacturing COU: Domestic manufacturing).

2650

2651 Import and Repackaging

2652 For the repackaging of DBP, dermal exposure from liquid contact is expected to be the dominant route 2653 of exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 15 to 2654 25 for average adult workers and females of reproductive age, while high-end dermal MOEs for the 2655 same populations and exposure scenarios ranged from 0.8 to 1.3 (benchmark = 30). The central tendency 2656 MOEs for the same populations and exposure scenarios ranged from 30 to 49 for inhalation exposure 2657 and 1.7 to 2.7 for dermal exposure. Aggregation of inhalation and dermal exposures led to negligible 2658 differences in risk when compared to risk estimates from dermal exposure alone. The MOEs presented 2659 in this paragraph are with no use of PPE. Section 4.3.2.4 and Table 4-17 provides more information on PPE that could be used to reduce the MOEs above the benchmark MOE. 2660

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2662 The high-end and central tendency worker inhalation exposure results for this OES are based on surrogate data from three different risk evaluations; each presented a single data point to characterize 2663 2664 full-shift exposure to workers during DBP manufacturing (ECB, 2008; ECJRC, 2004; SRC, 2001). To 2665 determine central tendency and high-end values, EPA used the mid-point and maximum value, respectively, due to limited data points. There is uncertainty about how well these data represent the true 2666 2667 distribution of actual inhalation concentrations for worker exposures in a specific facility, and the lack of 2668 ONU exposure data, for which EPA used worker data as surrogate data; and that there are only three 2669 data points used for the inhalation assessment.

2670

2671 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the 2672 chemical is contacted at least once per day. Because DBP has low volatility and relatively low 2673 absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until 2674 the skin is washed. Thus, in absence of exposure duration data, EPA has assumed that absorption of 2675 DBP from occupational dermal contact with materials containing DBP may extend up to 8 hours per day (U.S. EPA, 1991). However, if a worker uses proper PPE or washes their hands after contact with DBP 2676 2677 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-2678 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area 2679 of occupational dermal exposure, EPA assumed a high-end value of 1,070 cm² for male workers and 890 cm² for female workers. These high-end occupational dermal exposure surface area values are based on 2680 the mean two-hand surface area for adults EPA's Exposure Factors Handbook (U.S. EPA, 2011a). For 2681 central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand 2682 2683 (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for male workers and 445 cm² for female workers). 2684 2685

High-end and central tendency dermal exposures to liquid were determined using data from Doan et al.
(2010). The study estimated a dermal absorption rate from experiments on female hairless guinea pigs
using a formulation of 7 percent oil-in-water emulsion. Using the study's estimate for DBP absorption in
skin, 56.3 percent of the 1 mg/cm² dose over 24 hours, EPA estimated the steady-state flux of DBP and
the resultant dose based on exposure area. Although EPA determined that all data were of acceptable

quality without notable deficiencies and integrated all the data into the final exposure assessment, it's
uncertain how representative the use of a 7 percent oil-in-water emulsion formulation is for OESs where
the neat form of DBP is used. There is also uncertainty in the use of guinea pigs over human skin, as
guinea pig tissue is known to be more permeable than human tissue. Therefore, uncertainties about the
difference between human and guinea pigs skin absorption increase uncertainty.

2696

Due to limited inhalation data points, both the central and high-end exposure estimates are expected to be reflective of worker inhalation exposures for this OES. Also, since the dermal exposures are upperbound estimates, it can be conservatively assumed that the central tendency values of exposure estimates are expected to be most reflective of worker dermal exposures. This applies to COUs covered under the Import and repackaging OES (*i.e.*, Manufacture COU: Importing; processing COU: Repackaging COU [Laboratory chemicals in wholesale and retail trade; plasticizers in wholesale and retail trade; and plastics material and resin manufacturing]).

2704

2705 Incorporation into Formulations, Mixtures, or Reaction Products

2706 For the incorporation of DBP into formulations, mixtures, or reaction products, dermal exposure from 2707 liquid contact is expected to be the dominant route of exposure. MOEs for high-end acute, intermediate, 2708 and chronic inhalation exposure ranged from 15 to 25 for average adult workers and females of 2709 reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged 2710 from 0.8 to 1.3 (benchmark = 30). The central tendency MOEs for the same populations and exposure 2711 scenarios ranged from 30 to 49 for inhalation exposure and 1.7 to 2.7 for dermal exposure. Aggregation 2712 of inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates 2713 from dermal exposure alone. The MOEs presented in this paragraph are with no use of PPE. Section 2714 4.3.2.4 and Table 4-17 provides more information on PPE that could be used to reduce the MOEs above 2715 the benchmark MOE.

2716

2717 The high-end and central tendency worker inhalation exposure results for this OES are based on 2718 surrogate data from three different risk evaluations; each presented a single data point to characterize 2719 full-shift exposure to workers during DBP manufacturing (ECB, 2008; ECJRC, 2004; SRC, 2001). To 2720 determine central tendency and high-end values, EPA used the mid-point and maximum value, 2721 respectively, due to limited data points. There is uncertainty about how well these data represent the true 2722 distribution of actual inhalation concentrations for worker exposures in a specific facility, and the lack of 2723 ONU exposure data, for which EPA used worker data as surrogate data; and that there are only three 2724 data points used for the inhalation assessment.

2725

2726 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the 2727 chemical is contacted at least once per day. Because DBP has low volatility and relatively low 2728 absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until 2729 the skin is washed. Thus, in absence of exposure duration data, EPA has assumed that absorption of 2730 DBP from occupational dermal contact with materials containing DBP may extend up to 8 hours per day 2731 (U.S. EPA, 1991). However, if a worker uses proper PPE or washes their hands after contact with DBP 2732 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area 2733 2734 of occupational dermal exposure, EPA assumed a high-end value of 1,070 cm² for male workers and 890 2735 cm² for female workers. These high-end occupational dermal exposure surface area values are based on 2736 the mean two-hand surface area for adults EPA's *Exposure Factors Handbook* (U.S. EPA, 2011a). For 2737 central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand 2738 (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for male workers and 445 cm^2 for female workers). 2739

2740

2741 High-end and central tendency dermal exposures to liquid were determined using data from Doan et al. (2010). The study estimated a dermal absorption rate from experiments on female hairless guinea pigs 2742 2743 using a formulation of 7 percent oil-in-water emulsion. Using the study's estimate for DBP absorption in skin, 56.3 percent of the 1 mg/cm² dose over 24 hours, EPA estimated the steady-state flux of DBP, and 2744 the resultant dose based on exposure area. Although the Agency determined that all data were of 2745 2746 acceptable quality without notable deficiencies and integrated all the data into the final exposure 2747 assessment, it's uncertain how representative the use of a 7 percent oil-in-water emulsion formulation is 2748 for OESs where a higher concentration of DBP is used. There is also uncertainty in the use of guinea 2749 pigs over human skin, as guinea pig tissue is known to be more permeable than human tissue. Therefore, 2750 uncertainties about the difference between human and guinea pigs skin absorption increase uncertainty.

2751

2752 Due to limited inhalation data points, both the central and high-end exposure estimates are expected to 2753 be reflective of worker inhalation exposures for this OES. Also, since the dermal exposures are upper-2754 bound estimates, it can be conservatively assumed that the central tendency values of exposure estimates 2755 are expected to be most reflective of worker dermal exposures. This applies to the COUs covered under 2756 the "Incorporation into formulations, mixtures, or reaction products" OES (i.e., Processing COU: 2757 Processing as a reactant: [Intermediate in plastic manufacturing]; Incorporation into formulation, 2758 mixture, or reaction product: [Solvents (which become part of product formulation or mixture) in 2759 chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation 2760 manufacturing; adhesive manufacturing; and printing ink manufacturing]; [Plasticizer in paint and 2761 coating manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, 2762 and leather manufacturing; printing ink manufacturing; basic organic chemical manufacturing; and 2763 adhesive and sealant manufacturing]; and Pre-catalyst manufacturing).

2765 **PVC Plastics Compounding**

2766 For PVC plastics compounding, dermal contact with liquid DBP before it is incorporated into the 2767 formulation is expected to be the dominant route of exposure. MOEs for high-end acute, intermediate, 2768 and chronic inhalation exposure ranged from 5.3 to 8.6 for average adult workers and females of 2769 reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged 2770 from 0.8 to 1.3 (benchmark = 30). The central tendency MOEs for the same populations and exposure 2771 scenarios ranged from 44 to 71 for inhalation exposure and 1.7 to 2.6 for dermal exposure. Aggregation 2772 of inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates 2773 from dermal exposure alone. The MOEs presented in this paragraph are with no use of PPE. Section 2774 4.3.2.4 and Table 4-17 provides more information on PPE that could be used to reduce the MOEs above 2775 the benchmark MOE.

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2764

2777 EPA did not identify chemical- or OES-specific inhalation monitoring data for DBP from systematic 2778 review; however, EPA utilized surrogate vapor inhalation monitoring data from PVC plastics converting 2779 to assess worker inhalation exposure to DBP vapors (ECJRC, 2004). To assess the high-end worker 2780 exposure to DBP during the compounding process, EPA used the maximum available value (0.75)2781 mg/m^3). EPA assessed the average of the four available values as the central tendency (0.24 mg/m3). 2782 EPA estimated worker inhalation exposures to dust using the Generic Model for Central Tendency and 2783 High-End Inhalation Exposure to Total and Respirable Particulates Not Otherwise Regulated (PNOR 2784 Model) for dust exposures (U.S. EPA, 2021d). For inhalation exposure to PNOR, EPA determined the 2785 50th and 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS codes 2786 starting with 326 (Plastics and Rubber Manufacturing). EPA multiplied these dust concentrations by the 2787 industry provided maximum potential DBP concentration in PVC material (i.e., 45%) to estimate DBP

particulate concentrations in the air. Therefore, the differences in the central tendency and high-end dust
concentrations led to differences between the central tendency and high-end risk estimates.

2790

2791 There is uncertainty about how well the surrogate vapor monitoring data represent the true distribution 2792 of vapor inhalation concentrations for actual worker exposures in a specific facility. Also, though the 2793 PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a worker may 2794 experience in the compounding industry, the composition of workplace dust is uncertain. The exposure 2795 and risk estimates assume that the concentration of DBP in workplace dust is the same as the 2796 concentration of DBP in the PVC material. However, it is likely that workplace dust contains a variety 2797 of constituents that do not contain any DBP in addition to particles from DBP-containing plastic materials. The constituents that do not contain DBP would dilute the overall concentration of DBP in the 2798 2799 dust, and the concentration of DBP in workplace dust is likely less than the concentration of DBP in the 2800 plastic material. Therefore, the estimated inhalation exposures to dust are likely overestimated.

2801

2802 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the 2803 chemical is contacted at least once per day. Because DBP has low volatility and relatively low 2804 absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until 2805 the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of DBP 2806 from occupational dermal contact with materials containing DBP may extend up to 8 hours per day 2807 (U.S. EPA, 1991). However, if a worker uses proper PPE or washes their hands after contact with DBP 2808 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-2809 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area 2810 of occupational dermal exposure, EPA assumed a high-end value of $1,070 \text{ cm}^2$ for male workers and 890 2811 cm² for female workers. These high-end occupational dermal exposure surface area values are based on 2812 the mean two-hand surface area for adults in the Exposure Factors Handbook (U.S. EPA, 2011a). For 2813 central tendency estimates, the Agency assumed the exposure surface area was equivalent to only a 2814 single hand (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm^2 for male workers and 445 cm^2 for female workers). 2815

2816

2817 High-end and central tendency dermal exposures to liquid DBP were determined using data from Doan 2818 et al. (2010). The study estimated a dermal absorption rate from experiments on female hairless guinea 2819 pigs using a formulation of 7 percent oil-in-water emulsion. Using the study's estimate for DBP absorption in skin, 56.3 percent of the 1 mg/cm^2 dose over 24 hours, EPA estimated the steady-state flux 2820 2821 of DBP and the resultant dose based on exposure area. Although the Agency determined that all data 2822 were of acceptable quality without notable deficiencies and integrated all the data into the final exposure 2823 assessment, it is uncertain how representative the use of a 7 percent oil-in-water emulsion formulation is 2824 for OESs where a higher concentration of DBP is used. There is also uncertainty in the use of guinea 2825 pigs over human skin, as guinea pig tissue is known to be more permeable than human tissue. Therefore, 2826 uncertainties about the difference between human and guinea pigs skin absorption increase uncertainty. 2827

- For estimating high-end and central tendency occupational dermal exposures to solids, EPA assumed that DBP will first migrate from the solid matrix to a thin layer of moisture on the skin surface.
- 2830 Therefore, absorption of DBP from solid matrices is considered limited by aqueous solubility and is
- estimated using an aqueous absorption model (U.S. EPA, 2023c, 2004b) as described in Appendix C in
- 2832 the Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (DBP)
- 2833 (U.S. EPA, 2025q). EPA assumes that absorption of the aqueous material serves as a reasonable upper
- bound for contact with solid materials and used this to estimate the average absorptive flux of DBP and the resultant dose based on worker exposure area.
- 2836

2837 The PNOR Model uses conservative assumptions leading to upper-bound inhalation exposure estimates.

- 2838 The dermal exposure estimates are also upper-bound estimates as discussed above. Therefore, the 2839 central tendency values of exposure are expected to be most reflective of worker exposures within the
 - 2839 COUs covered under the PVC plastics compounding OES (*i.e.*, Processing COUs: Incorporation into
 - formulation, mixture, or reaction product [Plasticizer in plastic material and resin manufacturing]).
 - 2842

2843 **PVC Plastics Converting**

2844 For PVC plastics converting, inhalation exposure is expected to be the dominant route of exposure. 2845 MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 5.3 to 8.6 for 2846 average adult workers and females of reproductive age, while high-end dermal MOEs ranged from 62 to 2847 98 (benchmark = 30). For central tendency, MOEs for the same population and exposure scenarios 2848 ranged from 44 to 71 for inhalation exposure and 124 to 197 for dermal exposures. Aggregation of 2849 inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates 2850 from inhalation exposure alone. The MOEs presented in this paragraph are with no use of PPE. Section 2851 4.3.2.4 and Table 4-17 provides more information on PPE that could be used to reduce the MOEs above 2852 the benchmark MOE.

2853

2854 EPA identified vapor inhalation monitoring data from a risk evaluation completed by the European 2855 Commission's Joint Research Centre (ECJRC), which included four data points compiled from two sources (ECJRC, 2004). To assess the high-end worker exposure to DBP during the converting process, 2856 EPA used the maximum available value (0.75 mg/m^3) . EPA assessed the average of the four available 2857 values as the central tendency (0.24 mg/m^3) . The Agency estimated worker inhalation exposures to dust 2858 2859 using the PNOR Model for dust exposures (U.S. EPA, 2021d). For inhalation exposure to PNOR, EPA 2860 determined the 50th and 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS codes starting with 326 (Plastics and Rubber Manufacturing). EPA multiplied these dust 2861 2862 concentrations by the industry provided maximum potential DBP concentration in PVC material (*i.e.*, 2863 45%) to estimate DBP particulate concentrations in the air. Therefore, the differences in the central 2864 tendency and high-end dust concentrations led to differences between the central tendency and high-end 2865 risk estimates. 2866

2867 There is uncertainty about how well the surrogate vapor monitoring data represent the true distribution 2868 of vapor inhalation concentrations for actual worker exposures in a specific facility. Also, although the 2869 PNOR Model (i.e., dust) concentration data provides a reliable range of dust concentrations that a 2870 worker may experience in the converting industry, the composition of workplace dust is uncertain. The 2871 exposure and risk estimates assume that the concentration of DBP in workplace dust is the same as the 2872 concentration of DBP in the PVC material. However, it is likely that workplace dust contains a variety 2873 of constituents that do not contain any DBP in addition to particles from DBP-containing plastic 2874 materials. The constituents that do not contain DBP would dilute the overall concentration of DBP in the 2875 dust, and the concentration of DBP in workplace dust is likely less than the concentration of DBP in the 2876 plastic material. Therefore, the estimated inhalation exposures to dust are likely overestimated.

2877

2878 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the 2879 chemical is contacted at least once per day. Because DBP has low volatility and relatively low 2880 absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until 2881 the skin is washed. Thus, in absence of exposure duration data, EPA has assumed that absorption of 2882 DBP from occupational dermal contact with materials containing DBP may extend up to 8 hours per day 2883 (U.S. EPA, 1991). However, if a worker uses proper PPE or washes their hands after contact with DBP 2884 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-2885 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area

of occupational dermal exposure, EPA assumed a high-end value of 1,070 cm² for male workers and 890 cm² for female workers. These high-end occupational dermal exposure surface area values are based on the mean two-hand surface area for adults EPA's *Exposure Factors Handbook* (U.S. EPA, 2011a). For central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for male workers and 445 cm² for female workers).

2892

2893 For estimating high-end and central tendency occupational dermal exposures to solids, EPA assumed

that DBP will first migrate from the solid matrix to a thin layer of moisture on the skin surface.
Therefore, absorption of DBP from solid matrices is considered limited by aqueous solubility and is
estimated using an aqueous absorption model (U.S. EPA, 2023c, 2004b) as described in Appendix C in
the *Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (DBP)*(U.S. EPA, 2025q). EPA assumes that absorption of the aqueous material serves as a reasonable upper
bound for contact with solid materials and used this to estimate the average absorptive flux of DBP and
the resultant dose based on worker exposure area.

2901

The PNOR Model uses conservative assumptions leading to upper-bound inhalation exposure estimates. The dermal exposure estimates are also upper-bound estimates as discussed above. Therefore, the central tendency values of exposure are expected to be most reflective of worker exposures within the COUs covered under the "PVC plastics converting" OES (*i.e.*, Processing COUs: Incorporation into articles [Plasticizer in adhesive and sealant manufacturing; building and construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing]).

2909

2910 Non-PVC Materials Manufacturing (Compounding and Converting)

2911 For non-PVC materials manufacturing, dermal exposure from liquid contact to DBP is expected to be 2912 the dominant route of exposure. In support of this, MOEs for high-end acute, intermediate, and chronic 2913 inhalation exposure ranged from 9.0 to 15 for average adult workers and females of reproductive age, 2914 while high-end dermal MOEs for the same populations and exposure scenarios ranged from 0.8 to 1.3 2915 (benchmark = 30). The central tendency MOEs for the same populations and exposure scenarios ranged 2916 from 53 to 86 for inhalation exposure and 1.7 to 2.6 for dermal exposure. Aggregation of inhalation and 2917 dermal exposures led to negligible differences in risk when compared to risk estimates from dermal 2918 exposure alone. The MOEs presented in this paragraph are with no use of PPE. Section 4.3.2.4 and 2919 Table 4-17 provides more information on PPE that could be used to reduce the MOEs above the 2920 benchmark MOE.

2921

2922 EPA did not identify chemical-specific or OES-specific inhalation monitoring data for DBP from 2923 systematic review, however, EPA utilized surrogate vapor inhalation monitoring data from PVC plastics 2924 converting to assess worker inhalation exposure to DBP vapors (ECJRC, 2004). To assess the high-end 2925 worker exposure to DBP during the converting process, EPA used the maximum available value (0.75 2926 mg/m^3). EPA assessed the average of the four available values as the central tendency (0.24 mg/m^3). 2927 EPA estimated worker inhalation exposures using the PNOR Model for dust exposures (U.S. EPA, 2928 2021d). For inhalation exposure to PNOR, EPA determined the 50th and 95th percentiles of the 2929 surrogate dust monitoring data taken from facilities with NAICS codes starting with 326 (Plastics and 2930 Rubber Manufacturing). EPA multiplied these dust concentrations by the industry provided maximum 2931 potential DBP concentration in non-PVC material (*i.e.*, 20%) to estimate DBP particulate concentrations 2932 in the air. Therefore, the differences in the central tendency and high-end dust concentrations led to 2933 differences between the central tendency and high-end risk estimates.

2934

2935 There is uncertainty about how well the surrogate vapor monitoring data represent the true distribution 2936 of vapor inhalation concentrations for actual worker exposures in a specific facility Also, though the 2937 PNOR (*i.e.*, dust) concentration data provides a reliable range of dust concentrations that a worker may 2938 experience in the converting industry, the composition of workplace dust is uncertain. The exposure and 2939 risk estimates assume that the concentration of DBP in workplace dust is the same as the concentration 2940 of DBP in the non-PVC material. However, it is likely that workplace dust contains a variety of 2941 constituents that do not contain any DBP in addition to particles from DBP-containing non-PVC 2942 materials. The constituents that do not contain DBP would dilute the overall concentration of DBP in the 2943 dust, and the concentration of DBP in workplace dust is likely less than the concentration of DBP in the 2944 non-PVC material. Therefore, the estimated inhalation exposures to dust are likely overestimated.

2946 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the 2947 chemical is contacted at least once per day. Because DBP has low volatility and relatively low 2948 absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until 2949 the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of DBP 2950 from occupational dermal contact with materials containing DBP may extend up to 8 hours per day 2951 (U.S. EPA, 1991). However, if a worker uses proper PPE or washes their hands after contact with DBP 2952 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-2953 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area of occupational dermal exposure, EPA assumed a high-end value of 1,070 cm² for male workers and 890 2954 2955 cm^2 for female workers. These high-end occupational dermal exposure surface area values are based on the mean two-hand surface area for adults EPA's Exposure Factors Handbook (U.S. EPA, 2011a). For 2956 2957 central tendency estimates, the Agency assumed the exposure surface area was equivalent to only a 2958 single hand (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm^2 for male workers and 445 cm^2 for female workers). 2959

2960 2961 High-end and central tendency dermal exposures to liquid were determined using data from Doan et al. 2962 (2010). The study estimated a dermal absorption rate from experiments on female hairless guinea pigs 2963 using a formulation of 7 percent oil-in-water emulsion. Using the study's estimate for DBP absorption in skin, 56.3 percent of the 1 mg/cm² dose over 24 hours, EPA estimated the steady-state flux of DBP and 2964 the resultant dose based on exposure area. EPA defined central tendency exposure as the average surface 2965 2966 area of the exposed worker population's hand, while the high-end value is based on the surface area of 2967 two hands, therefore, the high-end value is twice that of the central tendency. Although EPA determined 2968 that all data were of acceptable quality without notable deficiencies and integrated all the data into the final exposure assessment, it's uncertain how representative the use of a 7 percent oil-in-water emulsion 2969 2970 formulation is for OESs where a higher concentration of DBP is used. There is also uncertainty in the 2971 use of guinea pigs over human skin, as guinea pig tissue is known to be more permeable than human 2972 tissue. Therefore, uncertainties about the difference between human and guinea pigs skin absorption 2973 increase uncertainty. For estimating high-end and central tendency occupational dermal exposures to 2974 solids, EPA assumed that DBP will first migrate from the solid matrix to a thin layer of moisture on the 2975 skin surface. Therefore, absorption of DBP from solid matrices is considered limited by aqueous 2976 solubility and is estimated using an aqueous absorption model (U.S. EPA, 2023c, 2004b) as described in 2977 Appendix C in the Draft Environmental Release and Occupational Exposure Assessment for Dibutyl 2978 *Phthalate (DBP)* (U.S. EPA, 2025q). EPA assumes that absorption of the aqueous material serves as a 2979 reasonable upper bound for contact with solid materials and used this to estimate the average absorptive 2980 flux of DBP and the resultant dose based on worker exposure area.

2981

2945

The PNOR Model uses conservative assumptions leading to upper-bound inhalation exposure estimates. The dermal exposure estimates are also upper-bound estimates as discussed above. Therefore, the

central tendency values of exposure are expected to be most reflective of worker exposures within the
COUs covered under the "Non-PVC materials manufacturing" OES (*i.e.*, Processing COUs:
Incorporation into formulation, mixture, or reaction product [Plasticizer in plastic material and resin
manufacturing; rubber manufacturing]; and Incorporation into articles [Plasticizer in adhesive and
sealant manufacturing; building and construction materials manufacturing; furniture and related product
manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing]).

2990

2991 Application of Adhesives and Sealants

2992 For application of adhesives and sealants containing DBP, dermal exposure to liquids is expected to be 2993 the dominant route of exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure 2994 ranged from 152 to 245 for average adult workers and females of reproductive age, while high-end 2995 dermal MOEs for the same populations and exposure scenarios ranged from 0.8 to 1.3 (benchmark = 2996 30). The central tendency MOEs for the same populations and exposure scenarios ranged from 304 to 2997 529 for inhalation exposure and 1.7 to 2.9 for dermal exposure. Aggregation of inhalation and dermal 2998 exposures led to negligible differences in risk when compared to risk estimates from dermal exposure 2999 alone. The MOEs presented in this paragraph are with no use of PPE. Section 4.3.2.4 and Table 4-17 3000 provides more information on PPE that could be used to reduce the MOEs above the benchmark MOE.

3001

3002 The high-end and central tendency worker inhalation exposure results for this OES are based on 19 3003 monitoring samples in NIOSH's HHE database (NIOSH, 1977). Six of the samples were PBZ samples, 3004 and the remaining 13 samples were area samples taken at various locations around an acrylic furniture 3005 manufacturing site. The site uses 2-part adhesives where the part B component is 96.5 percent DBP. 3006 Two of the area samples recorded values at the limit of detection, and the remaining 17 samples were 3007 below the limit of detection. All samples were collected on AA cellulose membrane filters with 0.8µm average pore size and a pump flow rate of 1 LPM. The detection limit was 0.01 mg/m³ by gas 3008 3009 chromatography. With all samples at or below the LOD, EPA assessed inhalation exposures as a range 3010 from 0 to the LOD. EPA estimated the high-end exposure as equal to the LOD and the central tendency 3011 as the midpoint (*i.e.*, half the LOD). There is uncertainty about how well these data represent the true 3012 distribution of actual inhalation concentrations in this scenario at a specific facility. In absence of ONU 3013 exposure data, EPA used worker data as analogous data for ONU exposure.

3014

3015 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the 3016 chemical is contacted at least once per day. Because DBP has low volatility and relatively low absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until 3017 3018 the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of DBP 3019 from occupational dermal contact with materials containing DBP may extend up to 8 hours per day 3020 (U.S. EPA, 1991). However, if a worker uses proper PPE, or washes their hands after contact with DBP 3021 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-3022 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area of occupational dermal exposure, EPA assumed a high-end value of 1,070 cm² for male workers and 890 3023 cm² for female workers. These high-end occupational dermal exposure surface area values are based on 3024 the mean two-hand surface area for adults EPA's Exposure Factors Handbook (U.S. EPA, 2011a). For 3025 3026 central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for 3027 male workers and 445 cm^2 for female workers). 3028

3029

High-end and central tendency dermal exposures to liquid were determined using data from Doan et al.
 (2010). The study estimated a dermal absorption rate from experiments on female hairless guinea pigs

3032 using a formulation of 7 percent oil-in-water emulsion. Using the study's estimate for DBP absorption in

3033 skin, 56.3 percent of the 1 mg/cm² dose over 24 hours, EPA estimated the steady-state flux of DBP and 3034 the resultant dose based on exposure area. Although EPA determined that all data were of acceptable 3035 quality without notable deficiencies and integrated all the data into the final exposure assessment, it's 3036 uncertain how representative the use of a 7 percent oil-in-water emulsion formulation is for OESs where 3037 a higher concentration of DBP is used. There is also uncertainty in the use of guinea pigs over human 3038 skin, as guinea pig tissue is known to be more permeable than human tissue. Therefore, uncertainties 3039 about the difference between human and guinea pigs skin absorption increase uncertainty.

3040

3041 As discussed above, inhalation exposure estimates are based on data which are below the LOD. EPA 3042 estimated the high-end exposure as equal to the LOD and the central tendency as the midpoint (i.e., half 3043 the LOD). Therefore, the inhalation exposure estimates are upper-bound estimates. Also, as discussed in 3044 the paragraph above, the dermal exposure estimates are upper-bound estimates. So, the central tendency 3045 values of exposure are expected to be most reflective of worker exposures within the COUs covered 3046 under the "Application of adhesives and sealants" OES (i.e., Industrial Use COU: Construction, paint, 3047 electrical, and metal products [Adhesives and sealants] and Commercial Use COU: Construction, paint, 3048 electrical, and metal products [Adhesives and sealants]).

3049

3050 Application of Paints and Coatings

3051 For the application of paints and coatings containing DBP, dermal and inhalation exposure routes are both expected to significantly contribute to exposures at both the central-tendency and high-end, with 3052 3053 dermal exposures expected to be slightly dominant in its contribution. MOEs for high-end acute, 3054 intermediate, and chronic inhalation exposure ranged from 2.9 to 4.7 for average adult workers and 3055 females of reproductive age, while high-end dermal MOEs for the same populations and exposure 3056 scenarios ranged from 0.8 to 1.3 (benchmark = 30). The central tendency MOEs for the same populations and exposure scenarios ranged from 18 to 30 for inhalation exposure and 1.7 to 2.7 for 3057 3058 dermal exposure. Aggregation of inhalation and dermal exposures led to lower MOEs compared to 3059 either individual route. The MOEs presented in this paragraph are with no use of PPE. Section 4.3.2.4 3060 and Table 4-17 provides more information on PPE that could be used to reduce the MOEs above the 3061 benchmark MOE.

3062

3063 To estimate inhalation exposures, EPA relied on monitoring data from OSHA's Chemical Exposure 3064 Health Data database from two different inspections, one from 2011 of a fabric coating mill and one from a janitorial services company (OSHA, 2019). EPA additionally found 12 8-hour TWA monitoring 3065 samples during systematic review completed by Rohm and Haas Co. which examined worker exposure 3066 from painting interior rooms with roller and spray applicators (Rohm & Haas, 1990). With a total of 14 3067 3068 data points, EPA characterized the data by taking the 95th percentile and the 50th percentile of the 3069 combined dataset to represent the high end and central tendency. There is uncertainty about how well 3070 these data represent the true distribution of actual inhalation concentrations in this scenario at a specific 3071 facility. In absence of ONU exposure data, EPA used worker data as analogous data for ONU exposure.

3072

3073For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the3074chemical is contacted at least once per day. Because DBP has low volatility and relatively low

3075 absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until

3076 the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of DBP

from occupational dermal contact with materials containing DBP may extend up to 8 hours per day

- 3078 (U.S. EPA, 1991). However, if a worker uses proper PPE, or washes their hands after contact with DBP 3079 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-
- 3080 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area
- 3081 of occupational dermal exposure, EPA assumed a high-end value of $1,070 \text{ cm}^2$ for male workers and 890

3082 cm² for female workers. These high-end occupational dermal exposure surface area values are based on 3083 the mean two-hand surface area for adults EPA's *Exposure Factors Handbook* (U.S. EPA, 2011a). For 3084 central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand 3085 (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for 3086 male workers and 445 cm² for female workers).

3087

3088 High-end and central tendency dermal exposures to liquid were determined using data from Doan et al. 3089 (2010). The study estimated a dermal absorption rate from experiments on female hairless guinea pigs 3090 using a formulation of 7 percent oil-in-water emulsion. Using the study's estimate for DBP absorption in 3091 skin, 56.3 percent of the 1 mg/cm² dose over 24 hours, EPA estimated the steady-state flux of DBP and the resultant dose based on exposure area. Although EPA determined that all data were of acceptable 3092 3093 quality without notable deficiencies and integrated all the data into the final exposure assessment, it's 3094 uncertain how representative the use of a 7 percent oil-in-water emulsion formulation is for OESs where 3095 different formulations of DBP are used. There is also uncertainty in the use of guinea pigs over human 3096 skin, as guinea pig tissue is known to be more permeable than human tissue. Therefore, uncertainties 3097 about the difference between human and guinea pigs skin absorption increase uncertainty.

3098

3099 Due to limited inhalation data points, both the central and high-end exposure estimates are expected to 3100 be reflective of worker inhalation exposures for this OES. Also, since the dermal exposures are upper-3101 bound estimates, it can be conservatively assumed that the central tendency values of exposure estimates 3102 are expected to be most reflective of worker dermal exposures. This applies to the COUs covered under 3103 the "Application of paints and coatings" OES (i.e., Industrial Use COU: Construction, paint, electrical, 3104 and metal products [Paints and coatings], Commercial Use COU: Construction, paint, electrical, and 3105 metal products [Paints and coatings], and Commercial Use COU: Packaging, paper, plastic, toys, hobby 3106 products [Ink, toner, and colorant products]).

3107

3108 Industrial Process Solvent Use

3109 For the use of DBP as an industrial process solvent, dermal exposure from liquid contact is expected to 3110 be the dominant route of exposure. MOEs for high-end acute, intermediate, and chronic inhalation 3111 exposure ranged from 15 to 25 for average adult workers and females of reproductive age, while high-3112 end dermal MOEs for the same populations and exposure scenarios ranged from 0.8 to 1.3 (benchmark = 3113 30). The central tendency MOEs for the same populations and exposure scenarios ranged from 30 to 49 3114 for inhalation exposure and 1.7 to 2.7 for dermal exposure. Aggregation of inhalation and dermal 3115 exposures led to negligible differences in risk when compared to risk estimates from dermal exposure 3116 alone. The MOEs presented in this paragraph are with no use of PPE. Section 4.3.2.4 and Table 4-17 3117 provides more information on PPE that could be used to reduce the MOEs above the benchmark MOE.

3118

3119 The high-end and central tendency worker inhalation exposure results for this OES are based on 3120 analogous data from three different risk evaluations; each presented a single data point to characterize 3121 full-shift exposure to workers during DBP manufacturing (ECB, 2008; ECJRC, 2004; SRC, 2001). To 3122 determine central tendency and high-end values, EPA used the mid-point and maximum value, 3123 respectively, due to limited data points. There is uncertainty about how well these data represent the true 3124 distribution of actual inhalation concentrations in this scenario at a specific facility; the lack of ONU 3125 exposure data, for which EPA used worker data as surrogate data; and that there are only three data 3126 points used for the inhalation assessment.

3127

3128 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the

- 3129 chemical is contacted at least once per day. Because DBP has low volatility and relatively low
- 3130 absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until

3131 the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of DBP 3132 from occupational dermal contact with materials containing DBP may extend up to 8 hours per day 3133 (U.S. EPA, 1991). However, if a worker uses proper PPE, or washes their hands after contact with DBP 3134 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-3135 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area 3136 of occupational dermal exposure, EPA assumed a high-end value of 1,070 cm² for male workers and 890 3137 cm² for female workers. These high-end occupational dermal exposure surface area values are based on 3138 the mean two-hand surface area for adults EPA's Exposure Factors Handbook (U.S. EPA, 2011a). For 3139 central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand 3140 (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for male workers and 445 cm^2 for female workers). 3141

3142

3143 High-end and central tendency dermal exposures to liquid were determined using data from Doan et al. 3144 (2010). The study estimated a dermal absorption rate from experiments on female hairless guinea pigs 3145 using a formulation of 7 percent oil-in-water emulsion. Using the study's estimate for DBP absorption in 3146 skin, 56.3 percent of the 1 mg/cm² dose over 24 hours, EPA estimated the steady-state flux of DBP, and 3147 the resultant dose based on exposure area. Although EPA determined that all data were of acceptable 3148 quality without notable deficiencies and integrated all the data into the final exposure assessment, it's 3149 uncertain how representative the use of a 7 percent oil-in-water emulsion formulation is for OESs where 3150 different formulations of DBP are used. There is also uncertainty in the use of guinea pigs over human 3151 skin, as guinea pig tissue is known to be more permeable than human tissue. Therefore, uncertainties 3152 about the difference between human and guinea pigs skin absorption increase uncertainty.

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Due to limited inhalation data points, both the central and high-end exposure estimates are expected to be reflective of worker inhalation exposures for this OES. Also, since the dermal exposures are upperbound estimates, it can be conservatively assumed that the central tendency values of exposure estimates are expected to be most reflective of worker dermal exposures. This applies to the COUs covered under the "Industrial process solvent use" OES (*i.e.*, Industrial Use (Non-incorporative activities [Solvent, including in maleic anhydride manufacturing technology]).

3161 Use of Laboratory Chemicals (solid)

3162 The use of laboratory chemicals was assessed for solid and liquid products containing DBP. For solid 3163 laboratory chemicals, inhalation exposure from dust generation is expected to be the dominant route of exposure for solid lab chemicals. MOEs for high-end acute, intermediate, and chronic inhalation 3164 exposure ranged from 28 to 45 for average adult workers and females of reproductive age, while high-3165 3166 end dermal MOEs ranged from 62 to 98 (benchmark = 30). For central tendency, MOEs for the same 3167 population and exposure scenarios ranged from 400 to 645 for inhalation exposure and 124 to 197 for 3168 dermal exposures. For solid laboratory chemicals exposure, the aggregation of inhalation and dermal 3169 exposures led to negligible differences in risk when compared to risk estimates from inhalation exposure 3170 alone. The MOEs presented in this paragraph are with no use of PPE. Section 4.3.2.4 and Table 4-17 3171 provides more information on PPE that could be used to reduce the MOEs above the benchmark MOE.

3172

3173 EPA estimated worker inhalation exposures to dust from solid lab chemicals using the PNOR Model for

dust exposures (U.S. EPA, 2021d). For inhalation exposure to PNOR, EPA determined the 50th and

3175 95th percentiles of the surrogate dust monitoring data taken from facilities with NAICS codes starting

3176 with 54 (Professional, Scientific, and Technical Services). EPA determined the 50th and 95th percentiles

of the surrogate dust monitoring data and multiplied these dust concentrations by the industry provided maximum potential DBP concentration in lab chemicals (*i.e.* 20%) to estimate DPP particulate

3179 concentrations in the air. Therefore, the differences in the central tendency and high-end dust3180 concentrations led to differences between the central tendency and high-end risk estimates.

3181

3182 Although the PNOR Model (*i.e.*, dust) concentration data provides a reliable range of dust

3183 concentrations that a worker may experience in the laboratory setting, the composition of workplace 3184 dust is uncertain. The exposure and risk estimates assume that the concentration of DBP in workplace 3185 dust is the same as the concentration of DBP in the laboratory chemical. However, it is likely that 3186 workplace dust contains a variety of constituents that do not contain any DBP in addition to particles 3187 from DBP-containing laboratory chemical. The constituents that do not contain DBP would dilute the 3188 overall concentration of DBP in the dust, and the concentration of DBP in workplace dust is likely less 3189 than the concentration of DBP in the laboratory chemical. Therefore, the estimated inhalation exposures 3190 to dust are likely overestimated.

3191

3192 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the 3193 chemical is contacted at least once per day. Because DBP has low volatility and relatively low 3194 absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until 3195 the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of DBP 3196 from occupational dermal contact with materials containing DBP may extend up to 8 hours per day 3197 (U.S. EPA, 1991). However, if a worker uses proper PPE, or washes their hands after contact with DBP 3198 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-3199 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area 3200 of occupational dermal exposure, EPA assumed a high-end value of 1,070 cm² for male workers and 890 3201 cm² for female workers. These high-end occupational dermal exposure surface area values are based on 3202 the mean two-hand surface area for adults EPA's *Exposure Factors Handbook* (U.S. EPA, 2011a). For central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand 3203 3204 (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for male workers and 445 cm^2 for female workers). 3205

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3207 For estimating high-end and central tendency occupational dermal exposures to solids, EPA assumed 3208 that DBP will first migrate from the solid matrix to a thin layer of moisture on the skin surface. 3209 Therefore, absorption of DBP from solid matrices is considered limited by aqueous solubility and is 3210 estimated using an aqueous absorption model (U.S. EPA, 2023c, 2004b) as described in Appendix C in the Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (DBP) 3211 3212 (U.S. EPA, 2025q). EPA assumes that absorption of the aqueous material serves as a reasonable upper 3213 bound for contact with solid materials and used this to estimate the average absorptive flux of DBP and 3214 the resultant dose based on worker exposure area.

3215

3216 The PNOR Model uses conservative assumptions leading to upper-bound inhalation exposure estimates.

- 3217 The dermal exposure estimates are also upper-bound estimates as discussed above. Therefore, the 3218 central tendency values of exposure are expected to be most reflective of worker exposures within the
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- 3220 [Laboratory Chemicals]).
- 3221

3222 Use of Laboratory Chemicals (Liquid)

For the use of liquid laboratory chemicals, dermal exposures to liquids are expected to be the dominant route of exposure. MOEs for high-end acute, intermediate, and chronic inhalation exposure ranged from 152 to 245 for average adult workers and females of reproductive age, while high-end dermal MOEs for

- 3226 the same populations and exposure scenarios ranged from 0.8 to 1.3 (benchmark = 30). The central
- 3227 tendency MOEs for the same populations and exposure scenarios ranged from 304 to 491 for inhalation

exposure and 2.2 to 3.6 for dermal exposure. Aggregation of inhalation and dermal exposures led to
negligible differences in risk when compared to risk estimates from dermal exposure alone. The MOEs
presented in this paragraph are with no use of PPE. Section 4.3.2.4 and Table 4-17 provides more

- 3231 information on PPE that could be used to reduce the MOEs above the benchmark MOE.
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3233 For liquid laboratory chemicals, no vapor inhalation exposure data was found from systematic review, 3234 and EPA used data from the adhesives and sealants OES as a surrogate data source due to the expected 3235 similarity in usage and concentrations. The adhesives and sealant data consists of 19 monitoring samples 3236 in a NIOSH HHE (NIOSH, 1977). Six of the samples were PBZ samples, and the remaining 13 samples 3237 were area samples taken at various locations around an acrylic furniture manufacturing site. With all 3238 samples at or below the LOD, EPA assessed inhalation exposures as a range from zero to the LOD. EPA 3239 estimated the high-end exposure as equal to the LOD and the central tendency as the midpoint (*i.e.*, half 3240 the LOD). There is uncertainty about how well these data represent the true distribution of actual 3241 inhalation concentrations in this scenario at a specific facility. In absence of ONU exposure data, EPA 3242 used worker data as analogous data for ONU exposure.

3244 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the 3245 chemical is contacted at least once per day. Because DBP has low volatility and relatively low 3246 absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until 3247 the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of DBP 3248 from occupational dermal contact with materials containing DBP may extend up to 8 hours per day 3249 (U.S. EPA, 1991). However, if a worker uses proper PPE, or washes their hands after contact with DBP 3250 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-3251 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area 3252 of occupational dermal exposure, EPA assumed a high-end value of 1,070 cm² for male workers and 890 3253 cm² for female workers. These high-end occupational dermal exposure surface area values are based on 3254 the mean two-hand surface area for adults EPA's *Exposure Factors Handbook* (U.S. EPA, 2011a). For 3255 central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand 3256 (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for male workers and 445 cm^2 for female workers). 3257

3259 High-end and central tendency dermal exposures to liquid were determined using data from Doan et al. (2010). The study estimated a dermal absorption rate from experiments on female hairless guinea pigs 3260 using a formulation of 7 percent oil-in-water emulsion. Using the study's estimate for DBP absorption in 3261 3262 skin, 56.3 percent of the 1 mg/cm² dose over 24 hours, EPA estimated the steady-state flux of DBP and 3263 the resultant dose based on exposure area. Although EPA determined that all data were of acceptable 3264 quality without notable deficiencies and integrated all the data into the final exposure assessment, it's 3265 uncertain how representative the use of a 7 percent oil-in-water emulsion formulation is for OESs where 3266 a higher concentration of DBP is used. There is also uncertainty in the use of guinea pigs over human 3267 skin, as guinea pig tissue is known to be more permeable than human tissue. Therefore, uncertainties 3268 about the difference between human and guinea pigs skin absorption increase uncertainty. 3269 As discussed above, inhalation exposure estimates is based on data which are below the LOD. EPA 3270 estimated the high-end exposure as equal to the LOD and the central tendency as the midpoint (*i.e.*, half 3271 the LOD). Therefore, the inhalation exposure estimates are upper-bound estimates. Also, as discussed in 3272 the paragraph above, the dermal exposure estimates are upper-bound estimates. So, the central tendency 3273 values of exposure are expected to be most reflective of worker exposures within the COUs covered 3274 under the "Use of laboratory chemicals" OES (i.e., Commercial use COU: Other uses: [Laboratory 3275 Chemicals]).

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3277 Use of Lubricants and Functional Fluids

3278 For the use of lubricants and functional fluids containing DBP, dermal exposure from liquid contact is 3279 expected to be the dominant route of exposure. MOEs for high-end acute, intermediate, and chronic 3280 inhalation exposure ranged from 152 to 15,330 for average adult workers and females of reproductive 3281 age, while high-end dermal MOEs for the same populations and exposure scenarios ranged from 1.0 to 3282 99 (benchmark = 30). The central tendency MOEs for the same populations and exposure scenarios 3283 ranged from 304 to 61,320 for inhalation exposure and 3.0 to 594 for dermal exposure. Aggregation of 3284 inhalation and dermal exposures led to negligible differences in risk when compared to risk estimates 3285 from dermal exposure alone. The MOEs presented in this paragraph are with no use of PPE. Section 3286 4.3.2.4 and Table 4-17 provides more information on PPE that could be used to reduce the MOEs above 3287 the benchmark MOE. 3288

3289 The high-end and central tendency worker inhalation exposure results for this OES are based on 19 3290 analogous adhesive and sealant use monitoring samples in NIOSH's HHE database (NIOSH, 1977). Six 3291 of the samples were PBZ samples, and the remaining 13 samples were area samples taken at various 3292 locations around an acrylic furniture manufacturing site. The site uses 2-part adhesives where the part B 3293 component is 96.5 percent DBP. Two of the area samples recorded values at the limit of detection, and 3294 the remaining 17 samples were below the limit of detection. All samples were collected on AA cellulose 3295 membrane filters with 0.8µ average pore size and a pump flow rate of 1 LPM. The detection limit was 3296 0.01 mg/m3 by gas chromatography. With all samples at or below the LOD, EPA assessed inhalation 3297 exposures as a range from 0 to the LOD. EPA estimated the high-end exposure as equal to the LOD and 3298 the central tendency as the midpoint (*i.e.*, half the LOD). There is uncertainty about how well these data 3299 represent the true distribution of inhalation concentrations in this scenario at a specific facility and in the 3300 lack of ONU exposure data, for which EPA used worker data as surrogate data.

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3302 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the 3303 chemical is contacted at least once per day. Because DBP has low volatility and relatively low 3304 absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until 3305 the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of DBP 3306 from occupational dermal contact with materials containing DBP may extend up to 8 hours per day 3307 (U.S. EPA, 1991). However, if a worker uses proper PPE, or washes their hands after contact with DBP 3308 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-3309 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area 3310 of occupational dermal exposure, EPA assumed a high-end value of 1,070 cm² for male workers and 890 3311 cm² for female workers. These high-end occupational dermal exposure surface area values are based on 3312 the mean two-hand surface area for adults EPA's *Exposure Factors Handbook* (U.S. EPA, 2011a). For 3313 central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand 3314 (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for male workers and 445 cm^2 for female workers). 3315

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3317 High-end and central tendency dermal exposures to liquid were determined using data from Doan et al. 3318 (2010). The study estimated a dermal absorption rate from experiments on female hairless guinea pigs 3319 using a formulation of 7 percent oil-in-water emulsion. Using the study's estimate for DBP absorption in 3320 skin, 56.3 percent of the 1 mg/cm² dose over 24 hours, EPA estimated the steady-state flux of DBP and 3321 the resultant dose based on exposure area. Although EPA determined that all data were of acceptable quality without notable deficiencies and integrated all the data into the final exposure assessment, it's 3322 3323 uncertain how representative the use of a 7 percent oil-in-water emulsion formulation is for OESs where 3324 a higher concentration of DBP is used. There is also uncertainty in the use of guinea pigs over human

skin, as guinea pig tissue is known to be more permeable than human tissue. Therefore, uncertainties
about the difference between human and guinea pigs skin absorption increase uncertainty.

3327

3328 As discussed above, inhalation exposure estimates is based on data which are below the LOD. EPA 3329 estimated the high-end exposure as equal to the LOD and the central tendency as the midpoint (*i.e.*, half 3330 the LOD). Therefore, the inhalation exposure estimates are upper-bound estimates. Also, as discussed in 3331 the paragraph above, the dermal exposure estimates are upper-bound estimates. So, the central tendency 3332 values of exposure are expected to be most reflective of worker exposures within the COUs covered 3333 under the "Use of lubricants and functional fluids" OES (*i.e.*, Commercial Use COU: Other Uses: 3334 [Lubricants and lubricant additives]; Furnishing, cleaning, treatment care products: [Cleaning and 3335 furnishing care products]; Automotive, fuel, agriculture, outdoor use products [Automotive care 3336 products]; and the Industrial use COU: Other uses: [Lubricants and lubricant additives]).

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3338 Use of Penetrants and Inspection Fluids

3339 For the use of penetrants and inspection fluids, dermal and inhalation exposure routes are both expected 3340 to significantly contribute to exposures at both the central-tendency and high-end ranges, with dermal 3341 exposures expected to be slightly dominant in its contribution. MOEs for high-end acute, intermediate, 3342 and chronic inhalation exposure ranged from 2.7 to 4.4 for average adult workers and females of 3343 reproductive age, while high-end dermal MOEs for the same populations and exposure scenarios ranged 3344 from 0.8 to 1.3 (benchmark = 30). The central tendency MOEs for the same populations and exposure 3345 scenarios ranged from 10 to 16 for inhalation exposure and 1.7 to 2.7 for dermal exposure. Aggregation 3346 of inhalation and dermal exposures led to lower MOEs compared to either individual route. The MOEs 3347 presented in this paragraph are with no use of PPE. Section 4.3.2.4 and Table 4-17 provides more 3348 information on PPE that could be used to reduce the MOEs above the benchmark MOE.

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3350 EPA based the central tendency and high-end exposure estimates on a near-field/far-field approach 3351 (AIHA, 2009) for aerosol modeling, and the product concentration was based on the range provided by 3352 the singular surrogate product which contained DINP (i.e., 10-20%) rather than DBP. As a result, 3353 calculated central tendency and high-end risk values were similar. Reliance on a single surrogate 3354 product for this OES adds uncertainty to the representativeness of the modeled inhalation exposures. 3355 Further, although the surrogate product information indicates that the product is aerosol and brush 3356 applied, EPA assessed only aerosol application due to limited data for this OES. The aerosolization of DBP-containing fluids generates a mist of droplets in the near-field, resulting in inhalation and dermal 3357 3358 exposure to workers, although dermal exposure is the primary contributor to the presented aggregate risk value. Aerosol application may overestimate inhalation exposures for brush application methods. Also, 3359 there is uncertainty related to the concentration of DBP in penetrant or inspection fluid products since 3360 3361 the only available product data were for DINP. However, central tendency levels of exposure from the 3362 near-field/far-field exposure modeling are expected to represent the 50th percentile of worker exposures 3363 from the use of aerosols containing DBP. High-end levels of exposure are generally associated with 3364 higher product concentrations and use rates. Although most worker exposures to DBP through aerosol application of inspection fluids and penetrants are expected to be closer to the central tendency exposure 3365 3366 values for this COU, a confluence of a subset of variables (e.g., low ventilation, high concentration, high3367 use rate) would result in risk below the benchmark. While most workers are not expected to experience 3368 these conditions, they may occur and expected for an acute 1-day exposure. 3369

For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the
chemical is contacted at least once per day. Because DBP has low volatility and relatively low
absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until
the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of DBP

3374 from occupational dermal contact with materials containing DBP may extend up to 8 hours per day (U.S. EPA, 1991). However, if a worker uses proper PPE, or washes their hands after contact with DBP 3375 3376 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-3377 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area 3378 of occupational dermal exposure, EPA assumed a high-end value of $1,070 \text{ cm}^2$ for male workers and 890 3379 cm² for female workers. These high-end occupational dermal exposure surface area values are based on 3380 the mean two-hand surface area for adults EPA's *Exposure Factors Handbook* (U.S. EPA, 2011a). For 3381 central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for 3382 3383 male workers and 445 cm^2 for female workers).

3384

3385 High-end and central tendency dermal exposures to liquid were determined using data from Doan et al. (2010). The study estimated a dermal absorption rate from experiments on female hairless guinea pigs 3386 3387 using a formulation of 7 percent oil-in-water emulsion. Using the study's estimate for DBP absorption in skin, 56.3 percent of the 1 mg/cm² dose over 24 hours, EPA estimated the steady-state flux of DBP and 3388 3389 the resultant dose based on exposure area. Although EPA determined that all data were of acceptable 3390 quality without notable deficiencies and integrated all the data into the final exposure assessment, it's 3391 uncertain how representative the use of a 7 percent oil-in-water emulsion formulation is for OESs where 3392 a higher concentration of DBP is used. There is also uncertainty in the use of guinea pigs over human 3393 skin, as guinea pig tissue is known to be more permeable than human tissue. Therefore, uncertainties 3394 about the difference between human and guinea pigs skin absorption increase uncertainty.

3395

3396 The central tendency values of exposure estimates are expected to be most reflective of worker 3397 inhalation exposures to reasonably expected conditions and the high-end values of exposure estimates 3398 are expected to be most reflective of workers exposed to potentially elevated (e.g., due to low 3399 ventilation, high concentration, high use rate) inhalation exposures. Also, since the dermal exposure 3400 estimates are upper-bound estimates, the central tendency values of exposure estimates are expected to 3401 be most reflective of worker exposures for dermal exposures. These exposures are experienced by 3402 workers within the COUs covered under the "Use of penetrants and inspection fluids" OES (i.e., 3403 Commercial Use COU: Other uses: [Inspection penetrant kit]).

3404

3405 Fabrication or Use of Final Product or Articles

3406 For fabrication or use of final product or articles, inhalation exposure was assessed from both vapors generated from materials that contain DBP and activities such as cutting, grinding, or drilling that may 3407 3408 generate dust. For this OES, dermal and inhalation exposure routes are both expected to equally 3409 contribute to exposures at the central tendency prediction range, but inhalation exposures are expected to 3410 be dominant at the high-end range. MOEs for high-end acute, intermediate, and chronic inhalation 3411 exposure ranged from 18 to 29 for average adult workers and females of reproductive age, while high-3412 end dermal MOEs for the same populations and exposure scenarios ranged from 62 to 98 (benchmark = 3413 30). For central tendency, MOEs for the same population and exposure scenarios ranged from 152 to 3414 245 for inhalation exposure and 124 to 197 for dermal exposures. Aggregation of inhalation and dermal 3415 exposures led to lower MOEs compared to either individual route. The MOEs presented in this 3416 paragraph are with no use of PPE. Section 4.3.2.4 and Table 4-17 provides more information on PPE 3417 that could be used to reduce the MOEs above the benchmark MOE.

3418

EPA estimated worker inhalation exposures to vapor from one sample that was taken at a facility that
melted, shaped, and joined plastics, and two inhalation exposure data points from the machine and
manual welding of plastic roofing materials (ECJRC, 2004; Rudel et al., 2001). With the three discrete

3422 data points, EPA could not create a full distribution of monitoring results to estimate central tendency

3423 and high-end exposures. To assess the high-end worker exposure to DBP during the fabrication process. 3424 EPA used the maximum available value (0.03 mg/m^3) and used the median of the three available values as the central tendency (0.01 mg/m³). EPA estimated worker inhalation exposures to solid particulate 3425 3426 using the PNOR Model for dust exposures (U.S. EPA, 2021d). For inhalation exposure to PNOR, EPA 3427 determined the 50th and 95th percentiles of the surrogate dust monitoring data taken from facilities with 3428 NAICS codes starting with 337 (Furniture and Related Product Manufacturing). EPA multiplied these 3429 dust concentrations by the maximum DBP concentration in PVC (*i.e.*, 45%) to estimate DBP particulate 3430 concentrations in the air. Therefore, the differences in the central tendency and high-end dust

- 3431 concentrations led to significant differences between the central tendency and high-end risk estimates.
- 3432

3433 There is uncertainty about how well the surrogate vapor monitoring data represent the true distribution 3434 of vapor inhalation concentrations for actual worker exposures in a specific facility the lack of ONU 3435 exposure data, for which EPA used worker data as surrogate data, and that there are only three data 3436 points used for the inhalation assessment. Also, although the PNOR Model (i.e., dust) concentration data 3437 provides a reliable range of dust concentrations that a worker may experience in the fabrication industry, 3438 the composition of workplace dust is uncertain. The exposure and risk estimates assume that the 3439 concentration of DBP in workplace dust is the same as the concentration of DBP in the material. 3440 However, it is likely that workplace dust contains a variety of constituents that do not contain any DBP 3441 in addition to particles from DBP-containing materials. The constituents that do not contain DBP would 3442 dilute the overall concentration of DBP in the dust, and the concentration of DBP in workplace dust is 3443 likely less than the concentration of DBP in the material. Therefore, the estimated inhalation exposures 3444 to dust are likely overestimated.

3445

3446 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the 3447 chemical is contacted at least once per day. Because DBP has low volatility and relatively low 3448 absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until 3449 the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of DBP 3450 from occupational dermal contact with materials containing DBP may extend up to 8 hours per day 3451 (U.S. EPA, 1991). However, if a worker uses proper PPE, or washes their hands after contact with DBP 3452 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-3453 hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area 3454 of occupational dermal exposure, EPA assumed a high-end value of 1,070 cm² for male workers and 890 3455 cm² for female workers. These high-end occupational dermal exposure surface area values are based on the mean two-hand surface area for adults EPA's Exposure Factors Handbook (U.S. EPA, 2011a). For 3456 3457 central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand 3458 (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for 3459 male workers and 445 cm^2 for female workers).

3460

3461 For estimating high-end and central tendency occupational dermal exposures to solids, EPA assumed 3462 that DBD will first migrate from the solid matrix to a thin layer of majoture on the skin surface.

that DBP will first migrate from the solid matrix to a thin layer of moisture on the skin surface.
Therefore, absorption of DBP from solid matrices is considered limited by aqueous solubility and is
estimated using an aqueous absorption model (U.S. EPA, 2023c, 2004b) as described in Appendix C in
the *Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (DBP)*(U.S. EPA, 2025q). EPA assumes that absorption of the aqueous material serves as a reasonable upper
bound for contact with solid materials and used this to estimate the average absorptive flux of DBP and
the resultant dose based on worker exposure area.

3469

3470 The PNOR Model uses conservative assumptions leading to upper-bound inhalation exposure estimates.

3471 The dermal exposure estimates are also upper-bound estimates as discussed above. Therefore, the

- 3472 central tendency values of exposure are expected to be most reflective of worker exposures within the
- 3473 COUs covered under the "Fabrication or final use of products or articles" OES (*i.e.*, Industrial Use 3474 COU: Other uses: [Automotive articles; Propellants]; and Commercial Use COU: Furnishing, cleaning
- 3474 COU: Other uses: [Automotive articles; Propellants]; and Commercial Use COU: Furnishing, cleaning, 3475 treatment care products: [Floor coverings; construction and building materials covering large surface
- treatment care products: [Floor coverings; construction and building materials covering large surface
 areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel; Furniture
- 3477 and furnishings]; Packaging, paper, plastic, toys, hobby products: [Packaging (excluding food
- 3478 packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with
- 3479 routine direct contact during normal use, including rubber articles; plastic articles (hard), Toys,
- 3480 playground, and sporting equipment]; Other uses: [Automotive articles, Chemiluminescent light sticks].
- 3481

3482 Recycling and Waste Handling, Treatment and Disposal

3483 The approaches for the recycling OES and the waste handling, treatment and disposal OES are identical 3484 and therefore consolidated here. For both OESs, the inhalation exposure from dust generation is 3485 expected to be the dominant route of exposure. MOEs for high-end acute, intermediate, and chronic 3486 inhalation exposure ranged from 9.7 to 16 for average adult workers and females of reproductive age, 3487 while high-end dermal MOEs for the same populations and exposure scenarios ranged from 62 to 98 3488 (benchmark = 30) for both OESs. The central tendency MOEs for the same populations and exposure 3489 scenarios ranged from 141 to 227 for inhalation exposure and 124 to 197 for dermal exposure for both 3490 OESs. Aggregation of inhalation and dermal exposures led to slight differences in risk when compared 3491 to risk estimates from inhalation exposure alone. The MOEs presented in this paragraph are with no use 3492 of PPE. Section 4.3.2.4 and Table 4-17 provides more information on PPE that could be used to reduce 3493 the MOEs above the benchmark MOE.

3494

3495 EPA estimated worker inhalation exposures using the PNOR Model for dust exposures (U.S. EPA, 3496 2021d). For inhalation exposure to PNOR, EPA determined the 50th and 95th percentiles of the 3497 surrogate dust monitoring data taken from facilities with NAICS codes starting with 56 (Administrative 3498 and Support and Waste Management and Remediation Services). EPA multiplied these dust 3499 concentrations by the industry provided maximum DBP concentration in PVC (*i.e.*, 45%) to estimate 3500 DBP particulate concentrations in the air. PVC concentration was used for this estimate because it is 3501 expected to be the predominant type of waste containing DBP that is recycled or disposed of. Therefore, 3502 the differences in the central tendency and high-end dust concentrations led to significant differences 3503 between the central tendency and high-end risk estimates.

