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Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency

Draft Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane

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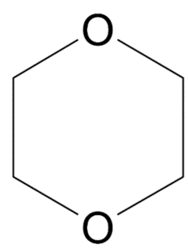

November 2020

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EXECUTIVE SUMMARY

This Draft Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane was developed in response to public and peer review comments on the draft risk evaluation, and includes additional conditions of use for 1,4-dioxane present as a byproduct in consumer products, as well as an analysis of recreational activities in ambient/surface water as an exposure pathway under all conditions of use included in the draft risk evaluation and this draft supplemental analysis. EPA plans to incorporate this Draft Supplemental Analysis to the draft risk evaluation into the final risk evaluation. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA), the Nation's primary chemicals management law, in June 2016. Under the amended statute, EPA is required, under TSCA § 6(b), to conduct risk evaluations to determine whether a chemical substance presents unreasonable risk of injury to health or the environment, under the conditions of use, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations (PESS), identified as relevant to the risk evaluation. Also, as required by TSCA § (6)(b), EPA established, by rule, a process to conduct these risk evaluations. *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726) (Risk Evaluation Rule). This Draft Supplemental Analysis is in conformance with TSCA § 6(b), and the Risk Evaluation Rule, and is to be used to inform risk management decisions. In accordance with TSCA Section 6(b), if EPA finds unreasonable risk from a chemical substance under its conditions of use in any final risk evaluation, the Agency will propose actions to address those risks within the timeframe required by TSCA. However, any proposed or final determination that a chemical substance presents unreasonable risk under TSCA Section 6(b) is not the same as a finding that a chemical substance is "imminently hazardous" under TSCA Section 7. The preliminary conclusions, findings, and determinations in this Draft Supplemental Analysis document will be integrated into the Final Risk Evaluation for 1,4-Dioxane for the purpose of identifying whether the chemical substance presents unreasonable risk or no unreasonable risk under the conditions of use, in accordance with TSCA Section 6, and are not intended to represent any findings under TSCA Section 7.

TSCA § 26(h) and (i) require EPA, when conducting risk evaluations, to use scientific information, technical procedures, measures, methods, protocols, methodologies and models consistent with the best available science and to base its decisions on the weight of the scientific evidence.[1] To meet these TSCA § 26 science standards, EPA used the TSCA systematic review process described in the Application of Systematic Review in TSCA Risk Evaluations document (U.S. EPA, 2018). The data collection, data evaluation and data integration stages of the systematic review process are used to develop the exposure, fate and hazard assessments for risk evaluations.

Approach

EPA used reasonably available information (defined in 40 CFR 702.33 in part as "*information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines . . . for completing the evaluation . . .*"), in a fit-for-purpose approach, to develop a risk evaluation that relies on the best available science and is based on the weight of the scientific evidence. EPA used previous analyses as a starting point for identifying key and supporting studies to inform the exposure, fate and hazard assessments. EPA also evaluated other studies that were published since these reviews. EPA reviewed reasonably available information and evaluated the quality of the methods and reporting

[1] Weight of the scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

of results of the individual studies using the evaluation strategies described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). To satisfy requirements in TSCA Section 26(j)(4) and 40 CFR 702.51(e), EPA has provided a list of studies considered in carrying out the risk evaluation and the results of those studies are in Appendix C and several supplemental files.

In the problem formulation and draft risk evaluation, EPA identified the conditions of use and presented two conceptual models and an analysis plan. These have been updated in this Supplemental Analysis where EPA has quantitatively evaluated the risk to the environment and human health, using both monitoring data and modeling approaches, for new conditions of use (identified in Section 1.4.1).[2] In this Draft Supplemental Analysis, EPA evaluated the risk to consumers from acute and chronic exposures to 1,4-dioxane in consumer products as a byproduct., as well as the risk to bystanders from acute exposures to 1,4-dioxane in consumer products as a byproduct. The Draft Supplemental Analysis also includes an evaluation of general population exposures to 1,4-dioxane in ambient surface water by comparing the estimated exposures to acute human health hazards.

Several of the points of departure (PODs) for evaluating human health risks from acute and chronic dermal and inhalation exposure were revised in response to peer review and public comment. The PODs identified through dose-response analysis in the draft risk evaluation are summarized below. These revised PODs are the basis for risk estimates presented in the risk characterization section.

