A Review and Analysis of EPA’s Use of Exposure Modeling Methods in TSCA Risk Evaluations

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Agenda

1. Brief Overview of Exposure Assessments in TSCA Risk Evaluations
2. Anatomy of TSCA Exposure Modeling Assessments
3. How Does EPA Select and Parameterize Models?
4. Review and Analysis of EPA Exposure Modeling Assessments

Brief Overview of Exposure Assessments in TSCA Risk Evaluations

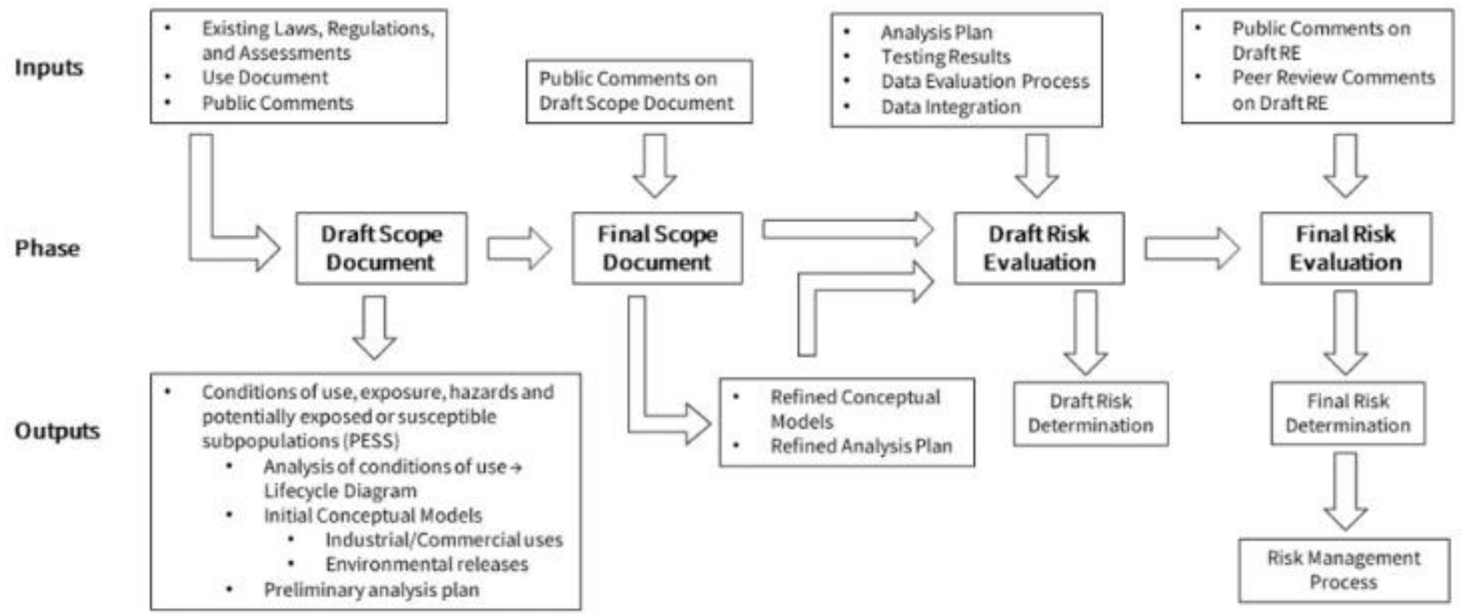
EPA TSCA Evaluation Process

- Source: EPA.gov, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca

Step 2 - The Risk Evaluation

Components of a Risk Evaluation

The figure below describes the major inputs, phases, and outputs/components of the TSCA risk evaluation process for existing chemicals, from scoping to releasing the final risk evaluation.



- **Exposure Assessments** are performed as a key component of this step

Source: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca

Focus of Today's Discussion

Review of Existing Risk Evaluations

- In collaboration with the American Chemistry Council (ACC), our research team has been performing detailed reviews and assessments of the ***exposure assessment*** components of the risk evaluations.

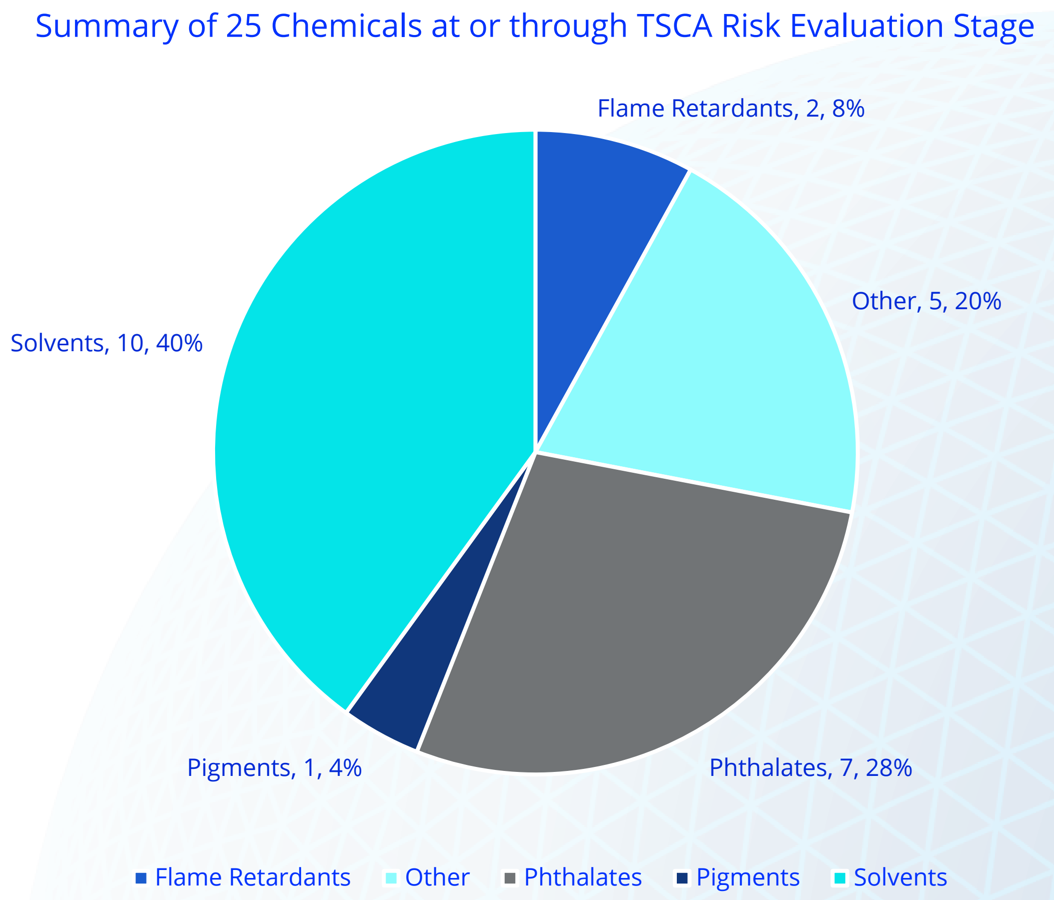
Chemicals with Risk Evaluations to Date (as of Jan 18, 2026)

Chemical	Risk Evaluation Date	Risk Assessment Status	EPA Chemical Class	Any Risk Management Rule?
Methylene Chloride	Jun-20	FINAL	Solvents	Final - April 2024
1-Bromopropane	Aug-20	FINAL	Solvents	Proposed - July 2024
Cyclic Aliphatic Bromide Cluster (HBCD)	Sep-20	FINAL	Flame Retardants	No
Carbon Tetrachloride	Nov-20	FINAL	Solvents	Final - December 2024
Trichloroethylene (TCE)	Nov-20	FINAL	Solvents	Final - December 2024
Asbestos (Part 1: Chrysotile)	Dec-20	FINAL	Other - Asbestos	Final - March 2024
1,4-Dioxane	Dec-20	FINAL, SUPPLEMENTED	Solvents	No
N-Methylpyrrolidone (NMP)	Dec-20	FINAL	Solvents	Proposed - June 2024
Perchloroethylene (PCE)	Dec-20	FINAL	Solvents	Final - December 2024
C.I. Pigment Violet 29	Jan-21	FINAL	Pigments	Proposed - December 2024
Tris(2-Chloroethyl) Phosphate (TCEP)	Sep-24	FINAL	Flame Retardants	No
Asbestos (Part 2: Legacy Uses)	Nov-24	FINAL	Other - Asbestos	No
Formaldehyde	Dec-24	FINAL, SUPPLEMENTED (draft)	Other - Formaldehyde	No
Diisodecyl Phthalate (DIDP)	Dec-24	FINAL	Phthalates	No
Diisononyl Phthalate (DINP)	Jan-25	FINAL	Phthalates	No
1,1-Dichloroethane	Jun-25	FINAL	Solvents	No
1,3-Butadiene	Dec-25	FINAL	Other - Butadiene	No
Dicyclohexyl Phthalate (DCHP)	Dec-25	FINAL	Phthalates	No
Diethylhexyl Phthalate (DEHP)	Dec-25	FINAL	Phthalates	No
Dibutyl Phthalate (DBP)	Dec-25	FINAL	Phthalates	No
Diisobutyl Phthalate (DIBP)	Dec-25	FINAL	Phthalates	No
Butyl Benzyl Phthalate (BBP)	Dec-25	FINAL	Phthalates	No
Octamethylcyclotetrasiloxane (D4)	Sep-25	DRAFT	Other - D4	No
1,2-Dichloroethane	Nov-25	DRAFT	Solvents	No
1,2-Dichloropropane	Nov-25	DRAFT	Solvents	No

Assessments: 22 final, 3 draft

RM Rules: 5 final, 3 proposed

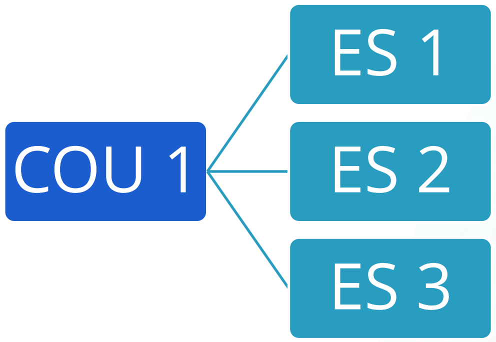
Chemicals Assessed to Date (as of Jan 18, 2026)



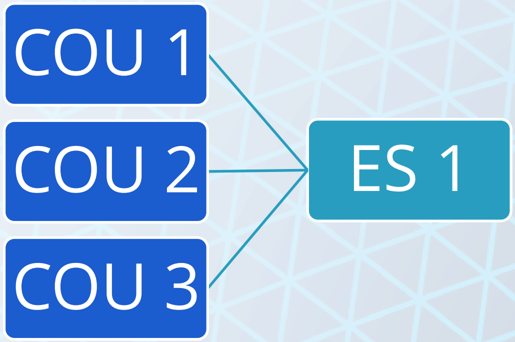
Terminology and Structure Overview: COU and ES

- Exposure assessments are completed at the “**Exposure Scenario” (ES)** level
    - OES = Occupational, Product/Article/CES = Consumer
- Risk evaluations are performed at the **“Condition of Use” (COU)** level

One-to-One Match



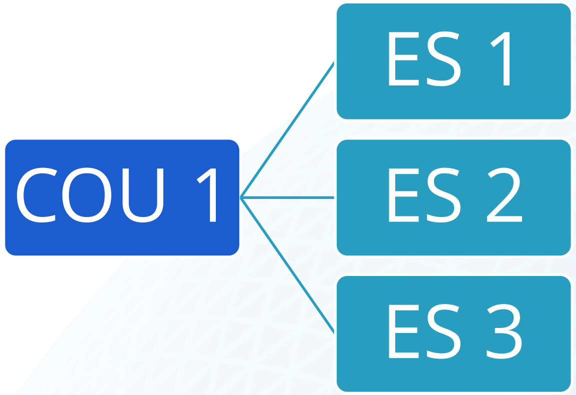
Separating one COU into multiple assessments to account for large differences in exposure potential and/or data gaps for COUs



Grouping COUs into one assessment due to similar exposure potential and/or data gaps

COU-ES Relationships in TSCA Risk Evaluations

- **IMPORTANTLY**, exposure assessments and risk assessments are completed for different groupings!