3504

3505 Though the PNOR Model (*i.e.*, dust) concentration data provides a reliable range of dust concentrations 3506 that a worker may experience in the recycling and disposal industry, the composition of workplace dust 3507 is uncertain. The exposure and risk estimates assume that the concentration of DBP in workplace dust is 3508 the same as the concentration of DBP in PVC Plastics. However, it is likely that workplace dust contains 3509 a variety of constituents that do not contain any DBP in addition to particles from DBP-containing PVC 3510 plastics materials. The constituents that do not contain DBP would dilute the overall concentration of 3511 DBP in the dust, and the concentration of DBP in workplace dust is likely less than the concentration of 3512 DBP in the PVC plastics material. Therefore, the estimated inhalation exposures to dust are likely overestimated. 3513

3514

3515 For occupational dermal exposure assessment, EPA assumed a standard 8-hour workday and the

3516 chemical is contacted at least once per day. Because DBP has low volatility and relatively low

- absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until
- 3518 the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of DBP 3519 from occupational dermal contact with materials containing DBP may extend up to 8 hours per day
- 3519 (U.S. EPA, 1991). However, if a worker uses proper PPE, or washes their hands after contact with DBP

or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-

- hour exposure duration for DBP may lead to overestimation of dermal exposure. Regarding surface area of occupational dermal exposure, EPA assumed a high-end value of 1,070 cm² for male workers and 890
- cm^2 for female workers. These high-end occupational dermal exposure surface area values are based on
- the mean two-hand surface area for adults EPA's *Exposure Factors Handbook* (U.S. EPA, 2011a). For central tendency estimates, EPA assumed the exposure surface area was equivalent to only a single hand
- 3527 (or one side of two hands) and used half the mean values for two-hand surface areas (*i.e.*, 535 cm² for 3528 male workers and 445 cm² for female workers).
- 3529

3530 For estimating high-end and central tendency occupational dermal exposures to solids, EPA assumed

that DBP will first migrate from the solid matrix to a thin layer of moisture on the skin surface.
Therefore, absorption of DBP from solid matrices is considered limited by aqueous solubility and is
estimated using an aqueous absorption model (U.S. EPA, 2023c, 2004b) as described in Appendix C in
the *Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (DBP)*(U.S. EPA, 2025q). EPA assumes that absorption of the aqueous material serves as a reasonable upper
bound for contact with solid materials and used this to estimate the average absorptive flux of DBP and
the resultant dose based on worker exposure area.

3538

The PNOR Model uses conservative assumptions leading to upper-bound inhalation exposure estimates.The dermal exposure estimates are also upper-bound estimates as discussed above. Therefore, the

3541 central tendency values of exposure are expected to be most reflective of worker exposures within the

3542 COUs covered under the COUs covered under the "Recycling" and the "Disposal" OESs (*i.e.*,

3543 Processing COU: "Recycling" and Disposal COU: "Disposal").

3544 3545 Distribu

3545 Distribution in Commerce

3546 For purposes of assessment in this draft risk evaluation, distribution in commerce consists of the 3547 transportation associated with the moving of DBP or DBP-containing products and/or articles between 3548 sites manufacturing, processing, and use COUs, or the transportation of DBP containing wastes to 3549 recycling sites or for final disposal. EPA expects all the DBP or DBP-containing products and/or articles 3550 to be transported in closed system or otherwise to be transported in a form (e.g., articles containing3551 DBP) such that there is negligible potential for releases except during an incident. Therefore, no 3552 occupational exposures are reasonably expected to occur, and no separate assessment was performed for 3553 estimating releases and exposures from distribution in commerce.

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4.3.2.1 Overall Confidence in Worker Risk Estimates for Individual DBP OES

3555 As described in Section 4.1.1.5 and the *Draft Environmental Release and Occupational Exposure* 3556 Assessment for Dibutyl Phthalate (U.S. EPA, 2025q), EPA has moderate to robust confidence in the 3557 assessed inhalation exposures, and robust confidence in the non-cancer POD selected to characterize risk from acute, intermediate, and chronic duration exposures to DBP (see Section 4.2). EPA also has 3558 3559 moderate to robust confidence that the dermal exposures estimated are upper bound of potential 3560 exposures to workers. Overall, EPA has moderate to robust confidence in the risk estimates calculated for worker and ONU inhalation and dermal exposure scenarios. Sources of uncertainty associated with 3561 3562 these occupational COUs are discussed above in Section 4.3.2.

4.3.2.2 Effect of Duration of Exposure on Dermal Risk Estimates

Because the dermal flux rate of DBP absorption is insufficient to deplete the loading dose applied to the hands during an 8-hour work shift, and because DBP has low volatility and is not expected to evaporate from the hands, it is possible that the chemical remains on the surface of the skin after dermal contact until the skin is washed. So, in absence of exposure duration data, EPA has assumed that absorption of

3568 DBP from occupational dermal contact with materials containing DBP may extend up to 8 hours per day 3569 (U.S. EPA, 1991). However, if a worker uses proper PPE, or washes their hands after contact with DBP 3570 or DBP-containing materials, dermal exposure may be eliminated. Therefore, the assumption of an 8-3571 hour exposure duration for DBP may lead to overestimation of dermal exposure. For example, for the 3572 Manufacturing OES, if the average adult worker's hand is in contact with DBP for over 25 minutes and 3573 female of reproductive age worker's hand is in contact with DBP for over 30 minutes the central 3574 tendency MOEs are below the benchmark MOE of 30.

4.3.2.3 Consideration of Personal Protective Equipment (PPE)

Occupational Safety and Health Adminstration (OSHA) and National Institute for Occupational Safety 3576 and Health (NIOSH) recommend employers utilize the hierarchy of controls⁴ to address hazardous 3577 exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, 3578 the use of elimination, substitution, engineering controls, administrative controls, and lastly PPE. The 3579 3580 hierarchy of controls prioritizes the most effective measures, which eliminate or substitute the harmful 3581 chemical (e.g., use a different process, substitute with a less hazardous material), thereby preventing or reducing exposure potential. Following elimination and substitution, the hierarchy recommends 3582 engineering controls to isolate employees from the hazard, followed by administrative controls or 3583 3584 changes in work practices to reduce exposure potential (e.g., source enclosure, local exhaust ventilationsystems). Administrative controls are policies and procedures instituted and overseen by the employer to 3585 3586 protect worker exposures. OSHA and NIOSH recommend the use of PPE (e.g., respirators, gloves) as 3587 the last means of control, when the other control measures cannot reduce workplace exposure to an 3588 acceptable level.

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4.3.2.3.1 Respiratory Protection

OSHA's Respiratory Protection Standard (29 CFR 1910.134) requires employers in certain industries to 3590 address workplace hazards by implementing engineering control measures and, if these are not feasible, 3591 3592 providing respirators that are applicable and suitable for the purpose intended. Respirator selection 3593 provisions are provided in section 1910.134(d) and require that appropriate respirators be selected based on the respiratory hazard(s) to which the worker will be exposed, in addition to workplace and user 3594 3595 factors that affect respirator performance and reliability. Assigned protection factors (APFs) are provided in Table 1 under section 1910.134(d)(3)(i)(A) (see below in Table 4-15) and refer to the level 3596 of respiratory protection that a respirator or class of respirators is expected to provide to employees 3597 3598 when the employer implements a respiratory protection program according to the requirements of 3599 OSHA's Respiratory Protection Standard.

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Workers are required to use respirators that meet or exceed the required level of protection listed in Table 4-15. Based on the APF, inhalation exposures may be reduced by a factor of 5 to 10,000, if respirators are properly worn and fitted.

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⁴ <u>https://www.osha.gov/sites/default/files/Hierarchy_of_Controls_02.01.23_form_508_2.pdf</u>

Loose-Half Full Helmet/ Ouarter Fitting **Type of Respirator** Mask Hood Mask Facepiece Facepiece 50 5 10 1. Air-Purifying Respirator 50 1,000 25/1,000 2. Power Air-Purifying Respirator (PAPR) _ 25 3. Supplied-Air Respirator (SAR) or Airline Respirator Demand mode 10 50 • _ 50 1,000 25/1,000 25 Continuous flow mode _ ٠ Pressure-demand or other positive-1.000 50 • _ _ pressure mode 4. Self-Contained Breathing Apparatus (SCBA) Demand mode 50 10 50 • _ Pressure-demand or other positive-10,000 10,000 _ ٠ _ pressure mode (*e.g.*, open/closed circuit) Source: 29 CFR 1910.134(d)(3)(i)(A)

3605 Table 4-15. Assigned Protection Factors for Respirators in OSHA Standard 29 CFR 1910.134

4.3.2.3.2 Glove Protection

Gloves are selected in industrial settings based on characteristics (permeability, durability, required task etc). Data on the frequency of glove use (*i.e.*, the proper use of effective gloves) in industrial settings is very limited. An initial literature review suggests that there is unlikely to be sufficient data to justify a specific probability distribution for effective glove use for handling of DBP specifically, for a given industry. Instead, EPA explored the impact of effective glove use by considering different percentages of effectiveness (*e.g.*, 25% vs. 50% effectiveness).

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3614 Gloves only offer barrier protection until the chemical breaks through the glove material. Using a conceptual model, Cherrie et al. (2004) proposed a glove workplace protection factor, defined as the 3615 3616 ratio of estimated uptake through the hands without gloves to the estimated uptake though the hands 3617 while wearing gloves. This protection factor is driven by flux, and thus the protection factor varies with 3618 time. The ECETOC TRA model v.3.2 represents the glove protection factor as a fixed, assigned value 3619 equal to 5, 10, or 20 (Marquart et al., 2017). Like the APR for respiratory protection, the inverse of the 3620 protection factor is the fraction of the chemical that penetrates the glove. Table 4-16 presents APFs for 3621 different dermal protection characteristics.

3622

Dermal Protection Characteristics	Setting	Protection Factor, PF
a. No gloves used, or any glove/gauntlet without permeation data		1
and without employee training	Industrial and	
b. Gloves with available permeation data indicating that the material of construction offers good protection for the substance	Commercial	5
c. Chemically resistant gloves (<i>i.e.</i> , as <i>b</i> above) with "basic" employee training	Uses	10
d. Chemically resistant gloves in combination with specific activity training (<i>e.g.</i> , procedure for glove removal and disposal) for tasks where dermal exposure can be expected to occur	Industrial Uses Only	20
Source: (<u>Marquart et al., 2017</u>)		

3623 Table 4-16. Assigned Protection Factors for Different Dermal Protection Strategies

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4.3.2.4 Occupational Risk Estimates and Effect of PPE

Table 4-17 below presents the acute duration risk estimates for female workers of reproductive age and 3626 3627 the corresponding PPE that would result in a worker MOE above the benchmark MOE. For occupational risk estimates, Female workers of reproductive age are the most sensitive exposed population with the 3628 3629 lowest worker MOEs. Furthermore, the acute exposure duration results in the lowest worker MOEs for 3630 this population. This means that PPE that raises the MOE above the benchmark for a female worker of 3631 reproductive age in the acute exposure duration will also raise the MOE above the benchmark for all 3632 other workers and exposure durations. Risk estimates for other populations, durations, and health effects 3633 for all the COUs/OES are included in the Draft Risk Calculator for Occupational Exposures for Dibutyl 3634 Phthalate (DBP) (U.S. EPA, 2025t). Additionally, the risk calculator contains MOE calculations and 3635 PPE information for all the OES.

3636

3637 Table 4-17 includes three main sections according to the route of exposure: inhalation, dermal, and aggregate exposure. For inhalation, typical respirator applied protection factor (APF) values of 10, 25, 3638 3639 50, 1000 and 10,000 were compared to the calculated MOE and the benchmark MOE to determine the level of APF that could be used to bring MOEs above the benchmark MOE. For dermal exposures, 3640 3641 typical dermal Protection Factor (PF) values of 5, 10, and 20 were compared to the calculated MOE and 3642 the benchmark MOE to determine the level of PF that could be used to bring MOEs above the benchmark MOE. For aggregate exposures, the APF and/or PF that could be used to bring MOEs above 3643 3644 the benchmark are also shown. In cases, when it is not possible to raise MOE to above the benchmark 3645 with the use of respiratory and/or dermal protection, PPE with maximum APF/PF and the corresponding 3646 MOE values are shown in the table. The appropriateness of any protection factor that demonstrates 3647 exposures resulting in a worker MOE above the benchmark MOE may require additional consideration. 3648 The presented protection factors simply represent a value by which corresponding PPE may theoretically increase the estimated worker MOE above the benchmark MOE. The practicality and 3649 feasibility of implementing any PPE corresponding to a protection factor is part of a larger evaluation of 3650 effective occupational control strategies. Such an evaluation should take into consideration the hierarchy 3651 3652 of hazard control options. The hierarchy of controls from most to least effective are elimination, substitution, engineering controls, administrative controls, and personal protective equipment. 3653 3654

For inhalation, based on the risk characterization in Section 4.3.2, either the central tendency or both the
 central tendency and high-end exposure estimates may be reflective of worker inhalation exposures
 depending on the OES. Table 4-17 shows that using PPE for inhalation scenarios when the MOEs are

below the benchmark MOE, reduces the exposures to above the benchmark MOE. For dermal, based on
the risk characterization in Section 4.3.2, the central tendency exposure estimates are expected to be
most reflective of worker dermal exposures for all OESs because the dermal exposure estimates are
upper-bounds. Table 4-17Table shows when dermal protection is used, the central tendency MOEs for
all OESs are increased to above the benchmark for dermal exposures.

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3664Table 4-17. Occupational Risk Estimation for Acute Exposure for Female of Reproductive Age3665(Benchmark MOE = 30)

			Inhalation			Dermal		Ag	gregate
Occupational Scenario	Expos. Level	Worker MOE No PPE	Worker MOE with PPE ^c	APF ^{bc}	Worker MOE No PPE	Worker MOE with PPE ^c	PF ^{bc}	Worker MOE No PPE	Worker MOE with PPE ^{b c}
Manafaatanina	СТ	30	At benchmark	N/A	1.8	36	PF 20	1.7	33 (APF 10, PF 20)
Manufacturing	HE	15	152	APF 10	0.9	18	PF 20	0.9	18 (APF 50, PF 20)
Import and	СТ	30	At benchmark	N/A	1.8	36	PF 20	1.7	33 (APF 10, PF 20)
repackaging	HE	15	152	APF 10	0.9	18	PF 20	0.9	18 (APF 50, PF 20)
Incorporation into formulations,	СТ	30	At benchmark	N/A	1.8	36	PF 20	1.7	33 (APF 10, PF 20)
mixtures, or reaction product	HE	15	152	APF 10	0.9	18	PF 20	0.9	18 (APF 50, PF 20)
PVC plastics	СТ	44	Above benchmark	N/A	1.8	36	PF 20	1.7	33 (APF 10, PF 20)
compounding	HE	5.3	53	APF 10	0.9	18	PF 20	0.8	18 (APF 1,000, PF 20)
PVC plastics	СТ	44	Above benchmark	N/A	135	Above benchmark	N/A	33	Above benchmark
converting	HE	5.3	53	APF 10	67	Above benchmark	N/A	4.9	45 (APF 25)
Non-PVC	СТ	53	Above benchmark	N/A	1.8	36	PF 20	1.7	34 (APF 10, PF 20)
materials manufacturing	HE	9.0	90	APF 10	0.9	18	PF 20	0.8	18 (APF 1,000, PF 20)
Application of	СТ	304	Above benchmark	N/A	1.8	36	PF 20	1.8	33 (PF 20)
adhesives and sealants	HE	152	Above benchmark	N/A	0.9	18	PF 20	0.9	18 (APF 10, PF 20)
Application of	СТ	18	184	APF 10	1.8	36	PF 20	1.7	30 (APF 10, PF 20)
paints and coatings	HE	2.9	73	APF 25	0.9	18	PF 20	0.7	18 (APF 1,000, PF 20)
Industrial process	СТ	30	At benchmark	N/A	1.8	36	PF 20	1.7	33 (APF 10, PF 20)
solvent use	HE	15	152	APF 10	0.9	18	PF 20	0.9	18 (APF 50, PF 20)

			Inhalation			Dermal		Ag	gregate
Occupational Scenario	Expos. Level	Worker MOE No PPE	Worker MOE with PPE ^c	APF ^{bc}	Worker MOE No PPE	Worker MOE with PPE ^c	PF ^{b c}	Worker MOE No PPE	Worker MOE with PPE ^{b c}
Use of laboratory	СТ	400	Above benchmark	N/A	135	Above benchmark	N/A	101	Above benchmark
chemicals (solid)	HE	28	282	APF 10	67	Above benchmark	N/A	20	54 (APF 10)
Use of laboratory	СТ	304	Above benchmark	N/A	2.4	49	PF 20	2.4	42 (PF 20)
chemicals (liquid)	HE	152	Above benchmark	N/A	0.9	18	PF 20	0.9	18 (APF 10, PF 20)
Use of lubricants	СТ	304	Above benchmark	N/A	3.3	33	PF 10	3.2	54 (PF 20)
and functional fluids	HE	152	Above benchmark	N/A	1.1	22	PF 20	1.1	22 (APF 25, PF 20)
Use of penetrants	СТ	10	101	APF 10	1.8	36	PF 20	1.5	32 (APF 25, PF 20)
and inspection fluids	HE	2.7	68	APF 25	0.9	18	PF 20	0.7	18 (APF 1,000, PF 20)
Fabrication or use	СТ	152	Above benchmark	N/A	135	Above benchmark	N/A	71	Above benchmark
of final product or articles	HE	18	181	APF 10	67	Above benchmark	N/A	14	49 (APF 10)
Desculing	СТ	141	Above benchmark	N/A	135	Above benchmark	N/A	69	Above benchmark
Recycling	HE	9.7	97	APF 10	67	Above benchmark	N/A	8.4	40 (APF 10)
Waste handling,	СТ	141	Above benchmark	N/A	135	Above benchmark	N/A	69	Above benchmark
treatment, and disposal	HE	9.7	97	APF 10	67	Above benchmark	N/A	8.4	40 (APF 10)

^{*a*} Benchmark MOE = 30. **Bold text** in a gray shaded cell indicates an MOE is below the benchmark value of 30.

^{*b*} CT = central tendency; HE = high-end; PPE = personal protective equipment, MOE = margin of exposure, PF = protection factor, APF = assigned protection factor

^{*c*} PPE with the least amount of APF/PF that could be used to reduce MOE values above the benchmark MOE are shown in the table with corresponding MOE values. In cases, when it is not possible to raise MOE to above the benchmark with PPE, PPE with maximum APF/PF and the corresponding MOE values are shown in the table.

^d The Draft Risk Calculator for Occupational Exposures for Dibutyl Phthalate (DBP) (U.S. EPA, 2025t) contains MOE calculations and PPE information for all the OES for all durations (acute, intermediate, and chronic).

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3668 Table 4-18. Occupational Risk Table for DBP

	COU		XX /o-1	E			Estimates			Estimates			Estimates
Life Cycle Stage –	Subcategory	OES	Worker Population	Exposure Level			OE = 30	`	1	10E = 30)	-		OE = 30
Category		Average Adult			Acute	Inter.	Chronic	Acute			Acute	Inter.	Chronic
				CT	34	46	49	1.7	2.3	2.4	1.6	2.2	2.3
Manufacturing			Worker	HE	17	23	25	0.8	1.1	1.2	0.8	1.1	1.2
	Domestic manufacturing	Manufacturing	Female of	СТ	30	41	44	1.8	2.5	2.7	1.7	2.3	2.5
manufacturing			Reproductive Age	HE	15	21	22	0.9	1.2	1.3	0.9	1.2	1.3
			ONU	СТ	34	46	49	N/A	N/A	N/A	34	46	49
	Importing		Average Adult	СТ	34	46	49	1.7	2.3	2.4	1.6	2.2	2.3
– Importing		-	Worker	HE	17	23	25	0.8	1.1	1.2	0.8	1.1	1.2
	Laboratory chemicals in wholesale and retail trade;	Import and	Female of	СТ	30	41	44	1.8	2.5	2.7	1.7	2.3	2.5
	plasticizers in wholesale and	repackaging	Reproductive Age	HE	15	21	22	0.9	1.2	1.3	0.9	1.2	1.3
	retail trade; and plastics material and resin manufacturing		ONU	СТ	34	46	49	N/A	N/A	N/A	34	46	49
	Intermediate in plastic manufacturing			СТ	34	46	49	1.7	2.3	2.4	1.6	2.2	2.3
Processing – Incorporation into formulation, mixture, or reaction product	Solvents (which become part of product formulation or mixture) in chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and printing ink manufacturing Plasticizer in paint and coating manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; and adhesive and sealant manufacturing	Incorporation into formulations, mixtures, or reaction product	Average Adult Worker	HE	17	23	25	0.8	1.1	1.2	0.8	1.1	1.2
	Pre-catalyst manufacturing		Female of	СТ	30	41	44	1.8	2.5	2.7	1.7	2.3	2.5
			Reproductive Age	HE	15	21	22	0.9	1.2	1.3	0.9	1.2	1.3
			ONU	CT	34	46	49	N/A	N/A	N/A	34	46	49

	COU					ion Risk	Estimates	Derma	ıl Risk I	Estimates	Aggreg	ate Risk	Estimates
Life Cycle		OES	Worker Population	Exposure Level	(Bench	mark M	OE = 30)	(Bench	mark M	$\mathbf{IOE} = 30$	(Bench	mark M	OE = 30)
Stage – Category	Subcategory		Topulation	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
Processing –			Average Adult Worker		49	67	71	1.7	2.3	2.4	1.6	2.2	2.3
Processing:			Worker	HE	5.9	8.0	8.6	0.8	1.1	1.2	0.7	1.0	1.1
incorporation into	Plasticizer in plastic material and		Female of	СТ	44	60	65	1.8	2.4	2.6	1.7	2.4	2.5
formulation, mixture, or	resin manufacturing	compounding	Reproductive Age	HE	5.3	7.2	7.8	0.9	1.2	1.3	0.8	1.0	1.1
reaction product			ONU	CT	49	67	71	124	169	181	35	48	51
	Plasticizer in adhesive and		Average Adult	СТ	49	67	71	124	169	181	35	48	51
Processing –	sealant manufacturing; building and construction materials		Worker	HE	5.9	8.0	8.6	62	85	90	5.4	7.3	7.8
Processing:	manufacturing; furniture and	PVC plastics	Female of	CT	44	60	65	135	184	197	33	45	49
incorporation into articles	related product manufacturing;	converting	Reproductive Age	HE	5.3	7.2	7.8	67	92	98	4.9	6.7	7.2
into articles	ceramic powders; plastics product manufacturing	converting I	ONU	СТ	49	67	71	124	169	181	35	48	51
Processing –	Plasticizer in plastic material and		Average Adult	СТ	59	80	86	1.7	2.3	2.4	1.6	2.2	2.3
Processing:	resin manufacturing; rubber manufacturing		Worker	HE	9.9	14	15	0.8	1.1	1.2	0.8	1.0	1.1
incorporation into	manufacturing			СТ	53	73	78	1.8	2.4	2.6	1.7	2.4	2.5
formulation, mixture, or reaction product		Non-PVC	Female of Reproductive Age										
Processing -	Plasticizer in adhesive and	materials		HE	9.0	12	13	0.9	1.2	1.3	0.8	1.1	1.2
Incorporation into articles	sealant manufacturing; building and construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing	manufacturing	ONU	CT	59	80	86	124	169	181	40	54	58

	COU						Estimates						Estimates
Life Cycle		OES	Worker Population	Exposure Level	(Bench	nmark M	(OE = 30)	(Bench	mark N	$\mathbf{IOE}=30$	(Bench	mark M	OE = 30)
Stage – Category	Subcategory		i opulation	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
Commercial	Adhesives and sealants		Average Adult	СТ	336	458	529	1.7	2.3	2.6	1.7	2.3	2.6
Use –			Worker	HE	168	229	245	0.8	1.1	1.2	0.8	1.1	1.2
Construction,				CT	304	415	479	1.8	2.5	2.9	1.8	2.5	2.8
paint, electrical, and metal		Application of	Female of										
products		adhesives and	Reproductive Age										
Industrial Use –	Adhesives and sealants	sealants		HE	152	207	222	0.9	1.2	1.3	0.9	1.2	1.3
Construction,			ONU	CT	336	458	529	1.7	2.3	2.6	1.7	2.3	2.6
paint, electrical,			0110	01	550	150	527	1.,	2.0	2.0	1.7	2.0	2.0
and metal													
products													
	Ink, toner, and colorant products		Average Adult	СТ	20	28	30	1.7	2.3	2.4	1.5	2.1	2.3
Use – Packaging,			Worker	HE	3.2	4.4	4.7	0.8	1.1	1.2	0.7	0.9	1.0
paper, plastic,		, ,	Female of	СТ	18	25	27	1.8	2.5	2.7	1.7	2.3	2.4
toys, hobby			Reproductive Age	HE	2.9	4.0	4.2	0.9	1.2	1.3	0.7	0.9	1.0
products		Application of	Reproductive rige										
Commercial		paints and	ONU	СТ	20	28	30	2.2	3.1	3.3	2.0	2.8	2.9
Use –		coatings											
Commercial use													
– Construction, paint, electrical,	Paints and coatings												
and metal													
products													
1			Average Adult	СТ	34	46	49	1.7	2.3	2.4	1.6	2.2	2.3
Industrial Use – Non-	Solvent, including in maleic	Industrial	Worker	HE	17	23	25	0.8	1.1	1.2	0.8	1.1	1.2
incorporative	anhydride manufacturing	process solvent	Female of	СТ	30	41	44	1.8	2.5	2.7	1.7	2.3	2.5
activities	technology	use	Reproductive Age	HE	15	21	22	0.9	1.2	1.3	0.9	1.2	1.3
			ONU	СТ	34	46	49	N/A	N/A	N/A	34	46	49
		Use of Wo laboratory chemicals	Average Adult	СТ	442	603	645	124	169	181	97	132	141
Commercial			Worker	HE	31	42	45	62	85	90	21	28	30
Use – Other uses	Laboratory chemicals		Female of	СТ	400	546	584	135	184	197	101	138	147
			Reproductive Age	HE	28	38	41	67	92	98	20	27	29
			ONU	СТ	442	603	645	124	169	181	97	132	141

	COU				Inhalat	ion Risk	Estimates				Aggreg	ate Risk	Estimates
Life Cycle	S-hards areas	OES	Worker Population	Exposure Level	(Bench	mark M	OE = 30)	(Bench	mark M	$\mathbf{IOE} = 30$	(Bench	mark M	OE = 30)
Stage – Category	Subcategory		ropulation	Lever	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
			Average Adult	СТ	336	458	491	2.2	3.1	3.3	2.2	3.0	3.3
Commercial Use – Other	Laboratory chemicals	Use of laboratory	Worker	HE	168	229	245	0.8	1.1	1.2	0.8	1.1	1.2
uses	Laboratory chemicals	chemicals	Female of	CT	304	415	444	2.4	3.3	3.6	2.4	3.3	3.5
		(liquid)	Reproductive Age	HE	152	207	222	0.9	1.2	1.3	0.9	1.2	1.3
		_	ONU	СТ	336	458	491	N/A	N/A	N/A	336	458	491
Commercial	Lubricants and lubricant		Average Adult	СТ	336	5,040	61,320	3.0	45	546	3.0	44	541
Use – Other	additives		Worker	HE	168	1,260	15,330	1.0	7.5	91	1.0	7.4	90
uses			Female of	CT	304	4,563	55,514	3.3	49	594	3.2	48	588
Industrial Use – Other uses	Lubricants and lubricant additives	Use of	Reproductive Age	HE	152	1,141	13,878	1.1	8.1	99	1.1	8.1	98
Commercial Use – Automotive, fuel, agriculture, outdoor use products	Automotive care products	lubricants and functional fluids	ONU	СТ	336	5,040	61,320	N/A	N/A	N/A	336	5,040	61,320
			Average Adult	СТ	11	15	16	1.7	2.3	2.5	1.5	2.0	2.1
Commercial		Use of penetrants and inspection	Worker	HE	3.0	4.1	4.4	0.8	1.1	1.2	0.7	0.9	1.0
Use – Other	Inspection penetrant kit		Female of	СТ	10	14	15	1.8	2.5	2.7	1.5	2.1	2.3
uses			Reproductive Age	HE	2.7	3.7	4.0	0.9	1.2	1.3	0.7	0.9	1.0
			ONU	СТ	329	449	487	1.7	2.3	2.5	1.7	2.3	2.5

	COU						Estimates						Estimates
Life Cycle Stage –	Subcategory	OES	Worker Population	Exposure Level	(Bench	mark M	OE = 30)	(Bench	mark M	IOE = 30)	(Bench	mark M	OE = 30)
Category	Subcategory		•		Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
t S Commercial p Use – c Furnishing, a	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel Furniture and furnishings		Average Adult Worker	СТ	168	229	245	124	169	181	71	97	104
treatment care products				HE	20	27	29	62	85	90	15	21	22
products			Female of	СТ	152	207	222	135	184	197	71	97	104
			Reproductive Age	HE	18	25	26	67	92	98	14	19	21
		Fabrication or	ONU	CT	168	229	245	124	169	181	71	97	104
Commerciai	Automotive articles	use of final product or											
	Chemiluminescent light sticks	articles											
	Propellants												
Commercial a Use – F Packaging, a paper, plastic, c toys, hobby i products a	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)												
	Toys, playground, and sporting equipment												
			Average Adult	CT	156	212	227	124	169	181	69	94	101
Processing –	Desualing	Deeveline	Worker	HE CT	11 141	15 192	16 206	62 135	85 184	90 197	9.1 69	<u>12</u> 94	13 101
Recycling	Recycling R		Female of Reproductive Age	HE	9.7	192 13	14	67	184 92	98	8.4	94 12	101
			ONU	CT	9. 7	212	227	124	92 169	181	6 .4	94	12

	COU				Inhalat	ion Risk	Estimates	Derma	al Risk H	Estimates	Aggreg	ate Risk	Estimates
Life Cycle		OES	Worker Population	Exposure Level	(Bench	mark M	OE = 30)	(Bench	mark M	$\mathbf{IOE}=30$	(Bench	mark M	$\mathbf{OE} = 30$
Stage – Category	Subcategory		- opunutori	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
		Waste	Average Adult	CT	156	212	227	124	169	181	69	94	101
Diamagal	Waste	Worker	HE	11	15	16	62	85	90	9.1	12	13	
Disposal – Disposal	Disposal	handling, treatment and	Female of	CT	141	192	206	135	184	197	69	94	101
Disposal		treatment, and disposal	Reproductive Age	HE	9.7	13	14	67	92	98	8.4	12	12
		ansposa	ONU	CT	156	212	227	124	169	181	69	94	101
populations (ave	The Draft Risk Calculator for Occupational Exposures for Dibutyl Phthalate (DBP) (<u>U.S. EPA, 2025t</u>) contains MOE values with PPE for all the OES for all populations (average adult workers, female of reproductive age, and ONUs) and all durations (acute, intermediate, and chronic). Bold text in a gray shaded cell indicates an MOE below the benchmark value of 30.												

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3670 4.3.3 Risk Estimates for Consumers

3671 Table 4-19 summarizes the dermal, inhalation, ingestion, and aggregate MOEs used to characterize non-3672 cancer risk for acute, intermediate, and chronic exposure to DBP, and presents these values for all 3673 lifestages for each COU. A screening level assessment for consumers considers high-intensity exposure scenario risk estimates and relies on conservative assumptions to assess exposures that would be 3674 3675 expected to be on the high end of the expected exposure distribution. MOEs for high-intensity exposure 3676 scenarios are shown for all consumer COUs, while MOEs for medium-intensity exposure scenarios are 3677 shown only for COUs with high-intensity MOEs at, or under the benchmark of 30, see listed COUs 3678 below. Further, Table 4-19 provides MOEs for the modeling indoor exposure assessment. The main 3679 objective in reconstructing the indoor environment using consumer products and articles commonly 3680 present in indoor spaces is to calculate exposure and risk estimates by COU, and by product and article, 3681 from indoor dust ingestion and inhalation. EPA identified article-specific information by COU to 3682 construct relevant and representative exposure scenarios. Exposure to DBP via ingestion of dust was assessed for all articles expected to contribute significantly to dust concentrations due to high surface 3683 3684 area (> $\sim 1 \text{ m}^2$) for either a single article or collection of like articles as appropriate. Articles included in 3685 the indoor environment assessment included: adult toys, children's toys (new and legacy), synthetic 3686 leather furniture, car mats, shower curtains, vinyl flooring, and wallpaper used in place. COUs 3687 associated with articles included in the indoor environment assessment are indicated with footnote c in 3688 Table 4-19. 3689

Of note, the risk summary below is based on the most sensitive non-cancer endpoint for all relevant
duration scenarios (*i.e.*, developmental toxicity for acute, intermediate, and chronic durations). MOEs
for all high-, medium- and low-intensity exposure scenarios for all COUs are described in the *Draft Consumer Risk Calculator for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025e).

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3695 COUs with MOEs for High-Intensity Exposure Scenarios Above Benchmark

The screening level assessment for consumers considers high-intensity exposure scenario risk estimates, MOEs, and relies on conservative assumptions to assess exposures that would be expected to be on the high end of the expected exposure distribution. If MOEs are above the benchmark of 30 for the highintensity use scenario then any exposures with lower intensity use inputs would result in larger MOEs. Consumer COUs that resulted in MOEs for high-intensity exposure scenarios above the benchmark of 30 for acute, chronic and intermediate exposures are summarized in Table 4-19 and in the following list:

- Furnishing, cleaning, treatment care products; floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
- Furnishing, cleaning, treatment care products: fabric, textile, and leather products
- Other uses; automotive articles
- Other uses; chemiluminescent light sticks
- Other uses; novelty articles
- Packaging, paper, plastic, toys, hobby products; packaging (excluding food packaging),
 including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine
 direct contact during normal use, including rubber articles; plastic articles (hard)

Variability in MOEs for these high-intensity exposure scenarios results from use of different exposure
 factors for each COU and product/article examples that led to different estimates of exposure to DBP.

3714 As described in the *Draft Consumer and Indoor Dust Exposure Assessment for Dibutyl phthalate (DBP)*

3717 As assented in the Drug Consumer and Indoor Dusi Exposure Assessment for Dibutyl philaddle (DDF 3715 (USEPA 2025c) and Draft Non-Cancer Human Health Hazard Assessment for Dibutyl Dethalate

- 3716 (*DBP*) (<u>U.S. EPA, 2024f</u>), EPA has moderate to robust confidence in the exposure estimates and robust
- confidence in the non-cancer hazard value used to estimate non-cancer risk for these COUs. EPA is
 confident that the high-intensity use scenarios used in the screening approach represent an upper-bound
 estimate and provide a health protective estimate for consumer exposures.
- 3720

3721 COUs with MOEs for Exposure Scenarios Below Benchmark

- The screening level assessment for consumers considers high-intensity exposure scenario risk estimates, MOEs, and relies on conservative assumptions to assess exposures that would be expected to be on the high-end of the expected exposure distribution. If MOEs are below the benchmark of 30 for the high-
- intensity use scenario, EPA reevaluates the approaches and inputs used and determines if refinement of
- those is needed. In addition, the Agency considers the medium-intensity use scenario as either a possible
- upper-bound estimate by reevaluating inputs and approaches or endeavors in the refinement of
 approaches by using other modeling tools or other input parameters within the same modeling tools. See
- 3729 Section 2 in *Draft Consumer and Indoor Dust Exposure Assessment for Dibutyl Phthalate (DBP)* (U.S.
- 3730 <u>EPA, 2025c</u>) for details about the consumer modeling approaches, sources of data, model
- 3731 parameterization, and assumptions. After reevaluating approaches and input parameters for each
- 3732 consumer COU with MOEs below the benchmark EPA concludes that further refinement of input
- arameters is not likely to result in different MOEs than those already presented in Table 4-19.
- Consumer COUs that resulted in MOEs for high-intensity exposure scenarios below the benchmark of
- 3735 30 for acute, chronic and intermediate exposures are summarized in Table 4-19 and in the following list:
 - Construction, paint, electrical, and metal products: adhesives and sealants
 - Construction, paint, electrical, and metal products: paints and coatings
 - Furnishing, cleaning, treatment care products: cleaning and furnishing care products
 - Packaging, paper, plastic, hobby products; toys, playground, and sporting equipment
- The consumer COUs that resulted in MOEs below the benchmark of 30 are discussed in further detail in
 the subsections below. Each subsection expands on each COU and the aspects driving the MOEs below
 the benchmark.
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3744 Construction, Paint, Electrical, and Metal Products: Adhesives and Sealants

This section summarizes the risk estimates, MOEs, below the benchmark of 30 for the titled COU. 3745 3746 Products with similar DBP content and expected use patterns were grouped together for modeling as 3747 described below. Some products were not assessed for inhalation exposure due to the small volume of 3748 the product which is expected to be used, short durations of use and thus a shorter duration for emissions 3749 to air to occur (e.g., adhesives with short working times (less than a few minutes) until solidification and 3750 liquids poured directly into a reservoir that is capped after product addition), and/or products used in 3751 outdoor conditions where air exchange rates are high and product application is not expected to generate 3752 aerosols. Three different product scenarios were assessed under this COU for products with differing use 3753 patterns including: adhesives for small repairs, automotive adhesives, and construction adhesives.

- 3754
- One all-purpose adhesive used for small repairs was identified with DBP content. The reported DBP content was less than 3 percent (Walmart, 2019). Because small volumes of this adhesive are expected to be used and the working time is short (<5 min), this product was evaluated for dermal exposure only.

3759

Two adhesive products for home repair or construction bonding were identified with DBP
 content. One anchoring adhesive used for anchoring metal rebar into cured concrete and masonry
 was reported to have a DBP content of 0.1 to 5 percent (<u>ITW Red Head, 2016</u>), and one paste

designed to watertight details in construction was reported to have a DBP content of 10 to 30
percent (Vaproshield, 2018). Both products are used outdoors in relatively small quantities and
not applied in a manner expected to generate significant aerosols. As such, these products were
modeled for dermal exposure only.

One metal bonding adhesive used for small to moderately sized automotive repairs was identified with DBP content of 1 to less than 3 percent (Ford Motor Company, 2015b). This product was modeled for dermal and inhalation (because of possible large amount uses) exposure. DBP weight fractions of 0.01, 0.015, and 0.03 w/w in low, medium, and high inhalation exposure scenarios.

3774 Of the three product scenarios assessed for this COU, only the acute doses (24-hour exposure; see Sections 2.2.1 and 2.2.2 and Appendix A in (U.S. EPA, 2025c) for details about acute, intermediate, and 3775 3776 chronic dose calculations) for automotive and construction adhesives resulted in MOEs less than the benchmark of 30. The automotive and construction adhesives COU resulted in MOEs less than 30 in the 3777 3778 dermal, acute, high- and medium-intensity use exposure scenarios. The MOEs for both automotive and 3779 construction adhesives were 7, 8, and 7 respectively for young teen, teenager, and adult in the high-3780 intensity exposure route. For the medium-intensity exposure route the MOEs were 28, 31 and 29 for 3781 young teen, teenagers, and adults. For construction adhesives and automotive adhesives, the duration of 3782 skin contact used in the high-, medium-, and low-intensity use scenarios were 120, 60, and 30 minutes 3783 respectively (Section 2.3.4 in U.S. EPA (2025c)). The contact area for the high-intensity use scenario 3784 corresponded to inside of two hands including palms and fingers, for medium-intensity scenario contact 3785 area was inside of one hand including palms and fingers, and low intensity scenario used 10 percent of 3786 hands (some fingers) (Section 2.3.4 in U.S. EPA (2025c)). 3787

For dermal exposure EPA used the liquid products dermal flux-limited approach, which was estimated based on DBP *in vitro* dermal absorption in guinea pigs. An overall moderate confidence in dermal assessment of adhesives was assigned. The difference between human and guinea pig skin absorption increase uncertainty and due to increased permeability of guinea pig skin as compared to human skin dermal absorption estimates likely overestimate exposures. Other parameters such as frequency and duration of use, and surface area in contact, are well understood and representative, resulting in an overall moderate confidence.

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3796 Construction, Paint, Electrical, and Metal Products: Paints and Coatings

This section summarizes the risk estimates, MOEs, below the benchmark of 30 for the titled COU.
Three different scenarios were assessed under this COU including: metal coatings, indoor sealing and
refinishing sprays, and outdoor sealing and refining sprays. All three scenarios were assessed for dermal
and inhalation exposures.

- 3801
- 3802 Outdoor sealing and refinishing sprays: Four waterproofing coating products for roofs, decks, • 3803 and walkway applications were identified with DBP content. Identified product examples were Hydrostop premium finish coat, Hydrostop premium foundation coat, Hydrostop traffic deck 3804 3805 coating, and Lanco seal (roof coating). The combined weight fractions used for the high-, medium-, and low-intensity use inhalation exposure scenarios were 0.0005, 0.017, and 0.1 w/w 3806 respectively. Though these products are for outdoor only use, inhalation exposure may be 3807 3808 significant due to relatively large volumes of product used and aerosol generation during spray application. As such, these products were modeled for both inhalation and dermal exposures 3809 3810 during product application or do-it-yourself (DIY) activities for young teens, teenagers, and

3811 adults. Bystanders (infants to middle childhood) were assessed for inhalation exposures while 3812 someone else, a DIYer, was using the product. Product application scenarios for inhalation and 3813 dermal contact were modeled to occur outside. The duration of skin contact used in the high-, 3814 medium-, and low-intensity use scenarios were 480, 240, and 120 minutes respectively, on the 3815 account of needing two coats for proper product application and covering a large surface 3816 (Section 2.3.4 in U.S. EPA (2025c)). The contact area for the high-, medium-, and low-intensity 3817 use scenario corresponded to 10 percent of hands (Section 2.3.4 in U.S. EPA (2025c)). While for other products in this COU it was assumed that users did not wash their hands until the task was 3818 3819 completed, these products are very sticky and likely require hand washing or at least wiping 3820 hands. EPA assumes that the user can wipe their hands while some of the product remains, 3821 therefore a surface area contact of 10 percent of the hands was selected. The dermal MOEs for 3822 the acute, high exposure intensity scenario for outdoor sealing and refinishing spray products 3823 were 9, 10, and 9 for young teens, teenagers, and adults. The MOE values for the medium-3824 intensity use exposure scenarios were 18, 19, and 18 for young teens, teenagers, and adults.

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3826 Indoor sealing and refinishing sprays: Four waterproofing coating products for roofs, decks, and 3827 walkway applications were identified with DBP content. Identified product examples were 3828 Franklin side out gym floor finish, crystal floor finish, SWC nature one 100% Acry EN CED, 3829 and SWC nature one renew. The combined weight fractions used for the high-, medium-, and 3830 low-intensity use inhalation exposure scenarios were 0.01, 0.02, and 0.03 w/w respectively. The 3831 products were assessed for inhalation and dermal exposures during product application or DIY 3832 activities for young teens, teenagers, and adults. Bystanders (infants to middle childhood) were 3833 assessed for inhalation exposures while someone else, a DIYer, was using the product. Product 3834 application scenarios for inhalation and dermal contact were modeled to occur indoors (garage). 3835 The duration of skin contact used in the high-, medium-, and low-intensity use scenarios were 3836 270, 180, and 90 minutes respectively on the account of needing two coats for proper product 3837 application on a semi large surface (smaller than for the outdoor products) (Section 2.3.4 in U.S. 3838 EPA (2025c)). The contact area for the high-intensity use scenario corresponded 10 percent of 3839 hands for the high-, medium-, and low-intensity use scenarios. These products are very sticky and likely require hand washing or at least wiping hands. EPA assumes that the user can wipe 3840 3841 their hands while some of the product remains, therefore a surface area contact of 10 percent of 3842 the hands was selected (Section 2.3.4 in U.S. EPA (2025c)). The MOEs for the high exposure 3843 intensity scenario for indoor sealing and refinishing sprays were 16, 17 and 16 respectively for 3844 young teen, teenage and adult. The medium-intensity MOEs were 23, 26, and 24 for the same 3845 lifestage categories.

3847 Metal coatings: Two metal coating products were assessed for inhalation and dermal exposures • 3848 during product application or DIY activities for young teens, teenagers, and adults. Bystanders (infants to middle childhood) were assessed for inhalation exposures while someone else, a 3849 3850 DIYer, was using the product. Product application scenarios for inhalation and dermal contact 3851 were modeled to occur indoors (garage). One anti-fouling boat coating was identified with 2.5 to 3852 10 percent DBP content, and one aluminum primer was identified with 1 to 2.5 percent DBP 3853 content. The combined weight fractions were 0.01 w/w, 0.04 w/w, and 0.1 used for the low, 3854 medium, and high-intensity use exposure scenarios. The durations of skin contact used in the 3855 high-, medium-, and low-intensity use scenarios were 120, 60, and 30 minutes respectively 3856 (Section 2.3.4 in U.S. EPA (2025c)). The contact area for the high-intensity use scenario corresponded to the inside of two hands (including palms and fingers), and the medium-intensity 3857 use scenario used the inside of one hand (Section 2.3.4 in U.S. EPA (2025c)). For the metal 3858

3859coatings COU, the MOEs for the acute, dermal, high-intensity scenario were 7, 8, and 73860respectively for young teen, teenage, and adult. For the dermal medium-intensity use exposure3861scenario, the MOEs were 28, 31, and 29.

The MOEs for the chronic, high-intensity, inhalation scenario were 26 and 28 for the infant and toddler 3863 3864 lifestages (assessed as bystanders which is a non-user of the product that is in the vicinity). The duration of use per event is the same as the duration of dermal contact for high-, medium-, and low-intensity used 3865 3866 exposure scenarios, 120, 60, and 30 minutes. For chronic exposures EPA assumed weekly uses during a 3867 year which is 52 events in one year of exposure. The preschoolers and middle childhood children MOE 3868 values were above 30. The differences between infants and toddlers with preschoolers and middle childhood is the inhalation rates and body weights ratio. The same exposure concentration is inhaled at a 3869 3870 faster rate for the younger lifestages while in a smaller body weight resulting in higher doses and lower 3871 MOEs.

3872

3885

3862

3873 For all three product scenarios assessed for this COU, the acute dermal pathway resulted in MOEs less 3874 than the benchmark of 30 in both the high and medium-intensity use scenarios for young teens, 3875 teenagers, and adults. For dermal exposure, EPA used the liquid products dermal flux-limited approach, 3876 which was estimated based on DBP in vitro dermal absorption in guinea pigs. EPA determined an 3877 overall moderate confidence in the dermal assessment for paints and coatings. The Agency assumes an 3878 excess of DBP is in contact with the skin and that the absorptive flux of DBP measured from in vitro 3879 guinea pig experiments serves as an upper-bound of potential absorptive flux of chemical into and 3880 through the skin for dermal contact with all liquid products. Uncertainties about the difference between 3881 human and guinea pig skin absorption increase uncertainty and due to increased permeability of guinea 3882 pig skin as compared to human skin dermal absorption estimates likely overestimate exposures. Other parameters such as frequency and duration of use, and surface area in contact, are well understood and 3883 3884 representative, resulting in a moderate overall confidence.

3886 The overall confidence in this COU's inhalation exposure estimate is robust because the CEM default 3887 parameters represent actual use patterns and location of use. Differences in MOEs between the high, 3888 medium, and low-intensity inhalation exposure scenarios result from use of different exposure 3889 parameters in CEM. Key parameters that differed between high- and medium-intensity scenarios include 3890 weight fraction (*i.e.*, 0.1 vs. 0.04 for metal coatings), product mass used (*i.e.*, 1.427 vs. 713 g for metal 3891 coatings), and inhalation rates used per lifestage. Inhalation rates for lifestages range from 0.74 to 0.46 3892 m^{3}/h for adults to infants respectively, with the largest difference between infants and the next lifestage. 3893 Other CEM exposure factors were kept constant between high- and medium-intensity inhalation 3894 scenarios (e.g., surface layer thickness, volume of use environment, interzone ventilation rate). In these 3895 product inhalation scenarios DBP is released into the gas-phase. The product inhalation scenario tracks 3896 chemical transport among the source, air, airborne and settled particles, and indoor sinks. The approach 3897 accounts for (1) emissions, (2) mixing within the gas phase, (3) transfer to particulates by partitioning, 3898 (4) removal due to ventilation, (5) removal due to cleaning of settled particulates and dust to which DBP 3899 has partitioned, and (6i) sorption or desorption to/from interior surfaces. The emissions from the product 3900 were modeled with a single exponential decay model. This means that chronic and acute exposure 3901 duration scenarios use the same emissions/air concentration data based on the weight fraction but have 3902 different averaging times for the air concentration used. The acute data uses concentrations for a 24-hour 3903 period at the peak, while the chronic data was averaged over the entire 1-year period. Because air 3904 concentrations for most of the year are significantly lower than the peak value, the air concentration 3905 used in chronic dose calculations is lower than acute. The overall confidence in this COU's inhalation 3906 and dust ingestion exposure estimates are robust because the CEM default parameters represent actual

use patterns and location of use (see Section 2.2.3.2 in U.S. EPA (<u>2025c</u>)), and the estimated surface
 area is well characterized and represents a wide range of plausible uses.

3909

3910 Aggregate risk estimates across all evaluated exposure routes (*i.e.*, dermal and inhalation) to DBP for

3911 metal coatings was also considered. The chronic high-intensity use aggregate exposure scenario MOE

for young teens to adults was below 30. The dermal and ingestion exposures contributed equally to the

- aggregated MOE values. The MOE values were 49, 54, and 51 for young teens, teenagers, and adults
 respectively for dermal exposure while the MOE values were 51, 62, and 75 for young teens, teenagers,
- and adults respectively for inhalation exposure. The aggregated MOEs for young teens, teenagers, and
- 3916 adults were 25, 29, and 30, respectively.
- 3917

3918 Furnishing, Cleaning, Treatment Care Products: Cleaning and Furnishing Care Products

3919 This section summarizes the risk estimates, MOEs, below the benchmark of 30 for the titled COU. Two 3920 different scenarios were assessed under this COU for two product types with differing use patterns: 3921 Spray cleaner and waxes and polishes. Both scenarios were assessed for dermal and inhalation 3922 exposures, but only the acute dermal high-intensity use scenario resulted in MOEs below the benchmark 3923 of 30 for the assessed lifestages: young teens and adults for the spray cleaner, and young teens, 3924 teenagers, and adults for the polishes and waxes. The acute dermal high-intensity use MOE values for 3925 spray cleaner were 28 and 29 for young teens and adults respectively, and the medium-intensity use scenario MOE values were 110 and 120 for young teens and adults respectively. The acute dermal high-3926 3927 intensity use MOE values for polishes and waxes were 14, 15, and 14 for young teens, teenagers, and 3928 adults respectively, and the dermal medium-intensity use scenario MOE values were 56, 62, and 58 for young teens, teenagers, and adults respectively. 3929

3930

Two cleaning and furnishing care products with DBP content were identified from a 2012 study on U.S. consumer products (Dodson et al., 2012). Due to the different format and application, these items were modeled separately. One spray cleaning product used for tub and tile cleaning was identified with reported DBP content. One polish/wax used for floors and furniture was identified with reported DBP content. EPA has a moderate confidence in using these products to generally represent this COU due to the age of the study (10+ years), and that it was only one source.

3930 3937

3938 Kev parameters for the dermal model include duration of dermal contact, frequency of dermal contact, 3939 total contact area, and dermal flux. An increase in any of these parameters results in an increase in 3940 exposure. For liquid and paste products, it was assumed that contact with the product occurs at the 3941 beginning of the period of use and the product is not washed off the skin until use is complete. As such, 3942 the duration of dermal contact for these products is equal to the duration of use applied in CEM 3943 modeling for products assessed for inhalation. The skin contact duration for spray cleaner for the high-3944 and medium-intensity use scenarios were 30 and 15 minutes respectively, and for waxes and polishes 60 3945 and 30 minutes (Section 2.3.4 in U.S. EPA (2025c)). EPA has a robust confidence in the input 3946 parameters used for skin contact duration.

3947

For contact area EPA used professional judgment based on product use descriptions from manufacturers. For spray cleaners and polishes and waxes, EPA assumed that these items would be in contact with the skin on the inside of two hands (palms, fingers) for the high-intensity use scenario, and the inside of one hand for the medium-intensity use scenario. EPA has robust confidence in the input parameters used for skin contact surface area.

3953

EPA used a screening dermal flux-limited approach, which was estimated based on DBP *in vitro* dermal
 absorption in guinea pigs. Though there is uncertainty regarding the magnitude of the difference

3956 between dermal absorption through guinea pigs' skin versus human skin for DBP, based on DBP 3957 physical and chemical properties (size, solubility), EPA is confident that the *in vitro* dermal absorption data using guinea pigs for (Doan et al., 2010) provides an upper-bound of dermal absorption of DBP. 3958 3959 Dermal contact with products or formulations that have low concentrations of DBP may exhibit lower 3960 rates of flux since there is less material available for absorption. Conversely, co-formulants or materials 3961 within the products or formulations may lead to enhanced dermal absorption, even at lower 3962 concentrations. Therefore, it is uncertain whether the dermal exposure to products or formulations 3963 containing DBP would result in decreased or increased dermal absorption.

3964

Based on the available dermal absorption data for DBP, EPA has made assumptions that result in
exposure assessments that are the most conservative representing upper-bound estimates. Considering
the unknown uncertainties from the flux-limited approach and input parameters such as frequency and
duration of use, and area of skin in contact, are well understood and representative, the overall
confidence in dermal exposure estimates for liquid and paste products is moderate.

3970

3971 Packaging, Paper, Plastic, Hobby Products; Toys, Playground, and Sporting Equipment

3972 This section summarizes the risk estimates, MOEs, below the benchmark of 30 for the titled COU. Four 3973 different scenarios were assessed under this COU for various articles with differing use patterns: legacy 3974 children's toys, new children's toys, tire crumb and artificial turf, and a variety of PVC articles with 3975 potential for routine contact. Children's toy scenarios were included in the indoor assessment for all 3976 exposure routes (inhalation, dust ingestion, mouthing, and dermal) with varying use patterns and inputs. 3977 Tire crumb was also part of the indoor assessment for all exposure routes except mouthing. Articles of 3978 routine contact were only assessed for dermal exposures since they are too small to result in impactful 3979 inhalation or ingestion exposures. Aggregate risk estimates for DBP exposure across all evaluated 3980 exposure routes for legacy children's toys were the only scenario within this COU with an MOE below 3981 the benchmark of 30. The acute, high-intensity use aggregate exposure scenario MOE for legacy toys 3982 was 23 for the infants. The high-intensity use scenario dermal, ingestion, and inhalation MOEs were 3983 112, 51, and 69, respectively. The ingestion and inhalation MOEs are the primary contributors to the 3984 aggregated MOE value of 23. 3985

3986 Children's toys were assessed for DBP exposure by inhalation, dust ingestion, dermal and mouthing 3987 routes. Under the Consumer Product Safety Improvement Act (CPSIA) of 2008 (CPSIA section 108(a), 3988 15 U.S.C. § 2057c(a);16 CFR § 1307.3(a)), Congress permanently prohibited the sale of children's toys or childcare articles containing concentrations of more than 0.1 percent DBP. However, it is possible 3989 3990 that some individuals may still have children's toys in the home that were produced before statutory and 3991 regulatory limitations. A relatively recent survey, 2020, by the Danish EPA of PVC products purchased 3992 from foreign online retailers found that DBP content in a toy bath duck of 1.7 percent exceeded the 3993 current Danish regulatory limit of 0.1 percent DBP (Danish EPA, 2020). In the U.S. market, the High 3994 Priority Chemicals Data System (HPCDS) database contained data for DBP measurements in 96 3995 toy/game items with reporting dates from 2017 to 2024. While there is some uncertainty about the 3996 materials these items are manufactured from, based on the limited descriptions in the database, EPA 3997 determined that these items are likely composed primarily of plastic and rubber components. For 3998 example, some of the descriptions provided for toys were dolls, puppets, action figures, board games, 3999 toy vehicles, soft toys, toy soldiers, glow in the dark plastic bugs, waterproof pouches, pink plastic 4000 recorder, and yellow bendy man. One item with DBP content over the statutory and regulatory limit of 4001 0.1 percent was listed as a non-ride toy vehicle (WSDE, 2020).

4002

4003 EPA assessed exposure to DBP in children's toys under two scenarios. In the first exposure scenario, 4004 new toys produced for the U.S. market are assumed to comply with statutory and regulatory limits and

were therefore assessed with DBP weight fractions of 0.001 w/w in low, medium, and high exposure scenarios. In the second scenario, legacy toys are assessed with weight fractions reported in the HPCDS database, (<u>WSDE, 2020</u>), that are above the statutory and regulatory limit of 0.001 w/w. Based on the reported data, the weight fractions of DBP used in low, medium, and high-intensity use exposure scenarios were 0.005 w/w, 0.0075 w/w, and 0.01 w/w. One new toy in the HPCDS database tested 8 or more years after the CPSIA had components with DBP content above (1 order of magnitude above) the statutory and regulatory limit of 0.01 percent (<u>WSDE, 2020</u>).

4012

4013 Children's toys generally have a small surface area for an individual item, but consumers may have 4014 many of the same type of item in a home. As phthalates are ubiquitous in PVC materials, it is reasonable 4015 to assume that in a collection of toys all of the items may have DBP content. As such, surface area for 4016 these items was estimated by assuming that a home has several of these items rather than one. The 4017 surface area of new and legacy toys was varied for the low-, medium-, and high-intensity use exposure 4018 scenarios based on EPA's professional judgment of the number and size of toys present in a bedroom. 4019 The low intensity use scenario was based on 5 small toys measuring 15 cm \times 10 cm \times 5 cm, the medium-intensity use scenario was based on 20 medium toys measuring $20 \text{ cm} \times 15 \text{ cm} \times 8 \text{ cm}$, and the 4020 4021 high-intensity use scenario was based on 30 large toys measuring 30 cm \times 25 cm \times 15 cm. EPA used the 4022 stay-at-home 20 hour exposure duration and bedroom for location of articles CEM inputs for inhalation 4023 and dust ingestion exposure estimates. The overall confidence in this COU's inhalation and dust 4024 ingestion exposure estimate is robust because of a good understanding of the CEM model parameter 4025 inputs and representativeness of actual use patterns and location of use.

4026

4027 For mouthing exposure, key parameters include the rate of chemical migration from the article to saliva 4028 $(\mu g/cm^2/h)$, surface area mouthed (cm²), and duration of mouthing (min/day). The mouthing parameters 4029 used, such as duration of use (39.2 min/day EPA Exposure Factors Handbook Table 4-23 (U.S. EPA, 4030 2011a)) and surface area for infants (standardized value of 10 cm² (Danish EPA, 2010; Niino et al., 4031 2003; Niino et al., 2001)) are very well understood. The chemical migration value is DBP specific, 4032 empirically derived, and the main sources of uncertainty are related to a large variability in empirical 4033 migration rate data for harsh, medium, and mild mouthing approaches. Additionally, there are 4034 uncertainties from the unknown correlation between chemical concentration in articles and chemical 4035 migration rates, and no data were reasonably available to compare and confirm selected rate parameters 4036 to better understand uncertainties.

4037

4038 Infants skin contact duration for the high-intensity use scenario was 137 minutes and the skin contact 4039 area was inside of two hands including palms and fingers (Section 2.3.4 in U.S. EPA (2025c)). Dermal 4040 absorption estimates are based on the assumption that dermal absorption of DBP from solid objects will 4041 be limited by aqueous solubility of DBP. EPA has moderate confidence for solid objects because the 4042 high uncertainty in the assumption of partitioning from solid to liquid and subsequent dermal absorption 4043 is not well characterized. Additionally, there are uncertainties associated to the flux-limited approach 4044 which likely results in overestimations due to the assumption about excess DBP in contact with skin. Other parameters like frequency and duration of use, and surface area in contact have unknown 4045 4046 uncertainties due to lack of information about use patterns, making the overall confidence of moderate. 4047

4048 Indoor Dust

4049 Exposure to DBP via ingestion of dust was assessed for all articles expected to contribute significantly 4050 to dust concentrations. The articles are included in the indoor assessment due to high surface area 4051 (exceeding $\sim 1 \text{ m}^2$) for either a single article or collection of like articles as appropriate. Articles included 4052 in the indoor assessment include in-place wallpaper, vinyl flooring, synthetic leather furniture, car mats, 4053 shower curtains, tire crumb, and children's toys (legacy and new). In a screening assessment for indoor

- 4054 dust ingestion, EPA considered the aggregation of chronic dust ingestion doses (Section 4.1.2.3).
- 4055 However, the indoor assessment was further refined to only consider articles assumed to be present in 4056 residential indoor environments because of the use of the stay-at-home CEM inputs would result in
- 4050 residential indoor environments because of the use of the stay-at-nome CEW inputs would result in 4057 greater exposures than other non-residential environment options. Articles considered in this indoor
- 4058 assessment include synthetic leather furniture, vinyl flooring, in-place wallpaper, shower curtains, and
- 4059 children's toys (new and legacy). Car mats and tire crumb were considered not to be continuously
- 4060 available in residential indoor environments, as car mats are present in vehicles, and tire crumb is
- 4061 present in gyms and outdoor recreational areas. The highest refined aggregated dose from indoor chronic 4062 ingestion of settled dust was for preschoolers, aged 3 to 5 years and resulted in an MOE of 7,500. See
- 4063 Draft Consumer Risk Calculator for Dibutyl Phthalate (DBP) (U.S. EPA, 2025e). All other doses were
- 4064 lower and would have resulted in even larger MOEs.

