

Common Engineering Defaults Used in EPA's New Chemical Assessments



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Notice

This document is not intended to be a comprehensive summary of all assumptions used in the review process; rather, it provides common assumptions that EPA uses in the absence of information. This document is an evolving guidance document and is not binding on either EPA or any outside party. EPA has the discretion to modify these assumptions and/or its assessment approach on a given chemical if it believes it is necessary to do so.

Acronyms

<i>ChemSTEER</i>	<i>Chemical Screening Tool for Exposures and Environmental Releases</i>
<i>EPA</i>	<i>Environmental Protection Agency</i>
<i>ESD</i>	<i>Emission Scenario Document</i>
<i>FCA</i>	<i>Fragrance Creators Association</i>
<i>GS</i>	<i>Generic Scenario</i>
<i>LEV</i>	<i>Local Exhaust Ventilation</i>
<i>NCS</i>	<i>New Chemical Substance</i>
<i>OECD</i>	<i>Organisation for Economic Co-operation and Development</i>
<i>OPPT</i>	<i>Office of Pollution Prevention and Toxics</i>
<i>OSHA</i>	<i>Occupational Safety and Health Administration</i>
<i>PEL</i>	<i>Permissible Exposure Limit</i>
<i>PMN</i>	<i>Pre-Manufacture Notice</i>
<i>TSCA</i>	<i>Toxic Substances Control Act</i>

Background

Under Section 5 of the Toxic Substances Control Act (TSCA), Environmental Protection Agency's (EPA) New Chemicals Division reviews new chemical substances to determine whether they present an unreasonable risk of injury to human health or the environment before they may be manufactured or processed or used. EPA's evaluation consists of an assessment of chemistry, environmental fate and transport, environmental release and occupational exposure (i.e., the engineering assessment), environmental, general population and consumer exposure, ecological hazard and risk, and human health hazard and risk.

EPA is committed to transparency and strives to provide helpful information to stakeholders. The purpose of this document is to summarize common "default values" that EPA typically uses in its engineering assessments when chemical-specific information is not provided or is not substantiated adequately with relevant documentation. These defaults provide a protective, screening-level approach for EPA's assessment in the absence of chemical-specific information. The values come from EPA Office of Pollution Prevention and Toxics (OPPT) models, which are built into the Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) used by EPA to conduct the engineering assessment. Some defaults may also come from EPA's Generic Scenario (GS) documents and Organisation for Economic Co-operation and Development's (OECD's) Emission Scenario Documents (ESDs).

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Common Engineering Defaults Used to Estimate Environmental Releases

The engineering assessment involves estimating environmental releases of and occupational exposures to new chemicals during their entire lifecycle, including manufacturing, processing, industrial, and commercial use. For each step of the lifecycle, EPA performs a mass balance (e.g., number of sites, days per year operation, daily and annual facility throughput) and develops exposure scenarios using chemical-specific information in the submissions or estimation approaches in ChemSTEER, EPA GS documents, and OECD ESDs. EPA considers the following routes of environmental release and worker exposures:

Exposure Routes	Media of Release
Inhalation	Air, Water, Landfill,
Dermal	Incineration

Table 1 summarizes common models used by EPA to estimate environmental releases, the associated default values, and their basis. These models are broadly applicable to many industrial and commercial operations and cover activities such as material transfer, including the unloading and loading of chemicals, equipment cleaning, and transport container cleaning. For non-volatile chemicals, EPA typically assumes media of release may include water, incineration, or landfill in the absence of specific information for the new chemical substance, use scenario, or industry sector. **Table 2** summarizes common models and defaults used by EPA to estimate dermal and inhalation exposures to workers. Additional details on these models can be found in EPA's ChemSTEER User Guide.¹

¹ U.S. EPA, 2015. ChemSTEER User Guide. Available online at: https://www.epa.gov/sites/default/files/2015-05/documents/user_guide.pdf.