RISK ASSESSMENTS AT COU GROUP

EXPOSURE ASSESSMENTS AT ES GROUP

Example of COU-OES Relationships in TSCA Evaluations

Condition of Use			OES	Risk Evaluation in Which Occupational Exposures Were Assessed
Life Cycle Stage	Category[a]	Subcategory[b]		
Industrial Use, Commercial Use	Laboratory chemicals	Chemical reagent	Laboratory chemicals	2020 RE
		Reference material		
		Spectroscopic and photometric measurement		
		Liquid scintillation counting medium		
		Stable reaction medium		
		Cryoscopic solvent for molecular mass determinations		
		Preparation of histological sections for microscopic examination		
	Adhesives and Sealants	Film cement	Film cement	2020 RE
	Other Uses	Spray polyurethane foam; Printing and printing compositions, including 3D printing; dry film lubricant; Hydraulic fracturing	Spray foam application	2020 RE
			Printing inks (3D)	2020 RE
			Dry film lubricant	2020 RE
			Hydraulic Fracturing	Supplemental RE
Consumer Use, Commercial Use	Paints and Coatings	Latex wall paint or floor lacquer	Paint and floor lacquer	Supplemental RE
	Cleaning and Furniture Care Products	Surface cleaner	Surface Cleaner	Supplemental RE
	Laundry and Dishwashing Products	Dish soap Dishwasher detergent Laundry detergent	Dish soap Dishwasher detergent Laundry detergent (industrial) Laundry detergent (institutional)	Supplemental RE
	Arts, Crafts, and Hobby Materials	Textile dye	Textile dye	Supplemental RE

Multiple COUs evaluated using 1 exposure assessment (OES)

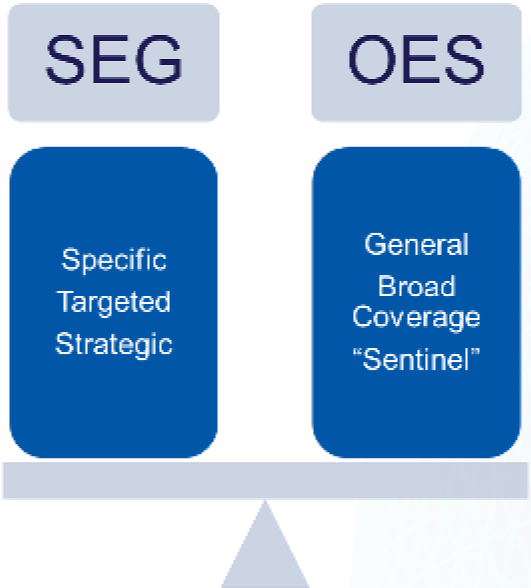
1 COU broken out into multiple OESs

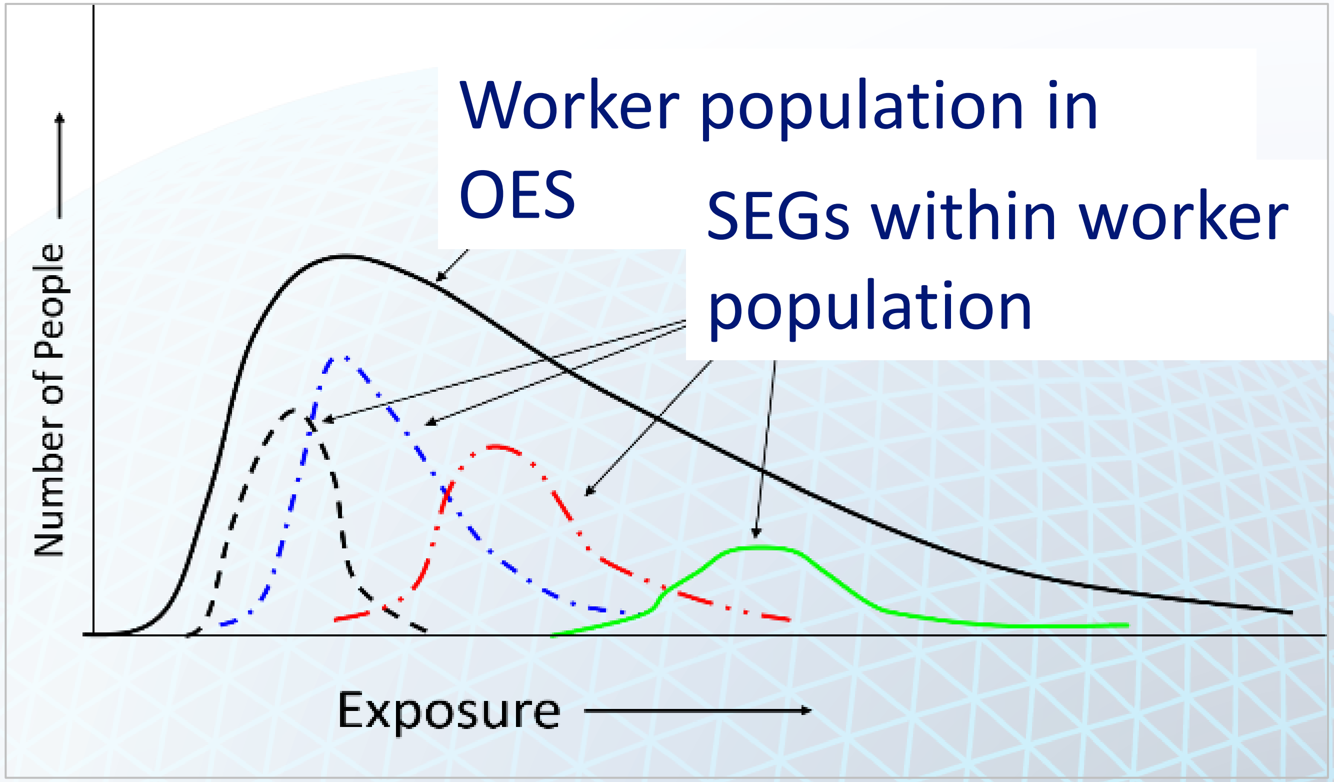
1 COU, 1 OES

Source: EPA (2020) 1,4-Dioxane Risk Assessment, Table Apx D1 from 1,4-dioxane draft supplement document.

SEG vs. OES for Occupational Exposures

- OESs are process-based and tend to cover broad groups of multiple SEGs
- SEGs are specific, targeted, and strategic



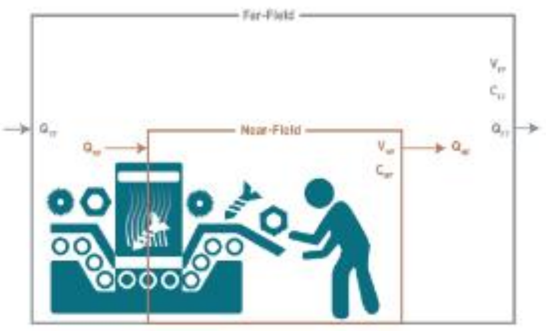


TSCA Exposure Assessments (as of December 23, 2025)

- Insight has fully reviewed the **first 23** of the 25 existing risk evaluations.
- In that set, there are **649** individual exposure assessments for workers and consumers.
- All use monitoring data, modeling or both.

Table_Apx A-3. Summary of Full-Shift Inhalation Monitoring Data for Processing as a Reactant

Row	Industry	Type of Sample	Worker Activity or Sampling Location	Methylene Chloride Airborne Concentration (mg/m^3) [a,b,c]	Number of Samples	Type of Measurement	Source	Score	Rationale for Inclusion / Exclusion
24	Olin Corporation – Crop Protection	Personal	Asst Operator	0.27	1	6.5 hr TWA	Olin Corp (1979)	2.2	Excluded – used higher quality data
25	Fluorochemicals Production	Personal	Not specified	CBI	Unknown	8-hr TWA	Bernstein (2017)	1.8	Excluded – used higher quality data
26	Industrial Gas Manufacturing	Personal	unknown	0.1	1	TWA	Finkel (2017)	2	Included – Worker Full-Shift TWA
27	Industrial Gas Manufacturing	Personal	unknown	21.4	1	TWA	Finkel (2017)	2	Included – Worker Full-Shift TWA
28	Pesticide and Other Agricultural Chemical Manufacturing	Personal	unknown	3.5	1	TWA	Finkel (2017)	2	Included – Worker Full-Shift TWA
29	Pesticide and Other Agricultural Chemical Manufacturing	Personal	unknown	4.9	1	TWA	Finkel (2017)	2	Included – Worker Full-Shift TWA
30	Pesticide and Other Agricultural Chemical Manufacturing	Personal	unknown	0.1	1	TWA	Finkel (2017)	2	Included – Worker Full-Shift TWA
31	Pesticide and Other Agricultural Chemical Manufacturing	Personal	unknown	0.1	1	TWA	Finkel (2017)	2	Included – Worker Full-Shift TWA
32	Pesticide and Other Agricultural Chemical Manufacturing	Personal	unknown	0.1	1	TWA	Finkel (2017)	2	Included – Worker Full-Shift TWA
33	Pesticide and Other Agricultural Chemical Manufacturing	Personal	unknown	0.1	1	TWA	Finkel (2017)	2	Included – Worker Full-Shift TWA



Figure_Apx F-3. The Near-Field/Far-Field Model as Applied to the Conveyorized Degreasing Near-Field/Far-Field Inhalation Exposure Model

The model design equations are presented below in Equation F.2-25 through Equation F.2-40
. Note the design equations are the same for each of the models discussed in this appendix.

Near-Field Mass Balance

Equation F.2-25

$$V_{NF}\frac{dC_{NF}}{dt} = C_{FF}Q_{NF} - C_{NF}Q_{NF} + G$$

Far-Field Mass Balance

Equation F.2-26

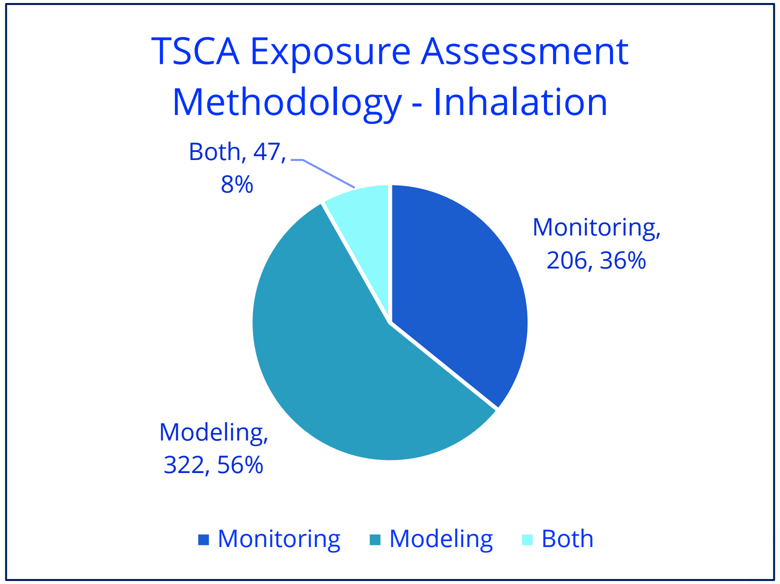
$$V_{FF}\frac{dC_{FF}}{dt} = C_{NF}Q_{NF} - C_{FF}Q_{NF} - C_{FF}Q_{FF}$$

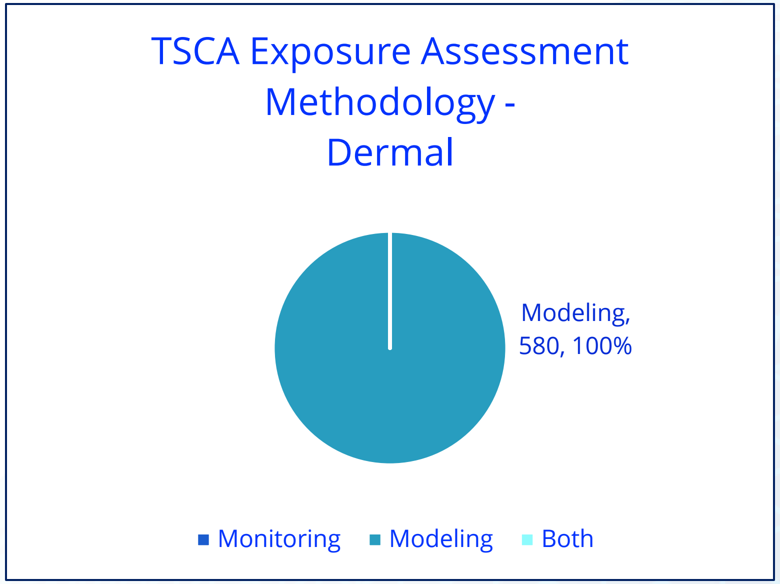
Where:

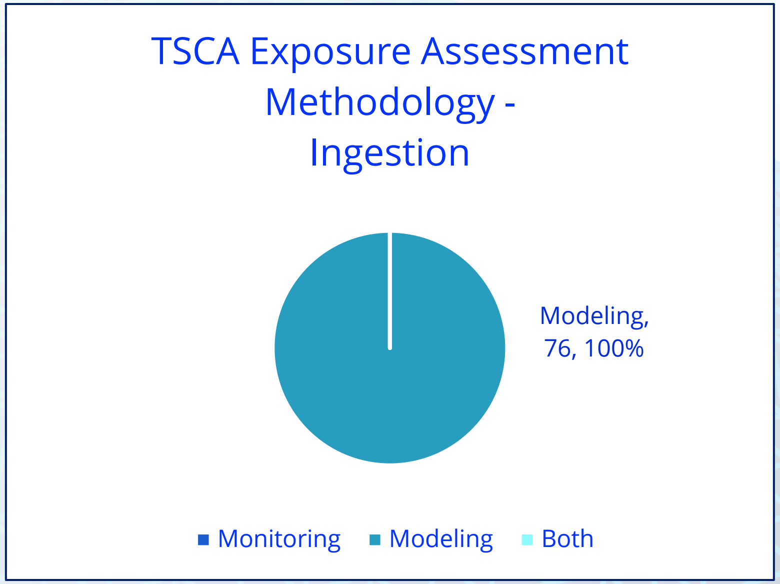
Source: EPA (2020) Methylene Chloride Risk Assessment, Supplemental File: Supplemental Information on Releases and Occupational Exposure Assessment

TSCA Exposure Assessments (as of December 23, 2025)