4065 **4.3.3.1 Overall Confidence in Consumer Risks**

4066 As described in Section 4.1.2 and in more detail in the *Draft Consumer and Indoor Exposure*

4067 Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025c), EPA has moderate and robust confidence

- 4068 in the assessed inhalation, ingestion, and dermal consumer exposure scenarios, and robust confidence in
- 4069 the non-cancer POD selected to characterize risk from acute, intermediate, and chronic duration
- 4070 exposures to DBP (see Section 4.2 and (<u>U.S. EPA, 2024f</u>)). The exposure doses used to estimate risk 4071 relied on conservative inputs and parameters that are considered representative of a wide selection of use
- 4071 patterns. Overall, EPA has moderate to robust confidence in the risk estimates calculated for consumers
- 4073 inhalation, ingestion, and dermal exposure scenarios. Sources of uncertainty associated with the ten
- 4074 consumer COUs with MOEs less than 30 are discussed above in Section 4.3.3.

4075 **Table 4-19. Consumer Risk Summary Table**

Life Crale Sterry COUL			E	Exposure				Lifestage (year Benchmark M			
Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Scenario (H, M, L) ^{<i>a</i>}	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
Consumer Uses: Automotive, fuel, agriculture, outdoor use products: Automotive care products				Uses were	e matched	l with auto	omotive adhes	ives.			
				Н	_	_	_	_	7	8	7
			Dermal	М	_	_	_	—	28	31	29
				L	_	_	_	_	140	150	140
		Acute	Ingestion	—	_	_	_	—	_	_	_
		Acute	Inhalation	Н	160 ^b	170 ^b	210 ^b	300 ^b	370	440	540
	Automotive			Н	_	-	_	-	7	8	7
	adhesives		Aggregate	М	_	-	_	-	28	31	29
				L	_	-	_	-	140	150	140
			Dermal	Н	_	-	_	-	210	230	220
		Intermed.	Ingestion	-	_	-	_	-	-	_	<u> </u>
			Inhalation	Н	4,800 ^b	5,100 ^b	6,200 ^b	9,000 ^b	1.1E04	1.3E04	1.6E04
			Aggregate	Н	_	-	_	_	210	230	210
		Chronic	_	_	_	-	_	_	_	_	_
Consumer Uses: Construction, paint,				Н	_	-	_	_	7	8	7
electrical, and metal products: Adhesives and sealants			Dermal	М	_	-	_	_	28	31	29
Adhesives and searants		Acute		L	_	-	_	_	140	150	140
			Ingestion	_	_	-	_	_	_	-	_
	Construction		Inhalation	-	_	_	_	_	_	_	_
	adhesives		Dermal	Н	_	_	_	_	210	230	220
		Intermed.	Ingestion	_	_	-	_	_	_	—	_
			Inhalation	-	_	_	_	_	_	_	_
		Chronic	_	_	_	_	_	_	_	_	—
			Dermal	Н	_	_	_	_	70	77	72
		Acute	Ingestion	_	_	-	-	_	_	_	<u> </u>
			Inhalation	1_	_	<u> </u>	_	 _	 _	_	<u> </u>
	Adhesives for small	Intermed.	_	 _	_	_	_	_	-	_	1_
	repairs		Dermal	Н	_	1_	_	_	490	540	510
		Chronic	Ingestion	_	_	_	_	_	_	_	<u> </u> _
		-	Inhalation	<u> _</u>	 _	1_	_	_		_	<u> </u>

Life Cycle Stage: COU:			Exposure	Exposure				Lifestage (year Benchmark M			
Subcategory	Product or Article	Duration	Route	Scenario (H, M, L) ^{<i>a</i>}	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
				Н	_	_	_	_	7	8	7
			Dermal	М	_	-	-	_	28	31	29
				L	-	-	_	_	140	150	140
		Acute	Ingestion	_	_	-	-	-	_	-	-
		Acute	Inhalation	Н	72 ^b	76 ^b	94 ^b	130 ^b	130	160	190
				Н	_	-	-	-	7	7	7
			Aggregate	М	_	_	-	_	24	26	26
	Metal coatings			L	_	-	—	_	89	100	100
		Intermed.	-	_	_	-	_	_	_	-	_
			Dermal	Н	_	_	—	_	49	54	51
			Ingestion	_	_	-	_	_	_	-	_
		Character	T 1 1	Н	26 ^b	28 ^b	34 ^b	49 ^b	51	62	75
		Chronic	Inhalation	М	130 ^b	140 ^b	170 ^b	250 ^b	290	340	420
				Н	_	_	_	_	25	29	30
			Aggregate	М	_	_	_	_	120	130	140
Consumer Uses: Construction, paint,			Dermal	Н	_	_	-	_	16	17	16
electrical, and metal products: Paints				М	_	_	_	_	23	26	24
and coatings				L	_	_	_	_	47	51	48
		Acute	Ingestion	_	_	_	_	_	_	_	_
		Acute	Inhalation	Н	100 ^b	110 ^b	140 ^b	190 ^b	260	300	380
	Indoor flooring			Н	-	-	_	_	15	16	15
	sealing and		Aggregate	М	-	-	_	_	22	24	23
	refinishing products			L	_	-	-	-	45	49	46
			Dermal	Н	_	-	-	-	470	510	480
		Intermod	Ingestion	_	_	_	_	_	_	_	_
		Intermed.	Inhalation	Н	3,100 ^b	3,300 ^b	4,100 ^b	5,800 ^b	7,800	9,100	1.1E04
			Aggregate	Н	_	-	_	_	440	490	460
		Chronic	-	_	_	-	_	_	_	-	_
				Н	_	_	_	_	9	10	9
			Dermal	М	_	-	-	_	18	19	18
	G 1. 1			L	_	-	-	_	35	39	36
	Sealing and refinishing sprays	Acute	Ingestion	_	_	-	-	_	_	_	-
	(outdoor use)		Inhalation	Н	92 ^b	98 ^b	120 ^b	150 ^b	49	66	73
	(Н	_	-	-	_	8	8	8
			Aggregate	М	_	—	_	_	15	16	16

Life Cycle Stage: COU:			Evnoguno	Exposure Exposure				Lifestage (year Benchmark M			
Subcategory	Product or Article	Duration	Route	Scenario (H, M, L) ^{<i>a</i>}	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
				L	_	_	_	_	35	38	36
			Dermal	Н	_	_	_	_	260	290	270
Consumer Uses: Construction, paint, electrical, and metal products: Paints	Sealing and refinishing sprays	Intermed.	Ingestion	-	_	_	_	_	_	_	_
and coatings	(outdoor use)	miermeu.	Inhalation	Н	2,800 ^b	2,900 ^b	3,600 ^b	4,500 ^b	1,500	2,000	2,200
	(outdoor use)		Aggregate	Н	_	_	_	—	220	250	240
		Chronic	-	-	_	_	_	-	_	-	_
			Damaal	Н	_	_	—	_	_	d	d
		A	Dermal	М	_	_	_	-	-	76	72
		Acute	Ingestion	_	_	_	_	-	_	_	_
Consumer Uses: Furnishing,	0 4 4 1 4		Inhalation	-	_	-	_	_	_	_	_
cleaning, treatment care products:	Synthetic leather clothing	Intermed.	_	-	_	_	_	-	-	_	_
Fabric, textile, and leather products	ciotining		Dama al	Н	_	-	_	_	_	d	d
		CI .	Dermal	М	_	_	_	_	_	540	510
		Chronic	Ingestion	-	_	-	_	_	_	_	_
			Inhalation	-	_	_	_	_	_	_	_
			Dermal	Н	_ d	d	d	d	d	$-^d$	d
				М	d	_ <i>d</i>	41	54	69	76	72
				L	_ <i>d</i>	140	160	200	250	280	260
				Н	83	140	220	2.3E06	4.1E06	5.2E06	12E06
			Ingestion c	М	280	380	670	2.3E07	4.1E07	5.2E07	1.2E08
			-	L	1.1E05	7.6E04	1.4E05	3.4E07	6.1E07	7.7E07	1.7E08
		Acute		Н	5.7E04	6.0E04	7.4E04	1.1E05	1.5E05	1.8E05	2.2E05
			Inhalation ^c	М	5.8E05	6.1E05	7.5E05	1.1E06	1.5E06	1.8E06	2.2E06
				L	8.8E05	9.3E05	1.1E06	1.6E06	2.3E06	2.7E06	3.4E06
Consumer Uses: Furnishing,	Synthetic leather			Н	83	140	220	1E05	1.5E05	1.7E05	2.1E05
cleaning, treatment care products: Fabric, textile, and leather products	furniture		Aggregate	М	280	380	39	54	69	76	72
a abrie, textile, and leather products				L	9.7E04	140	160	200	250	280	260
		Intermed.	_	_	_	_	_	_	_	_	_
				Н	d	_ d	d	d	d	d	d
			Dermal	М	d	_ d	41	54	69	76	72
				L	d	140	160	200	250	280	260
		Chronic		Н	83	140	220	2.5E06	4.5E06	5.7E06	1.3E07
			Ingestion c	М	280	380	670	2.5E07	4.5E07	5.7E07	1.3E08
				L	1.1E05	7.6E04	1.4E05	3.7E07	6.7E07	8.4E07	1.9E08
			Inhalation ^c	Н	5.9E04	6.3E04	7.7E04	1.1E05	1.6E05	1.8E05	2.3E05

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^{<i>a</i>}	Lifestage (years) MOE (Benchmark MOE = 30)							
					Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)	
Consumer Uses: Furnishing,	Synthetic leather furniture			М	6.0E05	6.4E05	7.9E05	1.1E06	1.6E06	1.9E06	2.3E06	
				L	9.2E05	9.7E05	1.2E06	1.7E06	2.4E06	2.8E06	3.5E06	
cleaning, treatment care products:			Aggregate	Н	83		220	1.1E05	1.5E05	1.8E05	2.2E05	
Fabric, textile, and leather products				М	280	380	39	54	69	76	72	
				L	120	140	160	200	250	280	260	
		Acute	Dermal	Н	240	280	320	400	510	550	520	
			Ingestion c	Н	2.4E04	1.9E04	1.7E04	4.8E04	8.6E04	1.1E05	2.4E05	
			Inhalation ^c	Н	800	850	1,000	1,500	2,100	2,500	3,100	
			Aggregate	Н	180	210	240	310	410	450	440	
		Intermed.	_	_	-	_	_	_	_	_	_	
		Chronic	Dermal	Н	240	280	320	400	510	550	520	
			Ingestion ^c	Н	7.9E04		5.7E04	1.6E05	2.9E05	3.6E05	8.1E05	
			Inhalation ^c	Н	3,800		4,900	7,100	1.0E04	1.2E04	1.5E04	
Consumer uses: Furnishing, cleaning,			Aggregate	Н	220	260	300	380	480	530	500	
treatment care products: Floor coverings; construction and building	Wallpaper (in– place)	Acute	Dermal	Н	120	140	160	200	250	280	_	
materials covering large surface areas			Ingestion ^c	Н	1.0E05	8.3E04	7.3E04	2.1E05	3.7E05	4.7E05	1.0E06	
including stone, plaster, cement,			Inhalation ^c	Н	3,500	3,700	4,500	6,500	9.2E3	1.1E04	1.3E04	
glass and ceramic articles; fabrics, textiles, and apparel			Aggregate	Н	120	130	160	190	250	270	1.3E04	
		Chronic	Dermal	Н	120	140	160	200	250	280	9.5E04	
			Ingestion c	Н	3.4E05	2.8E05	2.5E05	7.0E05	1.3E06	1.6E06	3.5E06	
			Inhalation ^c	Н	1.6E04	1.7E04	2.1E04	3.1E04	4.3E04	5.1E04	6.3E04	
			Aggregate	Н	120	140	160	200	250	280	3.8E04	
	Wallpaper (installation)	Acute	Dermal	Н	_	_	_	_	130	140	130	
			Ingestion	-	_	_	_	_	_	-	_	
			Inhalation	_	_	_	—	_		_	_	

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Lifestage (years) MOE (Benchmark MOE = 30)						
					Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
	Spray cleaner		Dermal	Н	_	-	_	_	28	31	29
				М	_	-	_	_	110	120	120
			Ingestion	-	_	-	_		_	-	-
Consumer uses: Furnishing, cleaning, treatment care products: Cleaning and furnishing care products			Inhalation	Н	6.7E04	7.1E04 ^b	8.7E04 ^b	1.3E05 ^b	3.7E04	4.8E04	5.5E04
				М	1.4E05 ^b	1.5E05 b	1.8E05 ^b	2.7E05 ^b	7.7E04	9.6E04	1.1E05
			Aggregate	Н	6.7E04	7.1E04	8.7E04	1.3E05	28	31	29
				М	1.4E05	1.5E05	1.8E05	2.7E05	110	120	120
		Chronic	Dermal	Н	_	_	_	_	200	220	200
			Ingestion	-	_	_	_	_	_	_	_
			Inhalation	Н	1.2E05 ^b	1.2E05 ^b	1.5E05 ^b	2.2E05 ^b	1.3E05	1.7E05	2.0E05
			Aggregate	Н	1.2E05	1.2E05	1.5E05	2.2E05	200	220	200
	Waxes and polishes	Acute	Dermal	Н	_	_	_	_	14	15	14
				М	_	_	_		56	62	58
			Ingestion	_	_	_	_	_	_	_	_
			Inhalation	Н	1.0E05 ^b	1.1E05 ^b	1.3E05 ^b	1.9E05 ^b	2.6E05	3.0E05	3.7E05
			Aggregate	Н	1.0E05	1.1E05	1.3E05	1.9E05	14	15	14
				М	1.6E05	1.7E05	2.0E05	2.9E05	56	62	58
		Chronic	Dermal	Н	_	_	_		99	110	100
			Ingestion	_	_	_	_	_	_	-	_
			Inhalation	Н	8,500 ^b	9,100 ^{<i>b</i>}	1.1E04 ^b	1.6E04 ^b	2.0E04	2.4E04	2.9E04
			Aggregate	Н	8,500	9,100	1.1E04	1.6E04	98	110	100
Consumer uses: Packaging, paper, plastic, toys, hobby products: Ink, toner, and colorant products	No consumer pr	oducts identi	ified. Foreseea	able uses were	matched	with adhe	sives for smal	l repairs becau	se similar use pa	itterns are exp	ected.

Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Lifestage (years) MOE (Benchmark MOE = 30)						
					Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
Consumer uses: Packaging, paper, plastic, toys, hobby products; Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles	Footwear components		Dermal	Н	60	70	81	100	130	140	130
			Ingestion	_	_	_	—	_	_		_
			Inhalation	_	_	_	—	_	_		_
			Dermal	Н	60	70	81	100	130	140	130
			Ingestion	-	-	_	-	_	_	_	_
			Inhalation	_	-	-	_	_	_	_	_
	Shower curtains	Acute	Dermal	Н	340		460		720	780	730
			Ingestion c	Н	1.1E06	9.0E05	8.0E05	2.3E06	4.1E06	5.1E06	1.1E07
			Inhalation ^c	Н	1.4E04	1.5E04	1.8E04			4.3E04	5.3E04
			Aggregate	Н	330		450		700	770	720
		Chronic	Dermal	Н	340		460	570	720	780	730
			Ingestion c	Н	3.7E06		2.6E06	7.5E06	1.3E07	1.7E07	3.8E07
(soft); other articles with routine			Inhalation ^c	Н	6.6E04		8.6E04	1.2E05	1.7E05	2.0E05	2.5E05
direct contact during normal use,			Aggregate	Н	340		450		710	780	730
including rubber articles; plastic	Small articles with semi routine contact; miscellaneous items	Acute	Dermal	Н	120	140	160	200	250	280	260
articles (hard)			Ingestion	—	_	-	—	_	_	_	-
			Inhalation	_	_	_	_	_	_	_	_
	including a pen, pencil case, hobby cutting board, costume jewelry, tape, garden hose, disposable gloves, and plastic bags/pouches		Dermal	Н	120	140	160	200	250	280	260
			Ingestion	_	_	_	_	_	_	_	_
			Inhalation	_	-	-	_	_	_		

		Duration	E	Exposure	Lifestage (years) MOE (Benchmark MOE = 30)							
Life Cycle Stage: COU: Subcategory	Product or Article		Exposure Route	Scenario (H, M, L) ^{<i>a</i>}	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)	
			Dermal	Н	110	130	150	190	240	260	_	
		Acute	Ingestion c	Н	52	200	380	8.5E04	1.5E05	1.9E05	4.3E05	
		Acute	Inhalation ^c	Н	690	740	900	1,300	1,800	2,200	2,700	
	Children's toys		Aggregate	Н	34	71	97	160	210	230	2,700	
	(New)		Dermal	Н	110	130	150	190	240	260	_	
		Chronic	Ingestion c	Н	52	200	390	2.8E05	5.1E05	6.4E05	1.4E06	
		Chronic	Inhalation ^c	Н	3,300	3,500	4,300	6,200	8,800	1.0E04	1.3E04	
			Aggregate	Н	35	77	110	180	230	250	1.3E04	
			Dermal	Н	110	130	150	190	240	260	_	
			Ingestion c	Н	51	190	340	8,500	1.5E04	1.9E04	4.3E04	
	Children's toys (legacy)	Acute	Inhalation ^c	Н	69	74	90	130	180	220	270	
			Aggregate	Н	23	38	49	76	100	120	270	
			Aggregate	М	64	91	120	180	230	250	1,400	
	(legacy)	Chronic	Dermal	Н	110	130	150	190	240	260	_	
			Ingestion c	Н	52	190	370	2.8E04	5.1E04	6.4E04	1.4E05	
Consumer uses: Packaging, paper, plastic, toys, hobby products: Toys,		Chronic	Inhalation ^c	Н	330	350	430	620	880	1,000	1,300	
playground, and sporting equipment			Aggregate	Н	32	64	86	140	190	210	1,300	
programme, and sporting equipment		Acute	Dermal	Н	_	_	1.1E06	1.2E06	1.6E06	1.8E06	1.7E06	
			Ingestion	Н	_	_	3.4E08	7.7E08	1.4E09	3.5E09	3.9E09	
			Inhalation	Н	_	_	2.5E08	3.7E08	1.9E08	3.6E08	3.9E08	
	T:		Aggregate	Н	_	-	1.1E06	1.2E06	1.5E06	1.8E06	1.7E06	
	Tire crumb		Dermal	Н	_	_	5.4E06	5.7E06	4.1E06	4.7E06	8.0E06	
		Character	Ingestion	Н	_	_	1.6E09	3.6E09	3.6E09	9.1E09	1.8E10	
		Chronic	Inhalation	Н	_	-	1.2E09	1.7E09	5.0E08	9.5E08	1.8E09	
			Aggregate	Н	_	_	5.3E06	5.7E06	4.1E06	4.6E06	8.0E06	
	Small articles with		Dermal	Н	120	140	160	200	250	280	260	
	semi routine	Acute	Ingestion				_	_	_	_		
	contact;		Inhalation				_	_	_	_		
	miscellaneous items including a football,		Dermal	Н	120	140	160	200	250	280	260	
	balance ball, and	Chronic	Ingestion	_	_	_	_			_	_	
	pet toys	Chronic	Inhalation	_	_	_	_		_	_	_	

Life Cycle Stage: COU:			Exposure	Exposure		Lifestage (years) MOE (Benchmark MOE = 30)							
Subcategory	Product or Article	Duration	Route	Scenario (H, M, L) ^{<i>a</i>}	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)		
			Dermal	Н	120	140	160	200	250	280	260		
		Acute	Ingestion	_	_	_	_	_	_	_	_		
Consumer uses: Other v:	Small articles with semi routine		Inhalation	_	-	_	-	_	_	-	_		
Chemiluminescent light sticks	contact; glow sticks		Dermal	Н	120	140	160	200	250	280	260		
	eoniaet, giow stiens	Chronic	Ingestion	_	_	_	-	-	-	-	_		
			Inhalation	_	_	-	_	_	_	_	_		
			Dermal	Н	_	_	_	_	1,800	2,000	1,800		
		A outo	Ingestion c	Н	3.8E06	3.1E06	2.8E06	7.7E06	1.3E07	1.7E07	3.4E07		
		Acute	Inhalation ^c	Н	6.1E04	6.5E04	7.9E04	1.1E05	1.6E05	1.9E05	2.4E05		
	Commente		Aggregate	Н	6.0E04	6.3E04	7.7E04	1.1E05	1,800	1,900	1,800		
	Car mats	Chronic	Dermal	Н	_	_	_	_	1.3E04	1.4E04	1.3E04		
			Ingestion c	Н	1.3E07	1.1E07	9.5E06	2.6E07	4.5E07	5.7E07	1.2E08		
			Inhalation c	Н	3.0E05	3.1E05	3.9E05	5.6E05	7.9E05	9.2E05	1.1E06		
			Aggregate	Н	2.9E05	3.1E05	3.7E05	5.4E05	1.2E04	1.4E04	1.3E04		
				Н	d	d	d	d	d	d	d		
			Dermal	М	d	d	41	54	69	76	72		
		Acute		L	d	140	160	200	250	280	260		
				Н	83	140	220	2.3E06	4.1E06	5.2E06	1.2E07		
			Ingestion ^c	М	280	380	670	2.3E07	4.1E07	5.2E07	1.2E08		
Consumer uses: Other uses:				L	1.1E05	7.6E04	1.4E05	3.4E07	6.1E07	7.7E07	1.7E08		
Automotive articles			Inhalation ^c	Н	5.7E04	6.0E04	7.4E04	1.1E05	1.5E05	1.8E05	2.2E05		
				М	5.8E05	6.1E05	7.5E05	1.1E06	1.5E06	1.8E06	2.2E06		
				L	8.8E05	9.3E05	1.1E06	1.6E06	2.3E06	2.7E06	3.4E06		
	Synthetic leather			Н	83	140	220	1.0E05	1.5E05	1.7E05	2.1E05		
	seats (see synthetic		Aggregate	М	280	380	39	54	69	76	72		
	leather furniture)			L	9.7E04	140	160	200	250	280	260		
				Н	d	d	d	d	d	d	d		
		Chronic	Dermal	М	d	d	41	54	69	76	72		
				L	d	140	160	200	250	280	260		
				Н	83	140	220	2.5E06	4.5E06	5.7E06	1.3E07		
			Ingestion ^c	М	280	380	670	2.5E07	4.5E07	5.7E07	1.3E08		
				L	1.1E05	7.6E04	1.4E05	3.7E07	6.7E07	8.4E07	1.9E08		
				Н	5.9E04	6.3E04	7.7E04	1.1E05	1.6E05	1.8E05	2.3E05		
		Chronic	Inhalation ^c	М	6.0E05	6.4E05	7.9E05	1.1E06	1.6E06	1.9E06	2.3E06		
				L	9.2E05	9.7E05	1.2E06	1.7E06	2.4E06	2.8E06	3.5E06		

Life Cuele Stages COU		Duration	Exposure Route	Exposure		Lifestage (years) MOE (Benchmark MOE = 30)							
Life Cycle Stage: COU: Subcategory	Product or Article			Scenario (H, M, L) ^{<i>a</i>}	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)		
				Н	83	140	220	1.1E05	1.5E05	1.8E05	2.2E05		
			Aggregate	М	280	380	39	54	69	76	72		
				L	120	140	160	200	250	280	260		
				Н	_	_	-	_	—	780	730		
			Dermal	М	_	_	_	_	_	1,100	1,000		
			. .	Н	_	_		_	_	d	_d		
		Acute	Ingestion	М	_	_	_	_	_	190	210		
			Inhalation	_	_	_	_	_	_	_	_		
	Adult toys		Aggregate	Н	_	_	_	_	_	d	d		
Consumer uses: Other uses: Novelty				М	_	_	_	_	_	160	170		
articles			Damaal	Н	_	_	_	_	—	780	730		
			Dermal	М	_	_	_	-	-	1,100	1,000		
			т.,·	Н	_	_	_	_	_	d	d		
			Ingestion	М	_	_	_	-	-	190	210		
			Inhalation	_	_	_	_	-	-	-	_		
			Aggragata	Н	_	_	-	_	_	d	d		
			Aggregate	М	_	_		_	_	160	170		
Consumer uses: Other uses: Lubricants and lubricant additives	No consumer pr	oducts identi	fied. Foresee	able uses were	matched	with adhe	sives for small	ll repairs becau	se similar use pa	atterns are exp	ected.		
 ^a Exposure scenario intensities include ^b MOE for bystander scenario ^c Exposure routes evaluated for indoo ^d Scenario was deemed to be unlikely Bold text in a gray shaded cell indic 	r environments. due to high uncertain	ties.		l.									

4077 4.3.4 Risk Estimates for General Population

4078 As described in the Draft Environmental Media and General Population Screening for Dibutyl 4079 *Phthalate (DBP)* (U.S. EPA, 2025p) and Section 4.1.3, EPA employed a screening level approach for general population exposures for DBP releases associated with TSCA COUs. Fenceline communities 4080 4081 were considered as part of the general population in proximity to releasing facilities as part of the 4082 ambient air exposure assessment by utilizing pre-screening methodology described in EPA's Draft 4083 TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline 4084 Communities (Version 1.0) (U.S. EPA, 2022b). For other exposure pathways, the Agency's screening 4085 method assessing high-end exposure scenarios used release data that reflect exposures expected to occur 4086 in proximity to releasing facilities, which would include fenceline communities.

4087

4088 EPA evaluated surface water, drinking water, fish ingestion, and ambient air pathways quantitatively. 4089 Land pathways (i.e., landfills and application of biosolids) were assessed qualitatively, and were 4090 inclusive of down-the-drain disposal of consumer products and landfill disposal of consumer articles 4091 (see Section 3.1.4 for details on the qualitative assessment of consumer disposal of DBP-containing 4092 products and articles). For pathways assessed quantitatively, high-end estimates of DBP concentration in 4093 the various environmental media were used for screening level purposes. EPA used an MOE approach 4094 using high-end exposure estimates to determine whether an exposure pathway had potential non-cancer 4095 risks. High-end exposure estimates were defined as those associated with the industrial and commercial 4096 releases from a COU and OES that resulted in the highest environmental media concentrations. 4097 Therefore, if there is no risk for an individual identified as having the potential for the highest exposure 4098 associated with a COU for a given pathway of exposure, then that pathway was determined not to be a 4099 pathway of concern and not pursued further. If any pathways were identified as a pathway of concern for 4100 the general population, further exposure assessments for that pathway would be conducted to include 4101 higher tiers of modeling when available and exposure estimates for additional subpopulations and 4102 COUs. Based on the screening level approach described in Section 4.1.3 and the qualitative assessment of landfill and biosolids pathways as described above, exposure to DBP through biosolids, landfills, 4103 4104 surface water, drinking water, fish ingestion, and ambient air were not determined to be pathways of 4105 concern for any COU listed in Table 3-1.

4106

4.3.4.1 Overall Confidence in General Population Risk

4107 As described in Sections 3.3.1.1 and 4.1.3.3 and in more technical detail in the Draft Environmental 4108 Media and General Population and Environmental Exposure for Dibutyl Phthalate (DBP) (U.S. EPA, 4109 2025p), EPA has robust confidence that modeled releases used for the screening level analysis are 4110 appropriately conservative for a screening level analysis. Therefore, EPA has robust confidence that no 4111 exposure scenarios will lead to greater doses than presented in this evaluation. Despite moderate confidence in the estimated values themselves, confidence in exposure estimates capturing high-end 4112 4113 exposure scenarios was robust given the conservative assumptions used for the estimates. Along 4114 with EPA's robust confidence in the non-cancer POD selected to characterize risk from acute, 4115 intermediate, and chronic duration exposures to DBP (see Section 4.2 and (U.S. EPA, 2024f)), EPA has 4116 robust confidence that the risk estimates calculated for the general population were conservative and 4117 appropriate for a screening level analysis.

4118 **4.3.5 Risk Estimates for Potentially Exposed or Susceptible Subpopulations**

EPA considered PESS throughout the exposure assessment and throughout the hazard identification and
 dose-response analysis supporting the draft DBP risk evaluation.

4122	Some population group lifestages may be more susceptible to the health effects of DBP exposure. As
4123	discussed in Section 4.2 and in Section 5.2 of EPA's Draft Non-cancer Human Health Hazard
4124	Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2024f), exposure to DBP leads to adverse effects
4125	on the developing male reproductive system consistent with a disruption of androgen action and
4126	phthalate syndrome in experimental animal models and therefore females of reproductive age, pregnant
4127	women, infants, children and adolescents are considered to be susceptible subpopulations. These
4128	susceptible lifestages were considered throughout the draft risk evaluation. For example, females of
4129	reproductive age were evaluated for occupational exposures to DBP for each COU (Section 4.3.2) and
4130	infants (<1 year), toddlers (1–2 years), and middle school children (6–10 years) were evaluated for
4131	exposure to DBP through consumer products and articles (Section 4.3.3). The non-cancer POD for DBP
4132	selected by EPA for use in risk characterization is based on the most sensitive developmental effect (<i>i.e.</i> ,
4133	reduced fetal testicular testosterone production) observed and is expected to be protective of susceptible
4134	subpopulations. Additionally, EPA used a value of 10 for the $UF_{\rm H}$ to account for human variability. The
4135	Risk Assessment Forum, in A Review of the Reference Dose and Reference Concentration Processes,
4136	discusses some of the evidence for choosing the default factor of 10 when data are lacking—including
4137	toxicokinetic and toxicodynamic factors as well as greater susceptibility of children and elderly
4138	populations (<u>U.S. EPA, 2002b</u>).
4139	populations (<u>0.5. DI II, 20020</u>).
4140	The available data suggest that some groups or lifestages have greater exposure to DBP. This includes
4141	people exposed to DBP at work, those who frequently use consumer products and/or articles containing
4142	high-concentrations of DBP, those who may have greater intake of DBP per body weight (<i>e.g.</i> , infants,
4143	children, and adolescents), and those exposed to DBP through certain age-specific behaviors (<i>e.g.</i> ,
4144	mouthing of toys, wires, and erasers by infants and children) leading to greater exposure. EPA
4145	accounted for these populations with greater exposure in the draft DBP risk evaluation as follows:
4146	• EPA evaluated a range of OESs for workers and ONUs, including high-end exposure scenarios
4147	for females of reproductive age (a susceptible subpopulation) and average adult workers.
4148	• EPA evaluated a range of consumer exposure scenarios, including high-intensity exposure
4149	scenarios for infants and children (susceptible subpopulations). These populations had greater
4150	intake per body weight and exposure due to age-specific behaviors (e.g., mouthing of toys by
4151	infants and children).
4152	• EPA evaluated a range of general population exposure scenarios, including high-end exposure
4153	scenarios for infants and children (susceptible subpopulations). These populations had greater
4154	intake per body weight.
4155	• EPA evaluated exposure of children to DBP through use of legacy and new toys.
4156	• EPA evaluated exposure to DBP through fish ingestion for subsistence fishers and Tribal
4157	populations.
4158	• EPA aggregated occupational inhalation and dermal exposures for each COU for females of
4159	reproductive age (a susceptible subpopulation) and average adult workers.
4160	• EPA aggregated consumer inhalation, dermal, and oral exposures for each COU for infants and
4161	children (susceptible subpopulations).
4162	• EPA evaluated cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP for the U.S. civilian
4163	population using NHANES urinary biomonitoring data and reverse dosimetry for females of
4164	reproductive age (16–49 years) and male children (3–5, 6–11, and 12–15 years of age) (discussed
4165	in Section 4.4).
4166	• For females of reproductive age, black non-Hispanic women had slightly higher 95th percentile
4167	cumulative exposures to DEHP, DBP, BBP, DIBP, and DINP compared to females of other races

4167 cumulative exposures to DEHP, DBP, BBP, DIBP, and DINP compared to females of other races
4168 (*e.g.*, white non-Hispanic, Mexican America). The 95th percentile cumulative exposure estimate
4169 for black non-Hispanic women served as the non-attributable national cumulative exposure

4170 estimate used by EPA to evaluate cumulative risk to workers and consumers (discussed in4171 Section 4.4).

4172 **4.4 Cumulative Risk Considerations**

4173 EPA developed a Revised Draft Technical Support Document for the Cumulative Risk Analysis of 4174 DEHP, DBP, BBP, DIBP, DCHP, and DINP Under TSCA (U.S. EPA, 2025x) (revised draft CRA TSD) 4175 for the CRA of six toxicologically similar phthalates being evaluated under Section 6 of TSCA: di(2-4176 ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), dicyclohexyl 4177 phthalate (DCHP), diisobutyl phthalate (DIBP), and diisononyl phthalate (DINP). EPA previously 4178 issued a Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a 4179 Manufacturer-Requested Phthalate under the Toxic Substances Control Act (draft 2023 approach), 4180 which outlined an approach for this assessment (U.S. EPA, 2023d). EPA's proposal was subsequently 4181 peer-reviewed by the Science Advisory Committee on Chemicals (SACC) in May 2023 (U.S. EPA, 4182 2023g). In the 2023 draft approach, EPA identified a cumulative chemical group and PESS [15 U.S.C. § 4183 2605(b)(4)]. Based on toxicological similarity and induced effects on the developing male reproductive 4184 system consistent with a disruption of androgen action and phthalate syndrome, EPA proposed a cumulative chemical group of DEHP, BBP, DBP, DCHP, DIBP, and DINP, but not diisodecyl phthalate 4185 4186 (DIDP). This approach emphasizes a uniform measure of hazard for sensitive subpopulations, namely 4187 females of reproductive age and/or male infants and children, however additional health endpoints are 4188 known for broader populations and described in the individual non-cancer human health hazard 4189 assessments for DEHP (U.S. EPA, 2024h), DBP (U.S. EPA, 2024f), DIBP (U.S. EPA, 2024i), BBP (U.S. EPA, 2024e), DCHP (U.S. EPA, 2024g), and DINP (U.S. EPA, 2024n), including hepatic, kidney, 4190 4191 and other developmental and reproductive toxicity. 4192

4193 EPA's approach for assessing cumulative risk is described in detail in the revised draft CRA TSD (U.S. 4194 EPA, 2025x) and incorporates feedback from the SACC (U.S. EPA, 2023g) on EPA's 2023 draft 4195 proposal (U.S. EPA, 2023d). The Agency is focusing its CRA on acute duration exposures of females of 4196 reproductive age, male infants, and male children to six toxicologically similar phthalates (*i.e.*, DEHP, 4197 DBP, BBP, DIBP, DCHP, DINP) that induce effects on the developing male reproductive system 4198 consistent with a disruption of androgen action and phthalate syndrome. The Agency is further focusing 4199 its CRA on acute duration exposures because there is evidence that effects on the developing male 4200 reproductive system consistent with a disruption of androgen action can result from a single exposure 4201 during the critical window of development (see Section 1.5 of (U.S. EPA, 2025x) for further details). To 4202 evaluate cumulative risk, EPA is using a relative potency factor (RPF) approach. RPFs for DEHP, DBP, 4203 BBP, DIBP, DCHP, and DINP were developed using a meta-analysis and benchmark dose (BMD) 4204 modeling approach based on a uniform measure (*i.e.*, reduced fetal testicular testosterone). EPA is also 4205 using NHANES data to supplement, not substitute, evaluations for exposure scenarios for TSCA COUs 4206 to provide non-attributable, total exposure for addition to the relevant scenarios presented in the 4207 individual risk evaluations.

4208

The analogy of a "risk cup" is used throughout Section 4.4 to describe cumulative exposure estimates. The risk cup term is used to help conceptualize the contribution of various phthalate exposure routes and pathways to overall cumulative risk estimates and serves primarily as a communication tool. The term/concept describes exposure estimates where the full cup represents the total exposure that leads to risk (cumulative MOE) and each chemical contributes a specific amount of exposure that adds a finite amount of risk to the cup. A full risk cup indicates that the cumulative MOE has dropped below the benchmark MOE (*i.e.*, total UF), whereas cumulative MOEs above the benchmark indicate that only a

4215 benchmark MOE (*i.e.*, total UF), whereas cumulative MOEs above the ben
4216 portion of the risk cup is full.

4218 The remainder of this human health CRA section is organized as follows:

- Section 4.4.1 Describes the approach used by EPA to derive draft RPFs for DEHP, DBP, BBP, DIBP, DCHP, and DINP based on reduced fetal testicular testosterone, which are used by EPA as part of the current CRA and to assess exposures to individual phthalates by scaling to an index chemical (RPF analysis). Section 2 of EPA's draft revised CRA TSD (U.S. EPA, 2025x) provides more details.
- Section 4.4.2 Briefly describes the approach used by EPA to calculate cumulative nonattributable phthalate exposure for the U.S. population using NHANES urinary biomonitoring and reverse dosimetry. Section 4 of EPA's draft revised CRA TSD (U.S. EPA, 2025x) provides additional details.
- Section 4.4.3 Describes how EPA combined exposures to DBP from individual consumer and occupational COUs/OES with cumulative non-attributable phthalate exposures from NHANES to estimate cumulative risk. An empirical example is also provided. Section 5 of EPA's draft revised CRA TSD (U.S. EPA, 2025x) provides additional details.
- Sections 4.4.4 through 4.4.6 Summarize risk estimates for workers, consumers, and the general population based on relative potency assumptions.
- 4234 For additional details regarding EPA's draft CRA, readers are directed to the following TSDs/reports:
- Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl)
 Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl
 Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the
 Toxic Substances Control Act (TSCA) (U.S. EPA, 2025x);
- Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone for Di(2ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024d);
- Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a
 Manufacturer-Requested Phthalate under the Toxic Substances Control Act (U.S. EPA, 2023d);
- Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act (U.S. EPA, 2023e); and
- Science Advisory Committee on Chemicals meeting minutes and final report, No. 2023-01 A set of scientific issues being considered by the Environmental Protection Agency regarding: Draft Proposed Principles of Cumulative Risk Assessment (CRA) under the Toxic Substances Control Act and a Draft Proposed Approach for CRA of High-Priority Phthalates and a Manufacturer-Requested Phthalate (U.S. EPA, 2023g).
- 4251 4.4.1 Hazard Relative Potency
- This section briefly summarizes the RPF approach used by EPA to evaluate phthalates for cumulative risk. Section 4.4.1.1 provides a brief overview and background for the RPF approach methodology, while Section 4.4.1.2 provides a brief overview of the draft RPFs derived by EPA for DEHP, DBP, BBP, DIBP, DCHP, and DINP based on decreased fetal testicular testosterone. Further details regarding the draft relative potency analysis conducted by EPA are provided in the following two TSDs:
- 4257 Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl)
 4258 Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl

- 4259 Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the
 4260 Toxic Substances Control Act (TSCA) (U.S. EPA, 2025x); and
- 4261
 Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone for Di(2-4262
 ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP),
- 4263 Diisobutyl Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024d).

4.4.1.1 Relative Potency Factor Approach Overview

4265 For the RPF approach, chemicals being evaluated require data that support toxicologic similarity (e.g., 4266 components of a mixture share a known or suspected common MOA or share a common apical 4267 endpoint/effect) and have dose-response data for the effect of concern over similar exposure ranges 4268 (U.S. EPA, 2023b, 2000, 1986). RPF values account for potency differences among chemicals in a 4269 mixture and scale the dose of one chemical to an equitoxic dose of another chemical (*i.e.*, the index 4270 chemical). The chemical selected as the index chemical is often among the best characterized 4271 toxicologically and considered to be representative of the type of toxicity elicited by other components 4272 of the mixture. Implementing an RPF approach requires a quantitative dose-response assessment for the 4273 index chemical and pertinent data that allow the potency of the mixture components to be meaningfully 4274 compared to that of the index chemical. In the RPF approach, RPFs are calculated as the ratio of the 4275 potency of the individual component to that of the index chemical using either (1) the response at a fixed 4276 dose, or (2) the dose at a fixed response (Equation 4-3).

4277

4279

4264

4278 Equation 4-3. Calculating RPFs

$$RPF_i = \frac{BMD_{R-IC}}{BMD_{R-i}}$$

4280 Where

4200	where.		
4281	BMD	=	Benchmark dose (mg/kg/day)
4282	R	=	Magnitude of response (<i>i.e.</i> , benchmark response)
4283	Ι	=	i th chemical
4284	IC	=	Index chemical

4285 After scaling the chemical component doses to the potency of the index chemical, the scaled doses are 4286 summed and expressed as index chemical equivalents for the mixture (Equation 4-4).

42874288 Equation 4-4. Calculating Index Chemical Equivalents

4289

Index Chemical Equivalents_{MIX} =
$$\sum_{i=1}^{n} d_i \times RPF_i$$

4290 Where:

4291 4292	Index chemical equivalents	=	Dose of the mixture in index chemical equivalents (mg/kg/day)
4293 4294 4295	di RPF _i	=	Dose of the i th chemical in the mixture (mg/kg/day) Relative potency factor of the i th chemical in the mixture (unitless)

Non-cancer risk associated with exposure to an individual chemical or mixture can then be assessed by
calculating an MOE, which in this case is the ratio of the index chemical's non-cancer hazard value
(*e.g.*, the BMDL) to an estimate of exposure expressed in terms of index chemical equivalents. The
MOE is then compared to the benchmark MOE (*i.e.*, the total uncertainty factor associated with the
assessment) to characterize risk.

4301 4.4.1.2 Relative Potency Factors

4302 Derivation of Draft RPFs

4303 To derive RPFs for DEHP, DBP, BBP, DIBP, DCHP, and DINP, EPA utilized a meta-analysis and

- 4304 BMD modeling approach similar to that used by NASEM (2017) to model decreased fetal testicular
- 4305 testosterone. As described further in EPA's *Draft Meta-Analysis and Benchmark Dose Modeling of*
- 4306 *Fetal Testicular Testosterone for DEHP, DBP, BBP, DIBP, and DCHP* (U.S. EPA, 2024d), the Agency
- 4307 evaluated benchmark responses (BMRs) of 5, 10, and 40 percent. For input into the CRA of phthalates,
- 4308 EPA has derived draft RPFs using BMD₄₀ estimates (Table 4-20). For further details regarding RPFs 4309 derivation see Section 2 of the draft CPA TSD (U.S. EPA 2025r)
- 4309 derivation, see Section 2 of the draft CRA TSD (<u>U.S. EPA, 2025x</u>).
 4310

4311 Selection of the Index Chemical

4312 As described further in Section 2 of (draft CRA TSD) (U.S. EPA, 2025x), EPA has preliminarily

- 4313 selected DBP as the index chemical. DBP has a high-quality toxicological database of studies
- 4314 demonstrating effects on the developing male reproductive system consistent with a disruption of
- 4315 androgen action and phthalate syndrome. Furthermore, studies of DBP demonstrate toxicity
- 4316 representative of all phthalates in the cumulative chemical group and DBP is well characterized for the
- 4317 MOA associated with phthalate syndrome. Finally, compared to other phthalates, including well-studied
- 4318 phthalates such as DEHP, DBP has the most dose-response data available in the low-end range of the
- 4319 dose-response curve where the BMD_5 and $BMDL_5$ are derived, which provides a robust and
- 4320 scientifically sound foundation of BMD and BMDL estimates on which the RPF approach is based.
- 4321
- 4322
- 4323

Table 4-20. Draft Relative Potency Factors Based on Decreased
Fetal Testicular Testosterone

Phthalate	BMD40 (mg/kg-day)	RPF Based on BMD40			
DBP (Index chemical)	149	1			
DEHP	178	0.84			
DIBP	279	0.53			
BBP	284	0.52			
DCHP	90	1.66			
DINP	699	0.21			

4324

4325 Index Chemical POD

4326 As with any risk assessment that relies on BMD analysis, the POD is the lower confidence limit used to mark the beginning of extrapolation to determine risk associated with human exposures. As described 4327 4328 further in the non-cancer human health hazards of DEHP (U.S. EPA, 2024h), DBP (U.S. EPA, 2024f), BBP (U.S. EPA, 2024e), DIBP (U.S. EPA, 2024i), DCHP (U.S. EPA, 2024g), and DINP (U.S. EPA, 4329 2024n) (see Appendices titled "Considerations for Benchmark Response (BMR) Selection for Reduced 4330 4331 Fetal Testicular Testosterone" in each hazard assessment), EPA has reached the conclusion that a BMR 4332 of 5 percent is the most appropriate and health protective response level for evaluating decreased fetal 4333 testicular testosterone. For the index chemical, DBP, the BMDL₅ for the best fitting linear-quadratic 4334 model is 9 mg/kg-day for reduced fetal testicular. Using allometric body weight scaling to the ³/₄- power 4335 (U.S. EPA, 2011c), EPA extrapolated an HED of 2.1 mg/kg-day to use as the POD for the index

- 4336 chemical in the CRA.
- 4337

4338 Selection of the Benchmark MOE

- 4339 Consistent with Agency guidance (U.S. EPA, 2022c, 2002b), EPA selected an intraspecies uncertainty 4340 factor (UF_H) of 10, which accounts for variation in susceptibility across the human population and the 4341 possibility that the available data might not be representative of individuals who are most susceptible to 4342 the effect. EPA used allometric body weight scaling to the ³/₄-power to derive an HED of 2.1 mg/kg-day 4343 DBP, which accounts for species differences in toxicokinetics. Consistent with EPA Guidance (U.S. 4344 EPA, 2011c), the interspecies uncertainty factor (UF_A), was reduced from 10 to 3 to account for 4345 remaining uncertainty associated with interspecies differences in toxicodynamics. Overall, a total 4346 uncertainty factor of 30 was selected for use as the benchmark margin of exposure for the CRA (based 4347 on an interspecies uncertainty factor $[UF_A]$ of 3 and an intraspecies uncertainty factor $[UF_H]$ of 10). 4348 4349 Weight of Scientific Evidence
- EPA has preliminary selected an HED of 2.1 mg/kg-day (BMDL₅ of 9 mg/kg-day) as the index chemical
 (DBP) POD. This POD is based on a meta-analysis and BMD modeling of decreased fetal testicular
 testosterone from eight studies of rats gestationally exposed to DBP. EPA has also derived draft RPFs of
 1, 0.84, 0.53, 0.52, 1.66, and 0.21 for DBP (index chemical), DEHP, DIBP, BBP, DCHP, and DINP,
 respectively, based on a common toxicological outcome (*i.e.*, reduced fetal testicular testosterone). EPA
 has robust overall confidence in the proposed POD for the index chemical (*i.e.*, DBP) and the derived
 draft RPFs.
- 4357

Application of RPF provides a more robust basis for assessing the dose-response to the common hazard
endpoint across all assessed phthalates. For a subset of the phthalates with a more limited toxicological
data set, scaling by the RPF and application of the index chemical POD provides a more sensitive and
robust hazard assessment than the chemical-specific POD. Readers are directed to the revised draft CRA
TSD (U.S. EPA, 2025x) for a discussion of the weight of evidence supporting EPA's preliminary
conclusions.

43644.4.2Cumulative Phthalate Exposure: Non-Attributable Cumulative Exposure to DEHP,4365DBP, BBP, DIBP, and DINP Using NHANES Urinary Biomonitoring and Reverse4366Dosimetry

This section briefly summarizes EPA's approach and results for estimating non-attributable cumulative
exposure to phthalates using NHANES urinary biomonitoring data and reverse dosimetry. Readers are
directed to Section 4 of EPA's revised draft CRA TSD (U.S. EPA, 2025x) for additional details.

4370

4371 NHANES is an ongoing exposure assessment of the U.S. population's exposure to environmental 4372 chemicals using biomonitoring. The NHANES biomonitoring data set is a national, statistical 4373 representation of the general, non-institutionalized, civilian U.S. population. CDC's NHANES data set 4374 provides an estimate of average aggregate exposure to individual phthalates for the U.S. population. 4375 However, exposures measured via NHANES cannot be attributed to specific sources, such as TSCA 4376 COUs or other sources. Given the short half-lives of phthalates, neither can NHANES capture acute, low 4377 frequency exposures. Instead, as concluded by the SACC review of the draft 2023 approach, NHANES 4378 provides a "snapshot" or estimate of total, non-attributable phthalate exposure for the U.S. population 4379 and relevant subpopulations (U.S. EPA, 2023g). These estimates of total non-attributable exposure can 4380 supplement assessments of scenario-specific acute risk in individual risk evaluations. 4381

4382 Monoester metabolites of BBP, DBP, DEHP, DIBP, and DINP in human urine are regularly measured 4383 as part of the NHANES biomonitoring program and are generally detectable in human urine at a high 4384 frequency, including during the most recent NHANES survey period (*i.e.*, 2017–2018). One urinary 4385 metabolite (*i.e.*, monocyclohexyl phthalate [MCHP]) of DCHP was included in NHANES from 1999 4386 through 2010, but was excluded from NHANES after 2010 due to low detection levels and a low

frequency of detection in human urine (detected in <10% of samples in 2009–2010 NHANES survey)
(CDC, 2013). Therefore, EPA did not use NHANES urinary biomonitoring data to estimate a daily
aggregate intake value for DCHP through reverse dosimetry.

4390

4391 EPA used urinary phthalate metabolite concentrations for DEHP, DBP, BBP, DIBP, and DINP

measured in the most recently available NHANES survey (2017–2018) to estimate the average daily
 aggregate intake of each phthalate through reverse dosimetry for

- 4394 1. Women of reproductive age (16-49 years);
- 4395 2. Male children (4 to <6 years, used as a proxy for male infants and toddlers);
- 4396 3. Male children (6–11 years); and
- 4397 4. Male children (12 to <16 years).

4398 Since NHANES does not include urinary biomonitoring for infants or toddlers, and other national data 4399 sets are not available, EPA used biomonitoring data from male children 3 to less than 6 years of age as a 4400 proxy for male infants (<1 year) and male toddlers (1–2 years). See Section 4 of (U.S. EPA, 2025x) for 4401 further details regarding the reverse dosimetry approach. Aggregate daily intake estimates for these 4402 populations are presented in Table 4-21.⁵ Aggregate daily intake values were also calculated for females 4403 of reproductive age stratified by race and socioeconomic status (Table 4-22). A similar analysis by race 4404 was not done for male children because the NHANES sample size is smaller for this population.

4405

4406 Aggregate daily intake values for each phthalate were then scaled by relative potency using the RPFs in
4407 Table 4-20, expressed in terms of index chemical (DBP) equivalents, and summed to estimate
4408 cumulative daily intake in terms of index chemical (DBP) equivalents using the approach outlined in
4409 Sections 4.4.1 and 4.4.3.

4410

Because EPA is focusing its CRA on acute exposure durations, EPA selected 95th percentile exposure
estimates from NHANES to serve as the non-attributable nationally representative exposure estimate for
use in its CRA. For females of reproductive age, EPA's analysis indicates that black, non-Hispanic
women have slightly higher 95th percentile cumulative phthalate exposure compared to other racial
groups; thus, 95th percentile cumulative estimates for black non-Hispanic females of

4416 reproductive age was selected for use in the CRA of DBP (Table 4-22).

The 95th percentile of national cumulative exposure serves as the estimate of non-attributable phthalate
exposure for its CRA of DBP as follows:

- Women of reproductive age (16-49 years, black non-Hispanic): 5.16 μg/kg-day index chemical (DBP) equivalents. This serves as the non-attributable contribution to worker and consumer females of reproductive age in Section 4.4.4 and Section 4.4.5.
- Males (3–5 years): 10.8 µg/kg-day index chemical (DBP) equivalents. This serves as the non-attributable contribution to consumer male infants (<1 year), toddlers (1–2 years), and preschoolers (3–5 years) in Section 4.4.5. Since NHANES does not include urinary biomonitoring for infants (<1 year) or toddlers (1–2 years), and other national data sets are not available, EPA used biomonitoring data from male children (3 to <6 years) as a proxy for male infants and toddlers.
- Males (6–11 years): 7.35 μg/kg-day index chemical (DBP) equivalents This serves as the nonattributable contribution to consumer male children (6–10 years) in Section 4.4.5.

⁵ EPA defines *aggregate exposure* as the "combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways" (<u>40 CFR section 702.33</u>).

- Males (12–15 years): 4.36 µg/kg-day index chemical (DBP) equivalents. This serves as the non-attributable contribution to consumer male teenagers (11–15 years) in Section 4.4.5.
- 44324.4.2.1Weight of Scientific Evidence: Non-Attributable Cumulative Exposure to
Phthalates

4434 Overall, EPA has robust confidence in the derived estimates of non-attributable cumulative exposure 4435 from NHANES urinary biomonitoring using reverse dosimetry. EPA used urinary biomonitoring data 4436 from the CDC's national NHANES dataset, which provides a statistical representation of the general, 4437 non-institutionalized, civilian U.S. population. To estimate daily intake values from urinary 4438 biomonitoring for each phthalate, EPA used reverse dosimetry. The reverse dosimetry approach used by 4439 EPA has been used extensively in the literature and has been used by CPSC (2014) and Health Canada 4440 (Health Canada, 2020) to estimate phthalate daily intake values from urinary biomonitoring data. 4441 However, given the short half-lives of phthalates, NHANES biomonitoring data are not expected to 4442 capture low frequency exposures and may be an underestimate of acute phthalate exposure.

Table 4-21. Cumulative Phthalate Daily Intake (μg/kg-day) Estimates for Women of Reproductive Age, Male Children, and Male
 Teenagers from the 2017–2018 NHANES Cycle

Population	Percentile	Phthalate	Aggregate Daily Intake (µg/kg-day)	RPF	Aggregate Daily Intake in DBP Equivalents (μg/kg-day)	% Contribution to Cumulative Exposure	Cumulative Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg- day)	% Contribution to Risk Cup (Benchmark = 30) ^a
		DBP	0.21	1	0.210	22.1			
		DEHP	0.53	0.84	0.445	46.9			
	50	BBP	0.08	0.52	0.042	4.38	0.950	2,211	1.4%
		DIBP	0.2	0.53	0.106	11.2			
Females (16–49 years;		DINP	0.7	0.21	0.147	15.5			
n = 1,620		DBP	0.61	1	0.610	17.2			
		DEHP	1.48	0.84	1.24	35.0		592	5.1%
	95	BBP	0.42	0.52	0.218	6.15	3.55		
	DIBP	0.57	0.53	0.302	8.51				
		DINP	5.6	0.21	1.18	33.1			
		DBP	0.56	1	0.560	18.4			
		DEHP	2.11	0.84	1.77	58.2	3.04	690	4.3%
	50	BBP	0.22	0.52	0.114	3.76			
		DIBP	0.57	0.53	0.302	9.93			
Males		DINP	1.4	0.21	0.294	9.66			
(3-5 years; n = 267)		DBP	2.02	1	2.02	18.6			
		DEHP	6.44	0.84	5.41	49.9			
	95	BBP	2.46	0.52	1.28	11.8	10.8	194	15.5%
		DIBP	2.12	0.53	1.12	10.4			
	DINP	4.8	0.21	1.01	9.30				
		DBP	0.38	1	0.380	20.1			
Males	50	DEHP	1.24	0.84	1.04	55.1	1.89	1 111	2 70/
(6-11 years; n = 553)	50	BBP	0.16	0.52	0.083	4.40	1.07	1,111	2.7%
		DIBP	0.33	0.53	0.175	9.26			

Population	Percentile	Phthalate	Aggregate Daily Intake (µg/kg-day)	RPF	Aggregate Daily Intake in DBP Equivalents (µg/kg-day)	% Contribution to Cumulative Exposure	Cumulative Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg- day)	% Contribution to Risk Cup (Benchmark = 30) ^a
		DINP	1	0.21	0.210	11.1			
		DBP	1.41	1	1.41	19.2			
		DEHP	4.68	0.84	3.93	53.5	7.35		
	95	BBP	0.84	0.52	0.437	5.94		286	10.5%
		DIBP	1.62	0.53	0.859	11.7			
		DINP	3.4	0.21	0.714	9.71			
		DBP	0.33	1	0.330	27.6	_	1,758	1.7%
		DEHP	0.66	0.84	0.554	46.4			
	50	BBP	0.14	0.52	0.073	6.09	1.19		
		DIBP	0.21	0.53	0.111	9.32			
Males		DINP	0.6	0.21	0.126	10.5			
(12-15 years; n = 308)		DBP	0.62	1	0.620	14.2			
		DEHP	2.51	0.84	2.11	48.3			
	95	BBP	0.64	0.52	0.333	7.63	4.36	482	6.2%
		DIBP	0.59	0.53	0.313	7.17]		
		DINP	4.7	0.21	0.987	22.6			

^{*a*} A cumulative exposure of 70 μ g DBP equivalents/kg-day would result in a cumulative MOE of 30 (*i.e.*, 2,100 μ g DBP-equivalents/kg-day \div 70 μ g DBP equivalents/kg-day = 30), which is equivalent to the benchmark of 30, indicating that the exposure is at the threshold for risk. Therefore, to estimate the percent contribution to the risk cup, the cumulative exposure expressed in DBP equivalents is divided by 70 μ g DBP equivalents/kg-day to estimate percent contribution to the risk cup.

4446 Table 4-22. Cumulative Phthalate Daily Intake (μg/kg-day) Estimates for Women of Reproductive Age (16–49 years old) by Race and
 4447 Socioeconomic Status from the 2017–2018 NHANES Cycle

Race/ Socioeconomic Status (SES)	Percentile	Phthalate	Aggregate Daily Intake (µg/kg-day)	RPF	Aggregate Daily Intake in DBP Equivalents (µg/kg-day)	% Contribution to Cumulative Exposure	Cumulative Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg-day)	% Contribution to Risk Cup (Benchmark = 30) ^a
		DBP	0.22	1	0.22	21.6			
		DEHP	0.59	0.84	0.50	48.6			
	50	BBP	0.10	0.52	0.05	5.1	1.02	2,058	1.5%
		DIBP	0.20	0.53	0.11	10.4			
Race: white non- Hispanic		DINP	0.70	0.21	0.15	14.4			
(n = 494)		DBP	0.58	1	0.58	17.6			
		DEHP	1.44	0.84	1.21	36.6			
	95	BBP	0.29	0.52	0.15	4.6	3.30	636	4.7%
		DIBP	0.55	0.53	0.29	8.8			
		DINP	5.10	0.21	1.07	32.4			
		DBP	0.10	1	0.10	15.0			
		DEHP	0.38	0.84	0.32	47.9			
	50	BBP	0.04	0.52	0.02	3.1	0.667	3,151	1.0%
		DIBP	0.15	0.53	0.08	11.9			
Race: black non- Hispanic		DINP	0.70	0.21	0.15	22.1			
(n = 371)		DBP	0.48	1	0.48	9.3			
		DEHP	4.28	0.84	3.60	69.7			
	95	BBP	0.30	0.52	0.16	3.0	5.16	407	7.4%
		DIBP	0.40	0.53	0.21	4.1			
		DINP	3.40	0.21	0.71	13.8			

Race/ Socioeconomic Status (SES)	Percentile	Phthalate	Aggregate Daily Intake (µg/kg-day)	RPF	Aggregate Daily Intake in DBP Equivalents (µg/kg-day)	% Contribution to Cumulative Exposure	Cumulative Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg-day)	% Contribution to Risk Cup (Benchmark = 30) ^a
		DBP	0.19	1	0.19	22.4			
		DEHP	0.49	0.84	0.41	48.5			
	50	BBP	0.06	0.52	0.03	3.7	0.849	2,474	1.2%
		DIBP	0.17	0.53	0.09	10.6			
Race: Mexican American		DINP	0.60	0.21	0.13	14.8			
(n = 259)		DBP	0.42	1	0.42	11.6			5.2%
()		DEHP	1.24	0.84	1.04	28.9			
	95	BBP	0.39	0.52	0.20	5.6	3.61	582	
		DIBP	0.46	0.53	0.24	6.8			
		DINP	8.10	0.21	1.70	47.1			
		DBP	0.26	1	0.26	25.3		2041	1.5%
		DEHP	0.64	0.84	0.54	52.2			
	50	BBP	0.07	0.52	0.04	3.5	1.03		
		DIBP	0.15	0.46	0.07	6.7			
Race: Other		DINP	0.60	0.21	0.13	12.2			
(n = 496)		DBP	0.84	1	0.84	20.7			
		DEHP	1.37	0.84	1.15	28.3			
	95	BBP	0.41	0.52	0.21	5.2	4.06	517	5.8%
		DIBP	0.46	0.53	0.24	6.0			
		DINP	7.70	0.21	1.62	39.8			

Race/ Socioeconomic Status (SES)	Percentile	Phthalate	Aggregate Daily Intake (µg/kg-day)	RPF	Aggregate Daily Intake in DBP Equivalents (µg/kg-day)	% Contribution to Cumulative Exposure	Cumulative Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg-day)	% Contribution to Risk Cup (Benchmark = 30) ^a
		DBP	0.21	1	0.21	22.0			
		DEHP	0.53	0.84	0.45	46.6			
	50	BBP	0.09	0.52	0.05	4.9	0.955	2,199	1.4%
		DIBP	0.20	0.53	0.11	11.1			
SES: Below poverty level		DINP	0.70	0.21	0.15	15.4			
(n = 1,056)		DBP	0.82	1	0.82	18.2			
		DEHP	1.75	0.84	1.47	32.7			
	95	BBP	0.34	0.52	0.18	3.9	4.50	467	6.4%
		DIBP	0.51	0.53	0.27	6.0			
		DINP	8.40	0.21	1.76	39.2			
		DBP	0.20	1.00	0.20	27.9			
		DEHP	0.31	0.84	0.26	36.3			
	50	BBP	0.06	0.52	0.03	4.3	0.718	2,924	1.0%
		DIBP	0.15	0.53	0.08	11.1			
SES: At or above		DINP	0.70	0.21	0.15	20.5			
poverty level $(n = 354)$		DBP	0.48	1.00	0.48	16.3			
× /		DEHP	1.07	0.84	0.90	30.5			
	95	BBP	0.45	0.52	0.23	7.9	2.94	713	4.2%
		DIBP	0.65	0.53	0.34	11.7			
		DINP	4.70	0.21	0.99	33.5			

Race/ Socioeconomic Status (SES)	Percentile	Phthalate	Aggregate Daily Intake (µg/kg-day)	RPF	Aggregate Daily Intake in DBP Equivalents (μg/kg-day)	% Contribution to Cumulative Exposure	Cumulative Daily Intake (DBP Equivalents, µg/kg-day)	Cumulative MOE (POD = 2,100 µg/kg-day)	% Contribution to Risk Cup (Benchmark = 30) ^a
		DBP	0.26	1.00	0.26	23.2			
	50	DEHP	0.67	0.84	0.56	50.1			1.6%
		BBP	0.06	0.52	0.03	2.8	1.12	1,870	
		DIBP	0.23	0.53	0.12	10.9			
SES: Unknown		DINP	0.70	0.21	0.15	13.1			
(n = 210)		DBP	0.60	1.00	0.60	25.5	2.35	893	3.4%
		DEHP	0.86	0.84	0.72	30.7			
	95	BBP	0.21	0.52	0.11	4.6			
		DIBP	0.35	0.53	0.19	7.9			
		DINP	3.50	0.21	0.74	31.2			

^{*a*} A cumulative exposure of 70 μ g DBP equivalents/kg-day would result in a cumulative MOE of 30 (*i.e.*, 2,100 μ g DBP-equivalents/kg-day \div 70 μ g DBP equivalents/kg-day = 30), which is equivalent to the benchmark of 30, indicating that the exposure is at the threshold for risk. Therefore, to estimate the percent contribution to the risk cup, the cumulative exposure expressed in DBP equivalents is divided by 70 μ g DBP equivalents/kg-day to estimate percent contribution to the risk cup.