Table 1. Common Model Default Values Used to Estimate Environmental Releases

Activity	Release Source	Applicable Scenario	Default Release Value	Key Rationale
Transferring liquid material to/from transport containers	Cleaning or disposing empty transport containers with New Chemical Substance (NCS) residues	Drums: ≥20 to < 100 gallons Note: 55-gallon drums are the default container assumed by EPA in lieu of chemical-specific information in PMN submission.	3% (default assumes drums are emptied by pumping) 0.6% if submission indicates drums are emptied by pouring	The high-end 3% loss is roughly equivalent to a one-inch heel in a standard 55-gallon drum. ¹
		Bulk containers (e.g., totes, tank trucks, rail cars) ≥100 gallons	0.2%	The default comes from a range of values from an EPA sponsored study on residuals in containers. ¹
		Small containers (e.g., bottles) <20 gallons	0.6%	
	Cleaning or disposing empty transport containers with NCS residues (fragrance chemicals only)	Drums: ≥20 to < 100 gallons	0.8% (default assumes drums are emptied by pumping)	Based on empirical data provided on drum residues for fragrance chemicals. ²
Transferring solid material to/from transport containers	Cleaning or disposing empty transport containers with solid NCS residues	Containers for solid materials	1%	The default comes from a range of values from an EPA sponsored study on residuals in containers. ¹
General industrial/commercial processes	Cleaning process vessels (e.g., reactor, mixing tank) with NCS residues	Process that involves only one vessel/equipment (e.g., single reactor)	1% (default assumes equipment is drained via pumping) 0.2% if submission indicates equipment is gravity-drained	Default based on the information and data (for pumping) in a 1988 PEI Associates study (see ChemSTEER User Guide ¹); this is considered a conservative estimate.
		Process that involves multiple pieces of equipment that need to be cleaned (e.g., multiple mixing tanks; a mixing tank followed by a filtration unit and an extruder).	2%	

² Fragrance Creators Association (FCA) drum handling practices survey (June 2025), FCA drum residue study (2006) and empirical drum residue data submitted under the new chemicals program.

Activity	Release Source	Applicable Scenario	Default Release Value	Key Rationale
Transferring solid materials Please include the transfer of liquid materials (default for vapor release during loading/unloading)	Dust/airborne particulates generated when handling transferring solid materials (powders, pellets, granules, flakes) containing NCS	Process/activity that involves transferring solid materials such as opening a package/container and unloading solid powder into a process tank	0.5% (released)	Defaults are derived from reviewing literature values for different engineering control technologies and accounting for a safety factor. ³
			<u>Capture efficiency:</u> 32.1% for unknown capture technology or Local Exhaust Ventilation (LEV) 95% for overhead capture hood or laboratory fume hood	
			<u>Control efficiency:</u> 26% for unknown control technology 99% for baghouse or HEPA filter (see scenario for additional alternative defaults)	
Industrial/ commercial use of coatings	Process losses (inefficiencies) during roll or curtain coating application	Applying formulated coating products onto substrates via roll or curtain coating operations	2 – 10%	Default range is based on transfer efficiency for paints and coatings from a Pennsylvania Department of Environmental Protection source. ⁴

³ U.S. EPA, 2020. Generic Model to Estimate Dust Releases from Transfer/Unloading/Loading Operations of Solid Powders. <https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios>

⁴ U.S. EPA, 2008. Releases from Roll Coating and Curtain Coating Operations – Generic Scenario for Estimating Occupational Exposure and Environmental Releases.

Table 2. Common Model Default Values Used to Estimate Worker Inhalation and Dermal Exposures

Activity	Exposure Source	Applicable Scenario	Default Exposure Value	Key Rationale
Handling solids (e.g., raw materials, formulated products) containing NCS	Airborne particulates/dusts generated during solid transferring activities	Inhalation exposure to airborne particulates/dusts when handling (e.g., scooping, weighing, pouring) <54 kg/site-day of material	0.161 mg/kg body weight	Default derived from a study of dye weighing and adapted for use in situations where workers are presumed to handle small volumes of solids in a manner similar to the handling in the study.
		Inhalation exposure to airborne particulates/dusts when handling ≥54 kg/site-day of material	15 mg/m ³ total particulates 5 mg/m ³ respirable particulates	Values are based on Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) for total and respirable particulates, as operations are generally expected to comply with OSHA's federal regulation.
	Dermal contact with solids containing the NCS	Dermal exposure to solids for various industrial and commercial activities	3,100 mg/event (high-end, value adjusted for weight fraction of NCS)	Default value reflects exposure without potential use of personal protective equipment (e.g., gloves).
Handling liquids containing NCS	Vapor emitted from open surfaces while handling liquids (if volatile)	Inhalation exposure to vapor when handling liquids (e.g., cleaning container/equipment, loading/unloading liquids)	Calculated, but exposure concentration is a function of the following ventilation rate: 237,600 cfm (outdoor, average) 500 – 3,000 cfm (indoor)	Indoor defaults based on general industry ventilation rate. Outdoor defaults based on average wind speed of 9 mph. See ChemSTEER User Guide ¹ for additional default.
	Dermal contact with liquid containing the NCS	Dermal exposure to liquids for various industrial and commercial activities	2.1 mg/cm ² -event (high-end, value adjusted for weight fraction of NCS) Surface area: 1,070 cm ² for two hands (default) and 535 cm ² for one hand ⁵	Default value reflects exposure without potential use of personal protective equipment (e.g., gloves).