Data Includes OESs and CESs





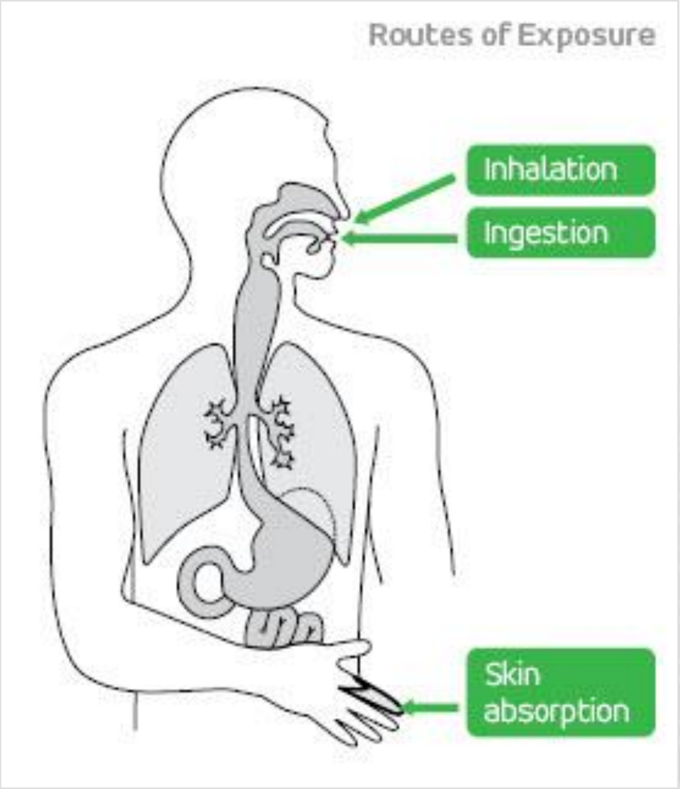


NOTE: DATA PRESENTED ON THIS SLIDE DOES NOT YET INCORPORATE the FINAL RISK EVALUATIONS FOR 5 PHTHALATES OR 1,3-BUTATIENE, THIS DATA USES DRAFT VERSIONS

Anatomy of TSCA Modeling Exposure Assessments

How TSCA Exposure Assessments are Structured

- Organized into exposure scenarios
  - **OES** = Occupational Exposure Scenario
  - **Product/Article/CES =** Consumer Exposure Scenario
  - *These are presented in separate supplemental documents*
- Assessments performed by route
  - Inhalation AND dermal routes are assessed for workers
  - Generally, only the inhalation route is assessed for Occupational Non-Users (ONUs), but this is not always true
  - Any of the three routes can be assessed for consumers depending on the specific use
- To date: only monitoring and modeling have been used. No banding or other judgement-based estimation approaches
  - Some OESs are "surrogated," which involves using results from another OES to assess the OES of interest. This is technically a partial judgement-based approach



Central Tendency and High-End Exposures

- Results for each OES are exposure concentrations or doses presented at two levels: **central tendency** and **high-end**
- EPA uses the 50th percentile (median) (preferred), mean (arithmetic or geometric), mode, or midpoint values as the central tendency scenario
- EPA uses exposures that occur at probabilities above the 90th percentile, typically the 95th percentile, as the high-end exposure scenario

Example – Formaldehyde Risk Evaluation:

Table 3-37. Summary of Inhalation Exposure Modeling Data for the Industrial Use of Lubricants

Exposure Concentration Type	Central Tendency (ppm)	High-End (ppm)	Data Quality Rating of Air Concentration Data
Inhalation exposure during container unloading or transferring	4.19E−01	1.50E00	N/A – Modeled data
Container cleaning exposure	2.71E−02	9.94E−02	
8-hour TWA (total exposure)	9.70E−03	3.45E−02	

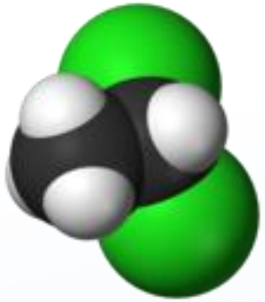
EPA used the vapor generation rate, exposure duration parameters, and the EPA Mass Balance Inhalation Model to determine a TWA exposure for each exposure point. EPA assumed the same worker performed each activity throughout their work shift and estimated the 8-hour TWA by combining the exposures from each exposure point and averaging over 8-hours within the Monte Carlo simulation. EPA assumed workers had no exposure outside each exposure activity. Table 3-37 summarizes the estimated 8-hour TWA exposures for use of formulations containing formaldehyde in industrial use of lubricants based on the two approaches to the second exposure point described above. The high-end values represent the 95th percentile and the central tendency values represent the 50th percentile of the simulation outputs.

Sources: EPA (1992). Exposure Assessment Guidelines.

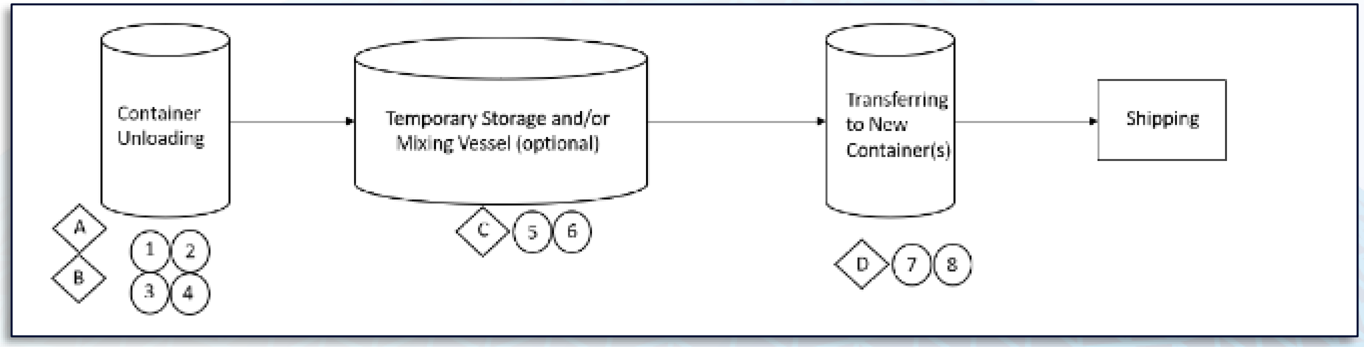
Insight Exposure & Risk Sciences (2024). ACGIH 2024 Web Series: A Comprehensive Overview of EPAs Risk Evaluations

EPA (2024) Formaldehyde Risk Assessment

Anatomy of TSCA Modeling Exposure Assessment



- Example OES : **1,1-DCA, Repackaging OES.**
- ECEL for 1,1-DCA is **0.044 ppm** as 8-h TWA.
- Ultimately, EPA used this exposure assessment in a risk assessment.
- Conclusion of RA was **unreasonable risk** through inhalation route.



Occupational Exposures:

A. Inhalation exposures to volatile liquids and dust and dermal exposure to solids and liquids from unloading transport containers.

B. Inhalation exposures to volatile liquids and dermal exposure to solids and liquids from transport container cleaning.

C. Inhalation exposures to volatile liquids and dermal exposure to solids and liquids from equipment cleaning.

D. Inhalation exposures to volatile liquids and dust and dermal exposure to solids and liquids from loading transport containers.

Source: EPA (2025) Risk Evaluation for 1,1-Dichloroethane Supplemental File: Supplemental Information on Environmental Release and Occupational Exposure Assessment

Anatomy of Exposure Assessment – Summary

- The relevant supplement (occupational/consumer) contains modeling methods and results.
- Organized by ES (use crosswalk table and TOC to find quickly)

5.4.4.3 Occupational Inhalation Exposure Results

For this scenario, EPA applied the EPA Mass Balance Inhalation Model to exposure points described in the July 2022 Chemical Repackaging *GS* (U.S. EPA, 2022a), particularly for the emptying of drums, filling of containers, and cleaning of drums process described in the process description. The EPA Mass Balance Inhalation Model estimates the concentration of the chemical in the breathing zone of the worker based on a vapor generation rate (G). An 8-hour TWA is then estimated and averaged over eight hours assuming no exposure occurs outside of those activities. Appendix E also describes the model equations and other input parameters used in the Monte Carlo simulation for this OES. Worker exposures were modeled for this OES; EPA did not have the approaches to separately model ONU exposures.

EPA used the vapor generation rate and exposure duration parameters from the *1991 CEB Manual* (CEB, 1991) in addition to those used in the EPA Mass Balance Inhalation Model to determine a time-weighted exposure for each exposure point. EPA estimated the time-weighted average inhalation exposure for a full work-shift (EPA assumed an 8-hour work-shift) as an output of the Monte Carlo simulation by summing the time-weighted inhalation exposures for each of the exposure points and assuming 1,1-dichloroethane exposures were zero outside these activities.

Source: EPA (2025) Risk Evaluation for 1,1-Dichloroethane Supplemental File: Supplemental Information on Environmental Release and Occupational Exposure Assessment

Anatomy of Exposure Assessment – Methods and Parameters – In Appendix

Table_Apx E-2. Models and Variables Applied for Exposure Points in the Processing—Repackaging OES

Exposure Point	Model(s) Applied	Variables Used
Exposure point A: Transfer Operation Exposures from Emptying Drum	*EPA/OPPT Mass Balance Inhalation Model* with vapor generation rate from *EPA/OAQPS AP-42 Loading Model* (Equation_Apx E-6)	Vapor Generation Rate: $F_{1,1-DCA}$; VP; $F_{saturation\_unloading}$; $MW_{1,1-DCA}$; V_{import_cont}; R; T; $RATE_{fill\_drum}$; Q; k; Vm Exposure Duration: $RATE_{fill\_drum}$
Exposure point B: Transfer Operation Exposure from Filling Small Containers	*EPA/OPPT Mass Balance Inhalation Model* with vapor generation rate from *EPA/OAQPS AP-42 Loading Model* (Equation_Apx E-6)	Vapor Generation Rate: $F_{1,1-DCA}$; VP; $F_{saturation\_loading}$; $MW_{1,1-DCA}$; V_{small_cont}; R; T; $RATE_{fill\_smallcont}$; Q; k; Vm Exposure Duration: V_{import_cont}; V_{fill_cont}; $RATE_{fill\_drum}$
Exposure point C: Exposures during Drum Cleaning	*EPA/OPPT Mass Balance Inhalation Model* with vapor generation rate from *EPA/OPPT Penetration Model* or *EPA/OPPT Mass Transfer Coefficient Model*, based on air speed (Equation_Apx E-6)	Vapor Generation Rate: $F_{1,1-DCA}$; $MW_{1,1-DCA}$; VP; $RATE_{air\_speed}$; $D_{opening\_cont-cleaning}$; T; P; Q; k; Vm Exposure Duration: $RATE_{fill\_drum}$

Equation_Apx E-6

$$Cv_{activity} = Minimum: \begin{cases} \left[\dfrac{170{,}000 * T * G_{activity}}{MW_{1,1-DCA} * Q * k}\right] \\ \left[\dfrac{1{,}000{,}000ppm * F_{correction\_factor} * VP}{P}\right] \end{cases}$$

Where:

$Cv_{activity}$	=	Exposure activity volumetric concentration [ppm]
$G_{activity}$	=	Exposure activity vapor generation rate [g/s]
MW_{TCEP}	=	1,1-dichloroethane molecular weight [g/mol]
Q	=	Ventilation rate [ft^3/min]
k	=	Mixing factor [unitless]
T	=	Temperature [K]
$F_{correction\_factor}$	=	Vapor pressure correction factor [unitless]
VP	=	1,1-dichloroethane vapor pressure [torr]
P	=	Pressure [torr]

Table_Apx E-3. Summary of Parameter Values and Distributions Used in the Processing—Repackaging Models

Input Parameter	Symbol	Unit	Deterministic Values	Uncertainty Analysis Distribution Parameters				Rationale / Basis
			Value	Lower Bound	Upper Bound	Mode	Distribution Type	
Air Speed	$RATE_{air\_speed}$	cm/s	10	1.3	202.2	–	Lognormal	See Section E.2.7
Container Loss Fraction	F_{loss_cont}	kg/kg	0.025	0.017	0.03	0.025	Triangular	See Section E.2.8
Saturation Factor Unloading	$F_{saturation\_unloading}$	unitless	0.5	0.5	1.45	0.5	Triangular	See Section E.2.10
Saturation Factor Loading	$F_{saturation\_loading}$	unitless	0.5	0.5	1.45	0.5	Triangular	See Section E.2.10
Import Container Volume	V_{import_cont}	gal/container	55	20	100	55	Triangular	See Section E.2.11
Small Container Volume	V_{prod_cont}	gal/container	5	5	20	5	Triangular	See Section E.2.11
Number of Sites	N_S	sites	2	–	–	–	–	"What-if" scenario input
Production Volume Assessed	PV_lb	lb/year	50,000	–	–	–	–	"What-if" scenario input
Production Volume	PV	kg/year	22,680	–	–	–	–	PV input converted to kilograms
Import Concentration	$F_{1,1-DCA\_import}$	kg/kg	1.0	–	–	–	–	Assumed pure 1,1-dichloroethane repackaged
Temperature	T	Kelvin	298	–	–	–	–	Process parameter
Pressure	P	torr	760	–	–	–	–	Process parameter
Gas Constant	R	L*torr/(mol*K)	62.36367	–	–	–	–	Universal constant
1,1-dichloroethane Vapor Pressure	VP	torr	227	–	–	–	–	Physical property
1,1-dichloroethane Density	$\rho_{1,1-DCA}$	kg/m^3	1,168	–	–	–	–	Physical property
1,1-dichloroethane Molecular Weight	$MW_{1,1-DCA}$	g/mol	98.95	–	–	–	–	Physical property
Fill Rate of Drum	$RATE_{fill\_drum}$	containers/hr	20	–	–	–	–	See Section E.2.12
Fill Rate of Small Container	$RATE_{fill\_small}$	containers/hr	60	–	–	–	–	See Section E.2.12