4449 **4.4.3 Estimation of Risk Based on Relative Potency**

4450 As described in the revised draft CRA TSD (U.S. EPA, 2025x), EPA is focusing its exposure assessment 4451 for the CRA for DBP on evaluation of exposures through individual TSCA consumer and occupational 4452 DBP COUs as well as non-attributable cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP 4453 using NHANES urinary biomonitoring data and reverse dosimetry. Furthermore, EPA is considering 4454 two options for characterizing cumulative risk. The Agency uses the first option to estimate cumulative 4455 risk in which all phthalate exposures are scaled by relative potency using the RPFs presented in Table 4456 4-20 to express phthalate exposure in terms of index chemical (DBP) equivalents. Exposures from 4457 individual DBP consumer or worker COUs/OES were then combined to estimate cumulative risk. 4458 Cumulative risk was estimated using the four-step process outlined below, along with one empirical 4459 example of how EPA calculated cumulative risk for one occupational OES for DBP (*i.e.*, PVC plastics 4460 converting). In the second option, which is presented in Section 5.2 of revised draft CRA TSD (U.S. 4461 EPA, 2025x), individual phthalate exposures for consumer and occupational COUs are not scaled by 4462 relative potency factors but use the individual phthalate hazard values and are combined with non-4463 attributable cumulative exposures estimated using NHANES. Both options are compared in Section 5.4 4464 of the revised draft CRA TSD and both options for calculating cumulative risk will be peer reviewed by 4465 the SACC in 2025. Following peer review and public comment, EPA will select one option for 4466 characterizing cumulative risk in the final DBP risk evaluation.

4467

Step 1: Convert DBP Exposure Estimates from Each Individual Consumer and Occupational COU to Index Chemical Equivalents (i.e., Occupational and Consumer Exposure from Sections 4.1.1 and 4470 4.1.2, Respectively)

In this step, DBP acute duration exposure estimates from each consumer and occupational COU/OES
are scaled by relative potency and expressed in terms of index chemical (DBP) equivalents using
Equation 4-5. This step is repeated for all individual exposure estimates for each route of exposure being
assessed for each COU (*i.e.*, inhalation and dermal exposures for occupational COUs; inhalation,
ingestion, and dermal exposure for consumer COUs).

4477 Equation 4-5. Scaling DBP Exposures by Relative Potency

4478	DBP	Exposure	$e(in DBP equivalents) = AD_{Route 1} x RPF_{DBP}$
4479	Where:	-	
4480	DBP exposure	=	Acute exposure for a given route of exposure from a single
4481			occupational or consumer COU expressed in terms of µg/kg index
4482			chemical (DBP) equivalents
4483	$AD_{Route I}$	=	Acute dose in μ g/kg from a given route of exposure from a single
4484			occupational or consumer COU/OES
4485	RPF_{DIBP}	=	The relative potency factor (unitless) for DBP (index chemical) is
4486			1.0. (Table 4-20).
4487			
4488	Example: 50th percentile	inhalation,	, dermal, and aggregate DBP exposures for female workers of

reproductive age are 47.4, 15.6, and $63.0 \ \mu g/kg$ for the PVC plastics converting OES (U.S. EPA, 2025q). Using Equation 4-5, inhalation, dermal, and aggregate DBP exposures for this OES can be scaled by relative potency. Because the RPF for DBP (index chemical) is 1.0, the inhalation, dermal, and aggregate DBP exposure estimates do not change.

- 4493
- 4494

4495	Step 2: Estimate Non-attributable Cumulative Exposure to DEHP, DBP, BBP, DIBP, and DINP
4496	Using NHANES Urinary Biomonitoring Data and Reverse Dosimetry (see Section 4.4.2 for Further
4497	Details)
4498	Non-attributable exposure for a national population to DEHP, DBP, BBP, DIBP, and DINP was
4499	estimated using Equation 4-6, where individual phthalate daily intake values estimated from NHANES
4500	biomonitoring data and reverse dosimetry were scaled by relative potency, expressed in terms of index
4501	chemical (DBP) equivalents, and summed to estimate non-attributable cumulative exposure in terms of
4502	DBP equivalents. Equation 4-6 was used to calculate the cumulative exposure estimates provided in
4503	Table 4-21 and Table 4-22.
4504	
4505	Equation 4-6. Estimating Non-attributable Cumulative Exposure to DEHP, DBP, BBP, DIBP, and
4506	DINP
4507	
4508	Cumulative Exposure (Non – attributable)
4509	$= (DI_{DEHP} x RPF_{DEHP}) + (DI_{DBP} x RPF_{DBP}) + (DI_{BBP} x RPF_{BBP})$
4510	$+ (DI_{DIBP} x RPF_{DIBP}) + (DI_{DINP} x RPF_{DINP})$
4511	Where:
4512	Cumulative exposure (non-attributable) is expressed in index chemical (DBP) equivalents
4513	$(\mu g/kg-day).$
4514	DI is the daily intake value (μ g/kg-day) for each phthalate that was calculated using NHANES
4515	urinary biomonitoring data and reverse dosimetry. DI values for each phthalate for each assessed
4516	population are provided in Table 4-21 and Table 4-22.
4517	<i>RPF</i> is the relative potency factor (unitless) for each phthalate from Table 4-20.
4518	
4519	<i>Example:</i> The 95th percentile cumulative exposure estimate of 5.16 µg/kg-day DBP equivalents for
4520	black, non-Hispanic females of reproductive age (Table 4-22) is calculated using Equation 4-6 as
4521	follows:
4522	
4523	5.16 μg/kg DBP equivalents
4524	$= (4.28 \mu\text{g/kg} DEHP x 0.84) + (0.48 \mu\text{g/kg} DBP x 1) + (0.30 \mu\text{g/kg} BBP x 0.52)$
4525	+ $(0.40 \mu\text{g/kg}DIBP x 0.53)$ + $(3.40 \mu\text{g/kg}DINP x 0.21)$
4526	
4527	Step 3: Calculate MOEs for DBP Exposures and for Each Phthalate Exposure Included in the
4528	Cumulative Scenario
4529	Next, MOEs are calculated for each exposure of interest that is included in the cumulative scenario
4530	using Equation 4-7. For example, this step involves calculating MOEs for inhalation and dermal DBP
4531	exposures for each individual COU/OES in Step 1, and an MOE for non-attributable cumulative
4532	phthalate exposure from Step 2 above.
4533	
4534	Equation 4-7. Calculating MOEs for Exposures of Interest for Use in the RPF and Cumulative
4535	Approaches
4536	$MOE_{1} = \frac{Index \ Chemical \ (DBP) \ POD}{Exposure_{1} \ in \ DBP \ Equivalents}$
4537	Where:
4538	MOE_1 (unitless) = The MOE calculated for each exposure of interest included
4539	in the cumulative scenario
4540	Index Chemical (DBP) $POD =$ The POD selected for the index chemical, DBP; the index
4541	chemical POD is $2,100 \ \mu g/kg$ (Section 4.4.1).

4542 $Exposure_1$ The exposure estimate in DBP equivalents for the pathway = 4543 of interest (*i.e.*, from Step 1 or 2 above).

4545 Example: Using Equation 4-7, the MOEs for inhalation and dermal DBP exposure estimates for the PVC 4546 plastics converting OES in DBP equivalents from Step 1 and the MOE for the non-attributable 4547 cumulative exposure estimate in DBP equivalents from Step 2 are 44, 135, and 407, respectively.

4549
$$MOE_{Cumulative Non-attributable} = 407 = \frac{2,100 \ \mu g/kg}{5.16 \ \mu g/kg}$$

4552

4548

4544

4551
$$MOE_{COU-Inhalation} = 44 = \frac{2,100 \,\mu g/kg}{47.4 \,\mu g/kg}$$

4553
$$MOE_{COU-Dermal} = 135 = \frac{2,100 \ \mu g/kg}{15.6 \ \mu g/kg}$$

4554

4562

4555 Step 4: Calculate the Cumulative MOE

4556 For the cumulative MOE approach, MOEs for each exposure of interest in the cumulative scenario are first calculated (Step 3). The cumulative MOE for the cumulative scenario can then be calculated using 4557 4558 Equation 4-8, which shows the addition of MOEs for the inhalation and dermal exposures routes from 4559 an individual DBP COU as well as the MOE for non-attributable cumulative exposure to phthalates from NHANES urinary biomonitoring and reverse dosimetry. Additional MOEs can be added to the 4560 4561 equation as necessary (e.g., for the ingestion route for consumer scenarios).

4563 **Equation 4-8. Cumulative Margin of Exposure Calculation**

 $MOE = \frac{1}{\frac{1}{MOE_{COU-Inhalation}} + \frac{1}{MOE_{COU-Dermal}} + \frac{1}{MOE_{Cumulative-Non-attributable}} \dots}$ 4565

4566 *Example:* The cumulative MOE for the PVC plastics converting OES is 31 and is calculated by 4567 summing the MOEs for each exposure of interest from Step 3 as follows:

4569

Cumulative MOE =
$$31 = \frac{1}{\frac{1}{44} + \frac{1}{135} + \frac{1}{407}}$$

4570 4.4.4 Risk Estimates for Workers Based on Relative Potency

This section summarizes RPF analysis risk estimates for female workers of reproductive age from acute 4571 duration exposures to DBP. In the RPF analysis, EPA focused its occupational risk assessment on this 4572 4573 population and exposure duration because as described in Section 4.4 and (U.S. EPA, 2025x), this 4574 population and exposure duration is considered most directly applicable to the common hazard outcome 4575 that serves as the basis for the RPF analysis (*i.e.*, reduced fetal testicular testosterone).

4576

4577 To evaluate cumulative risk to female workers of reproductive age, EPA combined inhalation and

- 4578 dermal exposures to DBP from each individual occupational COU/OES with non-attributable 4579 cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP (estimated from NHANES urinary
- 4580 biomonitoring using reverse dosimetry). As described in Section 4.4.3, for each individual phthalate
- 4581 exposures were scaled by relative potency per chemical, expressed in terms of index chemical (DBP)

equivalents, and summed to estimate cumulative exposure and cumulative risk for each COU. Because
DBP is the index chemical and the RPF is 1, scaling has no effect on individual DBP exposure
estimates. MOEs in Table 4-23 are shown both with (cumulative MOE) and without (MOEs for
individual DBP COU derived using the RPF analysis) the addition of non-attributable cumulative
exposure (estimated from NHANES using reverse dosimetry) so that MOEs scaled by relative potency
can be compared.

4588

4589 As discussed in Section 4.3.2, high-end aggregate MOEs ranged from 0.7 to 20 for all 16 OES evaluated 4590 in the individual DBP risk assessment, while central tendency aggregate MOEs ranged from 1.7 to 3.2 4591 for 11 of the 16 OESs evaluated in the individual DBP risk assessment. Addition of non-attributable 4592 cumulative exposure would have no impact on risk conclusions for these OES. For the remaining five 4593 OESs (i.e., PVC plastics converting; Use of laboratory chemicals [solids]; Fabrication or use of final 4594 products or articles; Recycling; and Waste handling, treatment, and disposal), central tendency 4595 aggregate MOEs ranged from 33 to 101 in the individual DBP risk assessment (Section 4.3.2). As can be seen from Table 4-23, for the same five OESs (i.e., PVC plastics converting; Use of laboratory 4596 4597 chemicals [solids]; Fabrication or use of final products or articles; Recycling; and Waste handling, 4598 treatment, and disposal), the addition of non-attributable cumulative exposure (from NHANES) resulted 4599 in central tendency cumulative acute MOEs ranging from 31 to 81 (cumulative benchmark = 30). 4600 Therefore, in no case did the addition of non-attributable cumulative exposure (from NHANES) result in

- 4601 MOEs dropping below the benchmark of 30.
- 4602

4.4.4.1 Overall Confidence in Cumulative Worker Risk Estimates

4603 As described in Section 4.1.1.5 and the Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (U.S. EPA, 2025q), EPA has moderate to robust confidence in the 4604 assessed inhalation and dermal OESs (Table 4-5). The Agency has robust confidence in the RPFs and 4605 index chemical POD used to calculate the RPF analysis and cumulative MOEs (Section 4.4.1.2). To 4606 derive RPFs and the index chemical POD, the Agency integrated data from multiple studies evaluating 4607 fetal testicular testosterone using a meta-analysis approach and conducted BMD modeling. Finally, the 4608 4609 Agency has robust confidence in the non-attributable cumulative exposure estimates for DEHP, DBP, BBP, DIBP, and DINP derived from NHANES urinary biomonitoring data using reverse dosimetry 4610 4611 (Section 4.4.2.1). Overall, EPA has moderate to robust confidence in the cumulative risk estimates 4612 calculated for worker exposure scenarios (Table 4-23). 4613

4614 **Table 4-23. Risk Summary Table for Female Workers of Reproductive Age Using the RPF Analysis**

				Acute N		Workers of Repr hmark = 30)	oductive Age
Life Cycle Stage – Category	Subcategory	OES	Exposure Level	Inhalation MOE (DBP COU; Exposure to DBP)	Dermal MOE (DBP COU; Exposure to DBP)	Aggregate MOE (DBP COU; Exposure to DBP)	Cumulative MOE (Aggregate DBP MOE + Cumulative Non-Attributable) ^a
Manufacturing – Domestic Manufacturing	Domestic Manufacturing	Manufacturing	CT HE	30 15	1.8 0.9	1.7 0.9	1.7 0.9
Manufacturing – Importing	Importing		CT HE	30 15	1.8 0.9	1.7 0.9	1.7 0.9
Processing – Repackaging	Laboratory chemicals in wholesale and retail trade; plasticizers in wholesale and retail trade; and plastics material and resin manufacturing	Import and repackaging					
Processing – Processing as a reactant	Intermediate in plastic manufacturing		СТ	30	1.8	1.7	1.7
Processing – Incorporation into formulation, mixture, or reaction product	Solvents (which become part of product formulation or mixture) in chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and printing ink manufacturing Plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; printing ink manufacturing; and adhesive and sealant manufacturing Pre-catalyst manufacturing	Incorporation into formulations, mixtures, or reaction products	HE	15	0.9	0.9	0.9

				Acute N	Acute MOEs for Female Workers of Reproductive Age (Benchmark = 30)				
Life Cycle Stage – Category	Subcategory	OES	Exposure Level	Inhalation MOE (DBP COU; Exposure to DBP)	Dermal MOE (DBP COU; Exposure to DBP)	Aggregate MOE (DBP COU; Exposure to DBP)	Cumulative MOE (Aggregate DBP MOE + Cumulative Non-Attributable) ^{<i>a</i>}		
Processing – Processing: incorporation into formulation, mixture, or reaction product	Plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic organic chemical manufacturing; and adhesive and sealant manufacturing	PVC plastics compounding	НЕ	44 5.3	0.9	0.8	0.8		
Processing – Processing: incorporation into articles	Plasticizer in adhesive and sealant manufacturing; building and construction materials	PVC plastics converting	НЕ	44 5.3	67	33	31		

				Acute MOEs for Female Workers of Reproductive Age (Benchmark = 30)				
Life Cycle Stage – Category	Subcategory	OES	Exposure Level	Inhalation MOE (DBP COU; Exposure to DBP)	Dermal MOE (DBP COU; Exposure to DBP)	Aggregate MOE (DBP COU; Exposure to DBP)	Cumulative MOE (Aggregate DBP MOE + Cumulative Non-Attributable) ^{<i>a</i>}	
Processing – Processing: incorporation into formulation, mixture, or	Plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation	Non-PVC materials manufacturing (compounding and converting)	СТ	53	1.8	1.7	1.7	
Processing –	manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic organic chemical manufacturing; and adhesive and sealant manufacturing Plasticizer in adhesive and sealant manufacturing; building and		HE	9.0	0.9	0.8	0.8	
articles	construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing							
Commercial Use – Construction, paint, electrical,	Adhesives and sealants	Application of	СТ	304	1.8	1.8	1.8	
and metal products Industrial Use – Construction, paint, electrical, and metal products	Adhesives and sealants	adhesives and sealants	HE	152	0.9	0.9	0.9	

				Acute MOEs for Female Workers of Reproductive Age (Benchmark = 30)					
Life Cycle Stage – Category	Subcategory	OES	Exposure Level	Inhalation MOE (DBP COU; Exposure to DBP)	Dermal MOE (DBP COU; Exposure to DBP)	Aggregate MOE (DBP COU; Exposure to DBP)	Cumulative MOE (Aggregate DBP MOE + Cumulative Non-Attributable) ^{<i>a</i>}		
Commercial Use – Packaging, paper, plastic, toys, hobby products	Ink, toner, and colorant products		СТ	18	1.8	1.7	1.7		
Commercial Use – Commercial use – Construction, paint, electrical, and metal products Industrial Use – Construction, paint, electrical, and metal products		Application of paints and coatings	HE	2.9	0.9	0.7	0.7		
Industrial Use – Non-incorporative	Solvent, including in maleic anhydride manufacturing	Use of Industrial Process Solvents	СТ	30	1.8	1.7	1.7		
activities	technology	Process Solvents	HE	15	0.9	0.9	0.9		
Commercial Use –	Laboratory chemicals	Use of laboratory	СТ	400	135	101	81		
Other uses	Laboratory enemicars	chemicals (Solid)	HE	28	67	20	19		
Commercial Use –	Laboratory chemicals	Use of laboratory	СТ	304	2.4	2.4	2.4		
Other uses		chemicals (Liquid)	HE	152	0.9	0.9	0.9		
Commercial Use –	Lubricants and lubricant additives		СТ	304	3.3	3.2	3.2		
Other uses	Chemiluminescent light sticks Lubricants and lubricant additives	Use of lubricants and functional fluids	HE	152	1.1	1.1	1.1		

				Acute MOEs for Female Workers of Reproductive Age (Benchmark = 30)					
Life Cycle Stage – Category	Subcategory	OES	Exposure Level	Inhalation MOE (DBP COU; Exposure to DBP)	Dermal MOE (DBP COU; Exposure to DBP)	Aggregate MOE (DBP COU; Exposure to DBP)	Cumulative MOE (Aggregate DBP MOE + Cumulative Non-Attributable) ^a		
Commercial Use – Other uses	Inspection penetrant kit	Use of penetrants and inspection fluids	CT HE	10 2.7	1.8 0.9	1.5 0.7	0.7		
	Cleaning and furnishing care products		СТ	152	135	71	61		
Commercial Use – Furnishing, cleaning, treatment care products	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel; Furniture and furnishings Automotive care products								
Automotive, fuel, agriculture, outdoor use products Commercial Use –	Automotive articles	Fabrication or use of final products or articles	HE	18	67	14	14		
Other Uses Industrial Use – Other Uses	Automotive articles Propellants	-							
Commercial Use – Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging), including rubber								
Processing – Recycling	Recycling	Recycling	CT HE	141 9.7	135 67	69 8.4	59 8.3		
Kuyunng	l		HE	9./	0/	ð.4	8.3		

				Acute MOEs for Female Workers of Reproductive Age (Benchmark = 30)					
Life Cycle Stage – Category	Subcategory	OES		Inhalation MOE (DBP COU; Exposure to DBP)	Dermal MOE (DBP COU; Exposure to DBP)	Aggregate MOE (DBP COU; Exposure to DBP)	Cumulative MOE (Aggregate DBP MOE + Cumulative Non-Attributable) ^{<i>a</i>}		
Disposal – Disposal		Waste handling, treatment, and disposal	CT HE	141 9.7	135 67	69 8.4	59 8.3		
cumulative non–attr biomonitoring data equivalents), (3) sur	^a The acute cumulative MOE is derived by summing inhalation exposure from each individual DBP COU with dermal exposure from the same DBP COU and the cumulative non–attributable exposure to DEHP, DBP, BBP, DIBP, and DINP. Non-attributable cumulative exposure was estimated from NHANES urinary biomonitoring data using reverse dosimetry. All exposure estimates were (1) scaled by relative potency, (2) expressed in index chemical equivalents (<i>i.e.</i> , DBP equivalents), (3) summed to calculate cumulative exposure in index chemical equivalents, and then (4) compared to the index chemical POD (<i>i.e.</i> , HED of 2.1 mg/kg-day) to calculate the cumulative MOE.								

4616	4.4.5 Risk Estimates for Consumers Based on Relative Potency
4617	This section summarizes cumulative risk estimates for consumers from acute duration exposures to
4618	DBP. EPA focused its CRA on females of reproductive age and male infants and children. EPA focused
4619	its consumer CRA on these populations for the acute exposure duration because, as described in Section
4620	4.4 and (U.S. EPA, 2025x), these populations and exposure duration are considered most directly
4621	applicable to the common hazard outcome that serves as the basis for the cumulative assessment (<i>i.e.</i> ,
4622	reduced fetal testicular testosterone). For consumers, EPA did not specifically evaluate females of
4623	reproductive age or male infants and children; however, consumer exposures of teenagers (16–20 years)
4624	and adults (21+ years) were considered a proxy for females of reproductive age, while infants (<1 year),
4625	toddlers (1–2 years), children (3–5 and 6–10 years), and young teens (11–15 years) were considered a
4626	proxy for male infants and children.
4627	
4628	To evaluate cumulative risk to consumers, EPA combined inhalation, dermal, and ingestion exposures to
4629	DBP from each individual consumer COU and product/article exposure scenario with non-attributable
4630	cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP (estimated from NHANES urinary
4631	biomonitoring using reverse dosimetry). As described in Section 4.4.3, for each individual phthalate
4632	exposures were scaled by relative potency per chemical, expressed in terms of index chemical (DBP)
4633	equivalents, and summed to estimate cumulative exposure and cumulative risk for each COU. Because
4634	DBP is the index chemical and the RPF is 1, scaling has no effect on individual DBP exposure
4635	estimates.
4636	
4637	As described in Section 4.3.3, EPA evaluated a number of product or article example exposure scenarios
4638	associated with five consumer COUs. Of the evaluated product or article examples, 14 (associated with
4639	5 COUs) have high-intensity cumulative MOEs ranging 46 to 482 (cumulative benchmark = 30) (listed
4640	below). Seven product or article examples (associated with 3 COUs) have high-intensity aggregate
4641	MOEs less than 30 (listed below). For these seven product or article examples, the addition of non-
4642	attributable cumulative exposure from NHANES has no effect on risk conclusions, and these seven
4643	product or articles examples are not further discussed. Two product or article examples (associated with
4644	2 COUs) have high-intensity cumulative MOEs ranging from 27 to 29 (benchmark = 30). Notably, one
4645	of these product or article examples also had high-intensity MOEs less than 30 for several consumer age
4646	groups in the individual DBP consumer risk characterization (Section 4.3.3; Table 4-19). However, for
4647	this one product or article example, several new consumer age groups have cumulative MOEs below 30
4648	that were above 30 in the individual DBP consumer risk characterization (Table 4-24). The newly
4649	identified consumer age groups for this product or article example are discussed further below.
4650	
4651	Product or Article Examples with Acute High-Intensity Cumulative Moes Ranging from 46 to 482
4652	As can be seen from Table 4-24, cumulative MOEs for high-intensity scenarios ranged from 46 to 482
4653	for all consumer age groups evaluated for 14 product or articles examples (associated with 5 COUs),
4654	including the following:
4655	• Construction, paint, electrical, and metal products: adhesives for small repairs (cumulative
4656	MOEs: 61–65);
4657	• Furnishing, cleaning, treatment/care products: vinyl flooring (cumulative MOEs: 94–221);
4658	 Furnishing, cleaning, treatment/care products: wallpaper (in-place) (cumulative MOEs: 72–395);
4659	 Furnishing, cleaning, treatment/care products: wallpaper (in piace) (cumulative MOEs: 72 595), Furnishing, cleaning, treatment/care products: wallpaper (installation) (cumulative MOEs:
4660	98–103);
1000	(-1)

- Other uses: car mats (cumulative MOEs: 194–379);
- Other uses: small articles with semi routine contact; glow sticks (cumulative MOEs: 74–166);

- Other uses: novelty articles: adult toys (cumulative MOEs: 262–268);
- Furnishing, cleaning, treatment care products: synthetic leather clothing (cumulative MOEs: 61–64);
- Furnishing, cleaning, treatment care products: synthetic leather furniture (cumulative MOEs: 58–4667 406);
- Packaging, paper, plastic, hobby products: footwear components (cumulative MOEs: 46–103);
- Packaging, paper, plastic, hobby products: shower curtains (cumulative MOEs: 122–286);
- Packaging, paper, plastic, hobby products: tire crumb (cumulative MOEs: 194–482);
- Packaging, paper, plastic, hobby products: small articles with semi routine contact;
 miscellaneous items including a pen, pencil case, hobby cutting board, costume jewelry, tape,
 garden hose, disposable gloves, and plastic bags/pouches (cumulative MOEs: 74–166); and
- Packaging, paper, plastic, hobby products: small articles with semi routine contact;
 miscellaneous items including a football, balance ball, and pet toy (cumulative MOEs: 74–166).
- 4677 Product or Article Examples with Acute High-Intensity Aggregate from the Individual DBP
 4678 Assessment and Cumulative Moes Less than 30
- As can be seen from Table 4-19 and Table 4-24, aggregate and cumulative MOEs for high-intensity
 scenarios were less than 30 for the same consumer age groups evaluated for seven product or article
 examples (associated with 3 COUs), including:
- Construction, paint, electrical, and metal products: metal coatings;
- Construction, paint, electrical, and metal products: indoor flooring sealing and refinishing products;
- Construction, paint, electrical, and metal products: sealing and refinishing sprays (outdoor use);
- Construction, paint, electrical, and metal products: automotive adhesives;
- Construction, paint, electrical, and metal products: construction adhesives;
- Furnishing, cleaning, treatment care products: waxes and polishes; and
- Packaging, paper, plastic, hobby products: children's toys (legacy).

4691 Product or Article Examples with Acute Cumulative Moes Ranging from 27 to 29

As can be seen from Table 4-24, cumulative MOEs for high-intensity scenarios ranged from 27 to 29 for two product or articles examples (associated with 2 COUs). One of these product or article examples also had MOEs less than 30 in the individual DBP consumer risk assessment (Section 4.3.3); however, at least one new consumer age group had a cumulative MOEs below 30 that was above 30 in the individual DBP consumer risk characterization (Table 4-19). These include the following:

- Furnishing, cleaning, treatment/care products: spray cleaner. Acute high-intensity cumulative MOEs ranged from 27 to 29 for young teens (11–15 years), teenagers (16–20 years), and adults (21+ years), while medium-intensity cumulative MOEs ranged from 90 to 95 for these same age groups (Table 4-24). All of these age groups, except teenagers (16–20 years) (high-intensity aggregate MOE = 31), also had high-intensity MOEs below 30 in the individual DBP consumer risk assessment (Table 4-19).
- Packaging, paper, plastic, hobby products: children's toys (new). The acute high-intensity cumulative MOE was 29 for infants (<1 year), while the medium-intensity cumulative MOE was 55 for the age group (Table 4-24). Comparatively, the acute high-intensity aggregate MOE was 34 for infants (<1 year) in the individual DBP consumer risk assessment (Table 4-19). Acute high-intensity cumulative MOEs ranged from 52 to 353 for other evaluated age groups.
- 4708

4709 EPA characterizes consumer COUs and product or article examples as part of the individual DBP

- 4710 assessment in Section 4.3.3, while these consumer COUs are characterized for cumulative risk above in 4711 this section. One factor contributes to the lower cumulative MOEs compared to the MOEs in the
- 4712 individual DBP consumer risk assessment—that is the addition of non-attributable cumulative phthalate
- 4713 exposure from NHANES. Because DBP is the index chemical and the RPF is 1, scaling by relative
- 4714 potency has no effect on DBP exposure estimates. Similarly, the same POD (HED of 2.1 mg/kg-day)
- based on reduced fetal testicular testosterone is used to calculate MOEs in the individual DBP
- 4716 assessment and in the cumulative risk assessment. EPA calculated non-attributable cumulative exposure
- to DEHP, DBP, BBP, DIBP, and DINP using NHANES urinary biomonitoring data from the 2017 to
 2018 survey (most recent data set available) and reverse dosimetry (see Section 4.4.2 and (U.S. EPA,
- 4719 2025x) for further details), representing exposure to a national population.
- 4720

4721 Non-attributable cumulative exposure estimates were scaled by relative potency and expressed in index 4722 chemical (DBP) equivalents. Non-attributable cumulative exposure was then combined with acute inhalation, dermal, and ingestion DBP exposures for each individual product or article example 4723 exposure scenario scaled by relative potency. For infants, toddlers, and preschoolers, EPA added a non-4724 4725 attributable cumulative exposure of 10.8 µg/kg index chemical (DBP) equivalents to calculate the 4726 cumulative MOE, which contributes 15.5 percent to the risk cup with a benchmark MOE of 30. For 4727 middle-aged children, EPA added a non-attributable cumulative exposure of 7.35 µg/kg index chemical 4728 (DBP) equivalents to calculate the cumulative MOE, which contributes 10.5 percent to the risk cup with 4729 a benchmark MOE of 30. For young teens (11-15 years), EPA added a non-attributable cumulative 4730 exposure of 4.36 µg/kg index chemical (DBP) equivalents to calculate the cumulative MOE, which 4731 contributes 6.2 percent to the risk cup with a benchmark MOE of 30. For teenagers (16-20 years) and 4732 adults (21+ years), EPA added a non-attributable cumulative exposure of 5.15 µg/kg index chemical 4733 (DBP) equivalents to calculate the cumulative MOE, which contributes 7.4 percent to the risk cup with a 4734 benchmark MOE of 30.

4735

4.4.5.1 Overall Confidence in Cumulative Consumer Risks

4736 As described in Section 4.1.2, and in more technical details in the Draft Consumer and Indoor Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025c), EPA has moderate or robust confidence in 4737 4738 the assessed inhalation, ingestion, and dermal consumer exposure scenarios. The Agency has robust 4739 confidence in the RPFs and index chemical POD used to calculate the cumulative MOEs (Section 4.4.1.2). To derive RPFs and the index chemical POD, EPA integrated data from multiple studies 4740 4741 evaluating fetal testicular testosterone using a meta-analysis approach and conducted BMD modeling. 4742 Finally, EPA has robust confidence in the non-attributable cumulative exposure estimates because they 4743 were calculated from CDC's NHANES biomonitoring dataset, which provides a statistically 4744 representative sampling of the U.S. civilian population (Section 4.4.2.1). Furthermore, the Agency used 4745 a well-established reverse dosimetry approach to calculate phthalate daily intake values from urinary biomonitoring data. Overall, EPA has moderate to robust confidence in the cumulative risk estimates 4746 4747 calculated for consumer exposure scenarios (Table 4-24).

4748 **Table 4-24. Consumer Cumulative Risk Summary Table**

		Exposure		Lifestage (Years) MOE (Based on All Exposures in Index Chemical Equivalents) (Benchmark MOE = 30)							
Life Cycle Stage: COU: Subcategory	Product or Article	Level (H, M, L) ^{<i>a</i>}	Exposure Scenario	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenager (16–20 years)	Adult (21+ years)	
Automotive, Fuel, Agriculture, Outdoor Use Products: Automotive care products			Uses were matched	d with auto	motive adhe	sives.					
Construction. Paint.	Automotive adhesives	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	88	90	100	146	7 ^c	7 ^c	7 ^c	
Electrical, and Metal Products: Adhesives and	Construction adhesives	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	_	-	-	_	7 ^c	8 ^c	7 ^c	
Products: Adhesives and sealants Construction, Paint,	Adhesives for small repairs	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	_	-	-	-	61	65	61	
	Metal coatings	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	194	194	194	286	7 ^c	8 ^c	7 ^c	
Electrical, and Metal	Indoor flooring sealing and refinishing products	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	68	70	80	116	14 ^c	16 ^{<i>c</i>}	15 ^c	
rioducts. Faints and coatings	Sealing and refinishing sprays (outdoor use)	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	62	65	74	98	7 ^c	8 ^c	8 ^c	
Furnishing, Cleaning,	Synthetic leather	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	-	-	-	-	_	_ e	_ e	
Treatment Care Products: Fabric, textile, and leather	clothing	М	Cumulative (Aggregate COU + Cumulative Non-attributable)	-	-	-	-	_	64	61	
products	Synthetic leather furniture	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	58	82	103	285	480	406	406	
Furnishing, Cleaning, Treatment/Care Products:	Vinyl flooring	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	94	100	108	150	221	214	212	
Floor coverings; construction and building materials	Wallpaper (in-place)	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	72	79	86	116	163	162	395	
covering large surface areas including stone, plaster, cement, glass, and ceramic articles; fabrics, textiles, and apparel	Wallpaper (installation)	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	_	_	_	-	100	103	98	

Life Cycle Stage: COU: Subcategory	Product or Article	Exposure Level (H, M, L) ^a	Exposure Scenario	Lifestage (Years) MOE (Based on All Exposures in Index Chemical Equivalents) (Benchmark MOE = 30)						
				Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenager (16–20 years)	Adult (21+ years)
Furnishing, Cleaning, Treatment/Care Products: Cleaning and furnishing care products	Spray cleaner	Н	Dermal (COU alone)	_	_	_	_	28	31	29
			Inhalation (COU alone)	66,922 ^d	71,040 ^d	87,390 ^d	125,504 ^d	37,467	47,754	55,143
			Aggregate (COU alone)	-	-	-	-	28	31	29
			Cumulative (NHANES)	194	194	194	286	482	407	407
			Cumulative (Aggregate COU + Cumulative NHANES)	194	194	194	285	27 ^c	29 ^b	27 ^c
		М	Dermal (COU alone)	-	-	-	-	113	123	115
			Inhalation (COU alone)	141,507 ^d	150,215 ^d	184,788 ^d	265,379 ^d	77,062	95,900	113,066
			Aggregate (COU alone)	_	-	-	-	113	123	115
			Cumulative (NHANES)	194	194	194	286	482	407	407
			Cumulative (Aggregate COU + Cumulative NHANES)	194	194	194	285	91	95	90
	Waxes and polishes	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	194	194	194	285	14 ^c	15 ^c	14 ^c
Packaging, paper, plastic, toys hobby products: Ink, toner, and colorant products	No consumer products identified. Foreseeable uses were matched with adhesives for small repairs because similar use patterns are expected.									
Packaging, Paper, Plastic, Hobby Products: Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft)	Footwear components	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	46	51	57	74	100	103	98
	Shower curtains	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	122	129	135	189	286	266	261
	Small articles with semi routine contact; miscellaneous items including a pen, pencil case, hobby cutting board, costume jewelry, tape, garden hose, disposable gloves, and plastic bags/pouches	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	74	81	88	118	166	165	159

Life Cycle Stage: COU: Subcategory	Product or Article	Exposure Level (H, M, L) ^a		Lifestage (Years) MOE (Based on All Exposures in Index Chemical Equivalents) (Benchmark MOE = 30)						
			Exposure Scenario	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenager (16–20 years)	Adult (21+ years)
	Children's toys (new)		Dermal (COU alone)	112	131	151	188	237	260	-
			Ingestion (COU alone)	52	197	382	84,935	151,691	191,207	427,072
			Inhalation (COU alone)	693	735	904	1,299	1,841	(16-20 years) (21+ years) 260 - 191,207 427,072 2,150 2,678 231 2,661 407 407 148 353 324 - 776,168 1,733,372 8,758 10,908 312 10,840 407 407 177 392 91 161 407 407 165 159	
		Н	Aggregate (COU alone)	34	71	97	164	210	231	2,661
			Cumulative (NHANES)	194	194	194	286	482	407	407
			Cumulative (Aggregate COU + Cumulative NHANES)	29 ^b	52	65	104	146	148	353
			Dermal (COU alone)	140	163	189	234	296	324	-
			Ingestion (COU alone)	177	444	1,323	344,795	615,767	776,168	1,733,372
Packaging, Paper, Plastic, Hobby Products: Toys, Playground, and Sporting Equipment			Inhalation (COU alone)	2,821	2,994	3,683	5,290	7,499	8,758	10,908
		М	Aggregate (COU alone)	76	115	158	224	285	312	10,840
			Cumulative (NHANES)	194	194	194	286	482	407	407
			Cumulative (Aggregate COU + Cumulative NHANES)	55	72	87	126	179	177	392
	Children's toys (legacy)	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	21 ^c	31	39	60	85	91	161
	Tire crumb	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	_	_	194	286	482	407	407
	Small articles with semi routine contact; miscellaneous items including a football, balance ball, and pet toy	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	74	81	88	118	166	165	159
Other Uses: Chemiluminescent light sticks	Small articles with semi routine contact; glow sticks	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	74	81	88	118	166	165	159
Other Uses: Automotive products, other than fluids	Car mats	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	194	194	194	285	379	336	333
	Synthetic leather seats (see synthetic leather furniture)	Н	Cumulative (Aggregate COU + Cumulative Non-attributable)	58	82	103	285	480	406	406
Other Uses: Novelty articles	Adult toys	Н	Cumulative (Aggregate COU + Cumulative NHANES)	_	-	-	-	_	268	262

Life Cycle Stage: COU: Subcategory	Product or Article	Exposure		Lifestage (Years) MOE (Based on All Exposures in Index (Benchmark MOE =	Chemical Equivalents)			
		Level (H, M, L) ^{<i>a</i>}	Exposure Scenario	Infant (<1 Year)	Toddler (1–2 Years)	Preschooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)
Other uses: Lubricants and lubricant additives	No consumer products identified. Foreseeable uses were matched with adhesives for small repairs because similar use patterns are expected.							
 ^a Exposure scenario intensities include high (H), medium (M), and low (L). ^b MOEs for this age group are <30 in the cumulative assessment, but not the individual DBP risk assessment. ^c MOEs for this age group are <30 in both the cumulative and individual DBP risk assessment. ^d MOE for bystander scenario. ^e Scenario was deemed to be unlikely due to high uncertainties. 								

4750 **Cumulative Risk Estimates for the General Population** 4.4.6

4751 For DBP, EPA did not evaluate cumulative risk for the general population from environmental releases. 4752 As discussed in Section 4.1.3, the Agency employed a screening level approach to assess risk from 4753 exposure to DBP for the general population from environmental releases. However, as discussed in 4754 Section 4.4.2, EPA did evaluate cumulative exposure and risk from exposure to phthalates DEHP, DBP, 4755 BBP, DIBP, and DINP using NHANES urinary biomonitoring data. As noted previously, the NHANES 4756 biomonitoring dataset is a national, statistical representation of the general, non-institutionalized, 4757 civilian U.S. population and provides estimates of average aggregate exposure to individual phthalates. 4758 As can be seen from Table 4-21, and as discussed in more detail in the *Revised Draft Technical Support* 4759 Document for the Cumulative Risk Analysis of DEHP, DBP, BBP, DIBP, DCHP, and DINP Under 4760 TSCA (U.S. EPA, 2025x), 95th percentile cumulative MOEs ranged from 194 to 592 (cumulative 4761 benchmark = 30) for females of reproductive age and male children. These MOEs indicate both that the 4762 risk cup is 6.2 to 15.5 percent full and that cumulative exposure to DEHP, DBP, DIBP, BBP, and DINP, based on the most recent NHANES survey data (2017–2018), does not currently pose a risk to most 4763 4764 male children or pregnant women within the U.S. civilian population.

4.5 Comparison of Single Chemical and Cumulative Risk Assessments 4765

4766 In support of the developed CRA, EPA has relied substantially on existing CRA-related work by the 4767 Agency's Risk Assessment Forum (RAF), EPA Office of Pesticide Programs (OPP), the Organisation 4768 for Economic Co-operation and Development (OECD), the European Commission, and the World 4769 Health Organization (WHO) and International Programme on Chemical Safety (IPCS):

- Guidelines for the Health Risk Assessment of Chemical Mixtures (U.S. EPA, 1986);
- Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common • Mechanism of Toxicity (U.S. EPA, 1999);
- 4773 • Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures (U.S. 4774 EPA, 2000);
 - General Principles for Performing Aggregate Exposure and Risk Assessments (U.S. EPA, 2001); •
 - Guidance on Cumulative Risk Assessment of Pesticide Chemicals that Have a Common Mechanism of Toxicity (U.S. EPA, 2002a);
 - Framework for Cumulative Risk Assessment (U.S. EPA, 2003);
 - Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple • Chemicals, Exposures, and Effects: A Resource Document (U.S. EPA, 2007a);
- 4781 Pesticide Cumulative Risk Assessment: Framework for Screening Analysis Purpose (U.S. EPA, 4782 2016b);
- 4783 Advances in Dose Addition For Chemical Mixtures: A White Paper (U.S. EPA, 2023b). •
- 4784 Phthalates and Cumulative Risk Assessment: The Tasks Ahead (NRC, 2008); ٠
 - State of the Art Report on Mixture Toxicity (Kortenkamp et al., 2009); ٠
- 4786 Risk Assessment of Combined Exposure to Multiple Chemicals: A WHO/IPCS Framework (Meek ٠ et al., 2011); and
- 4788 Considerations for Assessing the Risks of Combined Exposure to Multiple Chemicals (OECD, • 4789 2018).
- 4790 EPA has evaluated risks for workers (Section 4.3.2), consumers (Section 4.3.3), and the general
- 4791 population (Section 4.3.4) from exposure to DBP alone, as well as cumulative risks for workers (Section
- 4792 4.4.4) and consumers (Section 4.4.5) that take into account differences in relative potency and
- 4793 cumulative non-attributable exposure to DEHP, DBP, BBP, DIBP, and DINP from NHANES
- 4794 biomonitoring and reverse dosimetry.

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4795 4796 There are several notable differences between the individual DBP assessment (Section 4.3) and the CRA 4797 (Section 4.4). As part of the individual DBP assessment (Section 4.3), EPA considered all human health 4798 hazards of DBP and selected a POD based on a BMDL₅ for reduced fetal testicular testosterone to 4799 characterize risk from exposure to DBP. As part of its exposure assessment in the individual DBP 4800 assessment, EPA considered acute, intermediate, and chronic exposures durations for a broad range of 4801 populations—including female workers of reproductive age, average adult workers, ONUs, the general 4802 population, and consumers of various lifestages (e.g., infants, toddlers, children, adults). Furthermore, in 4803 the individual DBP assessment, EPA evaluated inhalation and dermal exposures to workers, as well as 4804 consumer exposure to DBP via the inhalation, dermal, and ingestion exposure routes. In contrast, the CRA is more focused in scope (Section 4.4). First, the CRA is based on a uniform measure of hazard 4805 4806 (*i.e.*, reduced fetal testicular testosterone) that serves as the basis for deriving RPFs and the index chemical (DBP) POD, which were derived via meta-analysis and BMD modeling (Section 4.4.1). 4807 4808 Second, the CRA is focused on acute duration exposures and the most sensitive populations (*i.e.*, 4809 females of reproductive age, male infants, male children) (Section 4.4). Finally, for the CRA, DBP exposures from individual consumer and worker COUs were combined with non-attributable cumulative 4810 4811 exposure to DEHP, DBP, BBP, DIBP, and DINP from NHANES.

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4813 Both the individual DBP assessment (Section 4.3) and the CRA (Section 4.4) led to the same 4814 conclusions regarding risk estimates for workers (Section 4.4.4). For consumers, the individual DBP 4815 assessment (Section 4.3) and the CRA (Section 4.4) led to similar conclusions regarding risk for 21 out 4816 of 23 product or article examples evaluated (Section 4.4.5). As discussed in Section 4.4.5, highintensity, acute, cumulative MOEs were less than 30 for several age groups for two product or articles 4817 4818 example exposure scenarios, whereas high-intensity, acute, aggregate MOEs were equal to or greater 4819 than 30 for these age groups in the individual DBP assessment. Overall, one factor influenced 4820 differences in risk estimates between the individual DBP assessment (Section 4.3) and the CRA (Section 4821 4.4); that is, addition of non-attributable cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP 4822 from NHANES. Overall, this non-attributable cumulative exposure contributes 6.2 to 15.5 percent to the 4823 risk cup, depending on the population and age group.

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4825 EPA has robust confidence in its CRA and moderate to robust confidence in its individual assessment of
4826 DBP for workers (Section 4.3.2.1), consumers (Section 4.3.3.1), and the general population (Section
4827 4.3.4). RPFs used to scale for relative potency were calculated based on a common hazard endpoint (*i.e.*,
4828 reduced fetal testicular testosterone) using data from multiple studies evaluating effects of phthalates on
4829 fetal testicular testosterone using a meta-analysis and BMD modeling approach for each of the six
4830 phthalates included in the cumulative chemical group (U.S. EPA, 2025x). This analysis provides a
4831 robust basis for assessing the dose-response for the common hazard endpoint (*i.e.*, reduced fetal

4832 testicular testosterone) across the six toxicologically similar phthalates included in the CRA.

4833 **5 ENVIRONMENTAL RISK ASSESSMENT**

DBP – Environmental Risk Assessment (Section 5): Key Points

EPA considered all reasonably available information identified through the systematic review process under TSCA to characterize environmental risk for DBP. The following bullets summarize the key points.

- Aquatic species:
 - RQs greater than 1 were identified with robust overall confidence from water releases from the Waste handling, treatment, and disposal OES and the associated Disposal COU for chronic exposure to DBP in aquatic vertebrates (RQ = 9.23) and aquatic invertebrates (RQ = 1.18).
 - This COU had robust overall confidence because the surface water release estimate (and associated surface water concentrations of DBP) for its associated OES was derived from data reported to DMR.
 - RQs greater than 1 were identified for the PVC plastics compounding OES and associated COUs for chronic exposure to DBP in aquatic vertebrates (RQ = 1.04). The same RQ was also identified for the PVC plastics converting and recycling OES, which used the PVC plastics compounding OES releases as a surrogate.
 - These OESs and associated COUs had robust overall confidence because the surface water release estimates (and associated surface water concentrations of DBP) for its associated OES was derived from data reported to TRI. EPA does not use RQ values as a bright-line to determine the unreasonable risk.
 - No RQs greater than 1 were identified for other OESs/COUs for aquatic species from releases to water.
- Benthic (sediment-dwelling) species:
 - No RQs greater than 1 were identified for chronic exposures to DBP in benthic organisms from releases to sediment.
- Terrestrial species:
 - No RQs greater than 1 were identified for exposures to DBP in terrestrial mammals through trophic transfer.
 - No RQs greater than 1 were identified for exposures to DBP soil invertebrates from releases to soil.
 - No RQs greater than 1 were identified for exposures to DBP in terrestrial plants from releases to soil.

4834 **5.1 Summary of Environmental Exposures**

4835 EPA assessed environmental concentrations of dibutyl phthalate (DBP) in air, water, and land for use in

4836 environmental exposure (Table 5-1). The environmental exposures are described in the *Draft Physical*

4837 *Chemistry and Fate and Transport Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2024j) and the

4838 Draft Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl

4839 *Phthalate (DBP)* (U.S. EPA, 2025p). DBP will preferentially sorb into sediments, soils, particulate

4840 matter in air, and in wastewater solids during wastewater treatment. High-quality studies of DBP
4841 biodegradation rates and physical and chemical properties indicate that DBP will have limited

4842 persistence and mobility in soils receiving biosolids. Surface water, pore water, and sediment concentrations of DBP were modeled using VVWM-PSC. The Waste handling, treatment, and disposal 4843 OES (refer to Table 3-2 for a crosswalk of COUs to each OES) resulted in the highest surface water 4844 4845 concentrations of DBP from reported releases, up to 14.40 µg/L in both chronic (>60 days) and acute 4846 (1–7 day) scenarios. Sediment concentrations from this OES ranged from 0.178 mg DBP/kg dry 4847 sediment (mg/kg) in chronic scenarios to 0.334 mg/kg sediment in acute scenarios. These DMR-reported 4848 releases are based on releases to surface water at the external outfall of a POTW; therefore, no additional 4849 wastewater treatment removal efficiency was applied.

4850

4862

4851 For the Use of lubricants and functional fluids OES, reported releases were not obtained by EPA and a generic release to water was modeled. Based on comparison with reported scenarios for DBP 4852 4853 wastewater release, the Agency does not expect high releases of DBP to the lowest-flow generic 4854 condition (P50 7Q10) water bodies. For this reason, EPA had higher confidence in the use of the P90 4855 7Q10 flow rate for this scenario, and this rate was used in the environmental assessment for the Use of 4856 lubricants and functional fluids OES and corresponding COUs. The use of the P90 flow rate resulted in modeled surface water concentrations that ranged from 0.03 µg/L in chronic (>60-day) scenarios to 2.42 4857 4858 ug/L in acute (1 to 7-day) scenarios. Sediment concentrations from this OES at the P90 flow rate ranged 4859 from 0.00065 mg/kg in chronic scenarios to 0.006 mg/kg in acute scenarios. Because all water and sediment concentrations were below concentrations of concern for this OES and associated COUs, the 4860 4861 P90 flow was used without consideration of wastewater treatment removal efficiency.

4863 Five OESs (Manufacturing, Application of adhesives and sealants, Application of paints and coatings, 4864 Use of laboratory chemicals, and Use of penetrants and inspection fluids) had modeled releases from generic scenarios for multimedia discharges to combinations of multiple of the following parameters: 4865 water, wastewater (POTW), incineration, landfill, and air. For these OESs, there was insufficient 4866 4867 information to determine the fraction of the release going to each of the reported media types, including 4868 to surface water. For these OESs, surface water, pore water, and sediment concentrations of DBP were 4869 estimated using VVWM-PSC and assuming a conservative scenario in which all of the multimedia 4870 releases were to surface water. Based on comparison with reported scenarios for DBP wastewater 4871 release, EPA does not expect high releases of DBP to the lowest-flow generic condition (P50 7010) 4872 water bodies. For this reason, the Agency had higher confidence in the use of the P90 7Q10 flow rate for 4873 this scenario and this rate was used in the environmental assessment. The use of the P90 flow rate 4874 resulted in modeled surface water concentrations for the highest OES (Manufacturing) that were up to 4.00 µg/L in both chronic (>60-day) and acute (1 to 7-day) scenarios without wastewater treatment. 4875 4876 Because these generic scenarios did not include wastewater treatment and some water concentrations 4877 were above concentrations of concern, as an additional refinement wastewater treatment removal 4878 efficiency was applied. Concentrations ranged between 0.080 μ g/L and 1.40 μ g/L with wastewater 4879 treatment based on estimated wastewater treatment removal efficiency of 65 to 98 percent (U.S. EPA, 4880 1982) (Table 2-2). Sediment concentrations from these OESs at the P90 flow rate ranged from 0.0499 4881 mg/kg in chronic scenarios to 0.093 mg/kg in acute scenarios.

4882

4883 There are uncertainties in the relevance of limited monitoring data for biosolids and landfill leachate to 4884 the COUs considered. However, based on high-quality physical and chemical property data, EPA determined that DBP will have low persistence potential and mobility in soils. Therefore, groundwater 4885 4886 concentrations resulting from releases to the landfill or to agricultural lands via biosolids applications were not quantified but were discussed qualitatively. Air releases of DBP from fugitive and stack 4887 emissions with deposition to soil were estimated using IIOAC, as described in Section 8.1.3 of the Draft 4888 4889 Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl 4890 *Phthalate (DBP)* (U.S. EPA, 2025p). The highest annual deposition rate to soil, $1.78 \,\mu g/kg/year$

4891 (0.00178 mg/kg/year), was based on a combination of fugitive emissions from the Application of paints,

4892 coatings, adhesives, and sealants OES and stack emissions from the Waste handling, treatment, and

disposal OES and was located 100 m from the point of release. These releases were combined to form a 4893 4894 single highest-emissions scenario for the screening analysis (see Section 4.1.3). Based on the half-life of

4895 DBP in soil, equilibrium soil concentrations from air releases are expected to be lower than this

4896 deposition rate (see Section 5.3.2).

4897

4898 Limited measured data were reasonably available from the scientific literature on DBP concentrations in 4899 soils, biosolids, soils receiving biosolids, and landfills. No monitoring data of DBP in these 4900 environments were reasonably available. Limited reasonably available information was available related to the uptake and bioavailability of DBP in soils. DBP is expected to have minimal air to soil deposition. 4901 4902 Based on estimated water solubility (11.2 mg/L) and hydrophobicity (log Kow = 4.5; log Koc = 3.14-4903 3.94), DBP is expected to have low bioavailability in soil. Based on the reasonably available evidence, trophic transfer of DBP in aquatic or terrestrial organisms is not expected and DBP has low

4904

4905 bioaccumulation and biomagnification potential.

4906

	Release		DBP Cor	ncentration		
OES ^a Medi		Environmental Media	Acute (1–7 days)	Chronic (>60 days)	Data Source	
Waste handling,	Water	Total water column (7Q10) ^b	14.40 µg/L	14.40 µg/L		
treatment, and disposal	Sediment	Benthic sediment (7Q10)	0.334 mg/kg	0.178 mg/kg	DMR (reported	
PVC plastics	Water	Total water column (7Q10)	1.63 µg/L	1.63 µg/L	release)	
compounding	Sediment	Benthic sediment (7Q10)	0.038 mg/kg	0.022 mg/kg		
		Total water column (7Q10), P50 flow c	703 µg/L	7.38 µg/L		
	Water	P75 flow	41 µg/L	0.57 μg/L		
Use of lubricants and		P90 flow	2.42 µg/L	0.03 µg/L	Generic release (wastewater)	
functional fluids	Sediment	Benthic sediment (7Q10), P50 flow	1.71 mg/kg	0.188 mg/kg		
		P75 flow	0.146 mg/kg	0.015 mg/kg		
		P90 flow	0.006 mg/kg	0.00065 mg/kg		
		Total water column (7Q10), P50 flow c	1,160 µg/L	1,160 µg/L		
		P75 flow	67.80 µg/L	67.80 μg/L		
	Water	P90 flow, no wastewater treatment	$4.00 \ \mu g/L$	4.00 µg/L		
Manufacturing	vi ator	P90 flow, 65% wastewater treatment efficiency	1.40 µg/L	1.40 µg/L	Generic release	
C C		P90 flow, 98% wastewater treatment efficiency	0.080 µg/L	0.080 µg/L	(multimedia)	
		Benthic sediment (7Q10), P50 flow	27.0 mg/kg	14.5 mg/kg		
	Sediment	P75 flow	1.57 mg/kg	0.839 mg/kg		
		P90 flow	0.093 mg/kg	0.0499 mg/kg		

4907 Table 5-1. DBP Concentrations Used in Environmental Risk Characterization

Release			DBP Cor	ncentration	
OES ^a	Media	Environmental Media	Acute (1–7 days)	Chronic (>60 days)	Data Source
		Total water column (7Q10), P50 flow c	920 µg/L	920 µg/L	Generic release
		P75 flow	53.6 µg/L	53.6 µg/L	(multimedia)
	Water	P90 flow, no wastewater treatment	3.17 µg/L	3.17 µg/L	
paints and		P90 flow, 65% wastewater treatment efficiency	1.11 µg/L	1.11 μg/L	
coatings (no spray control)		P90 flow, 98% wastewater treatment efficiency	0.063 µg/L	0.063 μg/L	
		Benthic sediment (7Q10), P50 flow	21.3 mg/kg	11.4 mg/kg	
	Sediment	P75 flow	1.24 mg/kg	0.664 mg/kg	
		P90 flow	0.073 mg/kg	0.039 mg/kg	
Fugitive: application of paints, coatings, adhesives, and sealants; stack: waste handling, treatment, and disposal	Air deposition to soil	Annual deposition rate to soil	1.78 μg/kg/yr (0.00178 mg/kg/yr)		NEI/TRI (Reported release)

^{*a*} Table 3-1 provides the crosswalk of OES to COUs.

4908

^b 7Q10 is the 7 consecutive days of lowest flow over a 10-year period.

^c The P50, P75, and P90 flows refer to the 50th, 75th, and 90th percentiles of the distribution of water body flow rates in generic release scenarios; see Appendix B of the *Draft Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025p).

5.2 Summary of Environmental Hazards

4909 EPA evaluated the reasonably available information for environmental hazard endpoints associated with 4910 DBP exposure to ecological receptors in aquatic and terrestrial ecosystems. The Agency reviewed a total 4911 of 98 references for DBP environmental hazard. Nine references included toxicity information for more 4912 than one taxonomic group; therefore, the number of studies considered by taxonomic group sums to 4913 more than 98. These references included acute and chronic exposures via water, soil, sediment, and 4914 food. EPA reviewed 68 studies for toxicity to aquatic organisms. Of these aquatic studies, 55 met the 4915 criteria for consideration for development of hazard thresholds. EPA reviewed 35 studies for toxicity to 4916 terrestrial wildlife organisms, including plants. Of these terrestrial studies, 30 met the criteria for consideration for development of hazard thresholds. In addition to the 30 high or medium quality 4917 terrestrial wildlife studies, EPA considered 13 terrestrial vertebrate studies for toxicity to DBP in human 4918 4919 health using animal model rodent species that contained ecologically relevant reproductive endpoints. 4920 Studies that were excluded from consideration either (1) received a data quality determination of low or 4921 uninformative, (2) demonstrated no acute or chronic effects up to the highest dose tested, (3) did not 4922 demonstrate any apical health effects, or (4) did not demonstrate any health effects up to the limit of 4923 DBP solubility in water as determined by EPA at 11.2 mg/L (U.S. EPA, 2024). Overall confidence in 4924 the hazard values for each taxonomic group and duration is provided in this section; for more information on the weight of scientific evidence, including the strengths and limitations of the data that 4925 4926 led to these overall confidence conclusions, see Section 2.4 of the Draft Environmental Hazard 4927 Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2024c).

4928

4929 Acute Aquatic Vertebrates, Aquatic Invertebrates, and Benthic Invertebrates

4930 EPA has robust confidence that DBP has acute effects on aquatic vertebrates, aquatic invertebrates, and

benthic invertebrates in the environment. This robust confidence is supported by a species sensitivity

distribution (SSD) incorporating 9 empirical studies with mortality endpoints, supplemented by 53

4933 estimated acute toxicity values from <u>Web-ICE version 4.0.</u> EPA estimated the HC₀₅ to obtain a 4934 concentration that would protect 95 percent of aquatic species from acute effects. Based on the HC₀₅

- 4934 concentration that would protect 95 percent of aquatic species from acute effects. Based on the HC_{05} 4935 derived from the SSD, the acute concentration of concern (COC) for acute effects on aquatic vertebrates 4936 and invertebrates is 347.6 μ g/L DBP.
- 4937

4938 Chronic Aquatic Vertebrates

4939 EPA has robust confidence that DBP has chronic effects on aquatic vertebrates in the environment. This 4940 robust confidence is supported by eleven studies in which effects on mortality, growth, reproduction, 4941 and development were observed in five fish species and two amphibian species. The COC was derived 4942 from a multigenerational study in Japanese medaka (Oryzias latipes) (EAG Laboratories, 2018). In this 4943 study, the growth of the F1 and F2 generations of fish was significantly affected by exposure to DBP. 4944 There was a significant inhibition of bodyweight in F1 generation males at the lowest concentration 4945 studied after exposure of the F0 generation through spawning, plus 112 days of exposure in the F1 generation, with an unbounded lowest-observed-effect concentration (LOEC) value of 15.6 µg/L DBP. 4946 4947 After applying an assessment factor (AF) of 10 (U.S. EPA, 2016c, 2014, 2012a), the chronic COC for 4948 aquatic vertebrates is 1.56 µg/L DBP.