Risk Characterization

This Draft Supplemental Analysis presents risk estimates for acute dermal and inhalation exposures to the general population that may occur from incidental contact with surface water. Calculated margin of exposure (MOE) values below the benchmark MOE (300) would indicate a potential safety concern. Risks from acute oral exposure through incidental ingestion of surface water are shown in Table 4-1 and risks from acute dermal exposure through swimming in surface water are shown in Table 4-2. This Draft Supplemental Analysis also presents human health risk estimates for acute and chronic dermal and inhalation exposures to consumers and acute dermal and inhalation exposures to bystanders following consumer use of products containing 1,4-dioxane as a byproduct.

Potentially Exposed or Susceptible Subpopulations

TSCA § 6(b)(4) requires that EPA conduct a risk evaluation to "*determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of cost or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use*." TSCA § 3(12) defines the term "potentially exposed or susceptible subpopulation" as *"a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly*."

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[2] EPA did not identify any "legacy uses" (*i.e.*, circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution) or "associated disposal" (*i.e.*, future disposal from legacy uses) of 1,4-dioxane, as those terms are described in EPA's Risk Evaluation Rule, 82 FR 33726, 33729 (July 20, 2017). Therefore, no such uses or disposals were added to the scope of the risk evaluation for 1,4-dioxane following the issuance of the opinion in *Safer Chemicals, Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019). EPA did not evaluate "legacy disposal" (*i.e.*, disposals that have already occurred) in the risk evaluation, because legacy disposal is not a "condition of use" under *Safer Chemicals*, 943 F.3d 397.

In developing the risk evaluation, the EPA analyzed the reasonably available information to ascertain whether some human receptor groups may have greater exposure or greater susceptibility than the general population to the hazard posed by a chemical. The results of the reasonably available human health data for all routes of exposure evaluated (*i.e.*, dermal and inhalation) indicate that there is no evidence of increased susceptibility for any single group relative to the general population. However, there is limited data on reproductive and developmental toxicity and a lack of quantitative information on how genetics, pre-existing disease, or other factors may contribute to increased susceptibility. For consideration of the most highly exposed groups in this Draft Supplemental Analysis, EPA considered 1,4-dioxane exposures to be higher amongst consumers and bystanders that are exposed through the use of consumer products containing 1,4-dioxane as a byproduct as compared to the general population based on greater exposure.

Unreasonable Risk Determination

This Draft Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane presents draft unreasonable risk determinations for eight consumer conditions of use. This document also presents draft unreasonable risk determinations for all conditions of use for the general population. This draft unreasonable risk determination for the general population includes the consumer conditions of use in this Draft Supplemental Analysis as well as the conditions of use presented in the Draft Risk Evaluation.

Unreasonable Risks of Injury to Health: EPA's draft determination of unreasonable risk for specific conditions of use of 1,4-dioxane listed below are based on health risks to consumers, bystanders, and the general population. For acute exposures to consumers and bystanders, EPA evaluated unreasonable risks for adverse non-cancer effects based on liver toxicity. For chronic exposures to consumers and bystanders, EPA evaluated unreasonable risks of cancer.

Unreasonable Risk of Injury to Health of the General Population: 1,4-Dioxane exposures to the general population may occur from the conditions of use due to releases to air, water or land. During the course of the risk evaluation process for 1,4-dioxane, EPA worked closely with the offices within EPA that administer and implement regulatory programs under the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), the Resource Conservation and Recovery Act (RCRA), and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA believes it is both reasonable and prudent to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with the statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadlines for completing risk evaluations. EPA has therefore tailored the scope of the risk evaluation for 1,4-dioxane using authorities in TSCA Sections 6(b) and 9(b)(1). EPA did not evaluate unreasonable risk to the general population from ambient air, drinking water, and sediment pathways for any conditions of use in this risk evaluation, and the draft unreasonable risk determinations do not account for exposures to the general population from ambient air, drinking water, and sediment pathways.

As part of this Draft Supplemental Analysis, EPA evaluated acute and chronic incidental exposures via oral and dermal routes from recreational swimming in ambient water and preliminarily determined that this activity presents no unreasonable risk to the general population from all conditions of use. In addition, because 1,4-dioxane has low bioaccumulation potential, EPA has preliminarily determined that fish consumption does not present an unreasonable risk to the general population from any of the conditions of use.