Source: EPA (2025) Risk Evaluation for 1,1-Dichloroethane Supplemental File: Supplemental Information on Environmental Release and Occupational Exposure Assessment

Anatomy of Exposure Assessment – Results

- Back to main section text.
- Results feed directly into risk assessment (in the main document)

Table 5-13. Summary of Modeled Worker Inhalation Exposures for Processing—Repackaging of 1,1-Dichloroethane for Laboratory Chemicals

Modeled Scenario	Exposure Concentration Type	High-End (ppm)	Central Tendency (ppm)	Data Quality Rating of Air Concentration Data
2 sites, 22680 kg/yr production volume	8-hr TWA Exposure Concentration	13	3.5	N/A: Modeled data
	AC based on 8-hr TWA	8.8	2.4	
	ADC based on 8-hr TWA	6.4	1.8	
	LADC based on 8-hr TWA	3.1	1.7E−01	
	$ADC_{int.}$ based on 8-hr TWA	1.6	6.8E−02	

- Results here exceed ECEL (0.044 ppm) by **80- to 300-fold**

Anatomy of Exposure Assessment – Uncertainty Assessment and Quality Assessment

- Find "weight of the scientific evidence conclusion(s)"

> EPA used EPA/OPPT models combined with Monte Carlo modeling to estimate 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 primary limitation is the uncertainty in the representativeness of values toward the true distribution of potential inhalation exposures. In addition, EPA lacks 1,1-dichloroethane facility production volume data; and therefore, throughput estimates are based on CDR reporting thresholds. Also, EPA could not estimate the number of exposure days per year associated with repackaging operations, so the exposure days per year estimates are based on an assumed site throughput of imported containers. Based on these strengths and limitations, EPA has concluded that the weight of scientific evidence for this assessment is slight to moderate and provides a plausible estimate of exposures.

- Use appendices and other supplemental documents to hunt down individual parameter selections for evaluation.

Input Parameter	Symbol	Unit	Deterministic Values	Uncertainty Analysis Distribution Parameters				Rationale / Basis
			Value	Lower Bound	Upper Bound	Mode	Distribution Type	
Diameter of Opening for Container Cleaning	$D_{opening\_container\_cleaning}$	cm	5.08	–	–	–	–	See Section E.2.9
Ventilation Rate	Q	ft³/min	3,000	500	10,000	3,000	Triangular	See Section E.2.13

E.2.13 Ventilation Rate

The CEB Manual (CEB, 1991) indicates general ventilation rates in industry range from 500 to 10,000 ft^3/min, with a typical value of 3,000 ft^3/min. The underlying distribution of this parameter is not known; therefore, EPA assigned a triangular distribution based on an estimated lower bound, upper bound, and mode of the parameter. EPA assumed the lower and upper bound using the industry range of 500 to 10,000 ft^3/min and the mode using the 3,000 ft^3/min typical value (CEB, 1991).

Source: EPA (2025) Risk Evaluation for 1,1-Dichloroethane Supplemental File: Supplemental Information on Environmental Release and Occupational Exposure Assessment

How Does EPA Select and Parameterize Models?

EPA – Exposure Models for TSCA

- No centralized rules or "complete" guidance specific to modeling.

Law

- 2024 TSCA Rule (40 CFR §702.39(d)) states that exposure modeling is a method that can be used, but provides no specific rules as to how to use models.

Guidelines

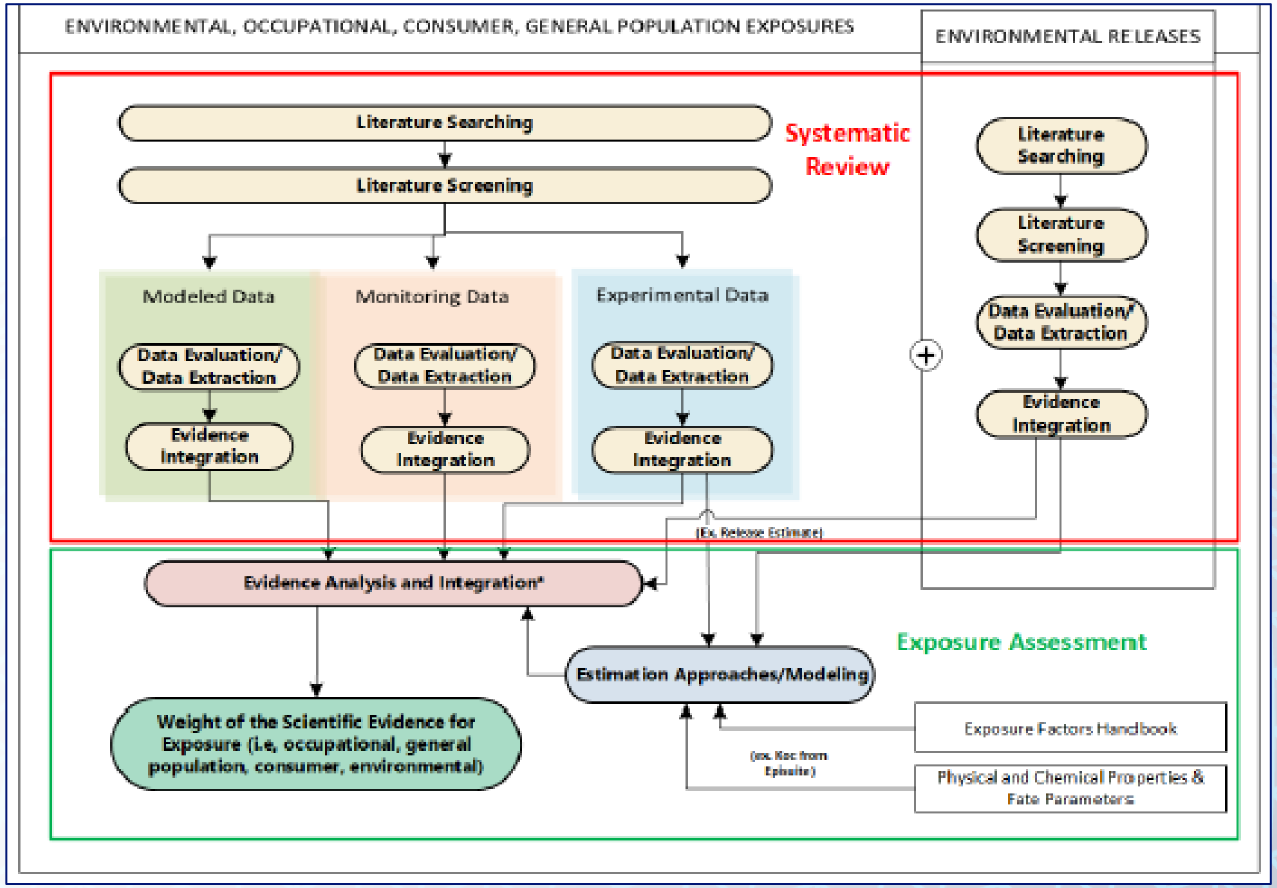
- 2021 DRAFT Systematic review protocol guidance for TSCA.
- Primary source of data assessment and data quality criteria.
- Provides the **method for evaluating selections of models and inputs**.

Sources of Guidance

- Varies and EPA can rely on any of their extensive modeling documentation, or other guidance.
- Existing guidance mostly focused on **non-occupational** populations.
- EPA 1992/2019 Exposure guidance, CEM manual, and EPA ChemSTEER 2015 guidance frequently cited.
- Web resources (2025)

Under TSCA Framework, EPA Uses Exposure Models for Two Reasons

- **Reason 1:** Monitoring data are unavailable. Modeling is used to create the primary exposure estimate
- **Reason 2:** Modeling is used as a confirmatory estimate to compare to available monitoring data
- *See Table 7-7 of draft TSCA systematic review protocol*



Source: EPA (2021). Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances. Version 1.0. A Generic TSCA Systematic Review Protocol with Chemical-Specific Methodologies. EPA Document #EPA-D-20-031. Washington, D.C.: U.S. Environmental Protection Agency (EPA).

Exposure Models in TSCA – Source of Hierarchy

Table 7-4: Models are **less preferred** than monitoring data under EPA TSCA Framework

Table 7-4. Hierarchy Guiding Integration of Occupational Exposure Data/Information

For occupational exposures, the generic hierarchy of preferences, listed from highest to lowest, is as follows (and may be modified based on the assessment)	
More Preferred	**Monitoring data:** Personal and directly applicable Area and directly applicable Personal and potentially applicable or similar Area and potentially applicable or similar
↑	**Modeling approaches:** Surrogate monitoring data: Modeling exposure for chemical "X" and condition of use "A" based on observed monitoring data for chemical "Y" and condition of use "A," assuming a known relationship (*e.g.*, a linear relationship) between observed exposure and physical property (*e.g.*, vapor pressure). Fundamental modeling approaches: Modeling exposure for chemical "X" for condition of use "A" based on fundamental mass transfer, thermodynamic, and kinetic phenomena for chemical "X" and data for condition of use "A" Fundamental modeling approaches (with surrogacy): A modeling approach following item 2.b, but using surrogate data in the model, such as data for condition of use "B" judged to be similar to condition of use "A" Statistical regression modeling approaches: Modeling exposure for chemical "X" in condition of use "A" using a statistical regression model developed based on: • Observed monitoring data for chemical "X" statistically correlated with observed data specific for condition of use "B" judged to be similar to condition of use "A" such that replacement of input values in the model can extrapolate exposure results to condition of use "A" • Observed monitoring data for chemical "Y" statistically correlated with physical properties and/or molecular structure such that an exposure prediction for chemical "X" can be made (*e.g.*, QSAR techniques)
Less Preferred	**Occupational exposure limits (OELs):** Company-specific OELs (for site-specific exposure assessments, *e.g.*, there is only one manufacturer who provides to EPA their internal OEL but does not provide monitoring data) OSHA PEL Voluntary limits (ACGIH TLV, NIOSH REL, Occupational Alliance for Risk Science [OARS] workplace environmental exposure level [WEEL; formerly by AIHA])

Source: EPA (2021). Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances. Version 1.0. A Generic TSCA Systematic Review Protocol with Chemical-Specific Methodologies. EPA Document #EPA-D-20-031. Washington, D.C.: U.S. Environmental Protection Agency (EPA).

EPA Stance on Modeling – Repeated in Recent Times

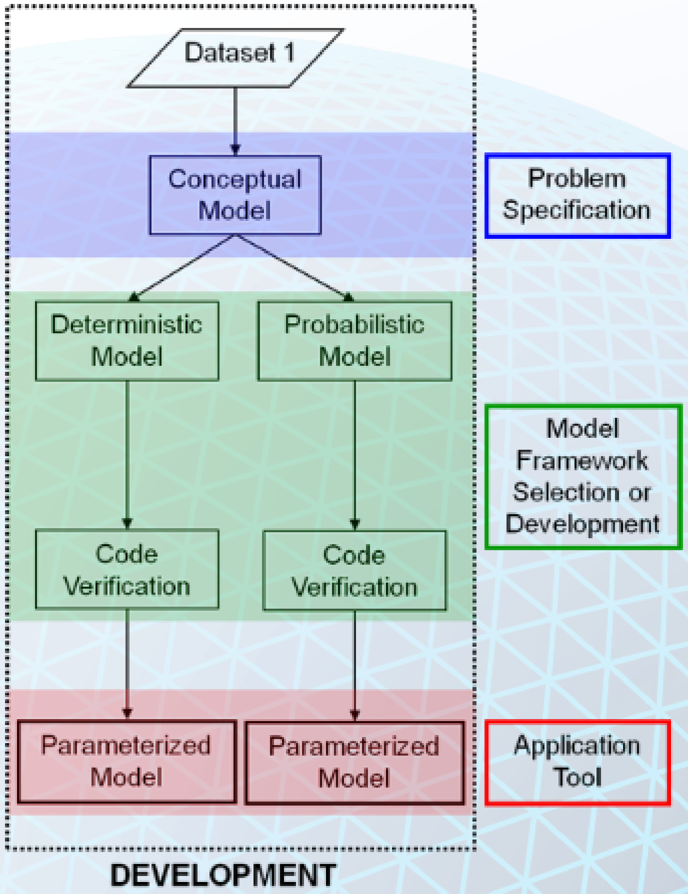
- In recent responses to public comments (Dec 2025), EPA consistently summarizes their position as follows:

*"**Monitoring data** are given the highest priority in EPA's hierarchy of approaches for occupational exposures as they are collected in actual workplace conditions. **Model results** are either used to help corroborate monitoring data, especially in cases where such data are limited, or to provide exposure estimates where monitoring data are not available."*

Source: EPA (2025) Risk Evaluation for 1,1-Dichloroethane Supplemental File: Supplemental Information on Environmental Release and Occupational Exposure Assessment

How to Select and Evaluate a Model?