4949

4950 Chronic Aquatic Invertebrates

4951 EPA has robust confidence that DBP has chronic effects on aquatic invertebrates in the environment. 4952 This robust confidence is supported by 8 studies in which effects on mortality, growth, reproduction, and 4953 development were observed in 10 species. The COC was derived from a 14-day study in the marine 4954 amphipod crustacean Monocorophium acheruscicum (Tagatz et al., 1983). In this study, a 14-day 4955 chronic value (ChV) of 122.3 µg/L DBP was observed for reduction in population abundance. 4956 Populations were reduced by 91 percent at the LOEC, which was 340 µg/L DBP. Higher doses resulted 4957 in a complete loss of amphipods in the aquaria. This study was rated medium quality. Based on the 4958 presence of a clear dose-response relationship and a population-level fitness endpoint, the 14-day ChV 4959 for reduction in population abundance in the marine amphipod crustacean was selected to derive the chronic COC for aquatic invertebrates. After applying an AF of 10 (U.S. EPA, 2016c, 2014, 2012a), the 4960 4961 chronic COC for aquatic invertebrates is 12.23 µg/L DBP.

4962

4963 Chronic Benthic Invertebrates

4964 EPA has robust confidence that DBP has chronic effects on benthic invertebrates in the environment. 4965 This robust confidence is supported by five studies in which effects on mortality, growth, and 4966 development were observed in six species. The COC was derived from a 10-day study in the midge 4967 (Chironomus tentans) (Lake Superior Research Institute, 1997). In this study, a 10-day ChV at 1,143.3 4968 mg DBP/kg dry sediment in medium total organic carbon (TOC) sediments (4.80% TOC) was observed for population loss. This study was rated high quality. This ChV was the middle of three for the midge; 4969 4970 the experiment was repeated with low, medium, and high TOC sediments and toxicity decreased with 4971 the increase in TOC, as expected for a relatively hydrophobic compound like DBP based on equilibrium 4972 partitioning theory. The chosen endpoint for deriving the COC, medium-TOC, was selected because it is 4973 the closest to the assumed TOC level (4%) used in Point Source Calculator to estimate DBP exposure in 4974 benthic organisms. Population was reduced by 76.7 percent at the LOEC, which was 3,090 mg DBP/kg 4975 dry sediment. Higher doses resulted in a similar degree of population loss in the medium-TOC 4976 treatment; however, all population losses were significantly different from controls (p < 0.05, one-way

4977 ANOVA with Dunnett's test). This endpoint was considered acceptable to derive a COC because of 4978 population-level relevance and a demonstrated dose-response relationship. After applying an AF of 10 to 4979 the ChV at 1,143.3 mg/kg (U.S. EPA, 2016c, 2014, 2012a), the chronic COC for benthic invertebrates is

- 4980 114.3 mg DBP/kg dry sediment.
- 4981

4982 Aquatic Plants and Algae

4983 EPA has moderate confidence that DBP has adverse effects on aquatic plants and algae in the 4984 environment. This moderate confidence is supported by seven high/medium quality studies, of which three identified hazard values below the DBP limit of water solubility, for one species of green algae 4985 4986 (Selenastrum capricornutum). The COC was derived from a 96-hour study in green algae (Adachi et al., 2006). In this study, a 96-hour ChV of 316 µg/L DBP was observed for reduced population abundance. 4987 4988 This study was rated medium quality. There was significant reduction in the algal population at the 4989 LOEC, which was 1,000 µg/L DBP, relative to an increase in the algal population at the NOEC of 100 4990 μ g/L DBP and in controls. The population reduction was increased with a higher dose of DBP. 4991 Therefore, this endpoint was considered acceptable to derive a COC because of population-level 4992 relevance and a demonstrated dose-response relationship. After applying an AF of 10 (U.S. EPA, 2016c, 4993 2014, 2012a), the COC for aquatic plants and algae is $31.6 \,\mu$ g/L DBP.

4994

4995 **Terrestrial Vertebrates**

4996 EPA has moderate confidence that DBP has adverse effects on terrestrial vertebrates in the environment.

- 4997 This moderate confidence is supported by thirteen studies in which effects on reproduction were 4998 observed in rats (Rattus norvegicus) and mice (Mus musculus). Two additional studies examined DBP
- 4999 exposure to eggs in the chicken (Gallus gallus) and the Japanese quail (Coturnix japonica), but no
- 5000 adverse effects were observed at any dose. The hazard value (HV) was derived from a three-generation reproduction study (NTP, 1995) in the Sprague-Dawley rat. In this study, a 17-week LOAEL was 5001
- 5002 observed for significant reduction in number of live pups per litter at 80 mg/kg-bw/day DBP intake in
- 5003 dams. This study was rated high quality. The above referenced study also found a LOAEL for reduced
- 5004 bodyweight in F2 pups at the same dose (80 mg/kg-bw/day). The lowest bounded NOAEL/LOAEL pair
- 5005 for which a ChV could be calculated was significantly reduced bodyweight in F1 pups at a ChV of 115.4 5006 mg/kg-bw/day, but this effect was not as sensitive as reduced number of live pups per litter. Other
- 5007 effects of DBP exposure included significantly decreased (1) female body weight in dams, (2) male sex
 - 5008 ratio (percentage of male pups), (3) mating index and pregnancy index in the F1 generation, and (4)
 - 5009
 - reduced male pup weight gain. Based on reduction in live pups per litter, the results found in NTP (1995) indicated that the HV for toxicity in terrestrial vertebrates is 80 mg/kg-bw/day DBP. 5010
 - 5011

5012 Soil Invertebrates

5013 EPA has robust confidence that DBP has adverse effects on soil invertebrates in the environment. This 5014 robust confidence is supported by two studies in which effects on mortality and reproduction were 5015 observed in two species. The HV was derived from a 21-day study in the springtail (Folsomia fimetaria) 5016 (Jensen et al., 2001), with an EC10 of 14 mg DBP/kg dry soil for reduced reproduction. This study was rated high quality. Reproduction was reduced by approximately 60 percent at the lowest concentration 5017

- tested, which was 100 mg DBP/kg dry soil, with reproduction completely eliminated at higher doses. 5018 5019 Based on an EC10 for reduced reproduction in the springtail, the HV for soil invertebrates is 14 mg
- 5020 DBP/kg dry soil.
 - 5021

5022 **Terrestrial Plants**

5023 EPA has moderate confidence that DBP has adverse effects on terrestrial plants in the environment. This

- 5024 moderate confidence is supported by 12 studies, of which 6 contained acceptable endpoints below the
 - 5025 limit of water solubility for DBP that identified effects on growth in 10 species. The HV was derived

5026 from a 40-day exposure in bread wheat (*Triticum aestivum*) (Gao et al., 2019). The lowest-observed-

adverse-effect-level (LOAEL) in this study for reduction in leaf and root biomass in bread wheat 5027 5028 seedlings was 10 mg/kg dry soil. There was a clear dose-response observed, with biomass reduction

5029 increasing as the dose of DBP increased. At the highest dose (40 mg/kg), root and leaf biomass were

5030 reduced by 29.93 and 32.10 percent, respectively. Because the most sensitive endpoint in this study was

5031 an unbounded LOAEL, the actual threshold dose might have been lower than the lowest dose studied.

5032 However, no information was available in the study to adjust the value to account for this uncertainty.

5033 The HV for terrestrial plants for DBP derived from this study is 10 mg/kg dry soil.

5.3 Environmental Risk Characterization 5034

5035

5.3.1 Risk Assessment Approach

5036 The environmental risk characterization of DBP was conducted to evaluate whether the potential 5037 releases and resultant exposures of DBP in water, air, or soil will exceed the DBP concentrations observed to result in hazardous effects to aquatic or terrestrial organisms. In evaluating the DBP 5038 5039 exposure concentrations, monitored and modeled DBP concentrations in surface water were used 5040 quantitatively. Concentrations of DBP in soil (biosolids, landfills, air deposition) and air is limited or is 5041 not expected to be bioavailable and were used qualitatively. In evaluating the environmental hazard of 5042 DBP, a weight of evidence approach (U.S. EPA, 2021a) was used to select hazard threshold 5043 concentrations for the derivation of risk quotients for aquatic organisms. The weight of evidence 5044 approach was also used to select hazard threshold concentrations for a description of risk for terrestrial 5045 organisms.

5046

5047 Environmental risk was characterized by calculating risk quotients or RQs (U.S. EPA, 1998; Barnthouse 5048 et al., 1982). The RQ is defined in Equation 5-1 below. 5049

5050 **Equation 5-1. Calculating the Risk Ouotient**

5051

5052 5053

$RQ = \frac{Predicted \ Environmental \ Concentration}{Hazard \ Threshold}$

5054 For aquatic organisms, the "effect level" is a derived COC based on a hazard effects concentration. The 5055 COC used to calculate ROs for aquatic organisms was derived from hazard values resulting from acute 5056 and chronic exposures to DBP. The benchmark value for RQs in environmental risk characterization is 5057 1. An RO equal to 1 indicates that the exposures are the same as the concentration that causes effects. If 5058 the RQ exceeds 1, the exposure is greater than the effect concentration. If the RQ is less than 1, the 5059 exposure is less than the effect concentration.

5060 5061 In addition to modeled environmental concentrations from releases of DBP (Section 3.3), environmental monitoring and biomonitoring data were reviewed to assess wildlife exposure to DBP (U.S. EPA, 5062 5063 2025p). EPA qualitatively assessed the potential for trophic transfer of DBP through food webs to wildlife using the available environmental monitoring information and physical and chemical properties. 5064 DBP is not expected to be persistent in the environment as it is expected to degrade rapidly under most 5065 5066 environmental conditions (although there is delayed biodegradation in low-oxygen media); and DBP's 5067 bioavailability is expected to be limited (U.S. EPA, 2024i). DBP is expected to have low 5068 bioaccumulation potential, biomagnification potential, and low potential for uptake based on estimated 5069 log BCF (bioconcentration factor) of 2.02 to 2.35 and a log BAF (bioaccumulation factor) of 2.20 to 5070 2.37.

5.3.2 Risk Estimates for Aquatic and Terrestrial Species

5072 EPA expects the main environmental exposure pathways for DBP to be releases to surface water and 5073 subsequent deposition to sediment, and limited dispersal from fugitive and stack air release deposition to 5074 soil. The Agency calculated an RO for aquatic and benthic organisms based on modeled environmental surface water and sediment DBP concentrations and for terrestrial organisms based on modeled soil 5075 5076 concentrations via air deposition near facilities releasing DBP. A summary of relevant exposure 5077 pathways to receptors and resulting qualitative risk estimates is presented in Table 5-2. EPA used a 5078 screening approach, followed by refinement if appropriate, to characterize environmental risk; an RO for 5079 the highest reference environmental concentration was first calculated for each receptor group, and if the 5080 RO did not exceed the benchmark value of 1 then no further ROs were calculated. If the RO exceeded 5081 the benchmark, then refinements were applied to the screening environmental concentration if 5082 appropriate. The risk characterization proceeded to the next-highest releasing COU/OES until the 5083 resulting RQs were less than 1 or all COU/OESs were characterized. Wastewater treatment removal was applied as a refinement to the approach for generic scenario COU/OES where such treatment was not 5084 5085 already reflected in estimated surface water releases if RQs greater than 1 were identified without 5086 treatment. For non-POTW TRI Form R or DMR-reported COU/OES, reported surface water releases are 5087 based on releases offsite (TRI Form R) or monitoring at the outfall to surface water (DMR) and already 5088 reflect any applicable pretreatment and wastewater treatment, and no additional wastewater treatment 5089 removal was applied (see Section 2.3.3.1 of the Draft Environmental Release and Occupational 5090 *Exposure Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025q).

5092Table 5-2. Exposure Pathway to Receptors and Corresponding Risk Assessment for the DBP5093Environmental Risk Characterization

Exposure Pathway	Receptor	Risk Assessment
	Acute exposure to aquatic and benthic organisms (aquatic and benthic vertebrates and invertebrates)	No RQ >1 identified
Surface water	Chronic exposure to aquatic vertebrates	RQ 9.23 for Waste handling, treatment, and disposal; 1.04 for PVC plastics compounding
	Chronic exposure to aquatic invertebrates	RQ 1.18 for Waste handling, treatment, and disposal
	Chronic exposure to benthic invertebrates	No RQ >1 identified
	Aquatic plants and algae	No RQ >1 identified
Sediment	Benthic organisms	No RQ >1 identified
Air deposition to soil	Soil invertebrates; terrestrial plants	No RQ >1 identified
Trophic transfer	Aquatic and terrestrial organisms	Qualitative; No RQ calculated
Biosolids	Terrestrial mammal	Qualitative; No RQ calculated
Landfills	Terrestrial mammal	Qualitative; No RQ calculated

5094

5071

5091

5095 Surface Water

5096 COCs were derived for several aquatic receptors in surface water for DBP, including acute and chronic 5097 exposures to aquatic vertebrates, aquatic invertebrates, and benthic invertebrates, and aquatic plants and 5098 algae.

5099

5100 Acute Exposure to Aquatic and Benthic Organisms: The COC for acute exposure to aquatic organisms,

5101 including aquatic and benthic vertebrates and invertebrates, was derived from an SSD containing

5102 empirical and modeled hazard data for more than 50 organisms (U.S. EPA, 2024c) and is 347.6 μ g/L 5103 DBP. This acute COC for mortality is based on 96 hours of exposure. The reference value for water 5104 concentration, based on the high-end release in the Waste handling, treatment, and disposal OES, is 5105 14.40 μ g/L over a 4-day averaging time, and the resulting RQ is 0.04. Risk quotients did not exceed 1 5106 for acute exposures to aquatic and benthic organisms for this OES and all others with lower estimated 5107 water concentrations.

5108

5109 *Chronic Exposure to Aquatic Vertebrates:* The COC for chronic exposure to aquatic vertebrates was
5110 derived from a 112-day exposure in a multigenerational study in Japanese medaka (*Oryzias latipes*)
5111 (EAG Laboratories, 2018) and is 1.56 µg/L DBP. EPA calculated RQs exceeding 1 for chronic exposure
5112 to aquatic vertebrates at the high end of estimated releases for the Waste handling, treatment, and
5113 disposal, Application of paints and coatings, and PVC plastics compounding OESs, with RQ of 9.23 and
5114 1.04, respectively. RQs also exceeded 1 for the PVC plastics converting OES and Recycling OES,
5115 which used the PVC plastics compounding OES releases as a surrogate.

5116

5117 *Chronic Exposure to Aquatic Invertebrates:* The COC for chronic exposure to aquatic invertebrates was 5118 derived from a 14-day study in the marine amphipod crustacean *Monocorophium acheruscicum* (Tagatz 5119 <u>et al., 1983</u>) and is 12.23 μ g/L DBP. EPA calculated RQs exceeding 1 for chronic exposure to aquatic 5120 invertebrates at the high end of estimated releases for the Waste handling, treatment, and disposal OES, 5121 with an RQ of 1.18.

5122

5123 *Aquatic Plants and Algae:* The COC for exposure to aquatic plants and algae was derived from a 96-5124 hour study in green algae (*Selenastrum capricornutum*) (Adachi et al., 2006) and is 31.6 µg/L DBP. The

5124 nour study in green argue (*Setemastrum capiteoritatum*) (<u>reactine et al., 2000</u>) and is 51.0 µg/1 DB1. The 5125 reference value for water concentration, based on the high-end release in the Waste handling, treatment,

and disposal OES, is 14.40 μ g/L over a 4-day averaging time, and the resulting RQ is 0.46. Risk

- 5127 quotients did not exceed 1 for exposures to aquatic plants and algae for this OES and all others with
- 5128 lower estimated water concentrations.
- 5129

Table 5-3. Environmental Risk Quotients (RQs) for Aquatic Organisms Associated with Surface Water Releases of DBP

OES	DBP Concentration (µg/L)	Receptor	Exposure Duration	Hazard Value (µg/L)	Risk Quotient	Overall Confidence
Waste handling, treatment, and disposal ^a ; high-end	14.40 (4-day average)	SSD ^b ; Acute aquatic and benthic organisms	4 days	347.6	0.04	Robust
Waste handling, treatment, and disposal; High-end	14.40 (286-day average)				9.23	Robust
Manufacturing ^{c d} ; high-end	1.40 (286-day average), 65% wastewater treatment efficiency	Japanese medaka (<i>Oryzias latipes</i>),			0.90	Moderate
Application of paints and coatings ^{c e} ; high end	1.11 (286-day average), 65% wastewater treatment efficiency	Chronic aquatic vertebrates	112 days	1.56	0.71	Moderate
PVC plastics compounding; PVC plastics compounding ^f ^s ; high-end	1.63 (246-day average)				1.04	Robust
Waste handling, treatment, and disposal; high-end	14.40 (21-day average)	Marine amphipod (<i>Monocorophium</i> <i>acheruscicum</i>), chronic aquatic invertebrates	14 days	12.23	1.18	Robust
Waste handling, treatment, and disposal; high-end	14.40 (4-day average)	Green algae (Selenastrum capricornutum), aquatic plants and algae	4 days	31.6	0.46	Robust

^a The associated COU for this OES is "Disposal."

^b Species sensitivity distribution; see Section 5.2.

^c These OES had multimedia releases; the RQs presented here assume all multimedia releases are to surface water; see Section 5.1.

^d The associated COU for this OES is Manufacturing; domestic manufacturing.

^{*e*} The associated COUs for this OES are Industrial uses; construction, paint, electrical, and metal products; paints and coatings; Commercial uses; construction, paint, electrical, and metal products; paints and coatings; and Commercial uses; packaging, paper, plastic, hobby products; Ink, toner and colorant products.

^f The associated COU for this OES is Processing; incorporation into formulation, mixture, or reaction product; plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic organic chemical manufacturing; and adhesive and sealant manufacturing.

⁸ The PVC plastics compounding OES release was used as a surrogate for the PVC plastics converting and Recycling OESs. The associated COUs for these OESs are Processing; incorporation into articles; plasticizer in adhesive and sealant manufacturing; building and construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing; and Recycling, respectively.

5132

5133 Sediment

- 5134 DBP is expected to partition primarily to soil and sediment, regardless of the compartment of
- environmental release (U.S. EPA, 2024j). DBP is not expected to undergo long-range transport and is 5135
- 5136 expected to be found predominantly in sediments near point sources, with a decreasing trend in sediment
- 5137 concentrations downstream due to DBP's strong affinity and sorption potential for organic carbon in
- 5138 sediment. EPA's reference sediment concentrations under low flow conditions of 0.334 mg DBP/kg 5139
- sediment (U.S. EPA, 2025p), corresponding to the Waste handling, treatment, and disposal OES, reflect 5140 the physical and chemical properties of DBP and its predicted affinity for sediment (U.S. EPA, 2024j),
- but may be overestimated due to conservative parameters and use of the VVM-PSC three compartment 5141
- 5142 model. DBP is not expected to be persistent in the environment as it is expected to degrade rapidly under
- 5143 most environmental conditions with delayed biodegradation in low-oxygen media (U.S. EPA, 2024i).
- 5144
- 5145 EPA derived a COC for chronic exposure to benthic organisms from a 10-day study in the midge
- 5146 (Chironomus tentans) (Lake Superior Research Institute, 1997) of 114.3 mg DBP/kg sediment. Because
- 5147 the screening value for sediment concentration, based on the Waste handling, treatment, and disposal
- OES, is 0.334 mg/kg and the associated RQ is 0.003, EPA did not identify RQs exceeding 1 for chronic 5148
- 5149 exposure to benthic organisms in sediment.
- 5150

5151 Table 5-4. Environmental Risk Quotients (RQs) for Benthic Organisms Associated with Sediment 5152 **Releases of DBP**

OES	Sediment Concentration (mg/kg)	Organism	Exposure Duration	Hazard Value (mg/kg)	RQ	Overall Confidence
Waste handling, treatment, and disposal ^a , high-end	0.334 (7-day average)	Midge (<i>Chironomus</i> <i>tentans</i>); benthic organism	10 days	114.3 mg/kg	0.003	Robust
^a The associated COU	for this OES is Dis	sposal.				

5153

5154 Air Deposition to Soil

- Modeling results indicate a rapid decline in DBP concentrations from air deposition to soil. The 5155
- 5156 Application of paints, coatings, adhesives and sealants and Waste handling, treatment, and disposal OES
- 5157 resulted in the highest fugitive and stack releases of DBP, respectively, with annual average deposition
- rates to soil at 100 m of 0.268 and 0.033 mg/m², respectively, for a total annual deposition rate of 0.302 5158
- mg/m^2 . This annual deposition rate corresponds to an annual contribution to average soil concentration 5159
- 5160 of 1.78 µg/kg/yr (0.00178 mg/kg/yr). Because the biodegradation half-life of DBP in aerobic soils is on
- 5161 the order of days to weeks (U.S. EPA, 2024j) and the half-life in anaerobic soils is up to 65 days
- 5162 (Shanker et al., 1985; Inman et al., 1984), use of this annual rate as the reference soil concentration
- likely overestimates the equilibrium soil concentration in the environment. Because DBP has low 5163
- 5164 bioaccumulation potential and experiences biodilution across trophic levels (U.S. EPA, 2024j;
- Mackintosh et al., 2004), the transfer of DBP through a food web is expected to dilute in each trophic 5165
- level and will be less than the amount deposited to soil. For soil invertebrates and terrestrial plants, the 5166
- hazard value is four orders of magnitude higher than the estimated soil concentration, with RQ values of 5167
- 1.27×10^{-4} and 1.87×10^{-4} , respectively. EPA did not identify RQs exceeding 1 for terrestrial animals and 5168 plants.
- 5169
- 5170

Table 5-5. Environmental Risk Quotients (RQs) for Terrestrial Organisms Associated with Air Deposition to Soil Releases of DBP

Release	Soil Concentration	Organism	Exposure Duration	Hazard Value	RQ	Overall Confidence
Fugitive: Application of paints, coatings, adhesives and	0.00178 mg/kg	Springtail (Folsomia fimetaria); soil invertebrate	21 days	14 mg/kg	1.27E-04	Robust
sealants ^{<i>a</i>} Stack: Waste handling, treatment, and disposal ^{<i>b</i>}	(365-day release)	Bread wheat (<i>Triticum</i> <i>aestivum</i>); terrestrial plant	40 days	10 mg/kg	1.78E-04	Robust

^{*a*} The associated COU for this OES is Industrial/commercial use; construction, paint, electrical, and metal products; adhesives and sealants/paints and coatings.

^b The associated COU for this OES is Disposal.

5173

5174 Landfill (to Surface Water, Sediment)

5175 Due to its high affinity for organic carbon and organic media (log $K_{OC} = 3.14 - 3.94$; log $K_{OW} = 4.5$),

5176 DBP is expected to be present at low concentrations in landfill leachate. No studies have directly

evaluated the presence of DBP in landfill or waste leachate. DBP that may present in landfill leachates isnot expected to be mobile in receiving soils and sediments due to its high affinity for organic carbon. No

5179 studies were identified which reported the concentration of DBP in landfills or in the surrounding areas.

5180 There is limited information regarding DBP in dewatered biosolids, which may be sent to landfills for 5181 dispessel DBP has been identified in U.S. based and intermediatel surgery of westwarder shades. A 2012

disposal. DBP has been identified in U.S.-based and international surveys of wastewater sludge. A 2012
 survey of North American wastewater plants (Canada and United States) identified DBP in sludge at

5183 concentrations ranging from 1.7 to 1,260 ng/g dry weight (<u>Ikonomou et al., 2012</u>). These concentrations 5184 were well below hazard values for benthic organisms (114.3 mg/kg; 1 ng/g is equivalent to 0.001 mg/kg)

were were were below hazard values for benunc organisms (114.5 mg/kg; 1 mg/g is equivalent to 0.001 mg/kg)
and below concentrations that might be expected to transfer up the food web via trophic transfer and
potentially affect terrestrial organisms. DBP is not likely to be persistent in groundwater/subsurface
environments unless anoxic conditions exist. As a result, the qualitative evidence indicates that DBP
migration from landfills to surface water and sediment is limited and not likely to lead to environmental

concentrations that exceed hazard values for aquatic and terrestrial organisms. For the same reasons,
DBP from down-the-drain disposal of consumer products or landfill disposal of consumer articles is not

5190 DBF from down-the-drain disposal of consumer products of randim disposal of consumer articles is in 5191 likely lead to environmental concentrations that exceed hazard values for aquatic and terrestrial

5192 organisms (see Section 3.1.4 for further details on the qualitative assessment of consumer disposal of

5193 DBP-containing products and articles).

5195 Biosolids

A 2012 survey of North American wastewater plants (Canada and United States) identified DBP in wastewater sludge at concentrations ranging from 1.7 to 1,260 ng/g dry weight (<u>Ikonomou et al., 2012</u>). Post-aerobic treatment of activated sludges has been shown to reduce the concentration of DBP (100% removal) and other phthalates (11–100% removal) (<u>Tomei et al., 2019</u>). There are currently no U.S.based studies reporting DBP concentration in biosolids or in soil following land application. DBP containing sludge and biosolids have not been reported for uses in surface land disposal or agricultural application.

5203

5194

5204 DBP is not expected to be persistent in topsoil if it is applied to land through biosolids applications. 5205 Several academic studies have reported on degradation of DBP in aerobic soils. The half-life of DBP in

5206 anaerobic soils range from less than 1 day to 19 days (<u>Cheng et al., 2018</u>; <u>Zhao et al., 2016</u>; <u>Yuan et al.</u>,

5207 2011; Xu et al., 2008; Wang et al., 1997; Russell et al., 1985; Shanker et al., 1985). In mixed aerobic 5208 and anaerobic conditions in which oxygen or terminal electron acceptors may not be readily replaced, the degradation of DBP may be slower. Current research suggests that the half-life of DBP may be 5209 5210 extended to as long as 65 days under evolving aerobic conditions (Inman et al., 1984). In strictly 5211 anaerobic soil conditions, DBP appears to degrade under comparable rates to aerobic or evolutionary 5212 conditions with half-lives reported from 19 to 36 days (Shanker et al., 1985; Inman et al., 1984). Based on the solubility (11.2 mg/L) and hydrophobicity (log $K_{OC} = 3.14 - 3.94$; log $K_{OW} = 4.5$), DBP is not 5213 5214 expected to have potential for significant bioaccumulation, biomagnification, or bioconcentration in

- 5215 exposed organisms.
- 5216

5217 High-end releases from industrial facilities are unlikely to be released directly to municipal wastewater 5218 treatment plants without pretreatment or to be directly land applied following on-site treatment at the

5219 industrial facility itself. The highest reported DBP concentrations within biosolids from reasonably

5220 available literature (1.7–1,260 ng/g; 1 ng/g is equivalent to 0.001 mg/kg) and estimated DBP soil

5221 concentrations following the application of biosolids to agricultural lands (up to 0.03 mg/kg; see Table

- 5222 3-2 of the Draft Environmental Media, General Population, and Environmental Exposure for Dibutyl
- 5223 *Phthalate (DBP)* (U.S. EPA, 2025p)) are several orders of magnitude below the hazard values for
- 5224 benthic organisms (114.3 mg/kg), soil organisms (14 mg/kg), or terrestrial plants (10 mg/kg). These
- 5225 comparisons support the qualitative assessment that potential DBP concentrations in biosolids are not

5226 likely to lead to environmental concentrations that exceed hazard values for environmental organisms.

5227

5.3.3 Environmental Risk Characterization Summary

Table 5-6 summarizes the environmental risk characterization for DBP. In summary, EPA's
environmental risk characterization indicates that environmental concentrations of DBP exceed hazard
values (*i.e.*, RQ >1) for environmental organisms based on the following COUs:

- Processing; incorporation into formulation, mixture, or reaction product; plasticizer in plastic
 material and resin manufacturing;
- Processing; incorporation into articles; plasticizer in adhesive and sealant manufacturing;
 building and construction materials manufacturing; furniture and related product manufacturing;
 ceramic powders; plastics product manufacturing; and rubber product manufacturing;
- Recycling; and
 - Disposal.

5237 5238

5239 Table 5-6. Environmental Risk Summary Table for DBP

Subcategory	OES	Organism	RQ (Benchmark = 1)	Overall Confidence
Domestic manufacturing	Manufacturing	Aquatic vertebrates, aquatic invertebrates, benthic invertebrates, aquatic plants and algae	RQ < 1 based on application of wastewater treatment efficiency (Table 2-2)	Moderate
		Terrestrial vertebrates, soil invertebrates, terrestrial plants	RQ < 1 based on screening assessment ^a	Robust
Importing				
Laboratory chemicals in wholesale and retail trade; plasticizers in wholesale and retail trade; and plastics material and resin manufacturing	Import and repackaging	All	RQ < 1 based on screening assessment ^a	Robust
Intermediate in plastic manufacturing				
Solvents (which become part of product formulation or mixture) in chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and printing ink manufacturing	Incorporation into formulations,	All	RQ < 1 based on	Robust
Plasticizer in paint and coating manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic organic chemical manufacturing; and adhesive and sealant manufacturing	mixtures, or reaction product		servening assessment	
	Domestic manufacturing Importing Laboratory chemicals in wholesale and retail trade; plasticizers in wholesale and retail trade; and plastics material and resin manufacturing Intermediate in plastic manufacturing Solvents (which become part of product formulation or mixture) in chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation manufacturing; and printing ink manufacturing; manufacturing; soap, cleaning compound, and toilet preparation manufacturing; nanufacturing; soap, cleaning compound, and toilet preparation manufacturing; basic organic chemical manufacturing; basic organic chemical manufacturing; and adhesive and	Domestic manufacturingManufacturingImportingImport and retail trade; plasticizers in wholesale and retail trade; and plastics material and resin manufacturingImport and repackagingIntermediate in plastic manufacturingIntermediate in plastic manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and printing ink manufacturing; textiles, apparel, and leather manufacturing; basic organic chemical manufacturing; and adhesive andIncorporation into formulations, mixtures, or reaction product	Domestic manufacturingManufacturingAquatic vertebrates, aquatic invertebrates, aquatic invertebrates, aquatic plants and algae Terrestrial vertebrates, terrestrial plantsImportingImport and repackagingAllLaboratory chemicals in wholesale and retail trade; plasticizers in wholesale and retail trade; and plastics material and resin manufacturingImport and repackagingAllIntermediate in plastic manufacturingIncorporation into formulations, mixtures, or reaction productIncorporation into formulations, mixtures, or reaction productAll	Domestic manufacturingManufacturingAquatic vertebrates, aquatic invertebrates, aquatic plants and algaeRQ < 1 based on application of wastewater treatment efficiency (Table 2-2)ImportingImportingImport and repackagingRQ < 1 based on screening assessment"Laboratory chemicals in wholesale and retail trade; and plastics material and resin manufacturingImport and repackagingRQ < 1 based on screening assessment"Intermediate in plastic manufacturing soap, cleaning compound, and toilet preparation manufacturing; basic organic chemical product and preparation manufacturing; textiles, apparel, and leather manufacturing; basic organic chemical andatcuring; basic organic chemical andracturing; and adhesive andIncorporation into formulations, mixtures, or reaction productRQ < 1 based on screening assessment"Plasticizer in paint and coating manufacturing; basic organic chemical product and preparation manufacturing; basic organic chemical manufacturing; basic organic chemical manufacturing; and adhesive andIncorporation into formulations, mixtures, or reactionPlasticizer in paint and coating manufacturing; basic organic chemical manufacturing; basic organic chemical manufacturing; and adhesive andIncorporation into formulations, mixtures, or reactionPlasticizer in paint and coating manufacturing; basic organic chemical manufacturing; basic organic chemical manufacturing; and adhesive andRQ < 1 based on screening assessment ^a

Life Cycle Stage; Category	Subcategory	OES	Organism	RQ (Benchmark = 1)	Overall Confidence
Processing; Processing:	Plasticizer in plastic material and resin	PVC plastics	Aquatic vertebrates, chronic	1.04	
incorporation into formulation, mixture, or reaction product	manufacturing	compounding	All others	RQ < 1 based on screening assessment ^{<i>a</i>}	Robust
Processing; Processing: incorporation into	Plasticizer in adhesive and sealant manufacturing; building and construction materials manufacturing;	PVC plastics	Aquatic vertebrates, chronic	1.04 (Surrogate from PVC plastics compounding OES)	Robust
articles	furniture and related product manufacturing; ceramic powders; plastics product manufacturing	converting	All others	RQ < 1 based on screening assessment ^a	Kobusi
Processing; Processing: incorporation into formulation, mixture, or reaction product	Plasticizer in plastic material and resin manufacturing; rubber manufacturing				
Processing; Incorporation into articles	Plasticizer in adhesive and sealant manufacturing; building and construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing	Non-PVC materials manufacturing	All	RQ < 1 based on screening assessment ^a	Robust
Commercial Use; Construction, paint, electrical, and metal products	Adhesives and sealants	Application of adhesives and	All	RQ < 1 based on	Robust
Industrial Use; Construction, paint, electrical, and metal products	Adhesives and sealants	sealants		screening assessment ^a	KODUSI

Life Cycle Stage; Category	Subcategory	OES	Organism	RQ (Benchmark = 1)	Overall Confidence
Commercial Use; Packaging, paper, plastic, toys, hobby products	Ink, toner, and colorant products		Aquatic vertebrates, aquatic invertebrates, benthic invertebrates, aquatic plants and algae	RQ < 1 based on application of wastewater treatment efficiency (Table 2-2)	Moderate
Commercial Use; Commercial use: construction, paint, electrical, and metal products	Paints and coatings	Application of paints and coatings	Terrestrial vertebrates, soil invertebrates, terrestrial plants	RQ < 1 based on screening assessment ^a	Robust
Industrial Use; Construction, paint, electrical, and metal products					
Industrial Use; Non-incorporative activities	Solvent, including in maleic anhydride manufacturing technology	Industrial process solvent use	All	RQ less than 1 based on screening assessment ^a	Robust
Commercial Use; Other uses	Laboratory chemicals	Use of laboratory chemicals (solid)	All	RQ less than 1 based on screening assessment ^{a}	Robust
Commercial Use; Other uses	Laboratory chemicals	Use of laboratory chemicals (liquid)	All	RQ less than 1 based on screening assessment ^a	Robust
Commercial Use; Other uses	Lubricants and lubricant additives				
Industrial Use; Other uses	Lubricants and lubricant additives	-			
Commercial Use; Automotive, fuel, agriculture, outdoor use products	Automotive care products	Use of lubricants and functional fluids	All	RQ less than 1 based on screening assessment ^a	Robust
Commercial Use; Furnishing, cleaning, treatment care products	Cleaning and furnishing care products				

Life Cycle Stage; Category	Subcategory	OES	Organism	RQ (Benchmark = 1)	Overall Confidence
Commercial Use; Other uses	Inspection penetrant kit	Use of penetrants and inspection fluids	All	RQ < 1 based on screening assessment ^{<i>a</i>}	Robust
Commercial Use; Furnishing, cleaning, treatment care products	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel Furniture and furnishings				
Commercial Use;	Automotive articles				
Other uses	Chemiluminescent light sticks	Fabrication or use of			
Industrial Use;	Automotive articles	final product or	All	Addressed qualitatively ^b	Robust
Other uses	Propellants	articles			
Commercial Use; Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)				
	Toys, playground, and sporting equipment				
Processing; Recycling	Recycling	Recycling	Aquatic vertebrates, chronic	1.04 (Surrogate from PVC plastics compounding OES)	Robust
Recyching			All others	RQ < 1 based on screening assessment ^{<i>a</i>}	
			Aquatic vertebrates, chronic	9.23	
Disposal; Disposal	Disposal	Waste handling, treatment and	Aquatic invertebrates, chronic	1.18	Robust
		disposal	All others	RQ < 1 based on screening assessment ^a	

Life Cycle Stage; Category	Subcategory	OES	Organism	RQ (Benchmark = 1)	Overall Confidence
Distribution in Commerce	Multiple	Multiple	All	Addressed qualitatively ^c	Robust
Consumer Use (All Uses, Disposal)	Multiple	Multiple	All	Addressed qualitatively ^d	Robust

^{*a*} See Section 5.3.1.

^b See Section 3.2.1. EPA did not quantitatively assess environmental releases for this COU due to the lack of process-specific and DBP-specific data; however, EPA expects releases from this COU to be small and dispersed in comparison to other upstream COU.

^c See Section 4.3.2. EPA expects all DBP or DBP-containing products and/or articles to be transported in closed systems or otherwise to be transported in a form (*e.g.*, articles containing DBP) such that there is negligible potential for releases except during an incident. Therefore, no environmental exposures are reasonably expected to occur, and no separate assessment was performed for estimating releases and exposures from distribution in commerce.

^d see Section 3.1.4 for further details on the qualitative assessment of consumer disposal of DBP-containing products and articles; disposal is the only pathway for environmental exposure to DBP from consumer COUs

Bold text in a gray shaded cell indicates an RQ exceeding the benchmark value of 1.

5240

52415.3.4Overall Confidence and Remaining Uncertainties in Environmental Risk5242Characterization

- 5243 The overall confidence in the environmental risk characterization synthesizes confidence from
- 5244 environmental exposures and environmental hazards. Exposure confidence is detailed in the *Draft*
- 5245 Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl
- 5246 *Phthalate (DBP)* (U.S. EPA, 2025p). Hazard confidence is detailed in the *Draft Environmental Hazard* 5247 *Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2024c). Confidence determinations for each group
 5248 of environmental organisms characterized are provided in Table 5-7.
- 5248 0 5249

5250 Environmental Exposure Confidence

5251 EPA modeled environmental exposure due to various exposure scenarios resulting from different 5252 pathways of exposure. Exposure estimates used high-end inputs for the purpose of a screening level 5253 analysis as demonstrated within the land pathway for modeled concentrations of DBP in biosolids-5254 amended soils at relevant COUs and air to soil deposition of DBP. EPA has robust confidence in its 5255 qualitative assessment and conclusions pertaining to exposures from biosolids and landfills.

5256

5257 For the water pathway, relevant flow data from the associated receiving water body were collected for 5258 facilities reporting to TRI. Quantified release estimates to surface water were evaluated with PSC 5259 modeling. For each COU with surface water releases, the highest estimated release to surface water was 5260 modeled as a conservative reference concentration for a screening assessment. Releases were evaluated 5261 for resulting environmental media concentrations at the point of release (*i.e.*, in the immediate receiving 5262 water body receiving the effluent). Wastewater treatment removal was applied as a refinement to the 5263 approach for generic scenario COU/OES where such treatment was not already reflected in estimated 5264 surface water releases if RQs greater than 1 were identified without treatment. For DMR-reported 5265 COU/OES, reported surface water releases are based on monitoring at the outfall to surface water and 5266 already reflect any applicable pretreatment and wastewater treatment, and no additional wastewater treatment removal was applied (see Section 2.3.3.1 of the Draft Environmental Release and 5267 5268 Occupational Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025q).

5269

5270 Within the water pathway, monitoring data were compared to modeled estimates to evaluate overlap, 5271 magnitude, and trends. Differences in magnitude between modeled and measured concentrations may be 5272 due to measured concentrations not being geographically or temporally close to known releasers of 5273 DBP. For reported releases, the high-end modeled concentrations in the surface water are the same order 5274 of magnitude as the high-end monitored concentrations found in surface water. This confirms EPA's 5275 expectation that a tiered screening approach beginning with high-end modeled reported releases is 5276 appropriate. Reported release estimates were modeled from data reported to the TRI and DMR 5277 databases. As such, EPA has moderate to robust confidence in the release data and the resulting modeled 5278 surface water concentrations at the point of release in the receiving water body. Despite slight to 5279 moderate confidence in the estimated absolute values themselves, confidence in exposure estimates 5280 capturing high-end exposure scenarios was robust given the many conservative assumptions which 5281 yielded modeled values exceeding those of monitored values. For those COUs in which surrogate water release data were used, EPA has moderate confidence in the applicability of the release data and the 5282 5283 resulting modeled surface water concentrations. For those COUs in which generic scenario water release 5284 data were used (including those with multimedia releases), EPA has slight confidence in the 5285 applicability of the release data and the resulting modeled surface water concentrations. The Agency has 5286 robust confidence that DBP has limited bioaccumulation and bioconcentration potential based on 5287 physical, chemical, and fate properties, biotransformation, and empirical metrics of bioaccumulation metrics. For further information on confidence in environmental exposure, see the Draft Environmental 5288

- 5289 *Media, General Population, and Environmental Exposure Assessment for Dibutyl Phthalate (DBP)* 5290 (U.S. EPA, 2025p).
- 5291

5292 Aquatic Species Overall Confidence

5293 The overall confidence in the risk characterization for the aquatic assessment is robust for COUs 5294 characterized by reported releases and those COUs that use reported releases as a surrogate, and 5295 moderate for those COUs that use generic releases. EPA has robust confidence that the release estimates 5296 modeled from TRI and DMR databases captures high-end exposure scenarios given the many 5297 conservative assumptions which yielded modeled values exceeding those of monitored values. EPA has 5298 moderate confidence that the full range of release estimates for generic scenarios capture high-end 5299 exposure scenarios because (1) these release estimates are based on generic industrial release scenarios 5300 rather than reported release data, and (2) EPA is not as confident in generic modeled estimates of 5301 receiving water body flows as it is less clear where generic releases occur relative to reported releases. 5302 EPA has slight confidence in the application of individual estimates of surface water and sediment 5303 concentrations from release estimates based on generic scenarios (including those with multimedia releases) because they are based on generic industrial release scenarios rather than reported release data 5304 5305 and it is unclear whether individual estimates of media releases (to water, landfills, air, etc) are an 5306 overestimate. Hazard confidence in the COCs for acute aquatic and benthic organisms, chronic aquatic 5307 vertebrates, and chronic aquatic invertebrates was robust, while hazard confidence in the COCs for 5308 chronic benthic invertebrates and aquatic plants and algae was moderate. For more information on the 5309 confidence values for hazard, see Section 2.4 in the Draft Environmental Hazard Assessment for Dibutyl 5310 Phthalate (DBP) (U.S. EPA, 2024c). 5311

5312 Terrestrial Species Overall Confidence

The overall confidence in the risk characterization for terrestrial mammals, soil invertebrates, and 5313 5314 terrestrial plants is robust. EPA has robust confidence in its qualitative assessment and conclusions 5315 pertaining to exposure from biosolids and landfills, and robust confidence in risk characterization 5316 conclusions based on its estimates of DBP air deposition to soil. Hazard confidence in the HV for soil 5317 invertebrates was robust, while hazard confidence in the HVs for terrestrial mammals and terrestrial 5318 plants was moderate. For terrestrial mammals, the HV was based on human health animal model rodent 5319 studies (Sprague-Dawley rat, *Rattus norvegicus*) because no reasonably available information was 5320 identified for exposures of DBP to mammalian wildlife. This resulted in moderate confidence in the HV 5321 due to extrapolation from laboratory rats to mammalian wildlife. For terrestrial plants, the HV was based 5322 on cultivated agricultural strains, and this resulted in moderate confidence in the HV due to 5323 extrapolation from agricultural plants to wild-type plants. For more information on the confidence 5324 values for hazard, see Section 2.4 in the Draft Environmental Hazard Assessment for Dibutyl Phthalate 5325 (DBP) (U.S. EPA, 2024c). Overall, because terrestrial concentrations of DBP are expected to be low and 5326 because DBP has low bioaccumulation and biomagnification potential in aquatic and terrestrial 5327 organisms, and thus low potential for trophic transfer through food webs, EPA has robust confidence in 5328 its screening level assessment that there is low potential for DBP exposures to terrestrial mammals and plants. The Agency has assessed that despite having moderate confidence in terrestrial mammalian and 5329 5330 terrestrial plant hazard values, EPA has robust confidence that environmental DBP exposures to 5331 terrestrial organisms will be far below those hazard values. Furthermore, EPA has robust confidence that 5332 soil exposures to DBP as estimated by a conservative screening approach are far below hazard values for 5333 soil invertebrates. EPA thus has robust confidence in its risk characterization for terrestrial organisms.

5334

5335 Trophic Transfer Overall Confidence

5336 EPA did not conduct a quantitative analysis of DBP trophic transfer. Due to the physical and chemical 5337 properties, environmental fate, and exposure parameters of the DBP, it is not expected to persist in

- 5338 surface water, groundwater, or air. DBP has a water solubility of 11.2 mg/L, a log K_{OC} value of 3.69, an 5339 estimated BCF value of 159.4 L/kg, monitored fish BAF values between 110 and 1,247 L/kg, monitored
- aquatic invertebrate BAF values between 500 and 6,600 L/kg, and a terrestrial biota-sediment
- 5341 accumulation factor (BSAF) between 0.35 and 11.8 kg/kg. DBP is expected to have low
- 5342 bioaccumulation potential, no apparent biomagnification potential, and thus low potential for uptake
- 5343 overall. For further information on the sources of these values, please see the Draft Chemistry, Fate, and
- 5344 *Transport Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2024j). Given the reasonably available
- data, EPA has robust confidence that that DBP is found in relatively low concentrations (or not at all) in
- aquatic organism tissues, especially at higher trophic levels. Furthermore, DBP has low bioaccumulation
- and biomagnification potential in aquatic and terrestrial organisms and therefore low potential for
- trophic transfer through food webs. For these reasons, EPA does not expect risk from trophic transfer inwildlife at environmentally relevant concentrations of DBP.
- 5350

5351 Table 5-7. DBP Evidence Table Summarizing Overall Confidence Derived for Environmental Risk 5352 Characterization

Types of Evidence	Exposure	Hazard	Trophic Transfer	Risk Characterization Confidence
	Aquatic			
Acute aquatic assessment	+++VVWM-PSC,	+++	+++	
Chronic aquatic vertebrate assessment	TRI/DMR Releases ^a	+++	+ + +	Robust for TRI/DMR
Chronic aquatic invertebrate assessment	+ + VVWM-PSC, Surrogate b	+++	+ + +	releases and
Chronic benthic assessment	+ VVWM-PSC,	+ +	+++	surrogates, Moderate
Aquatic plants and algae assessment	Generic ^{c} + + + AERMOD ^{d}	++	+++	for generic releases
	Terrestrial			
Chronic mammalian assessment	N/A (Not quantified)	+ +	+ + +	Robust
Soil invertebrate assessment	+ + + AERMOD	+++	+++	Robust
Terrestrial plant assessment	+++AERMOD	+ +	+ + +	Robust

^{*a*} EPA conducted modeling VVWM-PSC tool to estimate concentrations of DBP within surface water and sediment. ^{*b*} For some OESs with no identified releases from TRI/DMR, surrogates from other OESs were used. EPA has moderate confidence in the use of these surrogates for environmental risk characterization.

^c For some OESs, generic release scenarios (including those with multimedia releases) were used. EPA has slight confidence in the use of these generic releases for environmental risk characterization.

^d EPA used AERMOD to estimate ambient air concentrations and air deposition of DBP from EPA-estimated releases.

+ + + Robust confidence suggests thorough understanding of the scientific evidence and uncertainties. The supporting weight of scientific evidence outweighs the uncertainties to the point where it is unlikely that the uncertainties could have a significant effect on the risk estimate.

+ + Moderate confidence suggests some understanding of the scientific evidence and uncertainties. The supporting scientific evidence weighed against the uncertainties is reasonably adequate to characterize risk estimates.
+ Slight confidence is assigned when the weight of scientific evidence may not be adequate to characterize the scenario, and when the assessor is making the best scientific assessment possible in the absence of complete information. There are additional uncertainties that may need to be considered.

5354 6 UNREASONABLE RISK DETERMINATION

5355 TSCA section 6(b)(4) requires EPA to conduct a risk evaluation to determine whether a chemical 5356 substance presents an unreasonable risk of injury to health or the environment, without consideration of 5357 costs or other nonrisk factors, including an unreasonable risk to a PESS identified by EPA as relevant to 5358 this risk evaluation, under the COUs.

5359

5360 EPA is preliminarily determining that DBP presents unreasonable risk of injury to human health and the 5361 environment based on (1) identified risk to workers from 20 COUs, (2) risk to consumers from 4 COUs, 5362 and (3) on identified risk to the environment from 1 COU. The unreasonable risk results from risk 5363 identified for 25 out of 44 total COUs of DBP. Of the 31 occupational COUs, 9 have risk due to dermal exposure and 11 have risk due to dermal, inhalation, and aggregate exposure. Of the 13 consumer 5364 COUs, 4 have risk due to dermal exposure. Of the 44 COUs, only 1 (Disposal) had environmental risk 5365 5366 due to chronic exposure to DBP based on releases to surface water. This preliminary unreasonable risk 5367 determination is based on the information provided in previous sections of this draft risk evaluation, the 5368 appendices, and technical support documents for this draft risk evaluation in accordance with TSCA 5369 section 6(b). This preliminary unreasonable risk determination and the underlying evaluation are 5370 consistent with the best available science (TSCA section 26(h)) and based on the weight of scientific evidence (TSCA section 26(i)). 5371

- 5372
 5373 As noted in the Executive Summary, DBP is primarily used as a plasticizer in polyvinyl chloride (PVC)
 5374 in consumer, commercial, and industrial applications—although it is also used in adhesives, sealants,
 5375 paints, coatings, rubbers, and non-PVC plastics, as well as for other applications.
- EPA notes that human or environmental exposure to DBP through non-TSCA uses (*e.g.*, cosmetics, use
 of shells and cartridges as identified in 26 U.S.C. § 4181, and food additives such as food contact
 materials) were not specifically evaluated by the Agency because these uses are explicitly excluded from
 TSCA's definition of chemical substance. Thus, it is not appropriate to extrapolate from this preliminary
 risk determination to form conclusions about uses of DBP that are not subject to TSCA and that EPA did
 not evaluate.
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5384 Additionally, where relevant, the Agency conducted analyses on aggregate exposures and cumulative 5385 risk. Aggregate exposure analyses consider effects on populations that are exposed to DBP via multiple 5386 routes (e.g., dermal contact, ingestion, and inhalation). Cumulative risk analyses consider human health risks related to exposures to multiple chemicals. EPA included DBP in its draft cumulative risk analysis 5387 5388 TSD along with five other toxicologically similar phthalate chemicals (*i.e.*, DEHP, DINP, DIBP, BBP, 5389 and DCHP) that are also being evaluated under TSCA (U.S. EPA, 2025x). Based on the revised draft 5390 CRA TSD, the Agency has considered the draft cumulative risk (*i.e.*, human health risks related to 5391 exposures to multiple phthalates) and the NHANES biomonitoring data in this preliminary DBP 5392 unreasonable risk determination and concluded that aggregate MOEs for at least one consumer group 5393 dropped below the benchmark in the cumulative analysis for two product scenarios associated with two 5394 different COUs: Consumer use – packaging, paper, plastic, hobby products – toys, playground, sporting 5395 equipment and Consumer use – furnishing, cleaning, treatment/care products – cleaning and furnishing 5396 care products. Additional discussion about EPA's preliminary unreasonable risk determination for 5397 consumer uses is provided in Section 6.1.5 while information about the cumulative risk considerations 5398 and analysis is provided in Section 4.4.

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5400 EPA has preliminarily determined that the following 24 COUs may significantly contribute to 5401 upressonable risk to human health:

- Manufacturing domestic manufacturing (dermal and inhalation)
- Manufacturing importing (dermal and inhalation)

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- Processing processing as a reactant intermediate in plastic manufacturing (dermal and inhalation)
- Processing incorporation into formulation, mixture, or reaction product solvents (which become part of product formulation or mixture) in chemical product and preparation
 manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and printing ink manufacturing (dermal and inhalation)
- Processing incorporation into formulation, mixture, or reaction product pre-catalyst manufacturing (dermal and inhalation)
- Processing incorporation into formulation, mixture, or reaction product plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic organic chemical manufacturing; and adhesive and sealant manufacturing (dermal)
- Processing incorporation into article plasticizer in adhesive and sealant manufacturing;
 building and construction materials manufacturing; furniture and related product manufacturing;
 ceramic powders; plastics product manufacturing; and rubber product manufacturing (dermal)
- Processing repackaging laboratory chemicals in wholesale and retail trade; plasticizers in
 wholesale and retail trade; and plastics material and resin manufacturing (dermal and inhalation)
 - Industrial use non-incorporative activities solvent, including in maleic anhydride manufacturing technology (dermal and inhalation)
 - Industrial use construction, paint, electrical, and metal products adhesives and sealants (dermal)
- Industrial use construction, paint, electrical, and metal products paints and coatings (dermal and inhalation)
- Industrial use other uses lubricants and lubricant additives (dermal)
- 5429
 Commercial use automotive, fuel, agriculture, outdoor use products automotive care products
 5430 (dermal)
- 5431
 Commercial use construction, paint, electrical, and metal products adhesives and sealants (dermal)
- Commercial use construction, paint, electrical, and metal products paints and coatings (dermal and inhalation)
- 5435
 Commercial use furnishing, cleaning, treatment care products cleaning and furnishing care products (dermal)
- 5437
 Commercial use packaging, paper, plastic, toys, hobby products ink, toner, and colorant products (dermal and inhalation)
- Commercial use other uses laboratory chemicals (dermal)
- Commercial use other uses inspection penetrant kit (dermal and inhalation)
- Commercial use other uses lubricants and lubricant additives (dermal)
- Consumer use automotive, fuel, outdoor use products automotive care products (dermal)
- 5443
 Consumer use construction, paint, electrical and metal products adhesives and sealants (dermal)
- Consumer use construction, paint, electrical and metal products paints and coatings (dermal)
- Consumer use furnishing, cleaning, treatment/care products cleaning and furnishing care products (dermal)

- 5448 EPA has preliminarily determined that the following COU may significantly contribute to unreasonable 5449 risk to the environment:
- Disposal (aquatic vertebrates)

5451 EPA did not preliminarily identify an unreasonable risk of injury to human health or the environment 5452 from the following 19 COUs:

- Processing recycling
- Distribution in commerce
- Industrial use other uses automotive articles
- Industrial use other uses propellants
- 5457
 Commercial use furnishing, cleaning, treatment care products floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
- Commercial use furnishing, cleaning, treatment care products furniture and furnishings
- Commercial use packaging, paper, plastic, toys, hobby products packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles (soft); other articles (with routine direct contact during normal use, including rubber articles; plastic articles (hard)
- Commercial use packaging, paper, plastic, toys, hobby products toys, playground, and sporting equipment
- Commercial use other uses automotive articles
- Commercial use other uses chemiluminescent light sticks
- 5468
 Consumer use furnishing, cleaning, treatment/care products fabric, textile, and leather products
- Consumer use furnishing, cleaning, treatment/care products floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
- Consumer use packaging, paper, plastic, hobby products ink, toner, and colorant products
- Consumer use packaging, paper, plastic, hobby products packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)
- 5477 Consumer use packaging, paper, plastic, hobby products toys, playground, and sporting equipment
- Consumer use other uses automotive articles
- Consumer use other uses chemiluminescent light sticks
- Consumer use other uses lubricants and lubricant additives
- Consumer use other uses novelty articles
- For some COUs, the Agency has limited information to derive risk estimates (such as MOEs or RQs) to support a determination of whether the COU contributes to unreasonable risk of injury to human health or the environment. In such cases, EPA integrates reasonably available information (*e.g.*, read-across evidence, p-chem properties, available monitoring data) in a risk characterization using a weight of evidence approach and professional judgment to support conclusions. The risk characterizations of COUs without risk estimates are a best estimate of what EPA expects given the weight of scientific evidence without overstating the science.
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The unreasonable risk determination must be informed by science, and in making a finding of "presents unreasonable risk," EPA considers risk-related factors beyond exceedance of benchmarks. Risk-related

5493 factors include the type and severity of health effects under consideration, the reversibility of the health

5494 effects being evaluated, exposure-related considerations (e.g., duration, magnitude, frequency of 5495 exposure), or population exposed—particularly populations with greater exposure or greater 5496 susceptibility (PESS), and the confidence in the information used to inform the hazard and exposure 5497 values. EPA also considers, where relevant, the Agency's analyses on aggregate exposures and 5498 cumulative risk. For COUs evaluated quantitatively, as described in the risk characterization, EPA based 5499 the risk determination on the risk estimate that best represented the COU. Additionally, in the risk evaluation, the Agency describes the strength of the scientific evidence supporting the human health and 5500 5501 environmental assessments as robust, moderate, slight, or indeterminate.

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5503 Robust confidence suggests thorough understanding of the scientific evidence and uncertainties, and the supporting weight of scientific evidence outweighs the uncertainties to the point where it is unlikely that 5504 5505 the uncertainties could have a significant effect on the risk estimates. Moderate confidence suggests some understanding of the scientific evidence and uncertainties, and the supporting scientific evidence 5506 5507 weighed against the uncertainties is reasonably adequate to characterize risk. Slight confidence is assigned when the weight of scientific evidence may not be adequate to characterize the risk, and when 5508 5509 the Agency is making the best scientific assessment possible in the absence of complete information. 5510 This draft risk evaluation discusses important assumptions and key sources of uncertainty in the risk 5511 characterization, and these are described in more detail in the respective weight of scientific evidence 5512 conclusions sections for fate and transport (Section 2.2), environmental release (Sections 3.2.2 and 5513 3.2.3), environmental concentrations (Section 3.3.1), environmental exposures and hazards (Section 5514 5.3.4), and human health exposures and hazards (Sections 4.1.1.5, 4.1.2.4, and 4.1.3.3). It also includes 5515 overall confidence and remaining uncertainties sections for human health (Sections 4.3.2.1, 4.3.3.1, and 5516 4.3.4.1) and environmental (Section 5.3.4) risk characterizations. In general, EPA makes an 5517 unreasonable risk determination based on risk estimates that have an overall confidence rating of 5518 moderate or robust because those confidence ratings indicate the scientific evidence is adequate to 5519 characterize risk estimates despite uncertainties or is such that it is unlikely the uncertainties could have 5520 a significant effect on the risk estimates.

5521 6.1 Human Health

Calculated non-cancer risk estimates (MOEs⁶) can provide a risk profile of DBP by presenting a range 5522 of estimates for different health effects for different COUs. When characterizing the risk to human 5523 5524 health from occupational exposures during risk evaluation under TSCA, EPA conducts baseline 5525 assessments of risk and makes its determination of unreasonable risk in a manner that takes in 5526 consideration reasonably available information (e.g., test order information, site visits) regarding the use 5527 of respiratory protection or other PPE.⁷ This allows EPA to make unreasonable risk determinations based on the available information regarding workers. In addition, the risk estimates are based on 5528 5529 exposure scenarios with monitoring data that reflect existing requirements, such as those established by 5530 OSHA (*i.e.*, permissible exposure limit [PEL]) or through industry or sector best practices. In this draft 5531 risk evaluation, some of the risk estimates calculated do not reflect use of PPE; however, Table 4-17 5532 provides more information on PPE, including risk estimates calculated with PPE, that could be used to 5533 reduce the exposures, so that the risk estimates are above the benchmark MOE. Because EPA does not 5534 currently have information regarding use of PPE under the COUs, the preliminary risk determination is 5535 based on the risk estimates that do not reflect use of PPE.

⁶ EPA derives non-cancer MOEs by dividing the non-cancer POD (HEC [mg/m³] or HED [mg/kg-day]) by the exposure estimate (mg/m³ or mg/kg-day). Section 4.3.1 has additional information on the risk assessment approach for human health. ⁷ It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

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5537 To characterize risk from non-cancer endpoints, the estimated MOEs are compared to their respective benchmark MOE. The benchmark MOE accounts for the total uncertainty in a POD. The benchmark 5538 5539 MOE is the total of several individual uncertainty factors relevant to a given POD with values usually of 5540 1, 3, or 10. For DBP, two uncertainty factors were used to derive a benchmark MOE: (1) UF_A of 3 for 5541 the uncertainty in extrapolating animal data to humans (*i.e.*, interspecies variability), and (2) UF_H of 10 5542 for the variation in sensitivity among the members of the human population (*i.e.*, intrahuman/ 5543 intraspecies variability). Therefore, the benchmark MOE for DBP is 30; is based on effects on the 5544 developing male reproductive system; and was used to characterize risk from exposure to DBP for acute, 5545 intermediate, and chronic exposure scenarios. A lower benchmark MOE (e.g., 30) indicates greater 5546 certainty in the data (because the total UF for the relevant POD is low). A higher benchmark MOE (e.g., 5547 100) would indicate more extrapolation uncertainty for specific hazard endpoints and scenarios. 5548 Additional information regarding the non-cancer hazard identification and the benchmark MOE is 5549 provided in Section 4.2.2 of this draft risk evaluation. An MOE that is less than the benchmark MOE is a 5550 starting point for informing a determination of unreasonable risk of injury to human health, based on non-cancer effects. It is important to emphasize that these calculated risk estimates alone are not "bright-5551 5552 line" indicators of unreasonable risk.