⁵ EPA assumes dermal exposure to two hands as default in lieu of chemical-specific information in pre-manufacture notice (PMN) submission. EPA may assess exposure to one hand for activities such as sampling where potential for dermal contact is limited. As default, EPA assumes only one contact event per day.

Example 1

The new chemical substance is an emulsifier for paints and coatings. It is imported at a volume of 50,000 kg/yr as a neat liquid in containers and sold to a customer who blends and formulates it into commercial paint products.

EPA's Assessment: In this scenario, EPA typically considers potential releases to the environment from cleaning and disposal of empty transport containers. If the container type is unknown, EPA typically assumes 55-gallon (208L) drums as default. However, if specific container types are known for submitter-controlled operations, EPA would tailor the assessment to the specific containers used to transport the new chemical substance.

Default release estimate assumes NCS is imported in drums:

$$\text{Daily release} = \frac{55 \text{ gal}}{\text{container}} \times \frac{3.785 \text{ L}}{\text{gal}} \times \frac{1 \text{ kg}}{\text{L}} \times \frac{1 \text{ container}}{\text{site-day}} \times 0.03 \frac{\text{kg residue}}{\text{kg NCS}} = 6.2 \frac{\text{kg}}{\text{site-day}}$$

...over 240 days per year (240 drums for a total volume of 50,000 kg/yr)

Refined release estimate, if NCS is known to be imported in totes:

$$\text{Daily release} = \frac{550 \text{ gal}}{\text{container}} \times \frac{3.785 \text{ L}}{\text{gal}} \times \frac{1 \text{ kg}}{\text{L}} \times \frac{1 \text{ container}}{\text{site-day}} \times 0.002 \frac{\text{kg residue}}{\text{kg NCS}} = 4.2 \frac{\text{kg}}{\text{site-day}}$$

...over 24 days per year (24 totes for a total volume of 50,000 kg/yr)

Example 2

The new chemical substance is an additive used in plastics. It is imported at a volume of 500,000 kg/yr as a solid powder in super sacks and unloaded into a hopper, which connects to a mixing vessel where it is blended with other additives and plastic resins. The unloading occurs under Local Exhaust Ventilation (LEV) to capture potential dust generated during transfer. The facility operates 250 days per year and unloading occurs daily (i.e., daily throughput of 2,000 kg NCS/site-day).

EPA's Assessment: In this scenario, EPA typically considers potential dust releases from solid transferring activities (e.g., transferring/unloading/loading of solid powders). EPA's assessment would differ depending on what, if any, engineering control is present to capture and control potential dusts from the work area. The assessment would also consider supporting information provided on the capture/control technology and the associated uncertainty (e.g., if the process occurs at a submitter-controlled site or another known site). Note the example calculations below do not present captured/controlled portion of dusts, which is typically disposed as solid waste.

Release estimate if the transfer occurs under an overhead capture hood to capture dust from the workspace, and the hood is equipped with a HEPA filter to further remove dust from the vent stream (EPA assumes as default 95% capture efficiency and 99% control efficiency):

$$\begin{aligned} \text{Daily release (dust not captured)} &= \frac{2,000 \text{ kg}}{\text{site-day}} \times 0.005 \frac{\text{kg released}}{\text{kg handled}} \times (1 - 0.95) \\ &= 0.50 \frac{\text{kg}}{\text{site-day}} \end{aligned}$$

$$\begin{aligned} \text{Daily release (dust captured but not controlled)} \\ &= \frac{2,000 \text{ kg}}{\text{site-day}} \times 0.005 \frac{\text{kg released}}{\text{kg handled}} \times 0.95 \times (1 - 0.99) = 0.095 \frac{\text{kg}}{\text{site-day}} \end{aligned}$$

...over 250 days per year