- Varies by chemical!
- EPA 2019 is most recent EPA guideline on human exposure assessment modeling.
- FOR NON-OCCUPATIONAL POPULATIONS
  - Sections 6.2 and 6.3
  - Infrequently cited



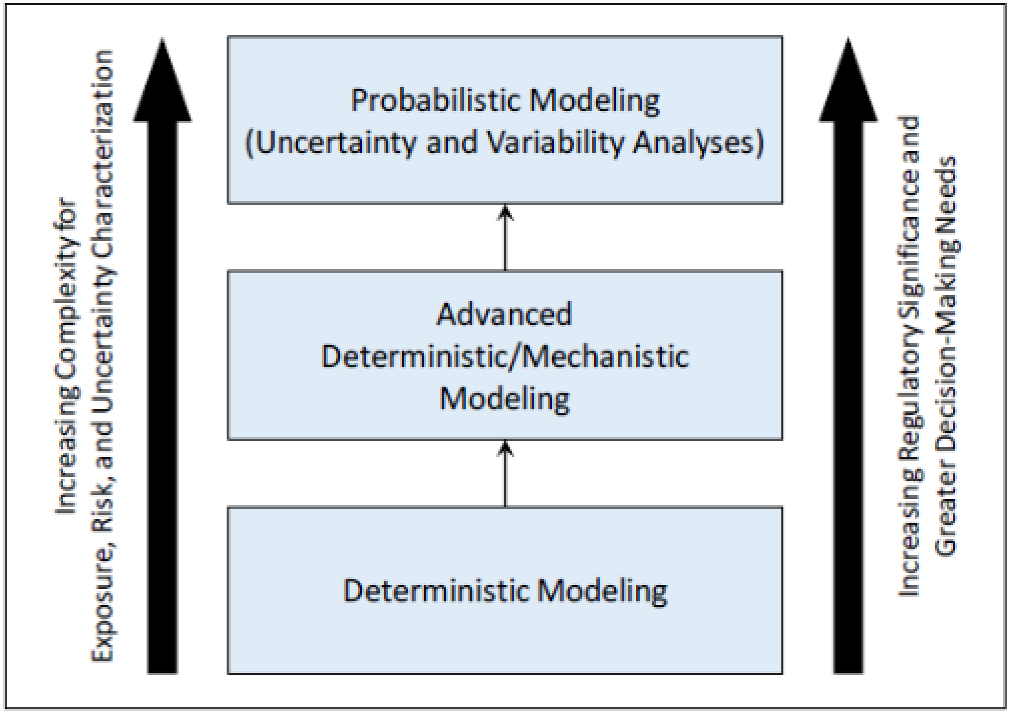
EPA (2019). Guidelines for Human Exposure Assessment. EPA Document #EPA/100/B-19/001. Washington, D.C.: U.S. Environmental Protection Agency (EPA).

EPA (2010). https://archive.epa.gov/epa/measurements-modeling/model-life-cycle-training-module.html

Tiered Approach?

- Tiered approach recommended in most recent EPA exposure assessment framework
- However, tiered approach generally not used in TSCA exposure assessments to date

Figure 6-1. A Tiered Approach for Modeling Analysis



Adapted from Özkaynak et al. (2011)

Source: EPA (2019). Guidelines for Human Exposure Assessment. EPA Document #EPA/100/B-19/001. Washington, D.C.: U.S. Environmental Protection Agency (EPA).

EPA TSCA Guidance – Model Evaluation Criteria

- Models are evaluated for selection according to six criteria
- See **Table Apx_M-12** in the 2021 TSCA Systematic Review Protocol

1. METHODOLOGY
2. GEOGRAPHIC SCOPE
3. APPLICABILITY
4. TEMPORALLY REPRESENTATIVE
5. METADATA COMPLETENESS
6. VARIABILITY AND UNCERTAINTY

Appendix M of 2021 Sys. Review Protocol – Model Eval. Criteria

- EPA uses a semiquantitative ranking method. High ranks are achieved as follows:

Methodology	Geographic Scope	Applicability	Temporally Representative	Metadata	Variability and Uncertainty
• The model is free of mathematical errors and is based on scientifically sound approaches or methods. Equations and choice of parameter values are appropriate for the model's application and use.	• The data are from the United States and are representative of the industry being evaluated.	• The model can be appropriately applied to an occupational scenario within the scope of the risk evaluation.	• The model is based on operations, equipment, and worker activities expected to be representative of current conditions. The model is based on data that are generally no more than 10 years old.	• Model approach, equations, and choice of parameter values are transparent and clear and can be evaluated. Rationale for selection of approach, equations, and parameter values is provided.	• The model characterizes variability and uncertainty in the results.

Appendix O of 2021 Sys. Review Protocol – Input Quality Criteria

- Very short – single page
- TSCA guidance focuses on general model evaluation, not specific inputs or parameters
  - Four questions asked by evaluator.
- No strict input-specific evaluation criteria used.
- As such, data quality review is up to individual assessment teams
- In practice, TSCA model inputs are evaluated in the data quality evaluation document, then model inputs are described in occ. exposure assessment

Appendix O DATA QUALITY CRITERIA OF EXPOSURE MODELS

When evaluating exposure assessment models to be used in draft risk evaluations, EPA will consult with EPA's *Guidance on the Development, Evaluation, and Application of Environmental Models* (U.S. EPA, 2009). The following information is excerpted from Chapter 4 of EPA (2009). Model evaluation provides information to help answer four main questions (Beck, 2002 as cited in U.S. EPA, 2009)

- How have the principles of sound science been addressed during model development?
- How is the choice of model supported by the quantity and quality of available data?
- How closely does the model approximate the real system of interest?
- How does the model perform the specified task while meeting the objectives set by quality assurance project planning?

*Some risk evaluations do not include the full, or any, input evaluation, input uncertainty assessment or data quality assessment (**example – TCEP**)*

Source: EPA (2021). Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances. Version 1.0. A Generic TSCA Systematic Review Protocol with Chemical-Specific Methodologies. EPA Document #EPA-D-20-031. Washington, D.C.: U.S. Environmental Protection Agency (EPA).

Input Quality Criteria – Quick Example

- From 1-BP Risk Evaluation, Brake Servicing OES

Table_Apx G-1. Summary of Parameter Values and Distributions Used in the Brake Servicing Near-Field/Far-Field Inhalation Exposure Model

Input Parameter	Symbol	Unit	Constant Model Parameter Values		Variable Model Parameter Values				Comments
			Value	Basis	Lower Bound	Upper Bound	Mode	Distribution Type	
Far-field volume	V_{FF}	m^3	—	—	206	70,679	3,769	Triangular	Distribution based on data collected by CARB (2000).
Air exchange rate	AER	hr^{-1}	—	—	1	20	3.5	Triangular	Demou et al. (2009) identifies typical AERs of 1 hr^{-1} and 3 to 20 hr^{-1} for occupational settings with and without mechanical ventilation systems, respectively. Hellweg et al. (2009) identifies average AERs for occupational settings utilizing mechanical ventilation systems to be between 3 and 20 hr^{-1}. Golsteijn, et al. (2014) indicates a characteristic AER of 4 hr^{-1}. Peer reviewers of EPA's 2013 TCE draft risk assessment commented that values around 2 to 5 hr^{-1} may be more likely (SCG, 2013), in agreement with Golsteijn et al. (2014). A triangular distribution is used with the mode equal to the midpoint of the range provided by the peer reviewer (3.5 is the midpoint of the range 2 to 5 hr^{-1}).

in OCC. EXP. ASSESSMENT

Source Citation:	Demou, E.,Hellweg, S.,Wilson, M. P.,Hammond, S. K.,McKone, T. E.. 2009. Evaluating indoor exposure modeling alternatives for LCA: A case study in the vehicle repair industry. Environmental Science and Technology.
Type of Data Source:	Occupational Exposure; Reports for Data or Information Other than Exposure or Release Data;
Hero ID	2591566

EXTRACTION

Parameter	Data
Life Cycle Stage:	Brake Servicing Model
Life Cycle Description (Subcategory of Use):	Brake Servicing Model
Route of Exposure:	Used to develop an inhalation exposure model.

EVALUATION

Domain	Metric		Rating	MWF*	Score	Comments
Domain 1: Reliability						
	Metric 1:	Methodology	High	× 1	1	Article is published in peer-reviewed scientific journal.
Domain 2: Representative						
	Metric 2:	Geographic Scope	Medium	× 1	2	Air ventilation rate data are at least in part based on European data (but may also include U.S. data).
	Metric 3:	Applicability	High	× 2	2	Ventilation rate data are applicable to the scope of the model.
	Metric 4:	Temporal Representativeness	Low	× 2	6	Paper published in 2009; data are based on 2006 and 1991 data. Data are in part more than than 20 years old (as measured from 2016).
	Metric 5:	Sample Size	Medium	× 1	2	Ventilation rate provided as range with uncertain distribution.
Domain 3: Accessibility/Clarity						
	Metric 6:	Metadata Completeness	Medium	× 1	2	Sources are cited, but does not provide details on how reported values were derived from cited sources.
Domain 4: Variability and Uncertainty						
	Metric 7:	Metadata Completeness	Medium	× 1	2	Variability of ventilation rates provided, but uncertainty not discussed.
Overall Quality Determination[1]			Medium		1.9	

in DATA QUALITY DOC

One More Resource – Updated Web Guidance

- Agency is Updating Web Guidance for Modeling under TSCA

Dec 2, 2025

Using Predictive Methods to Assess Exposure and Fate under TSCA

On this page:

- Information these models provide
- How and when to use the models
- Use considerations: monitoring data vs. models
- EPA's fate and exposure models and tools
- Fate and exposure guidance and publications

Nov 5, 2025

ChemSTEER-Chemical Screening Tool for Exposures and Environmental Releases

On this page:

- Key characteristics
- Hardware and software requirements
- Download and install instructions
- Terms and conditions of use
- Generic scenarios documents for Occupational exposure and release assessment

Jan 30, 2025

Approaches to Estimate Consumer Exposure under TSCA

On this page:

- Introduction to estimating consumer exposure
- Measured data
- Modeling approaches
  - Consumer Exposure Model (CEM)
  - Multi-chamber Concentration and Exposure Model (MCCEM)
  - IECCU- Simulation Program for Estimating Chemical Emissions from Sources and Related Changes to Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones
- Product/material specific exposure models
  - Wall Paint Exposure Model (WPEM)
  - Formaldehyde Indoor Air Model-Pressed Wood Products (FIAM-pwp)
- Other EPA applications
  - Source Ranking Database (SRD) for Indoor Air Pollutants
  - ADL Polymer Migration Estimation Model (AMEM)
- Terms and conditions of use
- EPA technical contact

Aug 26, 2025

Considerations When Evaluating Exposure Assessments

Considerations When Evaluating Exposure Assessments (PDF) provides guidance when evaluating the quality of modeling and monitoring data.

- Considerations When Evaluating Exposure Assessments (pdf) (55.81 KB)

May 16, 2025

Summary –How Does EPA Select and Parameterize Models for TSCA Assessments?

- No legal requirement other than modeling can be used.
- EPA 2021 Sys. Review Guidance:
  - Models selected using model evaluation criteria
  - Data inputs on best available science, short list of input quality criteria used
- Specific referenced guidance documents **vary as-needed by assessment.**
- Web Guidance Helpful
  - EPA 1992/2019 guidelines for exp. assess.
  - EPA 2015 ChemSTEER
  - CEM guidance for Consumers

Model Evaluation Criteria

- See EPA 2021 Appendix M

Input Quality Criteria

- See EPA 2021 Appendix O

Review and Analysis of EPA Exposure Modeling Assessments

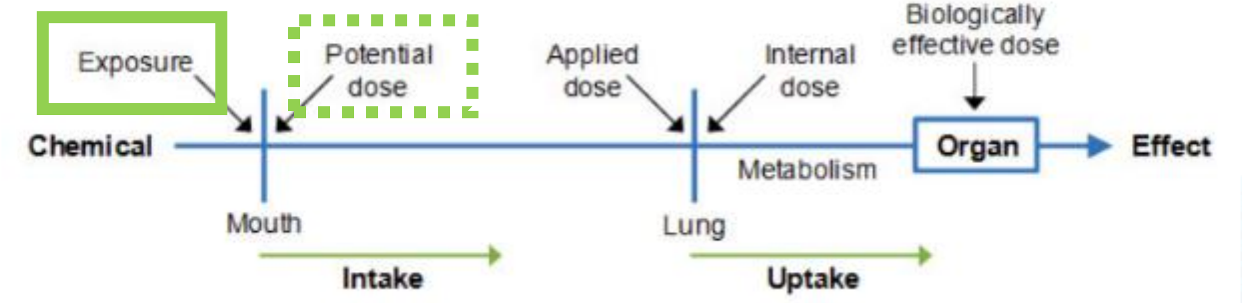
Defining Model Types

- Generation rate (mass/time) is often a key input to inhalation exposure models, and is typically determined using models.
- Exposure models calculate a concentration in air (mass/time) or dose rate (mass/time).
- This presentation covers **exposure models only**.