6.1.1 Populations and Exposures EPA Assessed for Human Health

5554 EPA has evaluated risk to workers (16+ years old), including ONUs and females of reproductive age 5555 directly working with DBP; consumers and bystanders (adults and children), as well as the general population (including fenceline communities) using reasonably available monitoring and modeling data 5556 5557 for inhalation, dermal, and ingestion exposures, as applicable. The Agency has evaluated risk from 5558 inhalation, incidental ingestion of inhaled dust, and dermal exposure of DBP to workers, including 5559 ONUs. EPA has also evaluated risk from inhalation, dermal, and ingestion exposures for consumers. For 5560 the general population, EPA has evaluated risk from (1) ingestion exposures via drinking water, 5561 incidental surface water ingestion during swimming, fish ingestion (including subsistence and Tribal fishers), and soil ingestion by children; (2) dermal exposure to surface water during swimming; (3) acute 5562 5563 and chronic inhalation exposure; and (4) exposures measured through urinary biomonitoring (*i.e.*, NHANES). EPA concluded it is not necessary to separately model risks to infants consuming the human 5564 milk of exposed individuals because the POD used in the assessment is based on male reproductive 5565 5566 effects resulting from maternal exposures in multi-generational studies. EPA therefore has confidence that the risk estimates calculated based on maternal exposures are protective of a nursing infant's greater 5567 susceptibility during this unique lifestage whether due to sensitivity or greater exposure per body 5568 5569 weight. Descriptions of the data used for human health exposure are in Section 4.1. Uncertainties for 5570 overall exposures are presented in the respective occupational, consumer, and general population 5571 exposure sections of this draft risk evaluation and are considered in the preliminary unreasonable risk 5572 determination.

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6.1.2 Summary of Human Health Effects

5574 EPA has preliminary determined that DBP presents unreasonable risk to human health because of non-5575 cancer phthalate syndrome-related effects on the developing male reproductive system (*i.e.*, decreased 5576 fetal testicular testosterone) in the following populations:

- workers from acute, intermediate, and chronic dermal and inhalation exposures; and
 - consumers from dermal exposures.

5579 With respect to health endpoints upon which EPA has based this unreasonable risk determination, the 5580 Agency has robust confidence in the developmental toxicity POD. The POD is based on phthalate 5581 syndrome-related effects on the developing male reproductive system (*i.e.*, decreased fetal testicular

5582 testosterone) and was derived used BMD modeling. Risk estimates based on the POD are relevant for females of reproductive age and males at any lifestage. Decreased fetal testicular testosterone is the most 5583 5584 sensitive endpoint for DBP. Additionally, there is epidemiological evidence that DBP exposure can 5585 adversely affect the developing male reproductive system consistent with phthalate syndrome in males 5586 of any age, and that DBP exposure at higher concentrations can cause other health effects in females as well (see the Draft Non-cancer Human Health Hazard Assessment for Dibutyl Phthalate (DBP) (U.S. 5587 EPA, 2024f)). Therefore, EPA considers the proposed decreased fetal testicular testosterone POD to be 5588 5589 relevant across sex, lifestage, and durations. The confidence in the POD and descriptions of the data 5590 used to determine the human health effects from DBP are explained in Section 4.2.2. Additional 5591 information about EPA's confidence in the human health hazard of DBP is provided in Section 4.2.2.

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5593 With respect to carcinogenicity, overall, EPA considers there to be some limited evidence to support the 5594 conclusion that chronic oral exposure to DBP causes pancreatic tumors in rats. Under the *Guidelines for*

5595 *Carcinogen Risk Assessment* (U.S. EPA, 2005), the Agency reviewed the weight of scientific evidence

for the carcinogenicity of DBP and has preliminarily determined that there is *Suggestive Evidence of*

5597 Carcinogenic Potential of DBP in rodents. According to the Guidelines for Carcinogen Risk

5598 Assessment, when there is Suggestive Evidence, "the Agency generally would not attempt a dose-

response assessment, as the nature of the data generally would not support one." Consistently, EPA is not conducting a dose-response assessment for DBP or evaluating DBP for carcinogenic risk to humans.

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The human health risk estimates for consumers and bystanders, and the general population are presented and characterized in Section 4.3. Human health risk estimates for workers including ONUs are presented in Table 4-18 and characterized in Section 4.3. Again, the benchmarks are not bright-lines, and EPA has discretion to consider other risk-related factors when concluding whether a COU significantly contributes to the unreasonable risk of the chemical substance.

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6.1.3 Basis for Unreasonable Risk to Human Health

In developing the exposure and hazard assessments for DBP, EPA has analyzed reasonably available 5608 5609 information to ascertain whether some human populations may have greater exposure and/or 5610 susceptibility than the general population to the hazard posed by DBP. For the DBP draft risk evaluation, EPA has accounted for the following PESS: females of reproductive age; pregnant women; 5611 5612 infants; children and adolescents; people who frequently use consumer products and/or articles containing high concentrations of DBP; people exposed to DBP in the workplace; people in proximity to 5613 5614 releasing facilities, including fenceline communities; and Tribes and subsistence fishers whose diets 5615 include large amounts of fish. Section 4.3.5 summarizes how PESS were incorporated into the risk 5616 evaluation through consideration of potentially increased exposures and/or potentially increased biological susceptibility and summarizes additional sources of uncertainty related to consideration of 5617 5618 PESS.

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5620 Because EPA was able to calculate risk estimates for PESS groups in this assessment (e.g., female workers of reproductive age, infants and children), the Agency did not always use risk estimates based 5621 5622 on high-end exposure levels as the basis of the unreasonable risk determination for DBP. Additionally, 5623 EPA considered whether high-end risk estimates represented sentinel exposure levels accurately. As 5624 explained in the human health risk characterization (Section 4.3), for most occupational COUs, central-5625 tendency risk estimates were used to preliminarily determine unreasonable risk. The assumptions of an 5626 8-hour exposure duration for DBP may overestimate dermal exposure; however, even a 25-minute 5627 exposure of a femal worker of reproductive age or 20-minute exposure to workers under the 5628 Manufacturing OES could result in risk estimates below the benchmark MOE. Similarly, for consumer 5629 COUs, high-intensity risk estimates were used to preliminarily determine unreasonable risk—except for

the consumer use of synthetic leather articles, automotive articles, and novelty articles. The UF_H of 10 for human variability that EPA has applied to MOEs accounts for increased susceptibility of populations. The non-cancer POD for DBP selected by the Agency for use in risk characterization is based on the most sensitive developmental effect (*i.e.*, reduced fetal testicular testosterone production) observed and is expected to be protective of susceptible subpopulations. More information on how EPA characterized sentinel and aggregate risks is provided in Section 4.1.5, and more information on how the Agency characterized PESS risks is provided in Section 4.3.5.

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5638 Additionally, EPA did not consider aggregate exposure scenarios across COUs because the Agency did 5639 not find any evidence to support such an aggregate analysis, such as statistics of populations using 5640 certain products represented across COUs or workers performing tasks across COUs. However, EPA 5641 considered combined exposure across all routes of exposure for each individual occupational and 5642 consumer COU to calculate aggregate risks (Sections 4.3.2 and 4.3.3). The Agency aggregated 5643 exposures across routes for workers, including ONUs, as well as consumers for COUs with quantitative risk estimates. EPA has identified at least one consumer COU where aggregating exposures across all 5644 exposure routes indicated risk where there was no risk indicated when considering a single route. EPA 5645 5646 did not consider aggregate exposure for the general population. As described in Section 4.1.3, the 5647 Agency employed a risk screening approach for the general population exposure assessment. More 5648 information on how EPA characterized sentinel and aggregate risks is provided in Section 4.1.5.

5650 In addition to the analysis done for DBP alone (referred to as "individual analysis"), EPA applied both 5651 the methods and principles of CRA (Draft Proposed Approach for Cumulative Risk Assessment (CRA) 5652 of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances 5653 Control Act (U.S. EPA, 2023c) as well as the Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl 5654 5655 Phthalate (BBP), Diisobutyl Phthalate (DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl 5656 Phthalate (DINP) Under the Toxic Substances Control Act (TSCA) (U.S. EPA, 2025x)) to derive noncancer risk estimates for occupational and consumer exposures. EPA's draft CRA includes cumulative 5657 5658 exposure to other toxicologically similar phthalates being evaluated under TSCA (*i.e.*, DEHP, DCHP, 5659 BBP, DIBP, and DINP) and uses an "Relative Potency Factor (RPF) analysis" to characterize risk. DBP 5660 was used as the index chemical for the meta-analysis and BMD modeling approach to model decreased 5661 fetal testicular testosterone. Because DBP is the index chemical and the RPF is 1, scaling by relative 5662 potency has no effect on the DBP exposure estimates used to derive DBP cumulative risk estimates. More information on how EPA characterized the risk from the cumulative exposure to the phthalates is 5663 provided in Section 4.4.1. 5664

The revised draft CRA TSD also includes the addition of a non-attributable cumulative exposure to DEHP, DBP, BBP, DIBP, and DINP as estimated from NHANES urinary biomonitoring data using reverse dosimetry. The NHANES exposure is non-attributable—meaning it cannot be attributed to specific COUs or other sources that may result in high-dose exposure scenarios (*e.g.*, occupational exposures to workers)—but likely includes exposures attributable to both COUs assessed under TSCA and other, non-TSCA sources (*e.g.*, diet, food packaging, cosmetics).

5672 **6.1.4 Workers**

5673 Based on the occupational risk estimates and related risk factors, EPA is preliminarily determining that 5674 DBP presents unreasonable risk due to

non-cancer risks from acute, intermediate, and chronic dermal and inhalation exposure to
 workers, including ONUs, that contribute to the preliminary determination of unreasonable risk
 due to certain COUs.

5678 More information on occupational risk estimates is in Section 4.3.2, including the effect of PPE on the 5679 occupational risk estimates (Section 4.3.2.4. and Table 4-17). The occupational risk estimates are not 5680 impacted by the results from the cumulative risk assessment, even with the addition of non-attributable 5681 cumulative exposure NHANES urinary biomonitoring data. EPA's confidence in the cumulative MOEs 5682 for workers is moderate to robust (Section 4.4.4.1).

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EPA is preliminarily determining that 20 COUs may significantly contribute to unreasonable risk of
injury to human health for workers, including ONUs.

5687 High-end inhalation risk estimates were used to preliminarily determine unreasonable risk due to eight COUs. High-end inhalation risk estimates were used for one occupational COU (Commercial use -5688 inspection penetrant kits) for the acute exposure duration because the high-end inhalation risk estimates 5689 5690 are expected to be most reflective of workers exposed to potentially elevated exposures (e.g., low 5691 ventilation, high concentration, high use rate) for an acute duration; however, central tendency risk 5692 estimates were used for intermediate and chronic inhalation exposure durations, as well as dermal 5693 exposure risk estimates, (see in Section 4.3.2, "Use of penetrants and inspection fluids"). For seven 5694 COUs—(1) Manufacturing – domestic manufacturing; (2) Manufacturing – importing; (3) Processing – 5695 processing as a reactant – intermediate in plastic manufacturing; (4) Processing – incorporation into 5696 formulation, mixture, or reaction product – solvents (which become part of product formulation or 5697 mixture) in chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and printing ink manufacturing; (5) Processing – 5698 5699 incorporation into formulation, mixture, or reaction product – pre-catalyst manufacturing; (6) Processing 5700 - repackaging; and (7) Industrial use - non-incorporative activities - solvent, including in maleic 5701 anhydride manufacturing technology)-due to limited inhalation data points, both the central and high-5702 end exposure estimates are expected to be reflective of worker inhalation exposures. Also, since the 5703 dermal exposures are upper-bound estimates, the central tendency values of exposure estimates are 5704 expected to be more reflective of worker dermal exposures (see Section 4.3.2). For all other COUs, EPA 5705 is using the central tendency risk estimates to preliminarily determine unreasonable risk due to 5706 inhalation, dermal, and aggregate exposure due to the uncertainties involved in the inhalation exposure 5707 estimates and the uncertainties present in the representativeness of the skin permeability data in the 5708 dermal exposure estimate, which varies with each OES mapped to occupational COUs, as described in 5709 Section 4.3.2. Overall, EPA has moderate to robust confidence in the risk estimates calculated for 5710 worker and ONU inhalation and dermal exposure scenarios.

5711

5712 For cases where occupational dermal exposure to liquid DBP was assessed, EPA used a flux-limited 5713 dermal absorption value derived from a study conducted by Doan et al. (2010) to estimate high-end and 5714 central tendency dermal exposures. For occupational dermal exposure to solid DBP, EPA used a flux-5715 limited dermal absorption model to estimate high-end and central tendency dermal exposures for 5716 workers in each OES. Both methods are described in the Draft Environmental Release and 5717 Occupational Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025q) (see also Section 5718 4.1.1.1). Dermal exposure for ONUs was assessed for COUs where contact with DBP-containing mist or 5719 dust on surfaces was expected. For the occupational dermal exposure assessment, EPA assumed a 5720 standard 8-hour workday and the chemical is contacted at least once per day. Because DBP has low 5721 volatility and relatively low absorption, it is possible that the chemical remains on the surface of the skin after dermal contact until the skin is washed. So, in absence of exposure duration data, EPA has assumed 5722

5723 that absorption of DBP from occupational dermal contact with materials containing DBP may extend up 5724 to 8 hours per day (U.S. EPA, 1991). However, if a worker uses proper PPE or washes their hands after 5725 contact with DBP or DBP-containing materials, dermal exposure may be eliminated. Therefore, the 5726 assumption of an 8-hour exposure duration for DBP may lead to overestimation of dermal exposure.

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5728 For average adult workers, the surface area of contact was assumed equal to the area of one hand (*i.e.*, 5729 535 cm²), or two hands (*i.e.*, 1.070 cm²), for central tendency exposures, or high-end exposures, 5730 respectively (U.S. EPA, 2011a). Despite moderate confidence in the estimated values themselves, EPA 5731 has robust confidence that the dermal liquid exposure estimates are upper bound of potential exposure 5732 scenarios. Additionally, there are uncertainties associated to the flux-limited approach which likely 5733 results in overestimations due to the assumption about excess DBP in contact with skin for the entire 5734 work duration. EPA has considered the weight of scientific evidence for dermal risk estimates to be 5735 sufficient for determining whether a COU significantly contributes to unreasonable risk. More 5736 information on the Agency's confidence in these risk estimates and the uncertainties associated with them can be found in Section 4.1.1.5. 5737

5738

5739 For three COUs (Industrial use – construction, paint, electrical, and metal products – paints and 5740 coatings; Commercial use - construction, paint, electrical, and metal products - paints and coatings; and Commercial use - packaging, paper, plastic, hobby products - ink, toner and colorant products), EPA is 5741 5742 preliminary determining that these COUs significantly contribute to the unreasonable risk of injury to 5743 human health due to acute, intermediate, and chronic dermal exposure (MOEs from 1.7–3.3 for each 5744 population assessed). The MOEs were below the benchmark for acute, intermediate, and chronic 5745 inhalation exposure; however, the intermediate and chronic duration risk estimates are at or only slightly 5746 below the benchmark (25+ for each population assessed). Taking into consideration the dermal exposure as well as the aggregate exposure assessment and risk estimates, the Agency believes that there is 5747 5748 enough evidence to support EPA's preliminary determination that these COUs also significantly 5749 contribute to unreasonable risk of injury to human health due to intermediate and chronic inhalation 5750 exposure, as well as acute inhalation exposure. However, EPA preliminarily finds that dermal exposure 5751 is the driver of unreasonable risk presented by DBP.

5752

5753 EPA has assessed one (the following) occupational COU without deriving risk estimates:

Distribution in commerce: EPA expects DBP to be transported in sealed containers from import sites to downstream processing and use sites, or for final disposal. EPA also expects under standard operating procedures, along with the expectation that DBP would be transported in a closed system, that there is negligible potential for releases except during an incident. Therefore, no occupational exposures are reasonably expected to occur and exposures and releases that could occur during distribution in commerce would not result in unreasonable risk.

- 5760 EPA's overall risk characterization confidence for workers is summarized in Section 4.3.2.1.
- **6.1.5 Consumers**

5762 Based on the consumer risk estimates and related risk factors, EPA is preliminarily determining that5763 DBP presents unreasonable risk due to non-cancer risk from

• acute dermal exposure for consumers.

5765 EPA is preliminarily determining that four COUs may significantly contribute to unreasonable risk of 5766 injury to human health for consumers.

5767

5768 EPA reviewed the parameters for the exposure scenarios analyzed under each COU and preliminarily

5769 determined risk based on the most representative intensity assessed. For eight COUs, the high-intensity

5770 risk estimates were used in making a preliminary unreasonable risk determination—even after 5771 considering the conservative assumptions used in the dermal assessment. However, for the follow

5771 considering the conservative assumptions used in the dermal assessment. However, for the following 5772 five COUs, different intensity risk estimates were considered for the preliminary unreasonable risk

- 5773 determination:
- High-intensity dermal and medium-intensity aggregate and ingestion risk estimates were used for 5775 Consumer use – other uses – novelty articles;
- 5776
 Low-intensity dermal for infants and toddlers and medium-intensity risk estimates for all other
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 5778
 Low-intensity dermal for infants and toddlers and medium-intensity risk estimates for all other
 texposure routes and lifestages were used for Consumer use furnishing, cleaning, treatment/care
 products fabric, textile, and leather products;
- Low-intensity dermal for infants and toddlers and medium-intensity risk estimates for all other
 exposure routes and lifestages were used for Consumer use other uses automotive articles;
- Medium-intensity inhalation risk estimates were used for infants and toddlers for Consumer use
 construction, paint, electrical, and metal products paints and coatings; and
- Medium-intensity risk estimates were used for Consumer use packaging, paper, plastic, toys,
 hobby products toys, playground, sporting equipment.

See Section 4.3.3 and the *Draft Consumer and Indoor Dust Exposure Assessment for Dibutyl phthalate*(*DBP*) (U.S. EPA, 2025c) for additional information.

5788 For dermal exposure, the CEM Model assumes infinite DBP migration from product to skin without 5789 considering saturation which results in overestimations of dose and subsequent risk, see Section 2.3 in 5790 U.S. EPA (2025c) for a detailed explanation. Because of this, CEM was not used to model consumer 5791 dermal exposures, and instead dermal exposures were estimated using a flux-limited dermal absorption 5792 approach for liquid and solid products (U.S. EPA, 2025d). For each exposure route, EPA used the 10th 5793 percentile, average, and 95th percentile value of an input parameter (*e.g.*, weight fraction, surface area) 5794 where possible to characterize low-, medium-, and high-intensities for a given COU. If only a range was 5795 reported, EPA used the minimum and maximum of the range as the low and high values, respectively. 5796 The average of the reported low and high values from the reported range was used for the medium 5797 exposure scenario. Section 4.1.2.1 includes a description of the uncertainties and methods used to 5798 evaluate dermal exposure for consumers. See Draft Consumer and Indoor Dust Exposure Assessment for 5799 Dibutyl Phthalate (DBP) (U.S. EPA, 2025c) for details about the consumer modeling approaches, 5800 sources of data, model parameterization, and assumptions. The largest chronic dose estimated was for 5801 dermal and inhalation exposure to metal coatings for young teens to adults, followed by dermal exposure 5802 to adhesives, footwear, and waxes. It is noteworthy that the dermal screening analysis with the flux-5803 limited approach has larger uncertainties than inhalation dose results; see Section 4.1.2.4 for a detailed 5804 discussion of uncertainties within approaches, inputs, and overall estimate confidence (Section 4.1.2.2).

- 5805 5806 One COU, Consumer use – construction, paint, electrical, and metal products – paints and coatings, was 5807 assessed using three different exposure scenarios: (1) metal coatings, (2) indoor sealing and refinishing 5808 sprays, and (3) outdoor sealing and refinishing spray. Metal coatings refer to consumer or DIY painttype products that can be sprayed in a home setting. The metal coatings exposure scenario was assessed 5809 5810 for bystanders for children under 10 years of age who could be exposed from consumers using those 5811 products at home. Per the Draft Consumer and Indoor Dust Exposure Assessment for Dibutyl phthalate 5812 (DBP) (U.S. EPA, 2025c), metal coating products are expected to be used in comparatively smaller 5813 scale projects and were thus modeled at use durations of 120, 60, and 30 minutes. For metal coating
- 5814 products, daily use was not considered likely, but the product could reasonably be used weekly for

5815 hobby projects or a variety of small projects. Therefore, this product was modeled at a use frequency of 5816 52 times per year. The overall confidence in this COU inhalation exposure estimate is robust because the CEM default parameters represent actual use patterns and location of use. The resulting chronic 5817 5818 inhalation MOEs for bystanders from the high-intensity scenario were below the benchmark of 30 for 5819 infants and toddlers (children <2 years old; MOEs of 26 and 28, respectively). However, based on the 5820 conservative assumptions used in the assessment, the frequency of use likely overestimates potential exposure, and the medium-intensity is a more representative scenario of exposure for this COU. 5821 5822 Medium-intensity exposure risk estimates for the metal coatings scenario were 130 and 140 for infants 5823 and toddlers, respectively. Therefore, EPA is preliminarily determining that this COU does not 5824 contribute to unreasonable risk for infants and toddlers for bystander inhalation exposure. EPA is also 5825 preliminarily determining that this COU significantly contributes to unreasonable risk for acute dermal 5826 and aggregate exposure for young teens, teenagers and adults using these products based on the metal 5827 coatings exposure scenario; see Table 6-2 for additional information. 5828

5829 For the COU Consumer use – packaging, paper, plastic, toys, hobby products – toys, playground, 5830 sporting equipment, EPA used four exposure scenarios: (1) children's toys (new); (2) children's toys 5831 (legacy); (3) small articles with semi routine contact – miscellaneous items including a football, balance 5832 ball, and pet toy; and (4) tire crumb. The individual chemical analysis indicated risk only to infants who 5833 use legacy toys and there was no risk indicated for infants who use newer toys (*i.e.*, toys containing 5834 <0.1% DBP) (MOE of 23 for high-intensity, acute aggregate exposure for legacy toys based on 5835 individual chemical analysis, and MOE of 21 for high-intensity, acute aggregate exposure for legacy 5836 toys based on cumulative assessment with non-attributable NHANES data). For new toys, after factoring 5837 in the non-attributable NHANES data, the MOE is 29 for aggregate exposure for infants (children <1 vear). This additional risk indicated by the draft cumulative analysis supports EPA's risk conclusion 5838 5839 about the overall COU because the individual chemical analysis also indicated acute aggregate risk for 5840 infants based on the high-intensity exposure scenario for the use of legacy toys (*i.e.*, toys containing 5841 >0.1% DBP).

5843 The legacy toys assessment provides a range of reasonable values that reflect possible exposures. The 5844 high-intensity risk estimates likely represent an upper boundary for exposure and may, in some cases, 5845 overestimate the highest possible dose expected. One such case is inhalation-ingestion of DBP in dust 5846 and particulates. CEM assumes that 100 percent of the chemical that is on the dust or particulate matter 5847 will be absorbed when the dust or particulate matter is inhaled or ingested. This is highly unlikely to be the case as bioavailability is generally reduced in inhaled particles as compared to gas phase or aerosol 5848 5849 chemicals. The bioavailable fraction of DBP in dust and particulate matter would be difficult to quantify 5850 due to the absence of quantitative data in literature. However, EPA recognizes that the assumption of 5851 100 percent absorption through inhalation of DBP in dust/particulate matter and ingestion of DBP in 5852 dust/particulate matter likely overestimate exposure by these routes.

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5854 The aggregation across routes for a high-intensity exposure scenario for infants resulted in an MOE 5855 value of 23. The inhalation and ingestion of surface dust are the main contributors to the overall 5856 aggregate MOE value. The inhalation scenarios are explained above. The surface dust ingestion scenario 5857 model estimates the DBP concentration in settled dust on a toy's surface, assuming primarily that DBP 5858 partitions directly from the toy to settled dust. The model assumes exposure to occur through dust intake 5859 via incidental ingestion assuming a daily stay-at-home dust ingestion rate per lifestage. The model, assuming instantaneous equilibrium is achieved for partitioning, represents an upper-bound scenario. 5860 Overestimation of DBP concentration in the dust compartment happens when incidental ingestion after 5861 5862 inhalation and hand-to-mouth are both included in every ingestion estimate. The model estimates that 5863 DBP enters the air phase and while suspended it can partition to dust particles generated by material

5864 wear and surfaces, which makes incidental ingestion after inhalation possible. Subsequently, the 5865 suspended particulate settles, which makes hand-to-mouth ingestion possible. The overestimation magnitude and effect cannot be quantified with any accuracy or certainty based on current literature. The 5866 5867 aggregated MOE overall confidence originates from compounding and intensifying the uncertainties from each aggregated exposure route. The overestimation for all three high-intensity exposure routes 5868 5869 suggest that the high-intensity use aggregate scenario may not reflect or capture realistic exposures. 5870 Given this information, the Agency is basing this preliminary risk determination on the medium-5871 intensity use of toys, as it is representative of the middle of the range of exposures; therefore, EPA is preliminary determining that, for DBP, the COU Consumer use – packaging, paper, plastic, toys, hobby 5872 5873 products – toys, playground, sporting equipment does not significantly contribute to unreasonable risk. 5874 More information on the cumulative risk considerations is provided in Section 4.4. 5875

5876 The DBP consumer exposure overall confidence to use the results for risk characterization ranges from 5877 moderate to robust, depending on COU scenario (Section 4.1.2.4). EPA's overall confidence in the 5878 acute, intermediate, and chronic consumer inhalation, ingestion, and dermal exposure risk estimates 5879 ranges from moderate to robust. The Agency has moderate to robust confidence in the risk 5880 estimates calculated for consumers inhalation, ingestion, and dermal exposure scenarios (Section 5881 4.3.3.1), and has robust confidence that dermal exposure scenarios represent a conservative, upperbound on exposure. EPA's confidence in the cumulative consumer MOEs is moderate to robust (Section 5882 5883 4.4.5.1).

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6.1.6 General Population

Based on the risk estimates, EPA did not identify risk to the general population from the following 5885 5886 exposure routes and pathways for DBP:

- 5887 exposure via the land pathway (*i.e.*, application of biosolids and landfills);
- incidental ingestion and dermal contact from swimming; 5888 •
- 5889 acute and chronic ingestion of drinking water; •
- 5890 • acute and chronic ingestion exposure from fish ingestion;
 - acute and chronic inhalation exposure to ambient air in proximity to releasing facilities, • including fenceline communities; and
 - soil ingestion exposure from air deposition to soil. •

5894 As stated in Section 4.3.4, EPA evaluated surface water, drinking water, fish ingestion, and ambient air 5895 pathways quantitatively using a screening level approach for DBP releases associated with COUs (see 5896 the Draft Environmental Media and General Population Screening for Dibutyl Phthalate (DBP) (U.S. 5897 EPA, 2025p) and Section 4.1.3 for additional details about the assessment and assessment process). 5898 Land pathways (*i.e.*, landfills and application of biosolids) were assessed qualitatively, and were 5899 inclusive of down-the-drain releases of consumer products and landfill disposal of consumer articles 5900 (see Section 3.1.4 for details on the qualitative assessment of consumer disposal of DBP-containing 5901 products and articles). For pathways assessed quantitatively, high-end estimates of DBP concentration in 5902 the various environmental media were used for screening level purposes. EPA used an MOE approach 5903 using high-end exposure estimates to determine whether an exposure pathway had potential non-cancer 5904 risks. High-end exposure estimates were defined as those associated with the industrial and commercial 5905 releases from a COU and OES that resulted in the highest environmental media concentrations. 5906 Therefore, if there is no risk for an individual identified as having the potential for the highest exposure 5907 associated with a COU for a given pathway of exposure, then that pathway was determined not to be a 5908 pathway of concern and not pursued further. Based on the screening level approach described in Section 5909 4.1.3, and the qualitative assessment of landfill and biosolids pathways described in Section 3.1.4, EPA

- did not identify risk to the general population from exposure to DBP through biosolids, landfills, surface
 water, drinking water, fish ingestion, and ambient air.
- 5912

5922

- 5913 EPA has robust confidence that the risk estimates calculated for the general population were
- 5914 conservative and appropriate for a screening level analysis. The Agency also has robust confidence that
- 5915 modeled releases used are appropriately conservative for a screening level analysis. Therefore, the
- Agency has robust confidence that no exposure scenarios will lead to greater doses than presented in this
- evaluation. Despite slight and moderate confidence in the estimated values themselves, confidence in
 exposure estimates capturing high-end exposure scenarios was robust given that many of the modeled
- exposure estimates capturing high-end exposure scenarios was robust given that many of the modeled
 values exceeded those of monitored values and exceeded total daily intake values calculated from
- 5920 NHANES biomonitoring data, adding to confidence that exposure estimates captured high-end exposure
- 5921 scenarios (Section 4.1.3.3).

6.2 Environment

Based on the environmental risk assessment, EPA is preliminarily determining that DBP presents 5923 5924 unreasonable risk of injury to the environment from the Disposal COU due to chronic exposure for 5925 aquatic vertebrates using a screening approach with refinements. For environmental pathways which 5926 were quantitatively assessed, EPA compared the highest release estimates to environmental media for a 5927 given pathway with the hazard values for aquatic and terrestrial plants. If the exposure for the COU with 5928 the highest amount of environmental release (*i.e.*, the COU with the highest environmental exposures, 5929 the most conservative exposure estimates) did not exceed the hazard threshold for aquatic or terrestrial 5930 plants, it was determined that exposures due to releases from other COUs would not lead to 5931 environmental risk. If the analysis indicated risk, then the next-highest releasing exposure scenario was 5932 evaluated until all COUs were characterized. Discussion of the screening approach and the refinements 5933 made can be found in Section 5.3.

5934

5935 Using the screening approach with refinements, EPA was able to calculate RQs. Calculated RQs can 5936 provide a risk profile by presenting a range of estimates for different environmental hazard effects for 5937 different COUs. An RQ equal to 1 indicates that the exposures are the same as the concentration that 5938 causes effects. An RO less than 1, when the exposure is less than the effect concentration, generally 5939 indicates that there is not a risk of injury to the environment that would support a determination of 5940 unreasonable risk for the chemical substance. An RQ greater than 1, when the exposure is greater than 5941 the effect concentration, generally indicates that there is risk of injury to the environment that would 5942 support a determination of unreasonable risk for the chemical substance. Additionally, if a chronic RQ is 5943 1 or greater, the Agency evaluates whether the chronic RO is 1 or greater for 30 days or more based on 5944 the exposure period of the hazard toxicity tests before making a determination of unreasonable risk.

- 5945
- Based on the quantitative screening approach with refinements, EPA is preliminarily determining thatone COU, Disposal, significantly contributes to unreasonable risk to the environment.
- 5948

EPA has qualitatively evaluated COUs without RQs and is preliminarily determining they do not
contribute to unreasonable risk to the environment, including distribution in commerce. Risk to the
environment from consumer down-the-drain releases and end-of-life disposal was assessed qualitatively
for the 13 consumer COUs under the Disposal COU (see Section 3.1.4). Based on the qualitative
assessment, EPA is preliminarily determining that consumer down-the-drain releases and end-of-life
disposal do not contribute to unreasonable risk to the environment; however the Disposal COU, may,

- 5955 because of the results of the quantitative environmental risk assessment. Results indicated chronic risk
- 5956 for aquatic vertebrates due to high-end releases to surface water. More information about how COUs

were assessed for risk to the environment are summarized in Table 5-2 and Table 5-6 of this draft riskevaluation.

5959 6.2.1 Populations and Exposures EPA Assessed for the Environment

5960 For aquatic organisms, EPA has evaluated exposures via surface water and trophic transfer. For benthic 5961 organisms, EPA has evaluated exposures via surface water and sediment. For aquatic plants and algae, 5962 the Agency evaluated exposures via surface water. For soil invertebrates and terrestrial plants, EPA 5963 evaluated exposures via air deposition to soil. For terrestrial organisms, the Agency has evaluated 5964 exposures via trophic transfer. Additionally, EPA evaluated terrestrial mammal exposures from 5965 biosolids and landfills.

5966

5967 For aquatic and terrestrial species, EPA expects the main environmental exposure pathways for DBP to 5968 be releases to surface water and subsequent deposition to sediment, and limited dispersal from fugitive 5969 and stack air release deposition to soil, respectively. Trophic transfer, biosolids, and landfills were all 5970 qualitatively assessed and did not indicate risk for the environment.

5971

5972 EPA's confidence in the aquatic exposure assessment ranges from slight (for COUs that were assessed

- 5973 using generic releases) to robust (for COUs with TRI/DMR releases). Additional information about the
- 5974 Agency's confidence in the aquatic, terrestrial, and trophic transfer exposure assessments is provided in
- 5975 Table 5-7 of this draft risk evaluation.
- 5976

6.2.2 Summary of Environmental Effects

5977 EPA is preliminarily determining that one COU, Disposal, may significantly contribute to unreasonable
5978 risk to the environment because of chronic effects for mortality, growth, reproduction, and development
5979 for aquatic vertebrates.

5980

5984

EPA has robust confidence that DBP has chronic effects on aquatic vertebrates in the environment.
More information about the Agency's confidence in the aquatic, terrestrial, and trophic transfer hazard
assessments is in Table 5-7 of this draft risk evaluation.

6.2.3 Basis for Unreasonable Risk to the Environment

5985 Based on the risk evaluation for DBP—including the risk estimates, the environmental effects of DBP, 5986 the exposures, physical and chemical properties of DBP, and consideration of uncertainties—EPA has 5987 preliminarily identified unreasonable risk to the environment from DBP.

5987/ p 5988

5989 EPA quantitatively evaluated surface water, sediment and air deposition to soil exposure pathways (with 5990 the exception of eight COUs as explained below), and qualitatively evaluated trophic transfer, biosolids 5991 and landfills exposure pathways. Consistent with the Agency's determination of unreasonable risk to 5992 human health, the RQ is not treated as a bright-line and other risk-based factors may be considered (*e.g.*, 5993 confidence in the hazard and exposure characterization, duration, magnitude, uncertainty) for purposes 5994 of making an unreasonable risk determination.

5995

Four COUs evaluated quantitatively resulted in RQs greater than 1. Three COUs have RQs of 1.04.
Although EPA has robust confidence in the risk characterization, the Agency does not use the RQ of 1
as a bright-line and considering the assumptions in the modeling of water concentrations, EPA is
preliminarily determining that these three COUs do not contribute to unreasonable risk to the
environment for DBP (see Table 5-6). One COU, Disposal, has RQs of 9.23 and 1.18 for chronic

6001 exposure to aquatic vertebrates and invertebrates, respectively. The RQs are based on wastewater release

from treatment plants and are inclusive of wastewater treatment removal of DBP. As stated in Section

6003 5.3.4, for reported releases, the high-end modeled concentrations in the surface water are the same order 6004 of magnitude as the high-end monitored concentrations found in surface water. However, per the *Draft* Environmental Media, General Population, and Environmental Exposure for Dibutyl Phthalate (DBP), 6005 6006 the modeled surface water concentration value for the Disposal COU is higher than the highest reported 6007 monitored concentration value found in data obtained through the Water Quality Portal (WOP), which 6008 houses publicly available water quality data from the USGS, EPA, and state, federal, Tribal, and local 6009 agencies. (The highest monitored concentration was $8.2 \,\mu g/L$, whereas the modeled concentration for 6010 the Disposal COU is 14.40 μ g/L) (U.S. EPA, 2025p). Given the conservative nature of the 6011 environmental risk assessment and that the Agency does not use a bright-line approach for determining 6012 unreasonable risk, EPA is preliminarily determining that the Disposal COU does not significantly contribute to unreasonable risk of injury to the environment from chronic exposure for aquatic 6013 invertebrates. However, EPA is still preliminarily determining that the Disposal COU significantly 6014 contributes to unreasonable risk to the environment because of chronic exposures to aquatic vertebrates 6015 6016 from wastewater discharge to surface water.

6017

6018 One COU evaluated with the Manufacturing OES (Manufacturing – domestic manufacturing) and three 6019 COUs evaluated with the Application of paints and coatings OES (Industrial use - construction, paint, 6020 electrical, and metal products - paints and coatings; Commercial use - construction, paint, electrical, 6021 and metal products - paints and coatings; and Commercial use - packaging, paper, plastic, hobby products - ink, toner and colorant products) indicated chronic risk for aquatic vertebrates due to surface 6022 6023 water exposure. However, EPA has slight confidence in the risk characterization for these COUs 6024 because they are based on generic industrial release scenarios rather than reported release data and it is 6025 unclear whether individual estimates of media releases (to water, landfills, air, etc.) are an overestimate 6026 (Section 5.3.4). Therefore, EPA is preliminarily determining, that for DBP, these four COUs do not contribute to unreasonable risk to the environment. 6027

6028

6029 For all environmental pathways, eight COUs do not appear to contribute to unreasonable risk to the 6030 environment for DBP based on a qualitative assessment of the Fabrication or use of final products or 6031 articles OES, indicating that environmental releases are expected to be minimal and dispersed. In 6032 addition, EPA evaluated activities resulting in exposures associated with distribution in commerce 6033 throughout the various life cycle stages and COUs (e.g., manufacturing, processing, industrial use, 6034 commercial use, transportation) rather than a single distribution scenario. EPA expects that 6035 environmental releases from distribution in commerce will be similar or less than the exposure estimates from the COUs evaluated that did not exceed hazard to ecological receptors. EPA further expects all the 6036 6037 DBP or DBP-containing products and/or articles to be transported in closed system or otherwise to be 6038 transported in a form (e.g., articles containing DBP) such that there is negligible potential for releases 6039 except during an incident. Therefore, no separate assessment was performed for estimating releases and 6040 exposures from distribution in commerce (see Table 5-6).

6041

6042 EPA evaluated down-the-drain releases of DBP for consumer COUs qualitatively. Although EPA 6043 acknowledges that there may be DBP releases to the environment via the cleaning and disposal of 6044 adhesives, sealants, paints, coatings, cleaner, waxes, and polishes, the Agency did not quantitatively 6045 assess down-the-drain and disposal scenarios of consumer products due to limited information from monitoring data or modeling tools. However, the consideration of the physical and chemical properties 6046 6047 of DBP allows the Agency to conduct a qualitative assessment. No studies were identified which reported the concentration of DBP in landfills or in the surrounding areas in the United States, but DBP 6048 6049 was identified in sludge in wastewater plants in China, Canada, and the United States. DBP is expected 6050 to have a high affinity to particulate and organic media which would limit leaching to groundwater. 6051 Because of its high hydrophobicity and high affinity for soil sorption, it is unlikely that DBP will

migrate from landfills via groundwater infiltration. Therefore, DBP from down-the-drain releases from
 consumer products or landfill disposal of consumer articles is not likely to pose risk to aquatic and
 terrestrial organisms (see Table 5-6).

6055

6056 EPA qualitatively assessed the potential for trophic transfer of DBP through food webs to wildlife. DBP

6057 is not expected to be persistent in the environment as it is expected to degrade rapidly under most

- 6058 environmental conditions (although there is delayed biodegradation in low-oxygen media); and DBP's
- 6059 bioavailability is expected to be limited (see Section 5.3.1). With respect to trophic transfer,
- 6060 concentrations of DBP in soil (biosolids, landfills, air deposition) and air is limited or is not expected to 6061 be bioavailable and were also assessed qualitatively.
- 6062

6063 There are uncertainties in the relevance of limited monitoring data for biosolids and landfill leachate to the COUs considered. However, based on high-quality physical and chemical property data, EPA 6064 determined that DBP will have low persistence potential and mobility in soils. Therefore, groundwater 6065 concentrations resulting from releases to the landfill or to agricultural lands via biosolids applications 6066 were not quantified but were discussed qualitatively. For ambient air/emissions to soil, where the highest 6067 6068 stack emissions were combined with the highest fugitive emissions for screening, EPA did not aggregate 6069 other COUs or environmental exposure pathways. This consideration is further detailed in the Draft Environmental Media, General Population, and Environmental Exposure Assessment for Dibutyl 6070 6071 Phthalate (DBP) (U.S. EPA, 2025p). Due to its physical and chemical properties, environmental fate, 6072 and exposure parameters, DBP is not expected to persist in surface water, groundwater, or air.

6073 6074 EPA's overall environmental risk characterization confidence levels range from moderate (for generic 6075 releases) to robust (for TRI/DMR releases and surrogates) for its qualitative and quantitative aquatic and terrestrial assessments for all pathways, with the exception of four COUs (Manufacturing - domestic 6076 6077 manufacturing; Industrial use – construction, paint, electrical and metal products – paints and coatings; 6078 Commercial use - construction, paint, electrical and metal products - paints and coatings; and 6079 Commercial use – packaging, paper, plastic, hobby products – ink, toner and colorant products) that 6080 have moderate confidence for the surface water pathway. EPA's confidence in the environmental risk assessment is summarized in Table 5-7 of this draft risk evaluation. 6081

6082
 6.3 Additional Information Regarding the Basis for the Risk
 6083 Determination

Table 6-1 and Table 6-2 summarize the basis for this preliminary unreasonable risk determination of injury to human health presented in this DBP risk evaluation. In these tables, bold text indicates that an MOE is below the benchmark value. These tables identify the duration of exposure (*e.g.*, acute, intermediate, chronic duration) and the exposure route to the population or receptor. As explained in Section 6.2, for this preliminary unreasonable risk determination, EPA has considered the effects of DBP to human health, including PESS, as well as a range of risk estimates as appropriate, risk-related factors, and the confidence in the analysis. See Sections 4.3 and 5.3 for a summary of risk estimates.

6091 **Table 6-1. Supporting Basis for the Unreasonable Risk Determination for Human Health (Occupational COUs)**

	COU		Worker	Exposure			Estimates OE = 30)			Estimates IOE = 30)			Estimate [OE = 30]
Life Cycle Stage – Category	Subcategory	OES	Population	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chroni
			Average Adult	СТ	34	46	49	1.7	2.3	2.4	1.6	2.2	2.3
Manufacturing			Worker	HE	17	23	25	0.8	1.1	1.2	0.8	1.1	1.2
	Domestic manufacturing	Manufacturing	Female of	СТ	30	41	44	1.8	2.5	2.7	1.7	2.3	2.5
manufacturing			Reproductive Age	HE	15	21	22	0.9	1.2	1.3	0.9	1.2	1.3
			ONU	СТ	34	46	49	N/A	N/A	N/A	34	46	49
	Importing		Average Adult	СТ	34	46	49	1.7	2.3	2.4	1.6	2.2	2.3
– Importing			Worker	HE	17	23	25	0.8	1.1	1.2	0.8	1.1	1.2
Processing –	Laboratory chemicals in	Import and	Female of	СТ	30	41	44	1.8	2.5	2.7	1.7	2.3	2.5
	wholesale and retail trade;	repackaging	Reproductive Age	HE	15	21	22	0.9	1.2	1.3	0.9	1.2	1.3
	plasticizers in wholesale and retail trade; and plastics material and resin manufacturing		ONU	СТ	34	46	49	N/A	N/A	N/A	34	46	49
Processing –	Intermediate in plastic manufacturing			СТ	34	46	49	1.7	2.3	2.4	1.6	2.2	2.3
Processing – Incorporation into formulation, mixture, or	Solvents (which become part of product formulation or mixture) in chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and printing ink manufacturing Plasticizer in paint and coating manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; printing ink manufacturing; and adhesive and sealant manufacturing	Incorporation into formulations, mixtures, or reaction product	Average Adult Worker	HE	17	23	25	0.8	1.1	1.2	0.8	1.1	1.2
	Pre-catalyst manufacturing		Female of	СТ	30	41	44	1.8	2.5	2.7	1.7	2.3	2.5
			Reproductive Age	HE	15	21	22	0.9	1.2	1.3	0.9	1.2	1.3
			ONU	СТ	34	46	49	N/A	N/A	N/A	34	46	49

	COU					ion Risk	Estimates	Derma	al Risk I	Estimates	Aggreg	ate Risk	Estimates
Life Cycle	Calendar	OES	Worker Population	Exposure Level	(Bench	nmark M	OE = 30)	(Bench	mark M	$\mathbf{IOE}=30$	(Bench	mark M	OE = 30)
Stage – Category	Subcategory		Topulation	Lever	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
Processing –			Average Adult	СТ	49	67	71	1.7	2.3	2.4	1.6	2.2	2.3
Processing:			Worker	HE	5.9	8.0	8.6	0.8	1.1	1.2	0.7	1.0	1.1
incorporation into	Plasticizer in plastic material and		Female of	CT	44	60	65	1.8	2.4	2.6	1.7	2.4	2.5
formulation, mixture, or	resin manufacturing	compounding	Reproductive Age	HE	5.3	7.2	7.8	0.9	1.2	1.3	0.8	1.0	1.1
reaction product			ONU	СТ	49	67	71	124	169	181	35	48	51
	Plasticizer in adhesive and		Average Adult	СТ	49	67	71	124	169	181	35	48	51
Processing –	sealant manufacturing; building and construction materials		Worker	HE	5.9	8.0	8.6	62	85	90	5.4	7.3	7.8
Processing:	manufacturing; furniture and	PVC plastics	Female of	CT	44	60	65	135	184	197	33	45	49
incorporation into articles	related product manufacturing;	converting	Reproductive Age	HE	5.3	7.2	7.8	67	92	98	4.9	6.7	7.2
into articles	ceramic powders; plastics product manufacturing		ONU	СТ	49	67	71	124	169	181	35	48	51
Processing –	Plasticizer in plastic material and		Average Adult	СТ	59	80	86	1.7	2.3	2.4	1.6	2.2	2.3
	resin manufacturing; rubber manufacturing		Worker	HE	9.9	14	15	0.8	1.1	1.2	0.8	1.0	1.1
into	manuracturing			CT	53	73	78	1.8	2.4	2.6	1.7	2.4	2.5
formulation, mixture, or reaction product		Non-PVC	Female of Reproductive Age										
Processing –	Plasticizer in adhesive and	materials		HE	9.0	12	13	0.9	1.2	1.3	0.8	1.1	1.2
Incorporation into articles	sealant manufacturing; building and construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing	manufacturing	ONU	СТ	59	80	86	124	169	181	40	54	58

	COU						Estimates			Estimates			Estimates
Life Cycle		OES	Worker Population	Exposure Level	(Bench	nmark M	(OE = 30)	(Bench	mark N	$\mathbf{IOE}=30$	(Bench	mark M	OE = 30)
Stage – Category	Subcategory		ropulation	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
Commercial	Adhesives and sealants		Average Adult	СТ	336	458	529	1.7	2.3	2.6	1.7	2.3	2.6
Use –			Worker	HE	168	229	245	0.8	1.1	1.2	0.8	1.1	1.2
Construction,				СТ	304	415	479	1.8	2.5	2.9	1.8	2.5	2.8
paint, electrical, and metal		Application of	Female of										
products		Application of adhesives and	Reproductive Age										
Industrial Use –	Adhesives and sealants	sealants		HE	152	207	222	0.9	1.2	1.3	0.9	1.2	1.3
Construction,	runesives une searants	Section	ONU	CT	336	458	529	1.7	2.3	2.6	1.7	2.3	2.6
paint, electrical,			0110	CI	550	+50	52)	1.7	2.5	2.0	1.7	4.5	2.0
and metal													
products													
	Ink, toner, and colorant products		Average Adult	СТ	20	28	30	1.7	2.3	2.4	1.5	2.1	2.3
Use –			Worker	HE	3.2	4.4	4.7	0.8	1.1	1.2	0.7	0.9	1.0
Packaging,				СТ	18	25	27	1.8	2.5	2.7	1.7	2.3	2.4
paper, plastic, toys, hobby			Female of	HE	2.9	4.0	4.2	0.9	1.2	1.3	0.7	0.9	1.0
products		Application of	Reproductive Age										
Commercial		paints and	ONU	СТ	20	28	30	2.2	3.1	3.3	2.0	2.8	2.9
Use –		coatings											
Commercial use		_											
	Paints and coatings												
paint, electrical,													
and metal products													
products			Average Adult	СТ	34	46	49	1.7	2.3	2.4	1.6	2.2	2.3
Industrial Use –	Solvent, including in maleic	Industrial	Worker	HE	17	23	25	0.8	1.1	1.2	0.8	1.1	1.2
Non-	anhydride manufacturing	process solvent	Female of	СТ	30	41	44	1.8	2.5	2.7	1.7	2.3	2.5
incorporative activities	technology	use	Reproductive Age	HE	15	21	22	0.9	1.2	1.3	0.9	1.2	1.3
			ONU	СТ	34	46	49	N/A	N/A	N/A	34	46	49
			Average Adult	СТ	442	603	645	124	169	181	97	132	141
Commercial		Use of	Worker	HE	31	42	45	62	85	90	21	28	30
Use – Other uses	e – Other Laboratory chemicals laboratory	Female of	СТ	400	546	584	135	184	197	101	138	147	
4505		(solid)	Reproductive Age	HE	28	38	41	67	92	98	20	27	29
			ONU	СТ	442	603	645	124	169	181	97	132	141

	COU				Inhalat	ion Risk	Estimates	Derma	ıl Risk I	Estimates	Aggreg	ate Risk	Estimates
Life Cycle	Call as to some	OES	Worker Population	Exposure Level	(Bench	mark M	OE = 30)	(Bench	mark M	$\mathbf{IOE} = 30$	(Bench	mark M	OE = 30)
Stage – Category	Subcategory		ropulation	Lever	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
			Average Adult	СТ	336	458	491	2.2	3.1	3.3	2.2	3.0	3.3
Commercial Use – Other	Laboratory chemicals	Use of laboratory	Worker	HE	168	229	245	0.8	1.1	1.2	0.8	1.1	1.2
uses	Laboratory chemicals	chemicals	Female of	CT	304	415	444	2.4	3.3	3.6	2.4	3.3	3.5
		(liquid)	Reproductive Age	HE	152	207	222	0.9	1.2	1.3	0.9	1.2	1.3
			ONU	CT	336	458	491	N/A	N/A	N/A	336	458	491
Commercial	Lubricants and lubricant		Average Adult	СТ	336	5,040	61,320	3.0	45	546	3.0	44	541
Use – Other	additives		Worker	HE	168	1,260	15,330	1.0	7.5	91	1.0	7.4	90
uses		-	Female of	СТ	304	4,563	55,514	3.3	49	594	3.2	48	588
Industrial Use – Other uses	Lubricants and lubricant additives	Use of	Reproductive Age	HE	152	1,141	13,878	1.1	8.1	99	1.1	8.1	98
Commercial Use – Automotive, fuel, agriculture, outdoor use products	Automotive care products	lubricants and functional fluids	ONU	СТ	336	5,040	61,320	N/A	N/A	N/A	336	5,040	61,320
			Average Adult	CT	11	15	16	1.7	2.3	2.5	1.5	2.0	2.1
Commercial		Use of	Worker	HE	3.0	4.1	4.4	0.8	1.1	1.2	0.7	0.9	1.0
Use – Other	Inspection penetrant kit	penetrants and inspection	Female of	СТ	10	14	15	1.8	2.5	2.7	1.5	2.1	2.3
uses		fluids	Reproductive Age	HE	2.7	3.7	4.0	0.9	1.2	1.3	0.7	0.9	1.0
			ONU	СТ	329	449	487	1.7	2.3	2.5	1.7	2.3	2.5

	COU						Estimates			Estimates			Estimates
Life Cycle Stage –	Subcategory	OES	Worker Population	Exposure Level	(Bench	mark M	(OE = 30)	(Bench	mark M	$\mathbf{IOE}=30$	(Bench	mark M	OE = 30)
Category	Subcategory				Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
Commercial Use – Furnishing,	Floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel		Average Adult Worker	СТ	168	229	245	124	169	181	71	97	104
cleaning, treatment care	Furniture and furnishings			HE	20	27	29	62	85	90	15	21	22
products			Female of	CT	152	207	222	135	184	90 197	71	21 97	104
	Fabria		Reproductive Age	HE	132	25	26	67	92	98	14	19	21
		Fabrication or	ONU	СТ	168	229	245	124	169	181	71	97	104
Commercial	Automotive articles	use of final				-				_			
Use – Other	Chemiluminescent light sticks	product or											
uses	Propellants	articles											
Commercial Use – Packaging, paper, plastic, toys, hobby products	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)												
	Toys, playground, and sporting equipment												
			Average Adult Worker	CT HE	156	212 15	227 16	124 62	169 85	181 90	69 9.1	94 12	101 13
Processing –	Recycling	Recycling	Female of	HE CT	11 141	15 192	206	62 135	85 184	90 197	9.1 69	94	13 101
Recycling		Recyching	Reproductive Age	HE	9.7	192	14	67	92	98	8.4	12	101
			ONU	CT	156	212	227	124	169	181	69	94	101

	COU										00 0		Estimates
Life Cycle		OES	Worker Population	Exposure Level	(Bench	mark M	$\mathbf{OE}=30$	(Bench	mark M	(OE = 30)	(Bench	mark M	OE = 30)
Stage – Category	Subcategory		i opulation	Level	Acute	Inter.	Chronic	Acute	Inter.	Chronic	Acute	Inter.	Chronic
			Average Adult	CT	156	212	227	124	169	181	69	94	101
D' 1			Worker	HE	11	15	16	62	85	90	9.1	12	13
Disposal – Disposal	IDISDOSAL	handling, treatment, and	Female of	CT	141	192	206	135	184	197	69	94	101
Disposal		disposal	Reproductive Age	HE	9.7	13	14	67	92	98	8.4	12	12
			ONU	CT	156	212	227	124	169	181	69	94	101
populations (ave	Calculator for Occupational Expos rage adult workers, female of repro- ray shaded cell indicates an MOE b	ductive age, and	ONUs) and all dura						for all th	e OES for	all		

6092

6093 Table 6-2. Supporting Basis for the Unreasonable Risk Determination for Human Health (Consumer COUs)

Table 6-2. Supporting Basi				Exposure			Life	stage (years) chmark MOI			
Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Scenario (H, M, L) ^{<i>a</i>}	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adult (21+ years)
Consumer Uses: Automotive, fuel, agriculture, outdoor use products: Automotive care products				Uses match	ned with au	itomotive a	dhesives				
			Dermal	Н	_	_	_	-	7	8	7
			Dennai	М	_	-	_	_	28	31	29
				L	_	-	_	_	140	150	140
		Acute	Ingestion	-	_	-	-	-	_	-	_
		Acute	Inhalation	Н	160 ^b	170 ^b	210 ^b	300 ^b	370	440	540
	Automotive			Н		_	_	—	7	8	7
	adhesives		Aggregate	М		_	_	—	28	31	29
				L	_	-	-	-	140	150	140
			Dermal	Н	_	_	_	_	210	230	220
		T (1	Ingestion	_	_	_	_	_	_	-	—
		Intermed.	Inhalation	Н	4,800 ^b	5,100 ^b	6,200 ^b	9,000 ^b	1.1E04	1.3E04	1.6E0
			Aggregate	Н	_	_	_	_	210	230	210
		Chronic	_	_	_	_	_	_	_	_	_
Consumer Uses: Construction,				Н	_	_	_	_	7	8	7
paint, electrical, and metal products: Adhesives and sealants			Dermal	М	_	_	_	_	28	31	29
products: Adnesives and sealants		Acute		L	_	_	-	_	140	150	140
			Ingestion	_	_	_	-	_	_	_	_
	Construction		Inhalation	_	_	_	-	_	_	_	_
	adhesives		Dermal	Н	_	_	-	_	210	230	220
		Intermed.	Ingestion	_	_	_	_	_	_	_	_
			Inhalation	_	_	_	_	_	_	_	_
		Chronic	_	_	_	_	_	_	_	_	—
			Dermal	Н	_	_	_	_	70	77	72
		Acute	Ingestion	_	_	_	_	_	_	_	
			Inhalation	_	_	_	_	-	_	_	-
	Adhesives for small	Intermed.	_	_	_	_	 _	_	_	_	_
	repairs		Dermal	Н	_	_	_	-	490	540	510
		Chronic	Ingestion	_	_	_	_	-	-	_	_
		-	Inhalation	_	_	L	<u> _</u>	_	_	_	<u> </u>

				Exposure				stage (years) chmark MOl			
Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Scenario (H, M, L) ^{<i>a</i>}	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
				Н	_	_	_	_	7	8	7
			Dermal	М	_	_	_	-	28	31	29
				L	_	_	_	_	140	150	140
		Acute	Ingestion	-	_	-	_	-	_	_	_
		1 10 000	Inhalation	Н	72 ^b	76 ^{<i>b</i>}	94 ^b	130 ^b	130	160	190
			Aggregate	Н	_	-	_	-	7	7	7
			nggregate	М	-	-	—	-	24	26	26
	Metal coatings			L	-	-	_	-	89	100	100
		Intermed.	-	-	_	-	_	-	-	-	
			Dermal	Н	_	-	_	-	49	54	51
			Ingestion	-	-	-	_	-	_	-	—
		Chronic	Inhalation	Н	26 ^b	28 ^b	34 ^b	49 ^b	51	62	75
			milalation	М	130 ^b	140 ^b	170 ^b	250 ^b	290	340	420
			Aggregate	Н	_	-	_	-	25	29	30
Consumer Uses: Construction,			Aggregate	М	_	_	_	-	120	130	140
paint, electrical, and metal				Н	_	_	_	_	16	17	16
products: Paints and coatings			Dermal	М	_	_	_	_	23	26	24
				L	_	-	_	-	47	51	48
		Acute	Ingestion	_	_	-	_	-	_	-	-
	Indoor flooring	Acute	Inhalation	Н	100 ^b	110 ^b	140 ^b	190 ^b	260	300	380
	sealing and		Aggragata	Н	-	-	—	-	15	16	15
	refinishing products		Aggregate	М	_	-	_	-	22	24	23
				L	-	-	-	-	45	49	46
			Dermal	Н	-	-	—	-	470	510	480
		Intermed.	Ingestion	-	-	-	-	—	—	-	_
			Inhalation	Н	3,100 ^b	3,300 ^b	4,100 ^b	5,800 ^b	7,800	9,100	1.1E04
			Aggregate	Н	-	-	—	-	440	490	460
		Chronic	-	-	-	-	-	-	-	-	-
	Sealing and			Н	-	-	-	-	9	10	9
	refinishing sprays	Acute	Dermal	М	-	-	—	-	18	19	18
	(outdoor use)			L	-	-	—	-	35	39	36
			Ingestion	—	-	-	_	—	-	—	-

				F				stage (years) chmark MOI			
Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
			Inhalation	Н	92 ^b	98 ^b	120 ^b	150 ^b	49	66	73
		Acute		Н	_	-	_	-	8	8	8
		Acute	Aggregate	М	-	-	-	-	15	16	16
Consumer Uses: Construction,	Sealing and			L	_	-	_	_	35	38	36
paint, electrical, and metal	refinishing sprays		Dermal	Н	_	-	_	_	260	290	270
products: Paints and coatings	(outdoor use)	Intermed	Ingestion	_	_	_	_	—	_	_	_
		Intermed.	Inhalation	Н	2,800 ^b	2,900 ^b	3,600 ^b	4,500 ^b	1,500	2,000	2,200
			Aggregate	Н	-	-	_	_	220	250	240
		Chronic	-	_	_	-	_	-	_	_	_
			D	Н	_	_	_	_	_	$-^d$	$-^d$
			Dermal	М	_	_	_	_	_	76	72
		Acute	Ingestion	_	_	_	_	_	_	_	_
Consumer Uses: Furnishing,			Inhalation	_	_	_	_	_	_	_	_
cleaning, treatment care products:	Synthetic leather	Intermed.	_	_	_	_	_	_	_	_	_
Fabric, textile, and leather products	clothing		D 1	Н	_	_	_	_	_	d	$-^d$
		C1 .	Dermal	М	_	_	_	_	_	540	510
		Chronic	Ingestion	_	_	-	_	_	_	_	_
			Inhalation	_	_	-	_	_	_	_	_
				Н	d	d	d	$-^d$	d	d	d
			Dermal	М	d	d	41	54	69	76	72
				L	d	140	160	200	250	280	260
				Н	83	140	220	2.3E06	4.1E06	5.2E06	12E06
			Ingestion c	М	280	380	670	2.3E07	4.1E07	5.2E07	1.2E08
			U	L	1.1E05	7.6E04	1.4E05	3.4E07	6.1E07	7.7E07	1.7E08
Consumer Uses: Furnishing,		Acute		Н	5.7E04	6.0E04	7.4E04	1.1E05	1.5E05	1.8E05	2.2E05
cleaning, treatment care products:	Synthetic leather		Inhalation c	М	5.8E05	6.1E05	7.5E05	1.1E06	1.5E06	1.8E06	2.2E06
Fabric, textile, and leather products	furniture			L	8.8E05	9.3E05	1.1E06	1.6E06	2.3E06	2.7E06	3.4E06
_				H	83	140	220	1E05	1.5E05	1.7E05	2.1E05
			Aggregate	М	280	380	39	54	69	76	72
			00 0	L	9.7E04	140	160	200	250	280	260
		Intermed.	_	_	_	_	_	_	_	_	_
				Н	d	d	d	d	d	d	d
		Chronic	Dermal	М	d	d	41	54	69	76	72

				Eurogung				stage (years) chmark MOl			
Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
			Dermal	L	$-^d$	140	160	200	250	280	260
				Н	83	140	220	2.5E06	4.5E06	5.7E06	1.3E07
			Ingestion ^c	М	280	380	670	2.5E07	4.5E07	5.7E07	1.3E08
Consumer Uses: Furnishing,				L	1.1E05	7.6004	1.4E05	3.7E07	6.7E07	8.4E07	1.9E08
cleaning, treatment care products:	Synthetic leather	Chronic		Н	5.9E04	6.3E04	7.7E04	1.1E05	1.6E05	1.8E05	2.3E05
Fabric, textile, and leather products	furniture	emonie	Inhalation ^c	М	6.0E05	6.4E05	7.9E05	1.1E06	1.6E06	1.9E06	2.3E06
				L	9.2E05	9.7E05	1.2E06	1.7E06	2.4E06	2.8E06	3.5E06
				Н	83	140	220	1.1E05	1.5E05	1.8E05	2.2E05
			Aggregate	М	280	380	39	54	69	76	72
				L	120	140	160	200	250	280	260
			Dermal	Н	240	280	320	400	510	550	520
		Acute	Ingestion ^c	Н	2.4E04	1.9E04	1.7E04	4.8E04	8.6E04	1.1E05	2.4E05
			Inhalation ^c	H	800	850	1,000	1,500	2,100	2,500	3,100
	Vinyl flooring		Aggregate	Н	180	210	240	310	410	450	440
		Intermed.	-	-	-	-	-	—	-	_	-
			Dermal	H	240	280	320	400	510	550	520
		Chronic	Ingestion ^c	H	7.9E04	6.4E04	5.7E04	1.6E05	2.9E05	3.6E05	8.1E05
Consumer uses: Furnishing,			Inhalation ^c	H	3,800	4,000	4,900	7,100	1.0E04	1.2E04	1.5E04
cleaning, treatment care products:			Aggregate	H	220	260	300	380	480	530	500
Floor coverings; construction and			Dermal	Н	120	140	160	200	250	280	-
building materials covering large surface areas including stone,		Acute	Ingestion ^c	Н	1.0E05	8.3E04	7.3E04	2.1E05	3.7E05	4.7E05	1.0E06
plaster, cement, glass and ceramic		Acute	Inhalation ^c	Н	3,500	3,700	4,500	6,500	9.2E03	1.1E04	1.3E04
articles; fabrics, textiles, and apparel	Wallpaper (in-place)		Aggregate	Н	120	130	160	190	250	270	1.3E04
apparei			Dermal	Н	120	140	160	200	250	280	9.5E04
		<i>a</i> .	Ingestion c	Н	3.4E05	2.8E05	2.5E05	7.0E05	1.3E06	1.6E06	3.5E06
		Chronic	Inhalation ^c	Н	1.6E04	1.7E04	2.1E04	3.1E04	4.3E04	5.1E04	6.3E04
			Aggregate	Н	120	140	160	200	250	280	3.8E04
	Wallmanar		Dermal	Н	_	_	_	_	130	140	130
	Wallpaper (installation)	Acute	Ingestion	I	_	_		_			
	(Inhalation	_	_	_	_	_	_	_	_

				Eurogung				stage (years) chmark MOI			
Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
			Dermal	Н	_	_	_		28	31	29
				М	_	_	_	-	110	120	120
			Ingestion	-	_	-	-	-	_	-	
		Acute	Inhalation	Н	6.7E04	7.1E04 ^b	8.7E04 ^b		3.7E04	4.8E04	5.5E04
			minanation	М	1.4E05 ^b	1.5E05 ^b	1.8E05 ^b	2.7E05 ^b	7.7E04	9.6E04	1.1E05
	Spray cleaner			Н	6.7E04	7.1E04	8.7E04	1.3E05	28	31	29
	Spray cleaner		Aggregate	М	1.4E05	1.5E05	1.8E05	2.7E05	110	120	120
			Dermal	Н	_	_	_	-	200	220	200
		<i>.</i>	Ingestion	-	_	-	_	_	_	_	-
Consumer uses: Furnishing, cleaning, treatment care products:		Chronic	Inhalation	Н	1.2E05 ^b	1.2E05 ^b	1.5E05 ^b	2.2E05 ^b	1.3E05	1.7E05	2.0E05
Cleaning and furnishing care			Aggregate	Н	1.2E05	1.2E05	1.5E05	2.2E05	200	220	200
products			Dermal	Н	_	_	_	-	14	15	14
			Dermai	М	_	_	_	_	56	62	58
			Ingestion	_	_	_	_	_	_	_	_
		Acute	Inhalation	Н	1.0E05 ^b	1.1E05 ^b	1.3E05 ^b	1.9E05 ^b	2.6E05	3.0E05	3.7E05
	Wayas and polishas		A	Н	1.0E05	1.1E05	1.3E05	1.9E05	14	15	14
	Waxes and polishes		Aggregate	М	1.6E05	1.7E05	2.0E05	2.9E05	56	62	58
			Dermal	Н	_	_	_	_	99	110	100
		Chronic	Ingestion	_	_	_	_	_	_	_	_
		Chronic	Inhalation	Н	8,500 ^{<i>b</i>}	9,100 ^{<i>b</i>}	1.1E04 ^b	1.6E04 ^b	2.0E04	2.4E04	2.9E04
			Aggregate	Н	8,500	9,100	1.1E04		98	110	100
Consumer uses: Packaging, paper, plastic, toys, hobby products: Ink, toner, and colorant products	No consumer product	s identified. I	Foreseeable u	ses were matc	hed with a	dhesives fo	r small repa	irs because si	milar use pa	tterns are exp	ected.