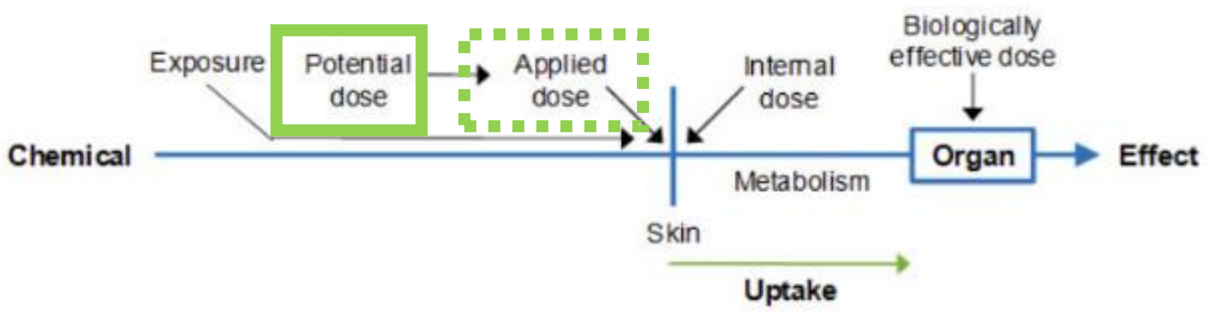
For more information on generation rate models, see **AIHce Exp 2020** presentation titled "Reliable Mass Balance Models in the Current U.S. Regulatory Environment and Application of Engineering Principles to Improve Generation Rate Estimations for a treatment of generation rate models."

Defining Model Types

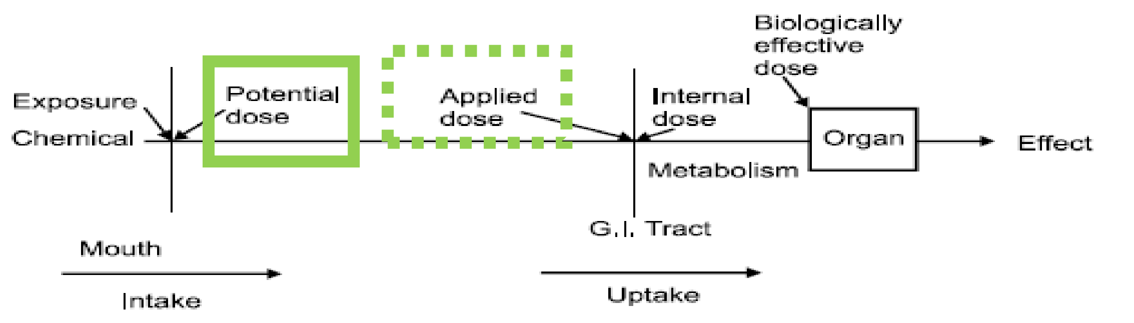
INHALATION ROUTE



DERMAL ROUTE



INGESTION ROUTE



OUTCOME OF EXPOSURE MODELING:

Mass concentration of the chemical in the air (mg/m^3)

Amount of contaminant available to be inhaled (i.e., amount that gets in the mouth or nose), not all of which is actually absorbed, per day

Dermal Potential Dose Rate (mg/day)

Amount of contaminant applied to skin, not all of which is actually absorbed, per day

Ingestion Dose Rate (mg/day)

Amount of contaminant applied to mouth, not all of which is actually absorbed, per day

Source: U.S. EPA. (1992). Guidelines for Exposure Assessment. (EPA/600/Z-92/001). Washington, DC.

Defining a Distinct Model: Example

Exposure Route

Mathematical Basis

Dermal

Direct Dermal Contact with Liquids:

$$APDR = S \times Q_u \times Y_{derm} \times FT$$

Flux-Based Approach:

$$APDR = (J \times S \times t_{abs}) / PF$$

Summary of Occupational Models: First 23 Risk Evaluations

Chemical	OESs	OESs that Use Inhalation Modeling	OES that Use Dermal Modeling	Occupational Model Types Used
Methylene Chloride	21	4	21	Two-Zone, DEVL
1-Bromopropane	17	12	16	Mass Balance, Two-Zone, DEVL
Cyclic Aliphatic Bromide Cluster (HBCD)	13	1	6	PNOR, Direct Dermal Contact with Container Surfaces, Direct Dermal Contact with Solids,
Carbon Tetrachloride	9	1	9	Mass Balance, DEVL
Trichloroethylene (TCE)	18	8	18	Two-Zone, DEVL
Asbestos (Part 1: Chrysotile)	7	0	0	-
1,4-Dioxane	20	9	20	Mass Balance, PNOR, DEVL
N-Methylpyrrolidone (NMP)	17	10	17	Mass Balance, RIVM Annex XV, Two-Zone, UV Roll Coating, Partial Exposure Model as Intermediate to PBPK
Perchloroethylene (PCE)	21	6	21	Mass Balance, Multi-Zone, Two-Zone, DEVL
C.I. Pigment Violet 29	4	0	0	-
Tris(2-Chloroethyl) Phosphate (TCEP)	10	6	8	Mass Balance, DEVL, Direct Dermal Contact with Container Surfaces
Asbestos (Part 2: Legacy Uses)	5	0	0	-
Formaldehyde	33	5	30	Mass Balance, PNOR, Direct Dermal Contact with Liquids
Diisodecyl phthalate (DIDP)	17	12	17	Automotive Refinishing Spray Coating Mist, PNOR, Two-Zone, Flux-Based Approach to Dermal Exposure
Diisononyl phthalate (DINP)	16	11	16	Automotive Refinishing Spray Coating Mist, Mass Balance, PNOR, Flux-Based Approach to Dermal Exposure
1,1-Dichloroethane	6	1	6	Mass Balance, DEVL
1,3-Butadiene	11	0	0	-
Dicyclohexyl phthalate (DCHP)	15	15	15	PNOR, Flux-Based Approach to Dermal Exposure
Diethylhexyl Phthalate (DEHP)	16	4	16	Automotive Refinishing Spray Coating Mist, PNOR, Flux-Based Approach to Dermal Exposure
Dibutyl Phthalate (DBP)	15	8	15	Two-Zone, PNOR, Flux-Based Approach to Dermal Exposure
Diisobutyl Phthalate (DIBP)	19	19	19	Mass Balance, Automotive Refinishing Spray Coating Mist, PNOR, Flux-Based Approach to Dermal Exposure
Butyl Benzyl Phthalate (BBP)	16	8	16	PNOR, Flux-Based Approach to Dermal Exposure
Octamethylcyclotetrasiloxane (D4)	16	6	16	Mass Balance, Automotive Refinishing Spray Coating Mist, Two-Zone, DEVL
TOTAL TO DATE (Oct 2025)	**342**	**146**	**302**	**-**

Summary of Inhalation Models - Occupational

Inhalation Model	Number of OESs in which Model is Used
EPA Mass Balance Inhalation Model (one-zone)	**55**
OSHA PNOR Model	**54**
Two-Zone Model (NF/FF)	**25**
Automotive Refinishing Spray Coating Mist Inhalation Model	10
RIVM Annex XV Proposal for a Restriction - NMP Report Model Basis	3
Dry Cleaning Multi-Zone Inhalation Model	2
IECCU Model	1
UV Roll Coating Model	1

Sums do not directly align with overview because some OESs use two modeling approaches.

Summary of Dermal Models - Occupational

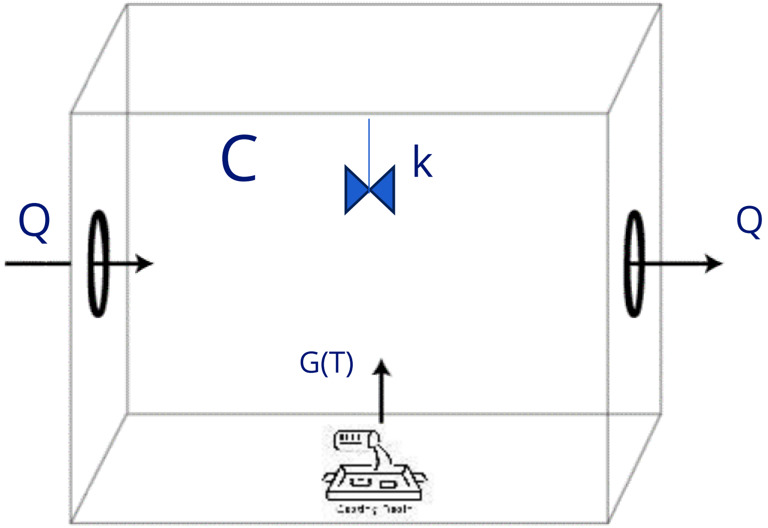
Dermal Model	Number of OESs in which Model is Used
Dermal Exposure to Volatile Liquids (DEVL) Model	**164**
Flux-Based Approach to Dermal Exposure Estimate of APDR	**114**
Partial Exposure Model as Intermediate to PBPK Model	17
Direct Dermal Contact with Solids Model	6
Direct Dermal Contact with Container Surfaces (Solids) Model	2

Analysis of Model Applicability

- Generally highly scenario-specific.
- Slowly working through input evaluations (**work in progress**)
- NO validations. Rather, checking to see if model descriptions and input selections are aligned with purpose of exposure assessment and stated scope of OES/CES.

What follows are profiles and examples for the most frequently used occupational models highlighted in the tables above

EPA Mass Balance Inhalation Model: Profile



EPA MASS BALANCE MODEL AS USED FOR INCORPORATION INTO ARTICLES OES in TCEP RISK EVALUATION

Formula: $C = \frac{170{,}000 \times T \times G}{Q \times k \times MW}\ (unsaturated)$

Source: Figure is presenter's original with imagery available on istock, based on narrative in EPA risk evaluation cited.
EPA (2015). ChemSTEER User Guide.

- Deemed most appropriate model by EPA for OESs where there is a clearly definable emission-factor based emission rate, OR the worker is working with a source of vapor at moderate distance from the source or in a dispersive manner.
- Used by EPA for volatile solvents, semi-volatiles, and particle-forming chemicals
- Model assumes exposure is in a 'single box' of unspecified volume and uses ideal gas approach
- Also includes "saturated vapor" equation
- Often uses ChemSTEER default values for parameters

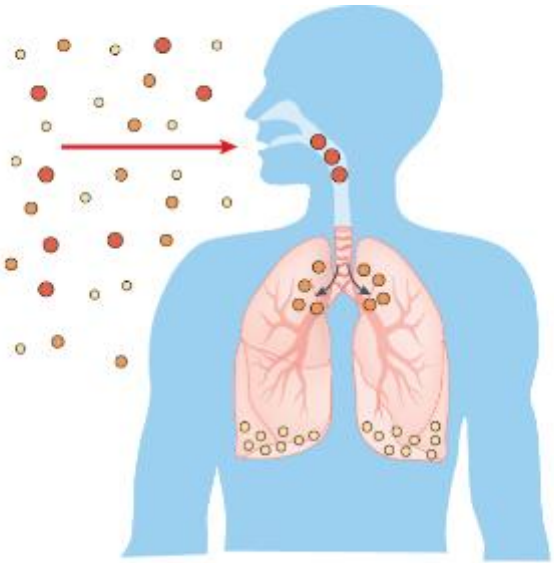
Parameter	Unit	EPA Input Research Basis
Vapor Generation Rate (G)	g/s	Modeled using an associated vapor generation approach, EPA/OPPT AP-42 Loading, Mass Transfer Coefficient, Penetration Model or other ChemSTEER generation rate models.
Temperature (T)	K	Default is 298 K from ChemSTEER manual, may modify depending on data submissions for TSCA.
Molecular Weight of Chemical (MW)	g/mol	Literature review
Ventilation Rate (Q)	ft^3/min	Defaults from ChemSTEER manual
Mixing Factor (k)	Dimensionless	0 < k ≤ 1; Defaults from ChemSTEER manual
Vapor Pressure of the Chemical (VP)	torr	Literature review or modeled using peer-reviewed model. Vapor correction of 0 ≤ X ≤ 1 may be applied
Exposure Duration (ED)	h/day	Default is 8 h/day from ChemSTEER manual

EPA Mass Balance Inhalation Model: Evaluation

Strengths and Limitations

- Better suited than higher-tier models for broad OES characterization
- Simple to use if emission factor is available
- Likely to **underestimate** exposures close to the source
- Concentration result is highly sensitive to emission-factor based generation rates and uncertainty rating can be high
- Not very customizable/tunable to specific scenarios beyond the selection of generation rate

OSHA PNOR Model: Profile



OSHA PNOR MODEL IS TECHNICALLY A MASS DOSE DATA-BASED MODEL, BUT ESTIMATION OF EXPOSURE COMPONENT (C) IS IMPORTANT

Formula: $EXP[\frac{mg}{day}] = C_{PNOR} \times R \times ED \times F_{chem}$

- Deemed most appropriate model by EPA for OESs involving handling of solid/powdered materials containing the chemical
- Model assumes exposure level no greater than the OSHA PEL for total and respirable particulates not otherwise regulated (PNOR), and uses OSHA inhalation monitoring data for various industries to define lower portion of concentration range (OSHA CEHD, 2020)
- Model allows lookup by facility NAICS code

Parameter	Unit	EPA Input Research Basis
Concentration of Particulate in Worker Breathing Zone (C_{PNOR})	mg/m^3	Default for total particulate: 2.1 mg/m^3 (central tendency) and 15 mg/m^3 (high-end) for unknown industry group; Default for respirable particulate is 0.28 mg/m^3 (central tendency) and 4.9 mg/m^3 (high-end) for unknown industry group (original data from OSHA CEHD, 2020). May supplement with use-specific data in TSCA information submission.
Typical Worker Breathing Rate (R)	m^3/hour	Default is 1.25 m^3/h (CEB, 1991)
Exposure Duration (ED)	h/day	Default is 8 h/day
Mass Fraction of Chemical in the Solid/Powdered Mixture (F_{chem})	kg chemical/kg mixture	TSCA information submissions or literature review

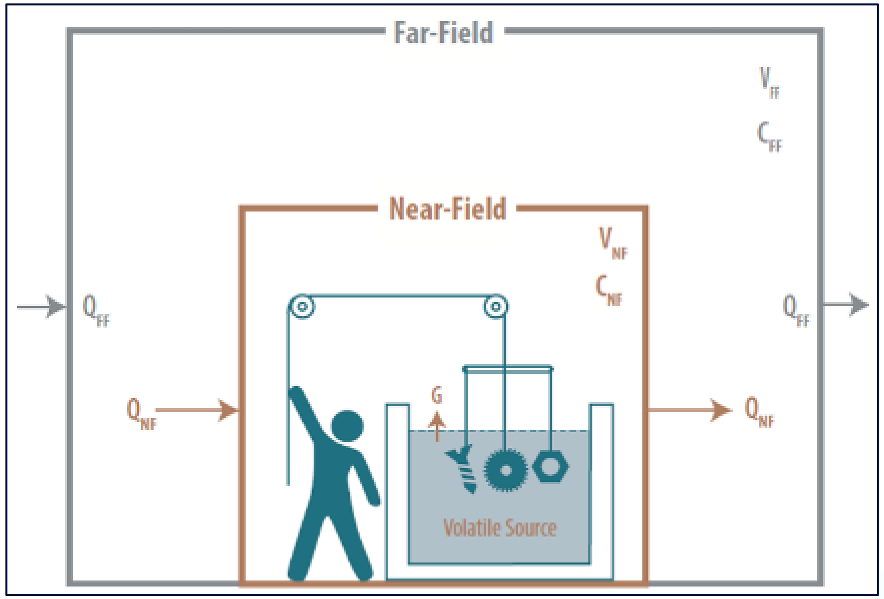
Sources: Morawska, L., & Buonanno, G. (2021). The physics of particle formation and deposition during breathing. *Nature Reviews Physics*, *3*(5), 300-301.
EPA (2015). ChemSTEER User Guide.

OSHA PNOR Model: Evaluation of Uses

Strengths and Limitations

- Simple model for particles
- Often includes large dataset from OSHA CEHD as basis
- Tends to **overestimate** particle exposures
  - OSHA CEHD are high-end inspection data
- Exposure concentrations are not chemical-specific and have to be adjusted by a fraction that is typically estimated by EPA, significant uncertainty!
- Simple NAICS-based lookup tends to blend myriad SEGs within industry, can **overestimate** some SEGs by orders of magnitude
- Exposure concentration is a blended estimate from existing data, not a true first-principles model.

Two-Zone Model: Profile



TWO-ZONE MODEL AS USED FOR COLD-CLEANING OES in PCE RISK EVALUATION

Formula : *See Next Slide*

- Deemed most appropriate model by EPA for OESs where a vapor generation source located inside the near-field diffuses into a larger work environment
- Mostly used by EPA for volatile solvents
- EPA puts populations in each zone (NF= workers, FF = ONUs)
- Probabilistic model with input distributions used for most OESs

Parameter	Unit	EPA Input Research Basis
Generation Rate (G)	mg/min	May be its own model; Emission rate reports; TSCA information submissions; IH and general literature; product manufacturing and/or testing data
Near-Field Shape and Volume (V_N)	ft^3	Assumption/estimate (most); IH literature (minority)
Near-Field Volume (V_F)	ft^3	Literature or available studies on specific type of operations in OES
Indoor Air Speed (s)	ft/min	IH literature (many OESs use Baldwin 1998)
Air Exchange Rate (AER)	h^{-1}	TSCA information submissions; IH literature
Exposure Duration (ED) / Averaging Time (t_{avg})	h	TSCA information submissions or assumption/estimate
Process Operating Duration (OH)	h/day	NEI inventory and/or TSCA information submissions

Source: EPA (2020). Final Risk Evaluation for Perchloroethylene Supplemental File: Releases and Occupational Exposure Assessment CASRN: 127-18-4. December 2020.

Two-Zone Model: Profile

$$V_N \frac{dC_N}{dt} = G + \beta \times C_F - \beta \times C_N \qquad V_F \frac{dC_F}{dt} = \beta \times C_N - \beta \times C_F - Q \times C_F$$

$Note$: β is interzonal air flow rate – calculated as a function of NF geometry and indoor air speed. Note Q is room air flow rate – calculated as a function of AER.

Example solution for NF (FF equation also used by EPA):

$$C_N(t) = \frac{G}{\frac{\beta}{\beta + Q} \times Q} + G \times \left(\frac{\beta \times Q + \lambda_2 \times V_N(\beta + Q)}{\beta \times Q \times V_N(\lambda_1 - \lambda_2)}\right) \times e^{\lambda_1 t} - G \times \left(\frac{\beta \times Q + \lambda_1 \times V_N(\beta + Q)}{\beta \times Q \times V_N(\lambda_1 - \lambda_2)}\right) \times e^{\lambda_2 t}$$

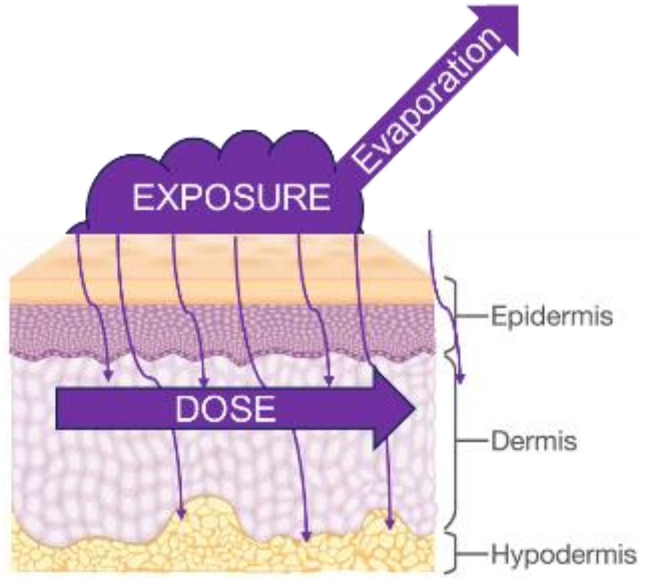
$$\lambda_1 = 0.5 \times \left(-\left(\frac{\beta \times V_F + V_N(\beta + Q)}{V_N \times V_F}\right) + \sqrt{\left(\frac{\beta \times V_F + V_N(\beta + Q)}{V_N \times V_F}\right)^2 - 4 \times \left(\frac{\beta \times Q}{V_N \times V_F}\right)}\right) \qquad \lambda_2 = 0.5 \times \left(-\left(\frac{\beta \times V_F + V_N(\beta + Q)}{V_N \times V_F}\right) - \sqrt{\left(\frac{\beta \times V_F + V_N(\beta + Q)}{V_N \times V_F}\right)^2 - 4 \times \left(\frac{\beta \times Q}{V_N \times V_F}\right)}\right)$$

Two-Zone Model: Evaluation

Strengths and Limitations

- Can closely approximate reality with well-researched inputs
- Can overestimate exposures in NF, particularly with compounding probabilistic input distributions containing high gen rate, low s
- Likely to **underestimate** some exposures in FF
- Highly customizable, but each input is highly research-intensive
- **Compounding conservatism** in input distributions is likely
- Difficult to achieve accurate results for broad OESs

EPA DEVL Model: Profile



EPA Dermal Exposures to Volatile Liquids (DEVL) Model

- Screening model
- Used by EPA for OESs involving direct handling of volatile or semi-volatile chemicals
- Model is similar to EPA ChemSTEER default model for dermal contact with liquids but incorporates a "fraction absorbed" parameter to account for evaporation

Formula:

$$APDR = S \times Q_U \times f_{abs} \times Y_{derm} \times FT$$

Parameter	Unit	EPA Input Research Basis
Surface Area (S)	cm^2	EPA Exposure Factors Handbook or estimate
Dermal Loading (Q_u)	mg/cm^2/ event	EPA memorandum: Updating CEB's Method for Screening-Level Assessments of Dermal Exposure; EPA technical report: A Laboratory Method to Determine the Retention of Liquids on the Surface of the Hands
Fractional Absorption (f_{abs})	unitless	Assumption/estimate from literature, experimental data, or surrogate chemical
Weight Fraction of Chemical (Y_{derm})	unitless	TSCA information submissions or assumption/estimate
Frequency of Events (FT)	events/day	Assumption/estimate

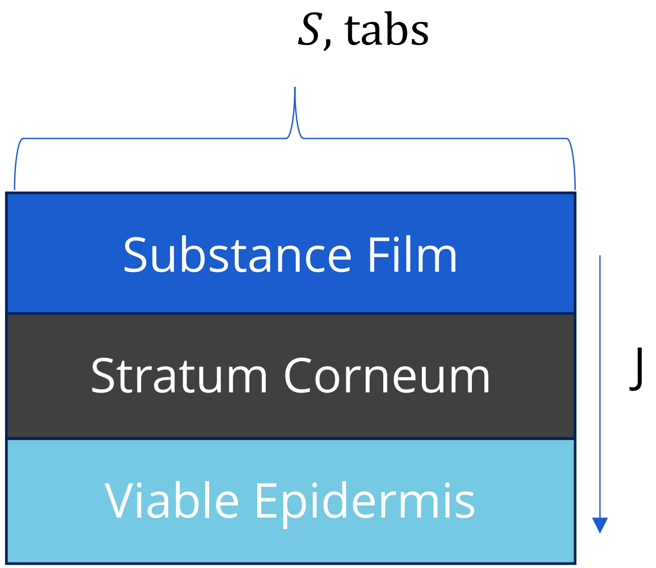
Source for image: Partial Image adapted from: https://www.proprofs.com/quiz-school/lesson/nzewnjuz0dqb
Source: EPA (2020). Final Risk Evaluation for Perchloroethylene Supplemental File: Releases and Occupational Exposure Assessment CASRN: 127-18-4. December 2020.

EPA DEVL Model: Evaluation

Strengths and Limitations

- Simple model for dermal exposures with limited parameters, most of which are defaults or easily defined
- Result extremely sensitive to f_{abs}
  - Model only includes fixed-value f_{abs}, and does not account for variable f_{abs} based on skin and loading conditions (including occlusion)
- High error when used for semi-volatile chemicals (like TCEP)

EPA Flux-Based Approach: Profile



EPA Steady-State Flux Model

- Used by EPA for OESs involving direct handling of solid/powdered materials containing the chemical
- Estimates acute potential dose rate (APDR) from occupational dermal exposures to chemicals that may be flux-limited
- Considers absorptive flux associated with chemicals as liquids or in formulations, or as solids or in articles
- Steady-state transport is assumed

Parameter	Unit	EPA Input Research Basis
Absorptive Flux (J)	mg/cm^2/h	IH literature and general literature; estimates based on surrogates. Steady-state assumption
Surface Area (S)	cm^2	EPA Exposure Factors Handbook or estimate
Absorption Time (t_{abs})	h	Assumption/estimate; assumed through entirety of 8-hour work shift for phthalates
Glove Protection Factor (PF)	unitless	ECETOC TRA model (PF = 5, 10, or 20); IH and general literature

Formula: $APDR = (J \times S \times t_{abs})/PF$

Source: Image is presenter's original
EPA (2024) Risk Evaluation for Diisodecyl Phthalate (DIDP). CASRNs: 26761-40-0 and 68515-49-1. EPA-740-D-24-007. Washington, DC: Office of Chemical Safety and Pollution Prevention, Office of Pollution Prevention and Toxics, USEPA.

EPA Flux-Based Approach: Evaluation

Strengths and Limitations

- Simple model for dermal exposures with limited parameters
- Flux can be difficult to define well, especially for mixtures and articles, and the model result is **extremely** sensitive to choice of flux as an input
- Model is only steady-state (screening) and cannot account for any differences in flux because of loading, depletion, etc.