				Eurogung				stage (years) chmark MOI			
Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Exposure Scenario (H, M, L) ^a	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
			Dermal	Н	60	70	81	100	130	140	130
		Acute	Ingestion	-	_	_	_	-	_	_	_
	Footwear		Inhalation	-	_	_	_	-	_	_	-
	components		Dermal	Н	60	70	81	100	130	140	130
		Chronic	Ingestion	-	_	_	—	-	—	_	_
			Inhalation	-	_	_	—	-	—	_	_
			Dermal	Н	340	400	460	570	720	780	730
		Acute	Ingestion ^c	Н	1.1E06	9.0E05	8.0E05	2.3E06	4.1E06	5.1E06	1.1E07
onsumer uses: Packaging, paper, astic, toys, hobby products;		Tieute	Inhalation ^c	Н	1.4E04	1.5E04	1.8E04	2.6E04	3.7E04	4.3E04	5.3E04
Packaging (excluding food	Shower curtains		Aggregate	Н	330	380	450	550	700	770	720
packaging), including rubber	Shower curums		Dermal	Н	340	400	460	570	720	780	730
articles; plastic articles (hard);		Chronic	Ingestion ^c	Н	3.7E06	3.0E06	2.6E06	7.5E06	1.3E07	1.7E07	3.8E07
plastic articles (soft); other articles		Chiome	Inhalation ^c	Н	6.6E04	7.0E04	8.6E04	1.2E05	1.7E05	2.0E05	2.5E05
with routine direct contact during			Aggregate	Н	340	390	450	560	710	780	730
normal use, including rubber	Small articles with		Dermal	Н	120	140	160	200	250	280	260
articles; plastic articles (hard)	semi routine contact;	Acute	Ingestion	-	_	_	_	-	_	-	_
	miscellaneous items including a pen,		Inhalation	—	—	_	—	-	—	_	—
ii p c c t t d a	pencil case, hobby cutting board,		Dermal	Н	120	140	160	200	250	280	260
	costume jewelry, tape, garden hose,	Chronic	Ingestion		_	_	_	-	_	-	-
	disposable gloves, and plastic bags/pouches		Inhalation	_	_	_	_	_	_	_	_

	Product or Article			Eurogung	Lifestage (years) MOE (Benchmark MOE = 30)						
Life Cycle Stage: COU: Subcategory		Duration	Exposure Route	Exposure Scenario (H, M, L) ^{<i>a</i>}	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
			Dermal	Н	110	130	150	190	240	260	-
		Acute	Ingestion ^c	Н	52	200	380	8.5E04	1.5E05	1.9E05	4.3E05
		Acute	Inhalation ^c	Н	690	740	900	1,300	1,800	2,200	2,700
	Children's toys		Aggregate	Н	34	71	97	160	210	230	2,700
	(New)		Dermal	Н	110	130	150	190	240	260	-
		Chronic	Ingestion ^c	Н	52	200	390	2.8E05	5.1E05	6.4E05	1.4E06
		Chronic	Inhalation ^c	Н	3,300	3,500	4,300	6,200	8,800	1.0E04	1.3E04
			Aggregate	Н	35	77	110	180	230	250	1.3E04
	Children's toys (Legacy)	Acute	Dermal	Н	110	130	150	190	240	260	-
			Ingestion ^c	Н	51	190	340	8,500	1.5E04	1.9E04	4.3E04
			Inhalation ^c	Н	69	74	90	130	180	220	270
			Aggregate	Н	23	38	49	76	100	120	270
			Aggregate	М	64	91	120	180	230	250	1,400
		Chronic	Dermal	Н	110	130	150	190	240	260	-
Consumer uses: Packaging, paper,			Ingestion ^c	Н	52	190	370	2.8E04	5.1E04	6.4E04	1.4E05
plastic, toys, hobby products: Toys, playground, and sporting			Inhalation ^c	Н	330	350	430	620	880	1,000	1,300
equipment			Aggregate	Н	32	64	86	140	190	210	1,300
equipment		Acute	Dermal	Н	_	_	1.1E06	1.2E06	1.6E06	1.8E06	1.7E06
			Ingestion	Н	_	_	3.4E08	7.7E08	1.4E09	3.5E09	3.9E09
			Inhalation	Н	_	_	2.5E08	3.7E08	1.9E08	3.6E08	3.9E08
	Tire crumb		Aggregate	Н	_	_	1.1E06	1.2E06	1.5E06	1.8E06	1.7E06
	The clumb		Dermal	Н	_	_	5.4E06	5.7E06	4.1E06	4.7E06	8.0E06
		C1 .	Ingestion	Н	_	_	1.6E09	3.6E09	3.6E09	9.1E09	1.8E10
		Chronic	Inhalation	Н	_	_	1.2E09	1.7E09	5.0E08	9.5E08	1.8E09
			Aggregate	Н	_	_	5.3E06	5.7E06	4.1E06	4.6E06	8.0E06
	Small articles with		Dermal	Н	120	140	160	200	250	280	260
	semi routine contact;	Acute	Ingestion	_	_	_	_	_	_	_	_
	miscellaneous items		Inhalation	_	_	_	_	_	_	_	_
	including a football, balance ball, and pet		Dermal	Н	120	140	160	200	250	280	260
	toys	Chronic	Ingestion	_	_	_	_	_	_	_	_
			Inhalation	-	_	_	_	_	_	_	_

				Exposure		Lifestage (years) MOE (Benchmark MOE = 30)						
Life Cycle Stage: COU: Subcategory	Product or Article	Duration	Exposure Route	Scenario (H, M, L) ^{<i>a</i>}	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)	
			Dermal	Н	120	140	160	200	250	280	260	
		Acute	Ingestion	_	_	-	_	_	_	-	-	
Consumer uses: Other:	Small articles with semi routine contact:		Inhalation	_	_	-	_	-	_	-	-	
Chemiluminescent light sticks	glow sticks		Dermal	Н	120	140	160	200	250	280	260	
	0	Chronic	Ingestion	_	_	-	_	_	-	-	-	
			Inhalation	_	_	-	_	_	-	-	-	
			Dermal	Н	_	-	_	_	1,800	2,000	1,800	
		Acute	Ingestion ^c	Н	3.8E06	3.1E06	2.8E06	7.7E06	1.3E07	1.7E07	3.4E07	
		Acute	Inhalation ^c	Н	6.1E04	6.5E04	7.9E04	1.1E05	1.6E05	1.9E05	2.4E05	
	Car mats		Aggregate	Н	6.0E04	6.3E04	7.7E04	1.1E05	1,800	1,900	1,800	
	Cai mats	Chronic	Dermal	Н	_	_	_	_	1.3E04	1.4E04	1.3E04	
			Ingestion c	Н	1.3E07	1.1E07	9.5E06	2.6E07	4.5E07	5.7E07	1.2E08	
			Inhalation c	Н	3.0E05	3.1E05	3.9E05	5.6E05	7.9E05	9.2E05	1.1E06	
			Aggregate	Н	2.9E05	3.1E05	3.7E05	5.4E05	1.2E04	1.4E04	1.3E04	
		Acute	Dermal	Н		d	$-^d$	$-^d$	$-^d$	d	d	
				М	$-^d$	$-^d$	41	54	69	76	72	
				L	$-^d$	140	160	200	250	280	260	
			Ingestion ^c	Н	83	140	220	2.3E06	4.1E06	5.2E06	1.2E07	
Consumer uses: Other uses:				М	280	380	670	2.3E07	4.1E07	5.2E07	1.2E08	
Automotive articles				L	1.1E05	7.6E04	1.4E05	3.4E07	6.1E07	7.7E07	1.7E08	
				Н	5.7E04	6.0E04	7.4E04	1.1E05	1.5E05	1.8E05	2.2E05	
			Inhalation ^c	М	5.8E05	6.1E05	7.5E05	1.1E06	1.5E06	1.8E06	2.2E06	
	Synthetic leather			L	8.8E05	9.3E05	1.1E06	1.6E06	2.3E06	2.7E06	3.4E06	
	seats (see synthetic			Н	83	140	220	1.0E05	1.5E05	1.7E05	2.1E05	
	leather furniture)		Aggregate	М	280	380	39	54	69	76	72	
				L	9.7E04	140	160	200	250	280	260	
				Н	$-^d$	$-^d$	$-^d$	$-^d$	$-^d$	$-^d$	$-^d$	
			Dermal	М	$-^d$	$-^d$	41	54	69	76	72	
		Chronic		L	$-^d$	140	160	200	250	280	260	
				Н	83	140	220	2.5E06	4.5E06	5.7E06	1.3E07	
			Ingestion ^c	М	280	380	670	2.5E07	4.5E07	5.7E07	1.3E08	
				L	1.1E05	7.6E04	1.4E05	3.7E07	6.7E07	8.4E07	1.9E08	

	Product or Article	Duration		F	Lifestage (years) MOE (Benchmark MOE = 30)						
Life Cycle Stage: COU: Subcategory			Exposure Route	Exposure Scenario (H, M, L) ^{<i>a</i>}	Infant (<1 Year)	Toddler (1–2 Years)	Pre- schooler (3–5 years)	Middle Childhood (6–10 years)	Young Teen (11–15 years)	Teenagers (16–20 years)	Adults (21+ years)
				Н	5.9E04	6.3E04	7.7E04	1.1E05	1.6E05	1.8E05	2.3E05
			Inhalation c	М	6.0E05	6.4E05	7.9E05	1.1E06	1.6E06	1.9E06	2.3E06
Consumer uses: Other uses:	Synthetic leather seats (see synthetic	Chronic		L	9.2E05	9.7E05	1.2E06	1.7E06	2.4E06	2.8E06	3.5E06
Automotive articles	leather furniture)	Chiome		Н	83	140	220	1.1E05	1.5E05	1.8E05	2.2E05
			Aggregate	М	280	380	39	54	69	76	72
				L	120	140	160	200	250	280	260
			Dermal	Н	_	_	_	_	_	780	730
	Adult toys	Acute		М	_	_	_	-	_	1,100	1,000
			Ingestion	Н	_	_	_	—	_	$-^d$	d
				М	_	_	_	—	_	190	210
			Inhalation	_	_	-	_	_	_	_	-
			Aggregate	Н	_	_	_	—	_	$-^d$	d
Consumer uses: Other uses:				М	_	_	_	_	_	160	170
Novelty articles			Dermal Ingestion	Н	_	_	_	—	_	780	730
				М	_	_	_	—	_	1,100	1,000
				Н	_	_	_	_	_	$-^d$	$-^d$
				М	_	_	_	-	_	190	210
			Inhalation	_	_	_	_	_	_	_	_
			Aggragata	Н	_	_	_	_	_	$-^d$	$-^d$
			Aggregate	М	_	_	_	_	-	160	170
Consumer uses: Other uses: Lubricants and lubricant additives No consumer products identified. Foreseeable uses were matched with adhesives for small repairs because similar use patterns are expected.											
^{<i>a</i>} Exposure scenario intensities inclu ^{<i>b</i>} MOE for bystander scenario ^{<i>c</i>} Exposure routes evaluated for inde ^{<i>d</i>} Scenario was deemed to be unlike Bold text in a gray shaded cell ind	oor environments. ly due to high uncertain	nties.).							

6094

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6819				

6820 APPENDICES

ADD

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6822 Appendix A KEY ABBREVIATIONS AND ACRONYMS

6823	ADD	Average daily dose
6824	ADC	Average daily concentration
6825	AERMOD	American Meteorological Society/EPA Regulatory Model
6826	BBP	Butyl benzyl phthalate
6827	BLS	Bureau of Labor Statistics
6828	CAP	Criteria Air Pollutant
6829	CASRN	Chemical Abstracts Service Registry Number
6830	CBI	Confidential business information
6831	CDC	Centers for Disease Control and Prevention (U.S.)
6832	CDR	Chemical Data Reporting
6833	CEHD	Chemical Exposure Health Data
6834	CEM	Consumer Exposure Model
6835	CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
6836	CFR	Code of Federal Regulations
6837	COC	Concentration of concern
6838	CPSC	Consumer Product Safety Commission
6839	CWA	Clean Water Act
6840	DBP	Dibutyl phthalate
6841	DCHP	Dicyclohexyl phthalate
6842	DEHP	Diethylhexyl phthalate
6843	DIBP	Diisobutyl phthalate
6844	DIDP	Diisodecyl phthalate
6845	DINP	Dicyclohexyl phthalate
6846	DIY	Do-it-yourself
6847	DMR	Discharge Monitoring Report
6848	ECJRC	European Commission's Joint Research Centre
6849	EPA	Environmental Protection Agency (or "the Agency")
6850	EPCRA	Emergency Planning and Community Right-to-Know Act
6851	ESD	Emission Scenario Document
6852	EU	European Union
6853	FDA	Food and Drug Administration
6854	FFDCA	Federal Food, Drug, and Cosmetic Act
6855	GS	Generic scenario
6856	K _{OC}	Soil organic carbon: water partitioning coefficient
6857	K _{OW}	Octanol: water partition coefficient
6858	HAP	Hazardous Air Pollutant
6859	HEC	Human equivalent concentration
6860	HED	Human equivalent dose
6861	HV	Hazard value
6862	IADD	Intermediate average daily dose
6863	IIOAC	Integrated Indoor/Outdoor Air Calculator (Model)
6864	IR	Ingestion rate
6865	LCD	Life cycle diagram
6866	LOD	Limit of detection

Average daily dose

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6867	LOAEL	Lowest-observed-adverse-effect level
6868	LOEC	Lowest-observed-effect concentration
6869	Log K _{OC}	Logarithmic organic carbon: water partition coefficient
6870	Log K _{OW}	Logarithmic octanol: water partition coefficient
6871	MBP	Monobutyl phthalate
6872	MOE	Margin of exposure
6873	NAICS	North American Industry Classification System
6874	NEI	National Emissions Inventory
6875	NHANES	National Health and Nutrition Examination Survey
6876	NHDPlus	National Hydrography Dataset Plus
6877	NICNAS	National Industrial Chemicals Notification and Assessment Scheme
6878	NOAEL	No-observed-adverse-effect level
6879	NOEC	No-observed-effect-concentration
6880	NPDES	National Pollutant Discharge Elimination System
6881	NTP	National Toxicology Program
6882	OCSPP	Office of Chemical Safety and Pollution Prevention
6883	OECD	Organisation for Economic Co-operation and Development
6884	OEL	Occupational exposure limit
6885	OES	Occupational exposure scenario
6886	OEV	Occupational exposure value
6887	ONU	Occupational non-user
6888	OPPT	Office of Pollution Prevention and Toxics
6889	OSHA	Occupational Safety and Health Administration (U.S.)
6890	P50	The 50th percentile or median flow rate of a distribution of hydrologic flows
6891	P75	The 75th percentile flow rate of a distribution of hydrologic flows
6892	P90	The 90th percentile flow rate of a distribution of hydrologic flows
6893	PBZ	Personal breathing zone
6894	PECO	Population, exposure, comparator, and outcome
6895	PEL	Permissible exposure limit (OSHA)
6896	PESS	Potentially exposed or susceptible subpopulations
6897	PND	Postnatal day
6898	PNOR	Particulates not otherwise regulated
6899	POD	Point of departure
6900	POTW	Publicly owned treatment works
6901	PPARα	Peroxisome proliferator activated receptor alpha
6902	PV	Production volume
6903	PVC	Polyvinyl chloride
6904	REL	Recommended Exposure Limit
6905	RPF	Relative potency factor
6906	SACC	Science Advisory Committee on Chemicals
6907	SDS	Safety data sheet
6908	SOC	Standard Occupational Classification
6909	SpERC	Specific Emission Release Category
6910	SSD	Species sensitivity distribution
6911	SUSB	Statistics of U.S. Businesses (U.S. Census)
6912	TOC	Total organic carbon
6912 6913	TRI	Toxic Release Inventory
6913 6914	TRV	Toxicity reference value
6914 6915	TSCA	Toxic Substances Control Act
0713	ISCA	TUXIC SUUSIAILES CUIIIIUI ACI

- 6916 TSD Technical support document
- 6917 TWA Time-weighted average
- 6918 UF Uncertainty factor
- 6919 U.S. United States
- 6920 VVWM-PSC Variable Volume Water Model with Point Source Calculator Tool
- 6921 WWTP Wastewater treatment plant
- 6922 7Q10 The lowest 7-day average flow that occurs (on average) once every 10 years
- 6923 30Q5 The lowest 30-day average flow that occurs (on average) once every 5 years

REGULATORY AND ASSESSMENT HISTORY Appendix B 6924

6925 6926

B.1 Federal Laws and Regulations

Table_Apx B-1. Federal Laws and Regulations 6927

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation					
	EPA statutes/regulations						
Toxic Substances Control Act (TSCA) – section 6(b)	EPA is directed to identify high- priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one- half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	Dibutyl phthalate is one of the 20 chemicals EPA designated as a High- Priority Substance for risk evaluation under TSCA (84 FR 71924, December 30, 2019). Designation of dibutyl phthalate as high-priority substance constitutes the initiation of the risk evaluation on the chemical.					
Toxic Substances Control Act (TSCA) – section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure- related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	Dibutyl phthalate manufacturing (including importing), processing and use information is reported under the CDR rule (<u>85 FR 20122</u> , April 9, 2020).					
Toxic Substances Control Act (TSCA) – section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States.	Dibutyl phthalate was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA Section 5 (<u>60 FR</u> <u>16309</u> , March 29, 1995).					
Toxic Substances Control Act (TSCA) – section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Seven substantial risk reports received for dibutyl phthalate (1996 -2010) (U.S. EPA, 2018). Accessed April 8, 2019).					
Toxic Substances Control Act (TSCA) – section 4	Provides EPA with authority to issue rules and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	In 1989, EPA entered an Enforceable Consent Agreement under TSCA Section 4 with six companies to perform certain chemical fate and environmental effects on certain Alkyl Phthalates (<u>54 FR 618</u> , January 9, 1989). Twelve chemical data submissions from test rules received for dibutyl phthalate: 1 acute aquatic plant toxicity, 8 acute aquatic toxicity, 2 chronic aquatic toxicity, and 1 vapor pressure. (<u>U.S. EPA, 2018</u>). Listings undated. Accessed April 8, 2019.					

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Emergency Planning and Community Right- To-Know Act (EPCRA) – section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (<i>e.g.</i> , quantities recycled, treated, combusted) and pollution prevention activities (under section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (<i>i.e.</i> , air, land and water).	Dibutyl phthalate is a listed substance subject to reporting requirements under <u>40 CFR 372.65</u> effective as of January 01, 1987.
Clean Air Act (CAA) – section 112(b)	Defines the original list of 189 Hazardous Air Pollutants (HAPs). Under 112(c) of the CAA, EPA must identify and list source categories that emit HAP and then set emission standards for those listed source categories under CAA section 112(d). CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance. Since 1990, EPA has removed two pollutants from the original list leaving 187 at present.	Dibutyl phthalate is listed as a HAP (<u>42</u> <u>U.S.C. 7412</u>).
Clean Air Act (CAA) – section 112(d)	Directs EPA to establish, by rule, NESHAPs for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to section 112(c)). For major sources, the standards must require the maximum degree of emission reduction that EPA determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT). For area sources, the standards must require generally achievable control technology (GACT) though may require MACT.	https://www.epa.gov/stationary- sources-air-pollution/national- emission-standards-hazardous-air-

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Clean Water Act (CWA) – section 304(a)(1)	Requires EPA to develop and publish ambient water quality criteria (AWQC) reflecting the latest scientific knowledge on the effects on human health that may be expected from the presence of pollutants in any body of water.	In 2015, EPA published updated AWQC for dibutyl phthalate, including a recommendation of 20 μ g/L for "Human Health for the consumption of Water + Organism" and 30 μ g/L for "Human Health for the consumption of Organism Only" for states and authorized tribes to consider when adopting criteria into their water quality standards. (Docket ID: <u>EPA-HQ-OW-</u> <u>2014-0135-0242</u>)
Clean Water Act (CWA) – sections 301, 304, 306, 307, and 402	Clean Water Act section 307(a) establishes a list of toxic pollutants or combination of pollutants under the CWA. The statute specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR Part 401.15. The "priority pollutants" specified by those families are listed in 40 CFR Part 423 Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules (sections 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in NPDES permits, see section 402(a)(1)(B). EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	Dibutyl phthalate is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such is subject to effluent limitations. (40 <u>CFR 401.15</u>). Under CWA section 304, dibutyl phthalate is included in the list of total toxic organics (TTO) (40 CFR 413.02(i)).
Clean Water Act (CWA) – sections 311(b) (2)(A) and 501(a) of the Federal Water Pollution Control Act.	Requires EPA to develop, promulgate, and revise as may be appropriate, regulations designating as hazardous substances, other than oil, which, when discharged present an imminent and substantial danger to the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches.	Dibutyl phthalate is a <u>designated</u> <u>hazardous substance in accordance with</u> <u>Section 311(b)(2)(A)</u> of the Federal Water Pollution Control Act.
Resource Conservation and Recovery Act (RCRA) – section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other	Dibutyl phthalate is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U069 (<u>40 CFR 261.33</u>).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	related factors such as flammability, corrosiveness, and other hazardous characteristics.	
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under section 103.	Dibutyl phthalate is a hazardous substance under CERCLA. Releases of dibutyl phthalate in excess of 10 lb must be reported (<u>40 CFR 302.4</u>).
	Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	
Superfund Amendments and Reauthorization Act (SARA) –	Requires the Agency to revise the hazardous ranking system and update the National Priorities List of hazardous waste sites, increases state and citizen involvement in the superfund program and provides new enforcement authorities and settlement tools.	Dibutyl phthalate is listed on SARA, an amendment to CERCLA and the <u>CERCLA Priority List of Hazardous</u> <u>Substances.</u> This list includes substances most commonly found at facilities on the CERCLA National Priorities List (NPL) that have been deemed to pose the greatest threat to public health.
	Other federal statutes/regulati	ons
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics.	Dibutyl phthalate is listed as an optional substance to be used in: adhesives to be used as components of articles intended for use in packaging, transporting, or holding food (<u>21 CFR 175.105</u>); the base sheet and coating of cellophane, alone or in combination with other phthalates where total phthalates do not exceed 5 percent (<u>21 CFR</u> <u>177.1200</u>). The FDA has reviewed phthalates in cosmetic products but does not
		cosmetic products but does not restrict their use.
Consumer Product Safety Improvement Act of 2008 (CPSIA)	Under section 108 of the Consumer Product Safety Improvement Act of 2008, CPSC prohibits the manufacture for sale, offer for sale, distribution in	The use of dibutyl phthalate at concentrations greater than 0.1 percent is banned in toys and child care articles (16 CFR part 1307).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	commerce or importation of eight phthalates in toys and childcare articles at concentrations greater than 0.1 percent: di-ethylhexyl phthalate, dibutyl phthalate, butyl benzyl phthalate, di-isononyl phthalate, di- isobutyl phthalate, di-n-pentyl phthalate, di-n-hexyl phthalate and dicyclohexyl phthalate.	
Federal Hazardous Materials Transportation Act (HMTA)	 Section 5103 of the Act directs the Secretary of Transportation to: Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce. 	Dibutyl phthalate is listed as a hazardous material with regard to transportation and is subject to regulations prescribing requirements applicable to the shipment and transportation of listed hazardous materials (70 FR 34381, June 14 2005). (49 CFR part 172.101 Appendix A)
Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C. § 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures, and respiratory protection.	Dibutyl phthalate is listed in <u>OSHA</u> <u>Table Z-1</u> . OSHA issued occupational safety and health standards for dibutyl phthalate that included a PEL of 5 mg/m ³ as an 8-hour TWA.

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6930 B.2 State Laws and Regulations

6931 6932

2 Table_Apx B-2. State Laws and Regulations

State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels: New Hampshire (<u>Env-A 1400: Regulated Toxic</u> <u>Air Pollutants</u>); Rhode Island (<u>Air Pollution Regulation No. 22</u>)
State Drinking Water Standards and Guidelines	Florida (<u>Fla. Admin. Code R. Chap. 62-550</u>); Michigan (<u>Mich. Admin. Code</u> <u>r.299.44 and r.299.49, 2017</u>); Minnesota (<u>Minn R. Chap. 4720</u>).
State PELs	California (PEL of 5 ppm and no STEL) (<u>Cal Code Regs. Title 8, § 5155</u>); Hawaii (PEL-TWA of 5 mg/m ³ and PEL-STEL of 10 mg/m ³) (<u>Hawaii</u> <u>Administrative Rules Section 12-60-50</u>)
State Right-to- Know Acts	Massachusetts (<u>105 Code Mass. Regs. § 670.000 Appendix A</u>); New Jersey (<u>8:59 N.J. Admin. Code § 9.1</u>); Pennsylvania (<u>P.L. 734, No. 159 and 34 Pa. Code § 323</u>)
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing dibutyl phthalate, including: Maine (<u>38 MRSA Chapter</u> <u>16-D</u>); Oregon (<u>Toxic-Free Kids Act, Senate Bill 478, 2015</u>); Vermont (<u>18</u> <u>V.S.A § 1776</u>); and Washington State (<u>Wash. Admin. Code 173-334-130</u>
Volatile Organic Compound (VOC) Regulations for Consumer Products	California regulations may set VOC limits for consumer products and/or ban the sale of certain consumer products as an ingredient and/or impurity. California (<u>Title 17, California Code of Regulations, Division 3, Chapter 1,</u> <u>Subchapter 8.5, Articles 1, 2, 3 and 4</u>). Under the Aerosol Coating Products Regulation, a Maximum Incremental Reactivity value has been established for dibutyl phthalate (<u>Subchapter 8.6, Article 1, § 94700</u>).
Other	California listed dibutyl phthalate on Proposition 65 in 2005 due to developmental toxicity, female and male reproductive toxicity (<u>Cal Code</u> <u>Regs. Title 27, § 27001</u>). Dibutyl phthalate is listed as a <u>Candidate Chemical under California's Safer</u> <u>Consumer Products Program (Health and Safety Code § 25252 and 25253</u>). California issued a Health Hazard Alert for dibutyl phthalate (<u>Hazard</u> <u>Evaluation System and Information Service, 2016</u>). Dibutyl phthalate is on the Massachusetts Toxic Use Reduction Act (TURA) list of 2019 (<u>300 CMR 41.00</u>).

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6935 **B.3 International Laws and Regulations**

6936 6937

Table_Apx B-3. International Laws and Regulations

Country/ Organization	Requirements and Restrictions
Canada	 Dibutyl phthalate is on the Domestic Substances List (Government of Canada. Managing substances in the environment. Substances search Database accessed April 10, 2019). Other regulations include: Canada's National Pollutant Release Inventory (NPRI). Canada Gazette Part II, Vol. 128, No. 9, May 04 1994, SOR/94-311 Dibutyl phthalate did not meet the criteria under subsection 73(1) of the Canadian Environmental Protection Act, 1999 (CEPA).
European Union	 Dibutyl phthalate is registered for use in the EU. (European Chemicals Agency (ECHA) database. Accessed April 10, 2019.) In 2008, dibutyl phthalate was listed on the Candidate list as a Substance of Very High Concern (SVHC) under regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals due to its reproductive toxicity (category 1B). In 2012, dibutyl phthalate was added to <u>Annex XIV of REACH</u> (Authorisation List) with a sunset date of December 21, 2015. After the sunset date, only persons with approved authorization applications may continue to use the chemical (European Chemicals Agency (ECHA) database. The exempted category of use is: uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC. Accessed April 10, 2019. Applications for authorizations to use, including in propellants, electronics manufacture and closed manufacturing processes: Under Annex XVII to REACH, dibutyl phthalate: 1. shall not be used as substances or in mixtures, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticized material, in toys and childcare articles individually or in any combination with the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticized material. In addition, di-isobutyl phthalate slisted in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticized material. 3. Shall not be placed on the market after 7 July 2020 in any combination with the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticized material. 3. Shall not be placed on the market after 7 July 2020 in articles, individually or in any combina

Country/ Organization	Requirements and Restrictions
	4. Paragraph 3 shall not apply to:(a) articles exclusively for industrial or agricultural use, or for use
	exclusively in the open air, provided that no plasticized material comes into contact with human mucous membranes or into prolonged contact
	with human skin;
	(b) aircraft, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft;
	(c) motor vehicles within the scope of Directive 2007/46/EC, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those vehicles, where the vehicles cannot function as intended
	without those articles;
	(d) articles placed on the market before 7 July 2020;(e) measuring devices for laboratory use, or parts thereof;
	(f) materials and articles intended to come into contact with food within the scope of Regulation (EC) No 1935/2004 or Commission Regulation (EU) No 10/20111;
	(g) medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof;
	(h) electrical and electronic equipment within the scope of Directive 2011/65/EU;
	(i) the immediate packaging of medicinal products within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC;
	(j) toys and childcare articles covered by paragraphs 1 or 2.5. For the purposes of paragraphs 1, 2, 3 and 4(a),
	(a) 'plasticized material' means any of the following homogeneous materials:
	- polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes,
	- any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings,
	- surface coatings, non-slip coatings, finishes, decals, printed designs,- adhesives, sealants, paints and inks.
	European Commission Directive (EU) <u>2015/863</u> of 31 March 2015 amended Annex II to Directive 2011/65/EU, to restrict dibutyl phthalate
	at 0.1% or greater so that: - The restriction of dibutyl phthalate shall apply to medical devices,
	including in vitro medical devices, and monitoring and control
	instruments, including industrial monitoring and control instruments, from 22 July 2021.
	- The restriction of dibutyl phthalate shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading
	of capacity of EEE placed on the market before 22 July 2019, and of

Country/ Organization	Requirements and Restrictions
	 medical devices, including <i>in vitro</i> medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, placed on the market before 22 July 2021. The restriction of dibutyl phthalate shall not apply to toys which are already subject to the restriction of di-ethylhexyl phthalate, butyl benzyl phthalate and dibutyl phthalate through entry 51 of Annex XVII to Regulation (EC) No 1907/2006. Dibutyl phthalate is subject to the <u>Restriction of Hazardous Substances</u> <u>Directive (RoHS), EU/2015/863</u>, which restricts the use of hazardous substances at more than 0.1% by weight at the 'homogeneous material' level in electrical and electronic equipment, beginning July 22, 2019. (European Commission RoHS).
Australia	Dibutyl phthalate was assessed under Human Health and Environment (Phthalate esters) Tier II of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). Dibutyl phthalate has been listed and assessed as a Priority Existing Chemical (PEC/36, November 2013). NICNAS found no reports of the phthalate being manufactured as a raw material in Australia. Dibutyl phthalate is imported into Australia mainly as a component of finished products or mixtures and also as a raw material for local formulation and processing. There are currently no restrictions on the manufacture, import or use of dibutyl phthalate in Australia.
	Dibutyl phthalate is listed in the Safe Work Australia List of Designated Hazardous Substances contained in the Hazardous Substances Information System (HSIS) as a Reproductive Toxicant Category 2 (requiring it to be labelled with the risk phrase [R61]—May cause harm to the unborn child); and Reproductive Toxicant Category 3 (requiring the risk phrase [R62]—Possible risk of impaired fertility). Data accessed April 10, 2019:
Japan	 Dibutyl phthalate is regulated in Japan under the following legislation: Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (<u>Chemical Substances Control Law; CSCL</u>) Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof Industrial Safety and Health Act (<u>ISHA</u>) <u>Air Pollution Control Law</u> As referenced in the National Institute for National Institute for Technology and Evaluation [NITE] Chemical Risk Information Platform [<u>CHRIP</u>]. Accessed April 10, 2019

Country/ Organization	Requirements and Restrictions
World Health Organization (WHO)	Established a tolerable daily intake of 66 µg dibutyl phthalate/kg body weight based on a LOAEL of 66 mg/kg body weight per day for developmental and reproductive toxicity in rats from a continuous breeding study, incorporating an uncertainty factor of 1,000. (WHO Environmental Health Criteria 189, 1997)
Australia, Austria, Belgium, Canada, Denmark, France, Germany, Ireland, Japan, Latvia, New Zealand, Norway, People's Republic of China, Poland, Romania, Singapore, South Africa, South Korea, Spain, Sweden, Switzerland, United Kingdom	Occupational exposure limits for dibutyl phthalate (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed February 14, 2025).

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6939 B.4 Assessment History

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Table_Apx B-4. Assessment History of DBP

Authoring Organization	Publication(s)/Hyperlink(s) and Year	
EPA publications		
National Center for Environmental Assessment	Integrated Risk Information System (IRIS), chemical assessment summary, dibutyl phthalate; CASRN 84-74-2 (<u>U.S. EPA, 1987</u>)	
Other U.Sb	based organizations	
National Academies of Sciences, Engineering, and Medicine	Application of systematic review methods in an overall strategy for evaluating low-dose toxicity from endocrine active chemicals (<u>NASEM</u> , 2017)	
U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (ATSDR)	Toxicological Profile for Di-n-Butyl Phthalate (<u>ATSDR</u> , <u>2001</u>)	
U.S. Consumer Product Safety Commission (U.S. CPSC)	Chronic Hazard Panel on Phthalates and Phthalate Alternatives Final Report (with Appendices) (<u>CPSC, 2014</u>) Toxicity Review of DBP (<u>CPSC, 2010</u>)	
National Toxicology Program (NTP), Center for the Evaluation of Risks to Human Reproduction (CERHR), National Institute of Health (NIH)	NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Di-n-Butyl Phthalate (DBP) (<u>NTP, 2003</u>)	

Office of Environmental Health Hazard Assessment (OEHHA), California Environmental Protection Agency	Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Di-(n-butyl)phthalate (DBP) (<u>OEHHA, 2007</u>)
In	ternational
European Union, European Chemicals Agency (ECHA), European Chemicals Bureau (ECB)	European Union risk assessment report: Dibutyl phthalate. Vol. 29, 1st priority list (<u>ECJRC, 2003</u>)
	European Union Risk Assessment Report: Dibutyl phthalate with addendum to the environmental section (ECJRC, 2004)
	Evaluation of new scientific evidence concerning the restrictions contained in Annex XVII to Regulation (EC) No 1907/2006 (REACH): Review of new available information for dibutyl phthalate (DBP) CAS No 84-74-2 Einecs No 201-557-4 (<u>ECHA, 2010</u>)
	Opinion on an Annex XV dossier proposing restrictions on four phthalates (DEHP, BBP, DBP, DIBP) (<u>ECHA, 2017b</u>)
	Annex to the Background document to the Opinion on the Annex XV dossier proposing restrictions on four phthalates (DEHP, BBP, DBP, DIBP) (<u>ECHA, 2017a</u>)
European Food Safety Authority (EFSA)	Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to di-Butylphthalate (DBP) for use in food contact materials (EFSA, 2005)
	Update of the Risk Assessment of Di-butylphthalate (DBP), Butyl-benzyl-phthalate (BBP), Bis(2- ethylhexyl)phthalate (DEHP), Di-isononylphthalate (DINP) and Di-isodecylphthalate (DIDP) for Use in Food Contact Materials (<u>EFSA, 2019</u>)
Government of Canada, Environment Canada, Health Canada	Canadian Environmental Protection Act: Priority Substances List Assessment Report: Dibutyl Phthalate (EC/HC, 1994)
	Screening Assessment: Phthalate Substance Grouping (<u>Health Canada, 2020</u>)
	State of the Science Report - Part 1: Phthalates Substance Grouping: Medium-Chain Phthalate Esters. Chemical Abstracts Service Registry Numbers 84-61-7; 84-64-0; 84- 69-5; 523-31-9; 5334-09-8; 16883-83-3; 27215-22-1; 27987-25-3; 68515-40-2; 71888-89-6 (EC/HC, 2015)
National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australian Government	Priority Existing Chemical Assessment Report: Dibutyl phthalate (<u>NICNAS, 2013</u>)
	Existing Chemical Hazard Assessment Report: Dibutyl Phthalate (<u>NICNAS, 2008</u>)

6942 Appendix C LIST OF TECHNICAL SUPPORT DOCUMENTS

- Appendix C incudes a list and citations for all supplemental documents included in the Draft RiskEvaluation for DBP.
- 6945
- 6946 Associated Systematic Review Protocol and Data Quality Evaluation and Data Extraction
- 6947 Documents Provide additional detail and information on systematic review methodologies used as
 6948 well as the data quality evaluations and extractions criteria and results.
- 6949

6964

- 6950 Draft Systematic Review Protocol for Dibutyl Phthalate (DBP) (U.S. EPA, 2025w) – In lieu of an 6951 update to the Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical 6952 Substances, also referred to as the "2021 Draft Systematic Review Protocol" (U.S. EPA, 2021a), this 6953 systematic review protocol for the Draft Risk Evaluation for DBP describes some clarifications and 6954 different approaches that were implemented than those described in the 2021 Draft Systematic 6955 Review Protocol in response to (1) SACC comments, (2) public comments, or (3) to reflect chemical-specific risk evaluation needs. This supplemental file may also be referred to as the "DBP 6956 Systematic Review Protocol." 6957
- 6958
 6959 Draft Data Quality Evaluation and Data Extraction Information for Physical and Chemical
 6960 Properties for Dibutyl Phthalate (DBP) (U.S. EPA, 2025k) Provides a compilation of tables for the
 6961 data extraction and data quality evaluation information for DBP. Each table shows the data point,
 6962 set, or information element that was extracted and evaluated from a data source that has information
 6963 relevant for the evaluation of physical and chemical properties.
- 6965 Draft Data Quality Evaluation and Data Extraction Information for Environmental Fate and
 6966 Transport for Dibutyl Phthalate (DBP) (U.S. EPA, 2025i) Provides a compilation of tables for the
 6967 data extraction and data quality evaluation information for DBP. Each table shows the data point,
 6968 set, or information element that was extracted and evaluated from a data source that has information
 6969 relevant for the evaluation for environmental fate and transport.
- 6971 Draft Data Quality Evaluation and Data Extraction Information for Environmental Release and
 6972 Occupational Exposure for Dibutyl Phthalate (DBP) (U.S. EPA, 2025j) Provides a compilation of
 6973 tables for the data extraction and data quality evaluation information for DBP. Each table shows the
 6974 data point, set, or information element that was extracted and evaluated from a data source that has
 6975 information relevant for the evaluation of environmental release and occupational exposure.
- 6977Draft Data Quality Evaluation and Data Extraction Information for Dermal Absorption for Dibutyl6978Phthalate (DBP) (U.S. EPA, 2025h) Provides a compilation of tables for the data extraction and6979data quality evaluation information for DBP. Each table shows the data point, set, or information6980element that was extracted and evaluated from a data source that has information relevant for the6981evaluation for dermal absorption.
- 6983Draft Data Quality Evaluation Information for General Population, Consumer, and Environmental6984Exposure for Dibutyl Phthalate (DBP) (U.S. EPA, 2025m) Provides a compilation of tables for the6985data quality evaluation information for DBP. Each table shows the data point, set, or information6986element that was evaluated from a data source that has information relevant for the evaluation of6987general population, consumer, and environmental exposure.
- 6988

6982

6989Draft Data Extraction Information for General Population, Consumer, and Environmental Exposure6990for Dibutyl Phthalate (DBP) (U.S. EPA, 2025g) – Provides a compilation of tables for the data6991extraction for DBP. Each table shows the data point, set, or information element that was extracted6992from a data source that has information relevant for the evaluation of general population, consumer,6993and environmental exposure.

6995 Draft Data Quality Evaluation Information for Human Health Hazard Epidemiology for Dibutyl
6996 Phthalate (DBP) (U.S. EPA, 2025o) – Provides a compilation of tables for the data quality
6997 evaluation information for DBP. Each table shows the data point, set, or information element that
6998 was evaluated from a data source that has information relevant for the evaluation of epidemiological
6999 information.

Draft Data Quality Evaluation Information for Human Health Hazard Animal Toxicology for
 Dibutyl Phthalate (DBP) (U.S. EPA, 2025n) – Provides a compilation of tables for the data quality
 evaluation information for DBP. Each table shows the data point, set, or information element that
 was evaluated from a data source that has information relevant for the evaluation of human health
 hazard animal toxicity information.

Draft Data Quality Evaluation Information for Environmental Hazard for Dibutyl Phthalate (DBP)
 (U.S. EPA, 20251) – Provides a compilation of tables for the data quality evaluation information for
 DBP. Each table shows the data point, set, or information element that was evaluated from a data
 source that has information relevant for the evaluation of environmental hazard toxicity information.

7011
7012 Draft Data Extraction Information for Environmental Hazard and Human Health Hazard Animal
7013 Toxicology and Epidemiology for Dibutyl Phthalate (DBP) (U.S. EPA, 2025f) – Provides a
7014 compilation of tables for the data extraction for DBP. Each table shows the data point, set, or
7015 information element that was extracted from a data source that has information relevant for the
7016 evaluation of environmental hazard and human health hazard animal toxicology and epidemiology
7017 information.

Associated Technical Support Documents (TSDs) – Provide additional details and information on
 exposure, hazard, and risk assessments.

7022 *Draft Fate & Physical Chemistry Assessment for Dibutyl Phthalate (DBP)* (U.S. EPA, 2024j). 7023

7024Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (DBP)7025(U.S. EPA, 2025q).

7027 Draft Consumer and Indoor Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025c).

7029 Draft Environmental Media, General Population, and Environmental Exposure for Dibutyl
 7030 Phthalate (DBP) (U.S. EPA, 2025p).

7032 Draft Environmental Hazard Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2024m).

7033
7034 Draft Non-cancer Human Health Hazard Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2024f).

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7037	Draft Cancer Human Health Hazard Assessment for Di(2-ethylhexyl) Phthalate (DEHP), Dibutyl
7038	Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate (DIBP), and Dicyclohexyl
7039	Phthalate (DCHP) (U.S. EPA, 2025b).
7040	
7041	Draft Consumer Exposure Analysis for Dibutyl Phthalate (DBP) (U.S. EPA, 2025d).
7042	
7043	Draft Consumer Risk Calculator for Dibutyl Phthalate (DBP) (U.S. EPA, 2025e).
7044	
7045	Draft Risk Calculator for Occupational Exposures for Dibutyl Phthalate (DBP) (U.S. EPA, 2025t).
7046	
7047	Draft Fish Ingestion Risk Calculator for Dibutyl Phthalate (DBP) (U.S. EPA, 2025r)
7048	
7049	Draft Surface Water Human Exposure Risk Calculator for Dibutyl Phthalate (DBP) (U.S. EPA,
7050	<u>2025v</u>)
7051	
7052	Draft Occupational and Consumer Cumulative Risk Calculator for Dibutyl Phthalate (DBP) (U.S.
7053	EPA, 2025s)
7054	
7055	Draft Ambient Air IIOAC Exposure Results And Risk Calculations for Dibutyl Phthalate (DBP)
7056	(U.S. EPA, 2025a)
7057	
7058	Draft Meta-Analysis and Benchmark Dose Modeling of Fetal Testicular Testosterone for Di(2-
7059	ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl
7060	Phthalate (DIBP), and Dicyclohexyl Phthalate (DCHP) (U.S. EPA, 2024d).
7061	
7062	Revised Draft Technical Support Document for the Cumulative Risk Analysis of Di(2-ethylhexyl)
7063	Phthalate (DEHP), Dibutyl Phthalate (DBP), Butyl Benzyl Phthalate (BBP), Diisobutyl Phthalate
7064	(DIBP), Dicyclohexyl Phthalate (DCHP), and Diisononyl Phthalate (DINP) Under the Toxic
7065	Substances Control Act (TSCA) (U.S. EPA, 2025x).
7066	
7067	Draft Summary of Human Health Hazard Animal Toxicology Studies for Dibutyl Phthalate (DBP) -
7068	Literature Published from 2014 to 2019 (U.S. EPA, 2025u).

7069 Appendix D UPDATES TO THE DBP CONDITIONS OF USE TABLE

- After the publication of the final scope document (<u>U.S. EPA, 2020c</u>), EPA received updated submissions from the 2020 CDR cycle (<u>U.S. EPA, 2020a</u>). In addition to new submissions received
- under the 2020 CDR cycle, the use and processing codes changed for the 2020 CDR cycle. Therefore,
- 7072 EPA amended the description of certain DBP COUs based on those new submissions and new use and
- processing codes. Also, the Agency received information from stakeholders about uses of DBP. For
- result and the state of the sta
- nomenclature was taken directly from the 2020 CDR cycle codes and categories. Table_Apx D-1
- summarizes the changes to the COUs based on the new codes in the 2020 CDR and any other additionalinformation reasonably available to EPA since the publication of the final scope document.
- 7078 7079

7080 Table_Apx D-1. Changes to Categories and Subcategories of Conditions of Use Based on CDR and 7081 Stakeholder Engagement

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
Manufacturing – Import	Import	Changed category and subcategory by adding "ing"	Importing
Processing – Processing as a reactant	Intermediates in all other basic organic chemical manufacturing	Removed based on stakeholder feedback (<u>U.S. EPA, 2024b</u>)	N/A
Processing – Processing as a reactant	Plasticizers in wholesale and retail trade	Consolidated subcategory into processing; incorporation into article, plasticizer to avoid duplication based on 2020 CDR reporting codes.	N/A
N/A	N/A	Added "intermediate in plastic manufacturing" subcategory due to stakeholder feedback (<u>W.R.</u> <u>Grace, 2024</u>).	Processing – processing as a reactant – intermediate in plastic manufacturing
Processing – Processing – Incorporating into formulation, mixture or reaction product	Solvents (which become part of product formulation or mixture) in all other chemical product and preparation manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy Consolidated "soap, cleaning compound, and toilet preparation manufacturing"; and "ink, toner, and colorant manufacturing" sectors under this COU. Consolidated functional fluids (closed systems) in printing and related support activities with the 2020 CDR reports of DBP as a solvent in printing ink manufacturing under one COU. The name was changed to "ink, toner, and colorant	Processing – incorporation into formulation, mixture, or reaction product – solvents (which become part of product formulation or mixture) in chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and ink, toner, and colorant manufacturing

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
		manufacturing" sector to be consistent with other phthalates.	
		Added "adhesive manufacturing" and "chemical product and preparation manufacturing" sectors based on a 2020 CDR report.	
Processing – Processing – Incorporating into formulation, mixture or reaction product	Intermediate in asphalt paving, roofing, and coating materials manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy. Consolidated subcategory into processing – incorporation into article, plasticizer to avoid duplication based on to the 2020 CDR codes and stakeholder feedback (U.S. EPA, 2024b)	Processing – incorporation into formulation, mixture, or reaction product – plasticizer in adhesive and sealant manufacturing; building and construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing
Processing – Processing – Incorporating into formulation, mixture or reaction product	N/A	Changed category by removing "ing" and replacing with incorporation, removed "processing –"to avoid redundancy. New COU based on stakeholder feedback (W.R. Grace, 2024).	Processing – incorporation into formulation, mixture, or reaction product – pre-catalyst manufacturing
Processing – Processing – Incorporating into formulation, mixture or reaction product	Plasticizer in paint and coating manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy. Consolidated with other plasticizer COUs under the "Processing – incorporation into formulation, mixture or reaction product – plasticizer in" COU.	Processing – incorporation into formulation, mixture, or reaction product – plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic chemical manufacturing; and adhesive and sealant manufacturing
Processing – Processing – Incorporating into formulation, mixture or reaction product	Adhesives and sealant chemicals in construction	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy. Consolidated with other plasticizer COUs under the "Processing – incorporation into formulation, mixture or reaction	Processing – incorporation into formulation, mixture, or reaction product – plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
		product – plasticizer in" COU, with a name change to "adhesive and sealant manufacturing" sector.	manufacturing; basic chemical manufacturing; and adhesive and sealant manufacturing
Processing – Processing – Incorporating into formulation, mixture or reaction product	Intermediates in petrochemical manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy.	N/A
		Removed COU based on feedback from stakeholder that it is not a correct use for DBP (<u>U.S. EPA, 2024b</u>)	
Processing – Processing – Incorporating into formulation, mixture or reaction product	Plasticizers in plastic material and resin manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy.	Processing – incorporation into formulation, mixture, or reaction product – plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap,
		Consolidated with other plasticizer COUs under the "Processing – incorporation into formulation, mixture or reaction product – plasticizer in" COU.	cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic chemical manufacturing; and adhesive and sealant manufacturing
Processing – processing – incorporating into formulation, mixture or reaction product	Plasticizers in plastic product manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy.	Processing – incorporation into formulation, mixture, or reaction product – plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap,
		Consolidated with other plasticizer COUs under the "Processing – incorporation into formulation, mixture or reaction product – plasticizer in" COU, specifically as "plastic material and resin manufacturing."	cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic chemical manufacturing; and adhesive and sealant manufacturing
Processing – processing – incorporating into formulation, mixture or reaction product	Functional fluids (closed systems) in printing and related support activities; solvent in printing ink manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy.	Processing – incorporation into formulation, mixture, or reaction product – solvents (which become part of product formulation or mixture) in chemical product and preparation manufacturing; soap,
		Consolidated under solvent in ink, toner, and colorant manufacturing sector under the "Processing – incorporation into	cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and ink, toner, and colorant manufacturing

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
		formulation, mixture, or reaction product; solvents" COU.	
Processing – processing – incorporating into formulation, mixture or reaction product	Intermediate in rubber product manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing – "to avoid redundancy. Consolidated with other plasticizer COUs under the "Processing – incorporation into formulation, mixture or reaction product – plasticizer in" COU, with a name change to "rubber manufacturing" sector.	Processing – incorporation into formulation, mixture, or reaction product – plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic chemical manufacturing; and adhesive and sealant manufacturing
Processing – processing – incorporating into formulation, mixture or reaction product	Plasticizers in soap, cleaning compound, and toilet preparation manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy. Consolidated with other plasticizer COUs under the "Processing – incorporation into formulation, mixture or reaction product – plasticizer in" COU.	Processing – incorporation into formulation, mixture, or reaction product – plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink manufacturing; basic chemical manufacturing; and adhesive and sealant manufacturing
Processing – processing – incorporating into formulation, mixture or reaction product	Solvents in soap, cleaning compound, and toilet preparation manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy. Consolidated under the "Processing – incorporation into formulation, mixture, or reaction product; solvents" COU as "soap, cleaning compound, and toilet preparation manufacturing" sector.	Processing – incorporation into formulation, mixture, or reaction product – solvents (which become part of product formulation or mixture) in chemical product and preparation manufacturing; soap, cleaning compound, and toilet preparation manufacturing; adhesive manufacturing; and ink, toner, and colorant manufacturing
Processing – incorporating into formulation, mixture or reaction product	Plasticizers in textiles, apparel, and leather manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy. Consolidated with other plasticizer COUs under the "Processing – incorporation into	Processing – incorporation into formulation, mixture, or reaction product – plasticizer in paint and coating manufacturing; plastic material and resin manufacturing; rubber manufacturing; soap, cleaning compound, and toilet preparation manufacturing; textiles, apparel, and leather manufacturing; printing ink

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
		formulation, mixture or reaction product – plasticizer in" COU.	manufacturing; basic chemical manufacturing; and adhesive and sealant manufacturing
Processing – processing – incorporating into articles	Plasticizers in adhesive manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy. Consolidated "plastics product manufacturing" and "rubber product manufacturing" sectors under this COU.	Processing – incorporation into article – plasticizer in adhesive and sealant manufacturing; building and construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing
		Added "building and construction materials manufacturing" and "furniture and related product manufacturing" sectors based on 2020 CDR cycle submissions.	
		Added "and sealant" to better describe the adhesive manufacturing sector based on 2020 CDR codes.	
		Added "ceramic powders" due to public comment (NASA, 2020).	
Processing – processing – incorporating into articles	Plasticizers in rubber product manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy. Consolidated with other plasticizer COUs under the "Processing – incorporation into articles – plasticizer in" COU.	Processing – incorporation into article – plasticizer in adhesive and sealant manufacturing; building and construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing
Processing; processing – incorporating into articles	Plasticizers in plastics product manufacturing	Changed category by removing "ing" and replacing with "incorporation," removed "processing –"to avoid redundancy. Consolidated with other plasticizer COUs under the "Processing – incorporation into articles; plasticizer in" COU.	Processing – incorporation into article – plasticizer in adhesive and sealant manufacturing; building and construction materials manufacturing; furniture and related product manufacturing; ceramic powders; plastics product manufacturing; and rubber product manufacturing
Processing – repackaging	Laboratory chemicals in wholesale and retail trade	Consolidated with "plasticizers in wholesale and retail trade" repackaging COU.	Processing – repackaging – laboratory chemicals in wholesale and retail trade; plasticizers in

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
		Added plastics material and resin manufacturing based on 2020 CDR data.	wholesale and retail trade; and plastics material and resin manufacturing
Industrial Uses; non- incorporative use	Solvent in Huntsman's maleic anhydride manufacturing technology	Changed "uses" in life cycle stage to "use." Consolidated with the "solvent" subcategory under this category to avoid redundancy. Changed subcategory to be more general to incorporate a 2020 CDR report of "absorbent in miscellaneous manufacturing."	Industrial use – non-incorporative activities – solvent, including in maleic anhydride manufacturing technology
Industrial Uses; Non- incorporative use	Solvent	Consolidated with the subcategory for "solvent in Huntsman's maleic anhydride manufacturing technology"	Industrial use – non-incorporative activities – solvent, including in maleic anhydride manufacturing technology
N/A	N/A	Changed "uses" in life cycle stage to "use." Added "Industrial use – construction, paint, electrical, and metal products – adhesives and sealants" based on public comment (<u>NASA, 2020</u> ; <u>MEMA,</u> <u>2019</u>).	Industrial use – construction, paint, electrical, and metal products – adhesives and sealants
N/A	N/A	Changed "uses" in life cycle stage to "use." Added "Industrial use – construction, paint, electrical, and metal products – paints and coatings" based on public comment (<u>NASA, 2020</u> ; <u>MEMA,</u> <u>2019</u>).	Industrial use – construction, paint, electrical, and metal products – paints and coatings
N/A	N/A	Changed "uses" in life cycle stage to "use." Added "Industrial Use – other uses – automotive articles" based on public comment (<u>MEMA,</u> <u>2019</u>).	Industrial use – other uses – automotive articles
N/A	N/A	Changed "uses" in life cycle stage to "use." Added "Industrial Use – other uses – lubricants" based on public comment (<u>MEMA, 2019</u>).	Industrial use – other uses – lubricants and lubricant additives

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
Commercial Uses – Explosive materials	Explosive materials	Changes "uses" in life cycle stage to "use." Updated life cycle stage to "industrial use" based on public comment (<u>AIA, 2019</u>) and reasonable available information (<u>Liang et al., 2021</u>); The name was changed to "other uses" and the subcategory to "propellants" to more accurately reflect the use of DBP in explosive materials regulated	Industrial use – other uses – propellants
N/A	N/A	under TSCA. Changed "uses" in life cycle stage to "use." Added "Commercial Use – automotive, fuel, agriculture, outdoor use products – automotive care products" to be consistent with 2020 CDR codes.	Commercial use – automotive, fuel, agriculture, outdoor use products – automotive care products
Commercial Uses – Adhesives and sealants	Adhesives and sealants	Changed "uses" in life cycle stage to "use." Changed the name of the category to "construction, paint, electrical, and metal products" to be consistent with 2020 CDR codes.	Commercial use – construction, paint, electrical, and metal products – adhesives and sealants
Commercial Uses – Paints and coatings	Paints and coatings	Changed "uses" in life cycle stage to "use." Changed the name of the category to "construction, paint, electrical, and metal products" to be consistent with 2020 CDR codes.	Commercial use – construction, paint, electrical, and metal products – paints and coatings
Commercial Uses – Cleaning and furnishing care products	Cleaning and furnishing care products	Changed "uses" in life cycle stage to "use." Changed the name of the category to "furnishing, cleaning, treatment care products" to be consistent with 2020 CDR codes.	Commercial use – furnishing, cleaning, treatment care products – cleaning and furnishing care products
Commercial Uses – Cleaning and furnishing care products	Floor coverings	Changed "uses" in life cycle stage to "use."	Commercial use – furnishing, cleaning, treatment care products – construction and building materials covering large surface areas including stone, plaster,

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
		Changed the name of the category to "furnishing, cleaning, treatment care products" to be consistent with 2020 CDR codes.	cement, glass and ceramic articles; fabrics, textiles, and apparel
		Changed the name of the subcategory to "construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles – fabrics, textiles, and apparel" to be consistent with 2020 CDR codes.	
Commercial Uses – Cleaning and furnishing care products	Furniture and furnishings not covered elsewhere	Changed "uses" in life cycle stage to "use." Changed the name of the category to "furnishing, cleaning, treatment care products" to be consistent with 2020 CDR codes. The new name does not include "not covered elsewhere."	Commercial use – furnishing, cleaning, treatment care products – furniture and furnishings
Commercial Uses – Ink, toner, and colorant products	Ink, toner, and colorant products	Changed "uses" in life cycle stage to "use." Changed the name of the category to "packaging, paper, plastic, toys, hobby products" to be consistent with 2020 CDR codes.	Commercial use – packaging, paper, plastic, toys, hobby products – ink, toner, and colorant products
Commercial Uses – rubber and plastic products not covered elsewhere	Rubber and plastic products not covered elsewhere	Changed "uses" in life cycle stage to "use." Changed the name of the category to "packaging, paper, plastic, toys, hobby products" to be consistent with 2020 CDR codes. Changed the name of the	Commercial use – packaging, paper, plastic, toys, hobby products – packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)
		subcategory to "packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft) – other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)" to be consistent with 2020 CDR codes.	