Summary Of Consumer Models: First 23 Risk Evaluations

Chemical	CESs	CESs that Use Inhalation Modeling	CESs that Use Dermal Modeling	CESs that Use Ingestion/Oral Modeling	Model Types Used
Methylene Chloride	15	15	15	0	CEM Building Room Model; CEM Dermal Fraction Absorbed Model; CEM Permeability Model
1-Bromopropane	9	9	8	0	CEM Two-Zone Model; MCCEM; IECCU; CEM Dermal Fraction Absorbed Model; CEM…
Cyclic Aliphatic Bromide Cluster (HBCD)	3	2	0	3	IECCU; Ingestion ADD Approach
Carbon Tetrachloride	0	0	0	0	-
Trichloroethylene (TCE)	25	25	25	0	CEM Building Room Model; CEM Dermal Fraction Absorbed Model; CEM Permeability Model
Asbestos (Part 1: Chrysotile)	2	0	0	0	-
1,4-Dioxane	8	8	8	0	CEM Two-Zone Model; MCCEM; CEM Dermal Fraction Absorbed Model; CEM Permeability…
N-Methylpyrrolidone (NMP)	8	8	0	8	CEM (unspecified/unclear); MCCEM
Perchloroethylene (PCE)	17	17	17	0	CEM Two-Zone Model; MCCEM; CEM Dermal Fraction Absorbed Model; CEM Permeability…
C.I. Pigment Violet 29	1	0	0	0	-
Tris(2-Chloroethyl) Phosphate (TCEP)	9	9	9	9	CEM One-Zone Model; CEM Dermal Dose Vapor Absorption Article Model; CEM Dermal…
Asbestos (Part 2: Legacy Uses)	14	0	0	0	-
Formaldehyde	27	27	20	0	CEM (unspecified/unclear); EPA Thin Film Model
Diisodecyl phthalate (DIDP)	25	16	25	9	CEM Two-Zone Model; CEM One-Zone Model; CEM (unspecified/unclear); Consumer…
Diisononyl phthalate (DINP)	35	22	35	14	CEM Building Room Model; CEM Two-Zone Model; CEM One-Zone Model; Consumer…
1,1-Dichloroethane	0	0	0	0	-
1,3-Butadiene	0	0	0	0	-
Dicyclohexyl phthalate (DCHP)	6	2	6	1	CEM Two-Zone Model; CEM One-Zone Model; Consumer Article Flux-Based Approach…
Diethylhexyl Phthalate (DEHP)	28	12	28	12	CEM Building Room Model; CEM Two-Zone Model; CEM One-Zone Model; EPA 2024 Tire…
Dibutyl Phthalate (DBP)	27	16	27	10	CEM Building Room Model; CEM Two-Zone Model; CEM One-Zone Model; EPA 2024 Tire…
Diisobutyl Phthalate (DIBP)	21	12	21	10	CEM Two-Zone Model; CEM One-Zone Model; EPA 2024 Tire Rubber Crumb Semi-Emp…
Butyl Benzyl Phthalate (BBP)	18	10	18	7	CEM Two-Zone Model; CEM One-Zone Model; EPA 2024 Tire Rubber Crumb Semi-Emp…
Octamethylcyclotetrasiloxane (D4)	19	13	17	3	CEM Building Room Model; CEM Two-Zone Model; IECCU; Mass Balance Inhalation…
TOTAL TO DATE (Oct 2025)	317	223	279	86	

Summary of Inhalation Models - Consumer

Inhalation Model	Number of OESs in which Model is Used
CEM (Two-Zone Model, various gen types) (P_INH2)	**68**
CEM (Building Room Model, various gen types) (P_INH1)	**63**
CEM (One-Zone Model, Room Emission) (A_INH1)	**58**
CEM (unspecified module)	**40**
EPA Mass Balance Inhalation Model (one-zone)	4
EPA 2024 Tire Rubber Crumb Semi-Empirical Model	4
IECCU Model	4
MCCEM	4

Sums do not directly align with overview because some OESs use two to four modeling approaches.

Summary of Dermal Models - Consumer

Dermal Model	Number of OESs in which Model is Used
Consumer Article Flux-Based Approach to Dermal Exposure	**156**
CEM Dermal Fraction Absorbed Model (P_DER2a)	**37**
CEM Dermal Permeability Model (P_DER2b)	**35**
EPA Thin Film Model	20
Dermal Exposure to Volatile Liquids (DEVL) Model	11
CEM Dermal Dose Skin Contact Article Model (A_DER2)	9
CEM Dermal Dose Vapor Absorption Article Model (A_DER1)	8
CEM Dermal Dose Skin Contact with Dust Model (A_DER3)	8
Diffusion-Based Permeation Model (Direct contact silanes)	6
EPA 2024 Tire Rubber Crumb Semi-Empirical Model	4

Sums do not directly align with overview because some OESs use two to three modeling approaches.

Summary of Ingestion (Oral) Models - Consumer

Ingestion Model	Number of OESs in which Model is Used
CEM Ingestion after Inhalation (Article) (A_ING1)	**58**
CEM Ingestion of Incidental Dust (A_ING3)	**58**
CEM Ingestion of Article Mouthed (A_ING2)	**38**
EPA 2024 Tire Rubber Crumb Semi-Empirical Model	4
Regression-based Chemical Migration Model	3
IECCU Model (Ingestion of Airborne Particles)	2
Other	2
CEM (Unspecified Module)	1

Sums do not directly align with overview because some OESs use two to three modeling approaches.

EPA CEM: Workhorse of Consumer Modeling Assessments

2. Summary of Models within CEM

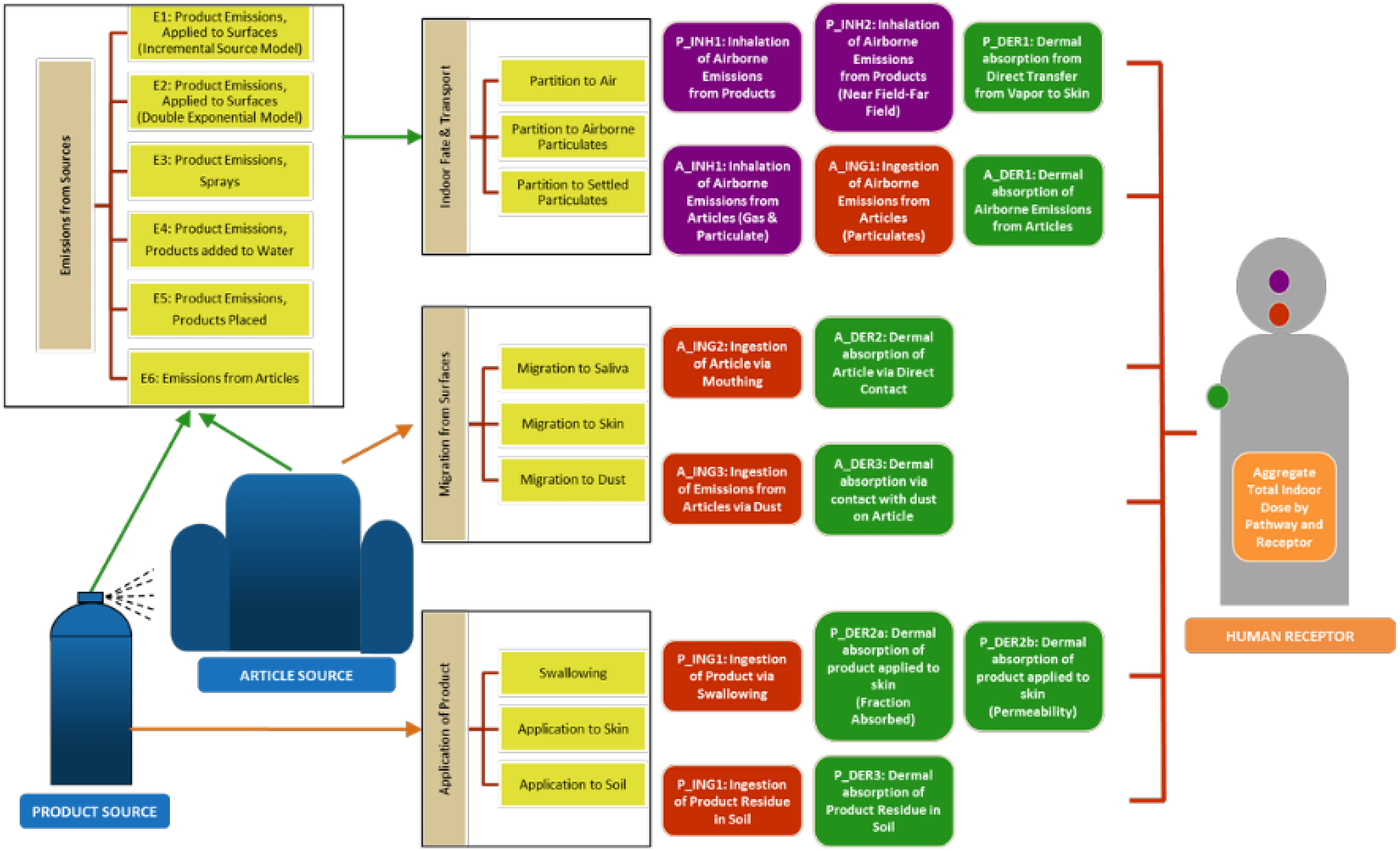


Figure 1. Schematic relationship showing exposure models included in CEM

Source: ICF (2023) Consumer Exposure Model 3.2 User Guide. Oct 2023.

Flux-Based Approach for Dermal (Consumer)

- Used by EPA for phthalate risk evaluations
- Flux-limited absorption calculated using simple algebra (duration, frequency and flux)
- Empirical estimates for flux.
- Steady-state transport is assumed

2.3.2 Flux-Limited Dermal Absorption for Liquids

Using the Dupont (2006b) estimate of 0.165 mg on a 0.64-cm^2 area of BBP (0.258 mg/cm^2) over an 8-hour period, the steady-state flux of neat BBP is estimated as 3.22×10^{-2} $mg/cm^2/h$. EPA assumed the steady-state flux is equal to the average flux.

2.3.3 Flux-Limited Dermal Absorption for Solids

Using the Dupont (2006a) estimate of 0.00057 mg over a 0.64 cm^2 area of BBP (0.0008906 mg/cm^2 of BBP) over an 8-hour period, the steady-state flux of neat BBP is estimated as 1.113×10^{-4} $mg/cm^2/h$. In the experimental set up, Dupont et al. (2006a) collected receptor fluid to ensure the concentration of the BBP in the receptor fluid did not exceed 10 percent of its maximum solubility at 0.5, 1, 4, and 8 hours but the absorption experiment was for 8 hours. EPA estimated the steady-state flux and assumed it is equal to the average flux.

Table 2-8. Key Parameters Used in Dermal Models

Product	Scenario	Duration of Contact (minutes)	Chronic Frequency of Contact ($year^{-1}$)	Acute Frequency of Contact (day^{-1})	Dermal Flux ($mg/cm^2/hour$) [a]	Contact Area
Adult toys	High	60	365	1	1.11E−04	Inside of 2 hands (palms, fingers)
	Medium	30			1.11E−04	
	Low	15			1.11E−04	
Car mats	High	60	52	1	1.11E−04	10% of hands (some fingers)
	Medium	30			1.11E−04	
	Low	15			1.11E−04	
Children's toys (legacy)	High	137	365	1	1.11E−04	Inside of 2 hands (palms, fingers)
	Medium	88			1.11E−04	
	Low	24			1.11E−04	

Source: EPA (2025) Consumer and Indoor Exposure Assessment for Butyl Benzyl Phthalate (BBP) Technical Support Document for the Risk Evaluation CASRN 85-68-7.

CEM Analysis (Work In Progress)

Unlike Occupational models, EPA's documentation of CEM inputs is weaker and it is difficult to track down individual inputs.

- Some trial and error with model required to recreate what EPA did.
- Often, consumer exposure scenarios are grouped in the discussion but separate sets of inputs were used.

Overall Analysis of Modeling Methods to Date

- Some important strengths:
  1. Model formulations generally grounded in sound scientific principles.
  2. Inputs are generally well-defined and easy to figure out occupational inputs and sources, with some exceptions.
  3. Methods are relatively straightforward to recreate.
  4. Models generally fit the description of the tasks in the problem statement for each OES (in occupational scenarios).
  5. Less complex models are overestimating (a strength for purposes of screening regulatory risk evaluation).
  6. Modeling allows for, and is the best approach to, assessment of key OESs with no monitoring data!

Overall Analysis of Modeling Methods to Date

Potential Shortcomings	Explanation
Lack of Tiered Approach	Conservatively high results from screening models are sometimes used as the final exposure assessment for UNREASONABLE risk categories, without further work to make the modeling approach more realistic.
Data Acquisition & Selection	Nontransparent literature integration and data selection criteria (the question of WHY the specific study was used for inputs selected is often unanswered).
Occupational Modeling Practices – OES vs SEG	Aggregation of tasks and selection of a “sentinel” task and assumptions that obscure real task-specific exposures and apply exposures for the highest-exposed SEG to the entire OES.
Methodological Protocols	Absence of clearly prespecified exposure modeling procedures to follow for each route. As discussed, this is mostly up to the specific group performing the assessment.
No Post-Control Modeling	Engineering and administrative controls are sometimes noted but not included in the modeling assessment. For example, engineering control use can be included in an input distribution.
Lack of Fit with Consumer Scenarios	Compounding assumptions and significant lack of information about product/articles use creates a lack-of-fit of the model for many consumer exposure scenarios (CESs).

Strengths and Limitations of TSCA Modeling Framework

STRENGTHS

- Most frequently used models have limited complexity
- Framework can evaluate entire OES with one model
- General reliance on peer-reviewed or well-cited regulatory approaches
- When used, probabilistic methods enhance validity of result

LIMITATIONS

- Substantial subjectivity in input selection
- No tiered approach
- Models tend to be overestimating/screening in many cases without further scoping
- Dermal models are screening-level and extremely sensitive to a parameter that is difficult to define

Wrap Up:

1. Modeling is a critical tool for EPA in their pursuit of high-quality risk evaluations.
2. Modeling is applied to exposure scenarios.
3. EPA is using models for the majority of their exposure assessments.
4. Substantial research goes into inputs and parameters but ultimately EPA is not using tiering, not considering controls, and not “scoping in” to accurately describe individual exposure scenarios.
5. Open question… how conservative is too conservative?

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Thank you!

- Thank you to the meeting organizers and thank you all for attending this session.
- Questions and discussion.
- Enjoy the meeting!