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
N/A	N/A	Added "Toys, playground, and sporting equipment" subcategory to the "Packaging, paper, plastic, toys, hobby products" category based on additional information (U.S. EPA, 2019a, f).	Commercial use – packaging, paper, plastic, toys, hobby products – toys, playground, and sporting equipment
Commercial Uses – Personal care products	Personal care products	Removed COU since no personal care products containing DBP were identified.	N/A
Commercial Uses – miscellaneous uses	Laboratory chemicals chemiluminescent light sticks inspection penetrant kit lubricants	Changed "uses" in life cycle stage to "use." Changed "miscellaneous" in the name of the category to "other" to be consistent with other phthalate risk evaluations. Split COU into different COUs with different subcategories for clarity.	Commercial use – other uses – laboratory chemicals Commercial use – other uses – chemiluminescent light sticks Commercial use – other uses – inspection penetrant kit Commercial use – other uses – lubricants and lubricant additives
N/A	N/A	Added "Automotive care products" subcategory and "Automotive, fuel, agriculture, outdoor use products" category based on 2020 CDR cycle submissions.	Consumer use – automotive, fuel, agriculture, outdoor use products – automotive care products
Consumer Uses – Adhesives and sealants	Adhesives and sealants	Changed "uses" in life cycle stage to "use." Changed name of category to "construction, paint, electrical, and metal products" to be consistent with 2020 CDR codes.	Commercial use – construction, paint, electrical, and metal products – adhesives and sealants
Consumer Uses – Paints and coatings	Paints and coatings	Changed "uses" in life cycle stage to "use." Changed name of category to "construction, paint, electrical, and metal products" to be consistent with 2020 CDR codes.	Consumer use – construction, paint, electrical, and metal products – paints and coatings
Consumer Uses – Cleaning and furnishing care products	Fabric, textile, and leather products not covered elsewhere	Changed "uses" in life cycle stage to "use." Change name of category to "furnishing, cleaning, treatment care products" to be consistent with 2020 CDR codes. The new name does not include "not covered elsewhere."	Consumer use – furnishing, cleaning, treatment care products – fabric, textile, and leather products

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
Consumer Uses – Floor coverings	Floor coverings	Changed "uses" in life cycle stage to "use." Changed name of category and subcategory to be consistent with 2020 CDR cycle codes.	Commercial use – furnishing, cleaning, treatment care products – floor coverings; construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
Consumer Uses – Cleaning and furnishing care products	Cleaning and furnishing care products	Changed "uses" in life cycle stage to "use." Changed name of category to "furnishing, cleaning, treatment care products" to be consistent with 2020 CDR codes.	Consumer use – furnishing, cleaning, treatment care products – cleaning and furnishing care products
Consumer Uses – Arts, crafts, and hobby materials	Arts, crafts, and hobby materials	Removed category and subcategory because it was not reported in CDR data in 2016, or 2020, and no relevant products could be identified.	N/A
Consumer Uses – Plastic and rubber products not found elsewhere	Plastic and rubber products not found elsewhere	Changed "uses" in life cycle stage to "use." Changed name of category to "packaging, paper, plastic, toys, hobby products" to be consistent with other phthalate risk evaluations. Changed name of subcategory to "packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)" to be consistent with 2020 CDR codes.	Consumer use – packaging, paper, plastic, toys, hobby products – packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft); other articles with routine direct contact during normal use, including rubber articles; plastic articles (hard)
N/A	N/A	Changed "uses" in life cycle stage to "use." Change name of category to "packaging, paper, plastic, toys, hobby products" to be consistent with 2020 CDR codes.	Consumer use – packaging, paper, plastic, toys, hobby products – toys, playgrounds, and sporting equipment
Consumer Uses – Miscellaneous Uses	Chemiluminescent light sticks	Changed "uses" in life cycle stage to "use."	Consumer use – other uses – chemiluminescent light sticks

Life Cycle Stage and Category in the Final Scope Document	Subcategory in the Final Scope Document	Occurred Change	Revised COU in the 2025 Draft Risk Evaluation
		Change name of category to "other uses" to be consistent with other phthalate risk evaluations.	
N/A	N/A	Added "automotive articles" based on stakeholder information received since publication of the final scope document (<u>MEMA</u> , <u>2019</u>).	Consumer use – other uses – automotive articles
N/A	N/A	Added "lubricants and lubricant additives" based on stakeholder information received since publication of the final scope document (MEMA, 2019).	Consumer use – Other uses – lubricants and lubricant additives
N/A	N/A	Added subcategory "novelty articles" based on additional information (<u>Stabile, 2013</u>).	Consumer use – other uses – novelty articles

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In addition, EPA is including further detail about edits to the following COUs, which are presented inTable_Apx D-1:

- In the 2016 CDR cycle, one company reported the use of DBP in processing processing as a reactant intermediates in all other basic organic chemical manufacturing (U.S. EPA, 2019b).
 Upon outreach with the stakeholder, they clarified that the report of DBP as an intermediate in all other basic organic chemical manufacturing was not a representative use for DBP (U.S. EPA, 2024b).
- 7092 In the 2020 CDR cycle, one company reported the use of DBP in processing – processing as a reactant – plasticizers in wholesale and retail trade (U.S. EPA, 2020a). EPA has determined not 7093 to include this activity as a separate COU and considers it captured under "processing, 7094 7095 incorporation into articles" and "processing, incorporation into formulation, mixture, or reaction 7096 product." DBP is not used as a reactant in a chemical reaction, rather DBP is used as plasticizer. 7097 The use as a plasticizer is better described as "processing – incorporation into formulation, 7098 mixture or reaction product" and/or as "processing - incorporation into articles. Therefore, EPA changed the functional use to plasticizer and consolidated this 2020 CDR submission under 7099 7100 "processing – incorporation into formulation, mixture, or reaction product– plasticizer."
- *"Processing processing as a reactant Intermediate in plastic manufacturing"* and
 "Processing incorporation into formulation, mixture, or reaction product Pre-catalyst manufacturing" were added after a stakeholder informed the Agency that DBP is used in
 polyolefin production as part of a catalyst and in reactions to make polyolefins (W.R. Grace,
 2024).
- *"Commercial Use toys, playground, and sporting equipment"* was added to the draft risk
 evaluation based on the use of recycled rubber tire crumb to build synthetic turf playing fields
 and playground contains DBP.
- 7111

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Consumer use – novelty articles" was added to the draft risk evaluation based on Agency research into the use of various phthalate in adult sex toys (*i.e.*, novelty products).

CONDITIONS OF USE DESCRIPTIONS Appendix E 7114

- 7115 The following descriptions are intended to include examples of uses so as not to exclude other activities
- that may also be included in the COUs of the chemical substance. To better describe the COU, EPA 7116
- 7117 considered CDR submissions from the last two CDR cycles for DBP (CASRN 84-74-2) and the COU
- 7118 descriptions reflect what EPA identified as the best fit for that submission. Examples of articles,
- 7119 products, or activities are included in the following descriptions to help describe the COU but are not 7120 exhaustive. EPA uses the terms "articles" and "products" or product mixtures in the following
- 7121 descriptions and is generally referring to articles and products as defined by 40 CFR Part 751. There
- 7122 may be instances where the terms are used interchangeably by a company or commenters, or by EPA in
- 7123 reference to a code from the CDR reports which are referenced; for example, "plastic products
- 7124 manufacturing," or "fabric, textile, and leather products." EPA will clarify as needed when these
- 7125 references are included throughout the COU descriptions below.

E.1 Manufacturing – Domestic Manufacturing 7126

7127 Domestic manufacturing means to manufacture or produce DBP within the Unites States. For purposes 7128 of the DBP risk evaluation, this includes the extraction of DBP from a previously existing chemical 7129 substance or complex combination of chemical substances and loading and repackaging (but not 7130 transport) associated with the manufacturing or production of DBP.

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7132 DBP is typically manufactured through the catalytic esterification of the phthalic anhydride with n-butyl 7133 alcohol in the presence of an acid as a catalyst. A typical manufacturing operation takes place in closed 7134 systems either via batch or more automated continuous operations and will involve the purification of 7135 dibutyl phthalate product streams via either vacuum distillation or by passing over activated charcoal as 7136 a means of recovering unreacted alcohols (U.S. EPA, 2020c). This condition of use includes the typical 7137 manufacturing process and any other similar manufacturing of DBP.

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7139 **Examples of CDR Submissions**

7140 In the 2016 CDR cycle, one company reported domestic manufacture of DBP, and in 2020, two 7141 companies reported domestic manufacture of DBP (U.S. EPA, 2020b, 2019b).

E.2 Manufacturing – Importing

7142 7143 Import refers to the import of DBP into the customs territory of the United States. This condition of use 7144 includes loading/unloading and repackaging (but not transport) associated with the import of DBP. In 7145 general, chemicals may be imported into the United States in bulk via water, air, land, and intermodal 7146 shipments. These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and 7147 intermodal tank containers (U.S. EPA, 2020c). Imported DBP is shipped in liquid form with

- 7148 concentrations ranging from 1 to 100 percent DBP (U.S. EPA, 2019b).
- 7149

7150 **Examples of CDR Submissions**

- 7151 In the 2016 CDR cycle, 11 companies reported importation of DBP as a liquid (U.S. EPA, 2019b). EPA 7152 has identified two sites that imported DBP directly to their sites for on-site processing or use and nine
- 7153 sites that imported DBP directly to other sites for processing or use (U.S. EPA, 2020c).
- 7154
- 7155 In the 2020 CDR cycle, seven companies reported importation of DBP as a liquid (U.S. EPA, 2020b).
- 7156 Five companies reported that the imported chemical substance is never physically at the reporting site
- 7157 (e.g., the chemical substance from a foreign country is directly imported to another location such as a

warehouse, a processing or use site, or a customer's site). One company reported the importation for the
purposes of repackaging in various industries.

E.3 Processing – Processing as a Reactant – Intermediate in Plastic Manufacturing

This COU refers to the use of a chemical as a reactant; that is, the use of DBP in a chemical reaction, which occurs when a chemical substance is added to a product or product mixture after its manufacture for distribution in commerce. In this case, DBP is used in a catalyst formulation for processing as a reactant in the generation of polyolefins (*i.e.*, polypropylene and polyethylene). EPA's understanding is that very small amounts of DBP are used as a catalyst for the associated chemical reactions (*i.e.*, 1 g used for 40,000 g of polypropylene). As the reaction progresses, the catalyst degrades and a small amount of DBP (1–3 parts per million) remains encapsulated in the final product (W.R. Grace, 2024).

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7170 This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.4 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Solvents (Which Become Part of Product Formulation or Mixture) in Chemical and Preparation Manufacturing; in Soap, Cleaning Compound, and Toilet Preparation Manufacturing; Adhesive Manufacturing; and in Printing Ink Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of DBP into formulation,
mixture, or a reaction product which occurs when a chemical substance is added to a product or product
mixture after its manufacture, for distribution in commerce, in this case as a solvent in various industrial
sectors.

7180

DBP can be used as a solvent in various sectors, including soap, cleaning compound, toilet preparation
manufacturing, all other chemical product and preparation manufacturing, adhesive manufacturing, and
printing ink manufacturing. In the soap, cleaning compound, and toilet preparation manufacturing
sector, DBP can be used as a cleaner or degreaser (U.S. EPA, 2019b).

7186 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DBP as a solvent for cleaning or degreasing in
soap, cleaning compound, and toilet preparation manufacturing. Additionally, one company reported the
use of DBP in functional fluids for printing ink manufacturing, and two companies reported the use of
DBP in the chemical product and preparation manufacturing sector (U.S. EPA, 2019b).

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7185

In the 2020 CDR cycle, one company reported the use of DBP as a solvent in adhesive manufacturing;
this company also reported the use of DBP as a solvent in printing ink manufacturing. Additionally, one
company reported the use of DBP in all other chemical product and preparation manufacturing (U.S.
<u>EPA</u>, 2020a).

7196 E.5 Processing – Incorporation into Formulation, Mixture, or Reaction 7197 Product – Pre-Catalyst Manufacturing

7198 This COU refers to the preparation of a product; that is, the incorporation of DBP into formulation,

mixture, or a reaction product which occurs when a chemical substance is added to a product (or product
 mixture) after its manufacture, for distribution in commerce.

DBP is used in pre-catalyst manufacturing prior to its use as a catalyst component for polyolefin
manufacturing. As part of this process, DBP is included in the solids in the pre-catalyst at about 10
percent as a solid that is suspended in a solvent or an oil (W.R. Grace, 2024).

7205

7206 Examples of CDR Submissions

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.6 Processing – Incorporation into Formulation, Mixture, or Reaction Product – Plasticizer in Paint and Coating Manufacturing; Plastic Material and Resin Manufacturing; Rubber Manufacturing; Soap, Cleaning Compound, and Toilet Preparation Manufacturing; Textiles, Apparel, and Leather Manufacturing; in Printing Ink Manufacturing; Basic Organic Chemical Manufacturing; and Adhesive and Sealant Manufacturing

This COU refers to the preparation of a product; that is, the incorporation of DBP into formulation,
mixture, or a reaction product which occurs when a chemical substance is added to a product (or product
mixture), after its manufacture, for distribution in commerce—in this case, processing of DBP as a
plasticizer into several different products for use in multiple sectors.

7219

7220 In manufacturing of plastic material and resin through non-PVC and PVC compounding, DBP is 7221 blended into polymers. Compounding involves the mixing of the polymer with the plasticizer and other 7222 chemical such as, fillers and heat stabilizers. The plasticizer needs to be absorbed into the particle to 7223 impart flexibility to the polymer. For PVC compounding, compounding occurs through mixing of 7224 ingredients to produce a powder (dry blending) or a liquid (Plastisol blending). The most common 7225 process for dry blending involves heating the ingredients in a high-intensity mixer and transfer to a cold 7226 mixer. The Plastisol blending is done at ambient temperature using specific mixers that allow for the 7227 breakdown of the PVC agglomerates and the absorption of the plasticizer into the resin particle. 7228

7229 Examples of CDR Submissions

In the 2016 CDR cycle, use of DBP as a plasticizer was reported for the following sectors: three companies in paint and coating manufacturing; one company in plastics product manufacturing; one company in textiles, apparel, and leather manufacturing; one company in soap, cleaning compound, and toilet preparation manufacturing; one company in petrochemical manufacturing; one company in all other basic organic chemical manufacturing; and one company in plastics material and resin manufacturing (U.S. EPA, 2019b).

7236

In the 2020 CDR cycle, one company reported the use of DBP as a plasticizer in plastics material and resin manufacturing; one company reported the use of DBP as a plasticizer in textiles, apparel, and

- 7239 leather manufacturing; and one company reported the use of DBP as a plasticizer in plastics product
- 7240 manufacturing (U.S. EPA, 2020a).

E.7 Processing – Incorporation into Article – Plasticizer in Adhesive and Sealant Manufacturing; Building and Construction Materials Manufacturing; Furniture and Related Product Manufacturing; Ceramic Powders; Plastics Product Manufacturing; and Rubber Product Manufacturing

7246 This COU refers to the preparation of an article; that is, the incorporation of DBP into articles, meaning 7247 DBP becomes a component of the article, after its manufacture, for distribution in commerce. In this 7248 case, DBP is present in a raw material such as rubber or plastic that contains a mixture of plasticizers 7249 and other additives, and this COU refers to the manufacturing of PVC and non-PVC articles, including 7250 rubber, plastic, and miscellaneous articles using those raw materials. PVC articles are manufactured 7251 after the formation of a raw material that can contain a mixture of plasticizer and other additives. The 7252 raw material is converted by processes such as calendaring, extrusion, injection molding, and plastisol spread coating (ACC, 2020). This COU encompasses the step that occurs immediately after PVC 7253 7254 compounding, where the compounded resin is sent to an extruder that shapes and sizes the plastic into an 7255 article or pellet to be used in downstream processing at PVC or non-PVC conversion sites (U.S. EPA, 7256 2021e). DBP also is an additive in inks, which are then incorporated into textiles and articles (U.S. EPA, 7257 2020c). This COU also includes the incorporation of the rubber or plastic and other articles into finished 7258 articles, such as electrical and electronic articles, machinery, mechanical appliances, fabric, textiles and 7259 leather articles, or furniture and furnishings. This COU also includes activities identified by the U.S. 7260 Department of Defense. 7261

Plastisol technology or film calendaring technology is used in the production of plastic and rubber
products such as textiles, apparel, and leather; vinyl tape; flexible tubes; profiles; and hoses (<u>ACC</u>,
2023).

In toy manufacturing, toys could contain up to 0.1 percent of DBP (U.S. EPA, 2019a). (The CPSC has a
regulatory limit of no more than 0.1 percent for DBP concentration in toys.) Additionally, it is possible
that DBP could be incorporated into playground equipment manufacturing due to its use as a plasticizer
in PVC and non-PVC articles that may be components of playground equipment.

EPA expects that the use of DBP in textiles, apparel, and leather manufacturing is associated with PVCapplications for durable vinyl articles, such as raincoats, boots, and gloves.

DBP is also reported to be used as a plasticizer in tapecasting for ceramic powders (<u>NASA, 2020</u>).

7276 Examples of CDR Submissions

In the 2016 CDR cycle, use of DBP as a plasticizer was reported for the following sectors: one company
in adhesive manufacturing; one company in rubber product manufacturing; and two companies in
plastics product manufacturing. Additionally, one company reported use of DBP as an intermediate in
asphalt paving, roofing, and coating materials manufacturing. EPA's understanding is that DBP, if used
as an intermediate for article manufacturing, likely is used as a plasticizer, which is why this CDR report
was included under this COU (U.S. EPA, 2019b).

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In the 2020 CDR cycle, use of DBP as a plasticizer was reported for the following sectors: one company

- in plastics material and resin manufacturing; one company in furniture and related product
- manufacturing and in construction; and one company in adhesives manufacturing and in plastics product
- manufacturing (U.S. EPA, 2020a).

E.8 Processing – Repackaging – Laboratory Chemicals in Wholesale and Retail Trade; Plasticizers in Wholesale and Retail Trade; and Plastics Material and Resin Manufacturing

Repackaging refers to the preparation of DBP for distribution in commerce in a different form, state, or quantity than originally received or stored by various industrial sectors, including wholesale and retail trade, laboratory chemicals manufacturing, and plastic material and resin manufacturing. This includes the transferring of a chemical substance from a bulk container into smaller containers. This COU would not apply to the relabeling or redistribution of a chemical substance without removing the chemical substance from the original container it was supplied in.

7297

7298 Examples of CDR Submissions

In the 2016 CDR cycle, two companies reported repackaging DBP as a plasticizer in wholesale and retail trade and one company reported repackaging DBP as a laboratory chemical (U.S. EPA, 2019b).

7301

In the 2020 CDR cycle, two companies reported repackaging DBP as a plasticizer in wholesale and
 retail trade and plastic material and resin manufacturing (U.S. EPA, 2020a).

7304 E.9 Processing – Recycling

This COU refers to the process of treating generated waste streams (*i.e.*, which would otherwise be disposed of as waste), containing DBP, that are collected, either on-site or at a third-party site, for commercial purpose (U.S. EPA, 2019b). DBP is primarily recycled industrially in the form of DBPcontaining PVC waste streams. New PVC can be manufactured from recycled and virgin materials (Lowe et al., 2021).

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7311 Examples of CDR Submissions

7312 In the 2016 CDR cycle, two companies reported recycling DBP (U.S. EPA, 2019b).

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This use does not have CDR data reported for the 2020 cycle.

7315 E.10 Distribution in Commerce

For purposes of assessment in this risk evaluation, distribution in commerce consists of the
transportation associated with the moving of DBP or DBP-containing products and/or articles between
sites manufacturing, processing, or recycling DBP or DBP-containing products and/or articles, or to
final use sites, or for final disposal of DBP or DBP-containing products and/or articles. More broadly
under TSCA, "distribution in commerce" and "distribute in commerce" are defined under TSCA section
3(5).

7322 E.11 Industrial Use – Non-Incorporative Activities – Solvent, Including in 7323 Maleic Anhydride Manufacturing Technology

- This COU refers to the DBP as it is used as a solvent in various industrial sectors. Specifically, this includes using DBP in the process of maleic anhydride manufacturing.
- 7326

EPA understands that DBP is used in the manufacturing of maleic anhydride; however, DBP is not

incorporated into the maleic anhydride product (<u>Huntsman, 2024</u>).

- 7329
- 7330 Examples of CDR Submissions

- One company reported the use of DBP in non-incorporative activities in the 2016 CDR cycle (U.S. EPA,
 2019b).
- 7333
- The use was reported again in the 2020 CDR cycle for "non-incorporative activities" under
- miscellaneous manufacturing, as an absorbent (U.S. EPA, 2020a).

7336 E.12 Industrial Use – Construction, Paint, Electrical, and Metal Products – 7337 Adhesives and Sealants

This COU refers to DBP as it is used in various industrial sectors as a component of adhesive or sealant mixtures, meaning the use of DBP after it has already been incorporated into an adhesive and/or sealant product or mixture, as opposed to when it is used upstream, (*e.g.*, when DBP is processed into the adhesive and sealant formulation).

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DBP is used in adhesives and sealant in the manufacture of automobiles (MEMA, 2019). DBP may be
found in adhesives, potting compounds, sealants, and putties used in the manufacture, operations and
maintenance of aerospace products (AIA, 2019). Specific application of DBP-containing adhesives in
aerospace includes adhesives critical to electrical/circuit boards, and as a processing aid for crosslinking
in cement for acrylic processing (AIA, 2019). DBP is a component of adhesives and sealants used in the
testing test articles and human-rated spaceflight hardware (NASA, 2020). This COU also includes
activities identified by the U.S. Department of Defense.

73507351 This use was not reported to EPA in the 2016 or 2020 CDR cycles.

7352 E.13 Industrial Use – Construction, Paint, Electrical, and Metal Products – 7353 Paints and Coatings

This COU refers to the use of DBP in various industrial sectors as a component of industrial paints and coatings. This includes the use of DBP after it has already been incorporated into a paint or coating product or mixture, as opposed to when it is used upstream (*e.g.*, when DBP is processed into the paint or coating formulation).

DBP is used in coatings in the manufacture of automobiles (MEMA, 2019). DBP may be found in
conductive and interior coatings used in the manufacture, operations, and maintenance of aerospace
products (AIA, 2019). This COU also includes activities identified by the U.S. Department of Defense.

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

7364 E.14 Industrial Use – Other Uses – Automotive Articles

This COU refers to the use of DBP in the automobile manufacturing sector as a component in various automotive articles. This is a use of DBP after it has already been incorporated into a plastic article, as opposed to when it is used upstream (*e.g.*, when DBP is processed into an article).

DBP was identified in numerous components in the exterior and interior of the vehicle, the powertrain,
the chassis, and the electrical system. DBP was identified in 391 parts, including those used in
replacement parts. Some examples of parts are the passenger side seat buckle, the engine assembly, the
trim panel assembly on the body of the door, and the center floor full console on the passenger side

trim panel assembly on the body of the door, and the center floor full console on the passenger side
 (MEMA, 2019). Based on DBP being found downstream in tire crumb applications for playgrounds and

- turf (<u>Armada et al., 2022</u>; <u>U.S. EPA, 2019f</u>), users may be handling DBP in tires for automobiles in
 industrial settings.
- 7376
- This use was not reported to EPA in the 2016 or 2020 CDR cycles.

7378 E.15 Industrial Use – Other Uses – Lubricants and Lubricant Additives

This COU refers to the industrial use of DBP incorporated within lubricant products. DBP is used in
products for industrial applications including synthetic lubricants and anti-seize compounds in
automobile and aerospace applications (NASA, 2020; U.S. EPA, 2020d; MEMA, 2019). For the
industrial use of these products, EPA expects them to be poured or applied by workers in factories and
other industrial settings. This COU also includes activities identified by the U.S. Department of Defense.

- 7384
- This use was not reported to EPA in the 2016 or 2020 CDR cycles.

7386 E.16 Industrial Use – Other Uses – Propellants

7387 This COU refers to the industrial use of DBP incorporated into propellants. This COU encompasses 7388 incorporating DBP into a propellant, loading of that propellant into a cartridge, and TSCA use of said 7389 cartridge, e.g., installing into aircraft ejection seats and use of aircraft ejection seats. DBP is included in 7390 some aerospace applications as a component of the propellant in aircraft ejection seats (AIA, 2019). 7391 DBP is also used by ammunition processors, although this COU does not include the use of ammunition 7392 (U.S. EPA, 2020a). DBP is used as a deterring agent in propellants where it coats the propellant granules 7393 and slows the combustion process so that the propellant burns slowly at first and increases gradually as 7394 the combustion process progresses (Liang et al., 2021). 7395

- This COU does not include use of dibutyl phthalate in propellants in articles, or components of articles
 subject to Section 4181 of the Internal Revenue Code of 1954; for example, ammunition, since such use
 is outside the scope of the definition of "chemical substance" TSCA section 3(2)(B)(v), is not being
 considered as a "condition of use" and will not be evaluated during risk evaluation (U.S. EPA, 2020c).
 This COU also includes activities identified by the U.S. Department of Defense.
- 7401

7402 Examples of CDR Submissions

In the 2020 CDR cycle, one company reported the use of DBP at an ammunition plant (U.S. EPA,
2020a).

E.17 Commercial Use – Automotive, Fuel, Agriculture, Outdoor Use Products – Automotive Care Products

- This COU refers to the commercial use of DBP in automotive care products. This COU includes the useof DBP-containing products for automotive upkeep in a commercial setting.
- 7409
- 7410 DBP is used in various automotive product applications. EPA notes that this reporting code in the 2020
- 7411 CDR cycle is intended to describe exterior car washes and soaps, exterior car waxes, polishes, and

7412 coatings, touch up paint, and interior car care products (U.S. EPA, 2022a).

7413

7414 Examples of CDR Submissions

- In the 2020 CDR cycle, one company reported the use of DBP as a plasticizer in interior car care
- 7416 products. Another company reported the use of DBP in exterior car waxes, polishes, and coatings (U.S. 7417 EPA 2020a)
- 7417 <u>EPA, 2020a</u>).

7418 E.18 Commercial Use – Construction, Paint, Electrical, and Metal 7419 Products – Adhesives and Sealants

This COU refers to the commercial use of DBP in adhesives and sealants. This includes the use of DBPcontaining adhesives and sealants in a commercial setting, such as a business or non-industrial job site, such as an office, property owned by a client for which commercial services are being provided, or an auto shop, as opposed to upstream use of DBP (*e.g.*, when DBP-containing products are used in the manufacturing of construction products) or use in an industrial setting. This COU also includes activities identified by the U.S. Department of Defense.

7426

Workers in a commercial setting generally apply adhesives and sealants that already have DBP
incorporated as a plasticizer. Adhesives and sealants (which could also be fillers and putties) are highly
malleable materials used to repair, smooth over or fill minor cracks in holds and buildings. EPA expects
that commercial applications of adhesives and sealants containing DBP would occur using nonpressurized methods based on products identified in the marketplace for DBP and other similar
chemicals.

- Final Field Several Commercially available (denoted as being possibly industrial, commercial, or
 consumer viable) adhesive products which contain DBP at various concentrations. These adhesive and
 sealants can be applied using a caulk gun (U.S. EPA, 2020e).
- 7437
 7438 DBP is an additive in polyester, vinyl ester, or epoxy resin for in-place repairs to pipes such as water
 7439 mains. Workers repair pipes in place by first inserting a resin-impregnated liner in the damaged pipe,
 7440 then forcing steam, hot water, or ultraviolet light across the liner to cure the resin (U.S. EPA, 2020c).
 7441
- DBP is used in adhesives and sealants in the manufacture of automobiles (MEMA, 2019). EPA expects
 that these types of products could also be used commercially in automobile repair applications.
- 7445 Examples of CDR Submissions
- In the 2016 CDR cycle, four companies reported the use of DBP in adhesives and sealants (U.S. EPA, 2019b).
 7448
- In the 2020 CDR cycle, one company reported the use of DBP in hot-melt adhesives and one company
 reported the use of DBP in fillers and putties (U.S. EPA, 2020a).

7451 E.19 Commercial Use – Construction, Paint, Electrical, and Metal Products 7452 – Paints and Coatings

- This COU refers to the commercial use of DBP already incorporated as a plasticizer in paints andcoatings.
- 7455
- EPA expects that some of these products are likely to be used for industrial applications; however, this
 COU only encompasses the products purchased by commercial operations and applied by professional
 contractors in various commercial settings. EPA also expects that compared to the industrial
- applications, these products would be used in smaller scale in commercial settings for similar purposes
- 7460 (*e.g.*, corrosion and water protection on structural components, residential construction). This COU
- encompasses solvent and water-based paints.
- 7462
- 7463 Examples of CDR Submissions

7464 In the 2016 CDR cycle, three companies reported the use of DBP in paints and coatings (U.S. EPA, 7465 2019b).

7466

7467 In the 2020 CDR cycle, one company reported the use of DBP in water-based paint and in solvent-based 7468 paint (U.S. EPA, 2020a).

7469

E.20 Commercial Use – Furnishing, Cleaning, Treatment Care Products – **Cleaning and Furnishing Care Products** 7470

7471 This COU refers to the commercial use of DBP in cleaning and furnishing care products. The 7472 commercial users of products under this category would be expected to apply cleaning and furnishing 7473 care products that contain DBP either manually or with automated equipment (U.S. EPA, 2020c). EPA 7474 expects that the type of products reported under this COU are likely to be both commercial and 7475 consumer in nature; however, this COU encompasses only the commercial uses of the products. This 7476 COU also includes activities identified by the U.S. Department of Defense. 7477

- 7478 DBP may be present in cleaning and furnishing care products, such as glass window cleaning 7479 formulations, carpet and floor cleaners, spot removers, and shoe care products (U.S. EPA, 2020c). DBP
- was also reported as present in polishes/waxes and in alternative tub/tile cleaner (Dodson et al., 2012). 7480
- 7481

7482 **Examples of CDR Submissions**

7483 In the 2016 CDR cycle, two companies reported the use of DBP in cleaning and furnishing care products 7484 (U.S. EPA, <u>2019b</u>).

E.21 Commercial Use – Furnishing, Cleaning, Treatment/Care Products – 7485

7486

7488

- 7487
- Floor Coverings; Construction and Building Materials Covering Large Surface Areas Including Stone, Plaster, Cement, Glass, and **Ceramic Articles; Fabrics, Textiles, and Apparel**

7489 This COU refers to the commercial installation of floor covering containing DBP covering large surface 7490 areas including stone, plaster, cement, glass and ceramic articles; and fabrics, textiles, and apparel. DBP 7491 is expected to be already incorporated into floor coverings, and this COU describes handling and 7492 installing tiles, carpeting, etc.

7493

7494 DBP may be a constituent of various building/construction materials because of its use as a general-7495 purpose plasticizer in PVC applications. EPA expects that certain building/construction materials that 7496 would be covered by this COU in commercial use would include items such as vinyl and PVC-backed 7497 carpeting, and other construction/building materials covering large surface areas.

7498

7499 **Examples of CDR Submissions**

7500 In the 2016 CDR cycle, one company reported the use of DBP in floor coverings (U.S. EPA, 2019b).

- 7501 In the 2020 CDR cycle, one company reported the use of DBP as a plasticizer in construction and
- building materials covering large surface areas including stone, plaster, cement, glass, and ceramic 7502 articles; fabrics, textiles, and apparel (U.S. EPA, 2020a). 7503

E.22 Commercial Use – Furnishing, Cleaning, Treatment Care Products – Furniture and Furnishings

- This COU refers to the commercial use of DBP already incorporated into furniture and furnishings. This
 COU includes use of DBP already incorporated into furniture upholstery or in plastic materials to make
 furniture (U.S. EPA, 2020c).
- 7510 This use was not reported to EPA in the 2016 or 2020 CDR cycles.

7511 E.23 Commercial Use – Packaging, Paper, Plastic, and Hobby Products – 7512 Ink, Toner, and Colorant Products

This COU is refers to the commercial use of DBP in inks, toner, and colorants, that can be used in
packaging, paper, plastic, toys, hobby products and articles. This COU also includes activities identified
by the U.S. Department of Defense.

7516

7509

DBP is used in printing ink and pigments (U.S. EPA, 2020e). EPA expects that the majority of ink, toner, and colorant products containing DBP would be commercial in nature; however, it is possible that these products are used by consumers for commercial purposes as many of the commercial products are available for consumer purchasers through various online vendors. This COU encompasses only the commercial uses of these products by workers and consumer DIYers. EPA would expect the commercial uses of these products by consumer DIYers to be similar to typical applications in commercial printing and drafting shops, albeit on a smaller scale.

7525 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DBP in ink, toner, and colorant products (U.S.
 <u>EPA</u>, 2019b).

E.24 Commercial Use – Packaging, Paper, Plastic, and Hobby Products – Packaging (Excluding Food Packaging), Including Rubber Articles; Plastic Articles (Hard); Plastic Articles (Soft); Other Articles with Routine Direct Contact During Normal Use, Including Rubber Articles; Plastic Articles (Hard)

This COU refers to the commercial use of DBP in various plastic and rubber packaging and in soft and 7533 hard plastic articles and rubber articles. EPA notes that the CDR use code for "packaging (excluding 7534 food packaging), including rubber articles; plastic articles (hard); plastic articles (soft)" includes 7535 7536 examples such as phone covers, personal tablet covers, styrofoam packaging, and bubble wrap. In 7537 addition, the CDR processing and use code for "other articles with routine direct contact during normal 7538 use including rubber articles; plastic articles (hard)" in the 2020 CDR cycle includes examples such as 7539 gloves, boots, clothing, rubber handles, gear lever, steering wheels, handles, pencils, and handheld device casing. This COU also includes activities identified by the U.S. Department of Defense. 7540

7541

The articles provided as examples under this code are likely to be both commercial and consumer in
nature. This COU refers to the commercial use of these articles. Soft packaging containing DBP would
be used during packaging of articles in commercial settings. Hard articles containing DBP would be
used in commercial settings.

- 7546
- 7547 Examples of CDR Submissions

7548 In the 2016 CDR cycle, two companies reported the use of DBP in plastic and rubber products not 7549 covered elsewhere, which is listed as both "packaging (excluding food packaging), including rubber 7550 articles; plastic articles (hard); plastic articles (soft)" and as "other articles with routine direct contact 7551 during normal use, including rubber articles; plastic articles (hard)" in the 2020 CDR cycle (U.S. EPA, 7552 2019b).

7553

7554

7561

E.25 Commercial Use – Packaging, Paper, Plastic, and Hobby Products – Toys, Playground, and Sporting Equipment

This COU refers to the commercial use of DBP in toys, playground, and sporting equipment. The COU 7555 7556 includes the commercial installation, use, and maintenance of toys, playgrounds, and sporting equipment that contain DBP (such as in daycare or school environments by workers such as teachers or providers). 7557 7558 This use refers to workers molding or otherwise fabricating articles already containing DBP into other 7559 articles for commercial and consumer applications, as well as during installation of sporting or 7560 playground equipment.

7562 DBP can be used as a plasticizer to provide flexibility to toys. The Consumer Product Safety Improvement Act (CPSIA) of 2008 placed a prohibition on DBP that limited manufacturers' use of DBP 7563 7564 in children's toys to 0.1 percent (U.S. EPA, 2019a). Toys containing DBP that were manufactured and/or processed prior to the CPSIA restriction in 2008 may still be in use. DBP is reported to be found 7565 7566 downstream in tire crumb applications for playgrounds and turf, and this COU includes the commercial use of playgrounds and turf that contains DBP (U.S. EPA, 2019f). 7567

7568

7569 This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.26 Commercial Use – Other Uses – Automotive Articles 7570

7571 This COU refers to the commercial use of DBP in automotive articles, which already have DBP 7572 incorporated into them. This COU refers to the use of DBP-containing automotive articles in a 7573 commercial setting, such as an automotive parts business or a worker driving a vehicle, as opposed to 7574 upstream use of DBP (e.g., when DBP-containing products are used in the manufacturing of the 7575 automobile) or use in an industrial setting. This COU also includes activities identified by the U.S. 7576 Department of Defense.

7577

7578 DBP was identified in numerous components in the exterior and interior of the vehicle, the powertrain, 7579 the chassis, and the electrical system. DBP was identified in 391 parts, including those used in 7580 replacement parts. Some examples of parts are the passenger side seat buckle, the engine assembly, the 7581 trim panel assembly on the body of the door, and the center floor full console on the passenger side 7582 (MEMA, 2019). DBP is reported to be found downstream in tire crumb applications for playgrounds and 7583 turf (Armada et al., 2022; U.S. EPA, 2019f).

- 7584
- 7585 This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.27 Commercial Use – Other Uses – Laboratory Chemicals 7586

This COU refers to the use of DBP as a laboratory chemical. 7587

7588

7589 DBP can be used as a laboratory chemical such as a chemical standard or reference material during 7590 analyses. Some laboratory chemical manufacturers identify use of DBP as a certified reference material

7591 and research chemical.

7592

- Commercial use of laboratory chemicals may involve handling DBP by hand-pouring or pipette and
- either adding to the appropriate labware in its pure form to be diluted later or added to dilute other
- chemicals already in the laborate. EPA expects that laboratory DBP products are pure DBP in neat liquid
- form. The Agency notes that the same applications and methods used for quality control can be applied
- in industrial and commercial settings.
- 7599 Examples of CDR Submissions
- In the 2016 CDR cycle, one company reported the use of DBP in laboratory chemicals (U.S. EPA,
 2019b).

7602 E.28 Commercial Use – Other Uses – Chemiluminescent Light Sticks

- This COU refers to the commercial use of DBP incorporated into chemiluminescent light sticks,
 sometimes referred to colloquially as glow sticks. DBP is present in chemiluminescent light sticks as
 part of some Department of Defense applications (U.S. EPA, 2020d). This COU also includes activities
 identified by the U.S. Department of Defense.
- 76077608 This use was not reported to EPA in the 2016 or 2020 CDR cycles.

7609 E.29 Commercial Use – Other Uses – Inspection Penetrant Kit

- This COU refers to the commercial use of DBP incorporated in inspection penetrant kits. Inspection
 fluids or penetrants are used to reveal surface defects on metal parts, including cracks, folds, or pitting.
 Penetrant testing can be used to detect imperfections and flaws that are not detectable by the eye. DBP is
 present in inspection penetrant kits as part of some government Agency applications (U.S. EPA, 2020d).
 This COU also includes activities identified by the U.S. Department of Defense.
- 7615
- This use was not reported to EPA in the 2016 or 2020 CDR cycles.

7617 E.30 Commercial Use – Other Uses – Lubricants and Lubricant Additives

- This COU refers to the commercial use of lubricants and lubricant additives that contain DBP for
 commercial applications such as synthetic lubricants and anti-seize compounds in automobile and
 aerospace applications (NASA, 2020; U.S. EPA, 2020d; MEMA, 2019; Texacone, 2016). Lubricants
 and lubricant additives may be poured or applied by workers in auto repair and other maintenance shops.
- This use was not reported to EPA in the 2016 or 2020 CDR cycles.

7624 E.31 Consumer Use – Automotive, Fuel, Agriculture, Outdoor Use Products 7625 – Automotive Care Products

- This COU refers to the consumer use of DBP in automotive care products. This COU includes the use ofDBP-containing products in a consumer DIY setting.
- 76287629 DBP is used in various automotive product applications. EPA notes that this reporting code in the 2020
- CDR cycle is intended to describe exterior car washes and soaps, exterior car waxes, polishes, and
 coatings, touch up paint, and interior car care (U.S. EPA, 2022a).
- 7632
- The consumer use was not reported to EPA in the 2016 or 2020 CDR cycles, but EPA expects the
- rice consumer use was not reported to Drivin the Doro of Dobe Oprice, but Driving output in the ported in the CDR cycles are available to consumers for use in a
 DIY setting.

E.32 Consumer Use – Construction, Paint, Electrical, and Metal Products – 7636 **Adhesives and Sealants** 7637 This COU refers to the consumer use of DBP in adhesives and sealants, including fillers and putties. 7638 7639 7640 EPA notes in the final scope that DBP is used as an adhesive and sealant (U.S. EPA, 2021c). The 7641 Agency expects that the use of these types of products would occur in commercial applications; 7642 however, EPA notes that this product are likely to be sourced by DIY consumers through various online 7643 vendors. DBP-containing adhesives and sealants are used in automotive applications (MEMA, 2019). 7644 7645 The Agency does expect the primary use of the automotive adhesives and sealants to be industrial and 7646 commercial in nature but the possibility for consumer use is still possible. This COU includes consumer 7647 DIYers who may perform exterior or interior car maintenance involving adhesives and sealants. Any product containing DBP which is applied as an undercover coating, would most likely be applied by 7648 7649 spraying the coating on the underside of the vehicle. 7650 **Examples of CDR Submissions** 7651 In the 2016 CDR cycle, two companies reported the use of DBP in adhesives and sealants (U.S. EPA, 7652 7653 2019b). 7654 In the 2020 CDR cycle, one company reported the use of DBP in fillers and putties (U.S. EPA, 2020a). 7655 E.33 Consumer Use – Construction, Paint, Electrical, and Metal Products – 7656 **Paints and Coatings** 7657 7658 This COU refers to the consumer use of DBP in paints and coatings. Consumers generally use paints and 7659 coatings containing DBP in an indoor environment and DIYers handle the paints and coatings that have DBP incorporated into the product. DBP is used in a variety of paint and coating products and is often 7660 7661 used as a surfactant in paints and coatings. 7662 7663 **Examples of CDR Submissions** 7664 In the 2020 CDR cycle, one company reported the use of DBP in water-based paint and in solvent-based 7665 paint (U.S. EPA, 2020a).

7666 E.34 Consumer Use – Furnishing, Cleaning, Treatment Care Products – 7667 Fabric, Textile, and Leather Products

This COU refers to the consumer use of DBP already incorporated as a plasticizer in fabric, textile, and
synthetic leather products and/or articles. This COU includes consumer wear and use of DBP-containing
textiles. EPA expects this COU to include consumer use of DBP in in apparel, including in cases where
DBP has been incorporated into the fabric as a plasticizer.

7672

The Washington State Department of Ecology identified 1,326 reports of DBP use in children's products, primarily in footwear between 2012 and 2019 (WSDE, 2023; U.S. EPA, 2020c).

7675

7676 Examples of CDR Submissions

This use was not reported to EPA in the 2016 or 2020 CDR cycle.

E.35 Consumer Use – Furnishing, Cleaning, Treatment/Care Products – Floor Coverings; Construction and Building Materials Covering Large Surface Areas Including Stone, Plaster, Cement, Glass, and Ceramic Articles; Fabrics, Textiles, and Apparel

This COU refers to the consumer use of DBP in solid flooring and construction and building materials. Consumers generally use flooring containing DBP in an indoor environment and DIYers handle the construction materials (*e.g.*, tiles, carpeting) that have DBP incorporated into the articles, which may involve cutting and shaping the articles for installation.

7687 Examples of CDR Submissions

In the 2016 CDR cycle, one company reported the use of DBP in floor coverings (U.S. EPA, 2019b).

In the 2020 CDR cycle, one company reported the use of DBP as a plasticizer in construction and
building materials covering large surface areas including stone, plaster, cement, glass, and ceramic
articles; fabrics, textiles, and apparel (U.S. EPA, 2020a).

7693 E.36 Consumer Use – Furnishing, Cleaning, Treatment/Care Products – 7694 Cleaning and Furnishing Care Products

This COU refers to the consumer use of cleaning and furnishing care products containing DBP. The consumer users of products under this category would be expected to manually apply cleaning and furnishing care products that contain DBP (U.S. EPA, 2020c).

DBP may be present in cleaning and furnishing care products, such as glass window cleaning
 formulations, carpet and floor cleaners, spot removers, and shoe care products (<u>U.S. EPA, 2020c</u>). EPA
 expects that the type of products reported under this COU are likely to be both commercial and
 consumer in nature; however, this COU refers to the consumer use only.

7703

7698

7686

7689

This use was not reported in the 2016 or 2020 CDR cycles.

E.37 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Ink, Toner, and Colorant Products

This COU refers to the consumer use of DBP in inks, toner, and colorants, that can be used inpackaging, paper, plastic, toys, hobby products and articles.

7709

DBP is used in ink, toner, and colorant products, including coloring agents, printing inks, digital inks,
and inks and toners used in the electronics industry (U.S. EPA, 2020c). EPA expects that the majority of
ink, toner, and colorant products containing DBP would be commercial in nature; however, it is possible
that these products are used by DIY consumers as many of the commercial products are available for
consumer purchasers through various online vendors. This COU refers to the consumer use of these
products. EPA would expect that if consumer DIYers were to use these products they would apply them
in the same fashion as industrial users, on a smaller scale in a non-commercial setting.

7717

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

E.38 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Packaging (Excluding Food Packaging), Including Rubber Articles; Plastic Articles (Hard); Plastic Articles (Soft); Other Articles with Routine Direct Contact During Normal Use, Including Rubber Articles; Plastic Articles (Hard)

7724 7725

This COU refers to the consumer use of DBP in various packaging, paper, plastic, and hobby products.

EPA notes that this use was reported as plastic and rubber products not covered elsewhere in the 2016
CDR reporting cycle and is intended to describe products such as phone covers, personal tablet covers,
styrofoam packaging, and bubble wrap. EPA also expects that the type of products reported under this
COU are likely to be both commercial and consumer in nature. This COU refers to the consumer use of
these products.

77317732 Examples of CDR Submissions

In the 2016 CDR cycle, two companies reported the use of DBP in plastic and rubber products not
covered elsewhere, which is listed as both "packaging (excluding food packaging), including rubber
articles; plastic articles (hard); plastic articles (soft)" and as "other articles with routine direct contact
during normal use, including rubber articles; plastic articles (hard)" in the 2020 CDR cycle (U.S. EPA,
2019b).

E.39 Consumer Use – Packaging, Paper, Plastic, Hobby Products – Toys, Playground, and Sporting Equipment

This COU refers to the consumer use of DBP in toys, playground, and sporting equipment. The COU
includes the consumer use or storage of toys, playgrounds, and sporting equipment that contain DBP.
The use also refers to the DIY building of home sporting equipment.

7743

DBP can be used as a plasticizer to provide flexibility to toys. The Consumer Product Safety
Improvement Act (CPSIA) of 2008 placed a prohibition on DBP that limited manufacturers' use of DBP
in children's toys to 0.1 percent (U.S. EPA, 2019a). Toys containing DBP that were manufactured
and/or processed prior to the CPSIA restriction in 2008 may still be in use. DBP is reported to be found
downstream in tire crumb applications for playgrounds and turf (U.S. EPA, 2019f).

The consumer use was not reported to EPA in the 2016 or 2020 CDR cycles, but EPA expects the
commercial toys, playground, and sporting equipment reported in the CDR cycles are available to
consumers for use.

7753 E.40 Consumer Use – Other Use – Automotive Articles

- This COU refers to the consumer use of DBP in automotive articles. This COU includes the use of DBP containing automotive articles in a consumer DIY setting or by consumers driving a vehicle.
- 7756

DBP is used in various automotive applications. DBP is used in auto parts and equipment maintenance
 (MEMA, 2019). DBP was identified in 391 auto parts. In total, in the IMDS data system, DBP is listed
 in approximately 76,000 parts. These parts are found spread throughout the body/exterior, the interior,

in approximately 76,000 parts. These parts are found spread throughout the body/exterior, the interior,
the powertrain, the chassis, and the electrical system, and include fuel tank assemblies, hose assemblies,

wiring and computers, seat parts, and mats and carpeting (MEMA, 2019). DBP is reported to be found

- downstream in tire crumb applications for playgrounds and turf (<u>Armada et al., 2022; U.S. EPA, 2019f</u>).
 Consumers may be exposed to tires when handling tires for replacement on automobiles.
- 7764
- This use was not reported to EPA in the 2016 or 2020 CDR cycles.

7766 E.41 Consumer Use – Other Uses – Chemiluminescent Light Sticks

- 7767 This COU refers to the consumer use of DBP incorporated into chemiluminescent light sticks,
- sometimes referred to colloquially as glow sticks. EPA was notified that DBP is present in
- chemiluminescent light sticks as part of some governmental applications (U.S. EPA, 2020d).
 Chemiluminescent light sticks are also available to consumers and are typically advertised as "glow"
- 7771 sticks;" the North Carolina poison control cites glow sticks containing DBP as a health hazard for
- 7772 consumers (<u>NC Poison Control</u>, 2023).
- 7773
- The consumer use was not reported to EPA in the 2016 or 2020 CDR reporting cycles.

7775 E.42 Consumer Use – Other Uses – Lubricants and Lubricant Additives

This COU refers to the consumer use of DBP incorporated within lubricant products. DBP is used in
products for consumer applications including synthetic lubricants and anti-seize compounds in
automotive applications (NASA, 2020; U.S. EPA, 2020d; MEMA, 2019). EPA expects that the type of
products for automotive applications reported under this COU are likely to be both commercial and
consumer in nature. This COU encompasses only the consumer use of these products. For the consumer
use of these products, EPA expects them to be poured or applied by consumers as part of DIY auto
repair activities.

This use was not reported to EPA in the 2016 or 2020 CDR cycles.

7785 **E.43 Consumer Use – Other – Novelty Articles**

- 7786 This COU refers to the consumer use of DBP in adult novelty articles.
- 77877788 This COU is describing adult sex toys that are available for consumer use in the United States. Although
- the U.S. Food and Drug Administration (FDA) classifies certain sex toys (such as vibrators) as
- obstetrical and gynecological therapeutic medical devices, many manufacturers label these products "for
 novelty use only" and are not subject to the FDA regulations (<u>Stabile, 2013</u>). This same study indicated
 tested concentrations of phthalates between 24 and 49 percent of the tested sex toys for creating a softer,
 more flexible plastic (<u>Stabile, 2013</u>), and EPA assumed that the concentration of DBP in these products
- to be analogous to the overall content of the mix of phthalates tested and found in this study.
- This use was not reported to EPA in the 2016 or 2020 CDR cycles.

7796 **E.44 Disposal**

7797 For purposes of the DBP risk evaluation, this COU refers to the DBP in a waste stream that is collected 7798 from facilities and households and are unloaded at and treated or disposed at third-party sites. Each of 7799 the COUs of DBP may generate waste streams of the chemical. This COU also encompasses DBP 7800 contained in wastewater discharged by consumers or occupational users to POTW or other, non-POTW 7801 for treatment, as well as other wastes. DBP is expected to be released to other environmental media, 7802 such as introductions of biosolids to soil or migration to water sources and through waste disposal (e.g., 7803 disposal of formulations containing DBP, plastic and rubber products, textiles, and transport containers). 7804 Disposal may also include destruction and removal by incineration (U.S. EPA, 2021b). Additionally, 7805 DBP has been identified in EPA's Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic

- 7806 Fracturing Water Cycle on Drinking Water Resources in the United States, December 2016 document to 7807 be a chemical reported to be detected in produced water, which is subsequently disposed (U.S. EPA, 2016a). Recycling of DBP and DBP-containing products is considered a different COU. Environmental 7808 7809 releases from industrial sites are assessed in each COU and are not considered as part of the Disposal 7810 COU. Activities and releases associated with the use of DBP in propellants in articles, or components of articles subject to Section 4181 of the Internal Revenue Code of 1954, which are outside the scope of the 7811 7812 definition of "chemical substance" TSCA section 3(2)(B)(v), are not considered as part of the Disposal 7813 COU.
- 7814
- 7815 Activities and releases associated with the use of dibutyl phthalate in propellants in articles, or
- 7816 components of articles subject to Section 4181 of the Internal Revenue Code of 1954, which are outside
- 7817 the scope of the definition of "chemical substance" TSCA section 3(2)(B)(v), are not considered as part
- 7818 of the disposal COU.

7819 Appendix F DRAFT OCCUPATIONAL EXPOSURE VALUE DERIVATION 7820 EPA has calculated a draft 8-hour existing chemical occupational exposure value to summarize the

PA has calculated a draft 8-nour existing chemical occupational exposure value to summarize the
occupational exposure scenario and sensitive health endpoints into a single value. This calculated draft
value may be used to support risk management efforts for DBP under TSCA section 6(a), 15 U.S.C. §
2605. EPA calculated the draft value rounded to 0.6 mg/m³ for inhalation exposures to DBP as an 8hour time-weighted average (TWA) and for consideration in workplace settings (see Appendix F.1)
based on the acute, non-cancer human equivalent concentration (HEC) for developmental toxicity (*i.e.*,
decreased fetal testicular testosterone).

TSCA requires risk evaluations to be conducted without consideration of costs and other non-risk factors, and thus this draft occupational exposure value represents a risk-only number. If risk management for DBP follows the finalized risk evaluation, EPA may consider costs and other non-risk factors, such as technological feasibility, the availability of alternatives, and the potential for critical or essential uses. Any existing chemical exposure limit used for occupational safety risk management purposes could differ from the draft occupational exposure value presented in this appendix based on additional consideration of exposures and non-risk factors consistent with TSCA section 6(c).

This calculated draft value for DBP represents the exposure concentration below which exposed workers
and ONUs are not expected to exhibit any appreciable risk of adverse toxicological outcomes,
accounting for PESS. It is derived based on the most sensitive human health effect (*i.e.*, decreased fetal
testicular testosterone) and exposure duration (*i.e.*, acute) relative to benchmarks and a standard
occupational scenario assumption of an 8-hour workday.

EPA expects that at the draft occupational exposure value of 0.05 ppm (0.6 mg/m³), a worker or ONU also would be protected against developmental toxicity from intermediate and chronic duration occupational exposures if ambient exposures are kept below this draft occupational exposure value. The Agency has not separately calculated a draft short-term (*i.e.*, 15-minute) occupational exposure value because EPA did not identify hazards for DBP associated with this very short duration.

NIOSH 5020 and OSHA 104 analytical methods can be used for detecting DBP in air.

The Occupational Safety and Health Administration (OSHA) set a permissible exposure limit (PEL) as an 8-hour TWA for DBP of 5 mg/m³ (OSHA, 2020). EPA located several occupational exposure limits for DBP (CASRN 84-74-2) in other countries (IFA, 2022). Identified 8-hour TWA values ranged from 0.58 mg/m³ in Germany, New Zealand, and Poland to 10 mg/m³ in South Africa. Additionally, EPA found that <u>New Zealand</u> and the <u>United Kingdom</u> have an established occupational exposure limit of 0.58 and 5 mg/m³ (8-hour TWA) in each country's code of regulation that is enforced by each country's worker safety and health agency.

7858 F.1 Draft Occupational Exposure Value Calculations

7859 This appendix presents the calculations used to estimate draft occupational exposure values using inputs 7860 derived in this draft risk evaluation. Multiple values are presented below for hazard endpoints based on 7861 different exposure durations. For DBP, the most sensitive occupational exposure value is based on non-7862 cancer developmental effects and the resulting 8-hour TWA is rounded to 0.6 mg/m³.

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7865 Draft Acute Non-Cancer Occupational Exposure Value

The draft acute occupational exposure value (EV_{acute}) was calculated as the concentration at which the
 acute MOE would equal the benchmark MOE for acute occupational exposures using Equation_Apx
 F-1:

7870 Equation_Apx F-1.

7871

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7872
$$EV_{acute} = \frac{HEC_{acute}}{Benchmark MOE_{acute}} * \frac{AT_{HECacute}}{ED} * \frac{IR_{resting}}{IR_{workers}} =$$

7874
$$\frac{1.0 \text{ ppm}}{30} * \frac{\frac{24h}{d}}{\frac{8h}{d}} * \frac{0.6125 \frac{\text{m}^3}{hr}}{1.25 \frac{\text{m}^3}{hr}} = 0.05 \text{ ppm}$$

7875

7876
$$EV_{acute} \left(\frac{\text{mg}}{\text{m}^{3}}\right) = \frac{EV \, ppm \, * MW}{Molar \, Volume} = \frac{0.05 \, ppm \, * 278.35 \frac{g}{mol}}{24.45 \, \frac{L}{mol}} = 0.6 \, \frac{\text{mg}}{\text{m}^{3}}$$

7877

7878 Draft Intermediate Non-Cancer Occupational Exposure Value

The draft intermediate occupational exposure value (EV_{intermediate}) was calculated as the concentration at
which the intermediate MOE would equal the benchmark MOE for intermediate occupational exposures
using Equation_Apx F-2:

7882

7883 Equation_Apx F-2.

7885
$$EV_{intermediate} = \frac{HEC_{intermediate}}{Benchmark MOE_{intermediate}} * \frac{AT_{HEC intermediate}}{ED * EF} * \frac{IR_{resting}}{IR_{workers}}$$

7886

$$= \frac{1.0 \text{ ppm}}{30} * \frac{\frac{24h}{d} * 30d}{\frac{8h}{d} * 22d} * \frac{0.6125 \frac{\text{m}^3}{hr}}{1.25 \frac{\text{m}^3}{hr}} = 0.07 \text{ ppm} = 0.8 \frac{\text{mg}}{\text{m}^3}$$

7888

7887

7889 Draft Chronic Non-Cancer Exposure Value

The draft chronic occupational exposure value (EV_{chronic}) was calculated as the concentration at which
the chronic MOE would equal the benchmark MOE for chronic occupational exposures using
Equation_Apx F-3:

7894 Equation_Apx F-3.

7895 7896

$$EV_{chronic} = \frac{HEC_{chronic}}{Benchmark MOE_{chronic}} * \frac{AT_{HEC chronic}}{ED * EF * WY} * \frac{IR_{resting}}{IR_{workers}}$$

7897

7898
$$= \frac{1.0 \text{ ppm}}{30} * \frac{\frac{24h}{d} * \frac{365d}{y} * 40 \text{ y}}{\frac{8h}{d} * \frac{250d}{y} * 40 \text{ y}} * \frac{0.6125 \frac{\text{m}^3}{hr}}{1.25 \frac{\text{m}^3}{hr}} = 0.07 \text{ ppm} = 0.8 \frac{\text{mg}}{\text{m}^3}$$

7899 7900

7901	Where:		
7902	AT_{hecate}	=	Averaging time for the POD/HEC used for evaluating non-cancer
7903			acute occupational risk based on study conditions and HEC
7904			adjustments (24 h/day).
7905	AT_{HEC} intermediate	=	Averaging time for the POD/HEC used for evaluating non-cancer
7906			intermediate occupational risk based on study conditions and/or
7907			any HEC adjustments (24 h/day for 30 days).
7908	AT _{HECchronic}	=	Averaging time for the POD/HEC used for evaluating non-cancer
7909			chronic occupational risk based on study conditions and/or HEC
7910			adjustments (24 h/day for 365 days/year) and assuming the
7911			same number of years as the high-end working years (WY, 40
7912			years) for a worker.
7913	Benchmark MOE _{acute}	=	Acute non-cancer benchmark margin of exposure, based on the
7914			total uncertainty factor of 30
7915	Benchmark MOE _{intermedia}	$_{te} =$	Intermediate non-cancer benchmark margin of exposure, based on
7916			the total uncertainty factor of 30
7917	Benchmark MOE _{chronic}	=	Chronic non-cancer benchmark margin of exposure, based on the
7918			total uncertainty factor of 30
7919	EV_{acute}	=	Acute occupational exposure value
7920	$EV_{intermediate}$	=	Intermediate occupational exposure value
7921	EV _{chronic}	=	Chronic occupational exposure value
7922	ED	=	Exposure duration (8 h/day)
7923	EF	=	Exposure frequency (1 day for acute, 22 days for intermediate, and
7924			250 days/year for chronic and lifetime)
7925	HEC	=	Human equivalent concentration for acute, intermediate, or chronic
7926			non-cancer occupational exposure scenarios
7927	IR	=	Inhalation rate (default is $1.25 \text{ m}^3/\text{h}$ for workers and $0.6125 \text{ m}^3/\text{h}$
7928			assumed from "resting" animals from toxicity studies)
7929	Molar Volume	=	24.45 L/mol, the volume of a mole of gas at 1 atm and 25 $^{\circ}$ C
7930	MW	=	Molecular weight of DBP (278.35 g/mole)
7931	WY	=	Working years per lifetime at the 95th percentile (40 years).
7932			

7933 *Unit conversion:*

- 7934 1 ppm = 11.38 mg/m³ (see equation associated with the EV_{acute} calculation)
- 7935
- 7936