Unreasonable Risk of Injury to Health of Consumers: 1,4-Dioxane may be found as a contaminant in consumer products. It is present as a result of byproduct formation during manufacture of ethoxylated chemicals that are subsequently formulated into products. In the draft risk evaluation, EPA did not evaluate exposures to consumers and bystanders from byproduct or contaminant exposure, explaining that EPA's intention was to consider 1,4-dioxane byproduct and contaminant uses in the scope of any risk evaluation of ethoxylated chemicals. In response to peer review and public comments, in this draft Supplemental Analysis, EPA evaluated eight consumer uses of products that contain 1,4-dioxane as a contaminant to preliminarily determine if there was unreasonable risk of injury to consumers' health. For each of the eight uses, EPA evaluated non-cancer effects to consumers from acute inhalation and dermal exposures. For four of the products, based on the exposure assessment, EPA also evaluated cancer risks to consumers from chronic inhalation and dermal exposures. A full description of EPA's draft unreasonable risk determination for each condition of use is in Section 5.

Unreasonable Risk of Injury to Health of Bystanders (from consumer uses): Because this supplemental evaluation includes an evaluation of hazards and exposures for consumers, EPA evaluated hazards and exposures for bystanders to consumer uses. Specifically, EPA evaluated non-cancer effects to bystanders from acute inhalation exposures from eight consumer uses of products that contain 1,4-dioxane as a contaminant to preliminarily determine if there was unreasonable risk of injury to bystanders' health. EPA did not estimate chronic inhalation exposures to bystanders because bystanders would be exposed to lower levels than the user based on the model bystander placement in the home during the product's use. EPA also did not evaluate non-cancer effects from dermal exposures to bystanders because bystanders are not dermally exposed to 1,4-dioxane. A full description of EPA's draft unreasonable risk determination for each condition of use is in Section 5.

Based on the Draft Supplemental Analysis, EPA has preliminarily determined that the following conditions of use of 1,4-dioxane do not present an unreasonable risk of injury to health or the environment. The details of these determinations are in Section 5.2.

Conditions of Use that Do Not Present an Unreasonable Risk
• Consumer use: Arts, crafts, and hobby materials – Textile dye • Consumer use: Automotive care products – Antifreeze • Consumer use: Cleaning and furniture care products – Surface cleaner • Consumer use: Laundry and dishwashing products – Dish soap • Consumer use: Laundry and dishwashing products – Dishwasher detergent • Consumer use: Laundry and dishwashing products – Laundry detergent • Consumer use: Paints and coatings – Paint and floor lacquer • Consumer use: Other uses – Spray polyurethane foam

1 INTRODUCTION

This document presents a Draft Supplemental Analysis to the Draft Risk Evaluation that will be incorporated into the Final Risk Evaluation for 1,4-Dioxane under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act, the Nation's primary chemicals management law, in June 2016. In this Draft Supplemental Analysis, EPA evaluated the risk to consumers and bystanders from 1,4-dioxane in consumer products, and the general population exposed to 1,4-dioxane in ambient surface water by comparing the estimated exposures to acute and chronic human health hazards.

The Agency published the Scope of the Risk Evaluation for 1,4-dioxane (EPA, 2017) in June 2017, and the problem formulation in June, 2018 (EPA, 2018b), which represented the analytical phase of risk evaluation in which "the purpose for the assessment is articulated, the problem is defined, and a plan for analyzing and characterizing risk is determined" as described in Section 2.2 of the Framework for Human Health Risk Assessment to Inform Decision Making. The EPA received comments on the published problem formulation and draft risk evaluation for 1,4-dioxane and has considered the comments specific to 1,4-dioxane, as well as more general comments regarding the EPA's chemical risk evaluation approach for developing the risk evaluations for the first 10 chemicals the EPA is evaluating.

This Draft Supplemental Analysis document is structured such that the Introduction presents a background on uses, conditions of use and conceptual models, with emphasis on any changes since the publication of the draft risk evaluation. This section also includes a discussion of the systematic review process utilized in this Supplemental Analysis. The exposures section provides a discussion and analysis of the human exposures expected based on the conditions of use for 1,4-dioxane evaluated in this Draft Supplemental Analysis. The hazards section summarizes the human health hazards of 1,4-dioxane. The risk characterization section integrates and assesses reasonably available information on human health hazards and exposures, as required by TSCA (15 U.S.C 2605(b)(4)(F)). The risk determination section is included, in which the agency presents the draft determinations of whether risk posed by the chemical substance under the conditions of use is unreasonable as required under TSCA (15 U.S.C. 2605(b)(4)).

EPA is providing the opportunity for public comment on this Draft Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane. The final risk evaluation may change in response to public comments received and/or in response to peer review on the draft risk evaluation, as well as in response to public comments received on this Draft Supplemental Analysis. The draft supplemental analysis is not being peer reviewed for the sake of expediency to finalize the first ten risk evaluations. The EPA will respond to public and peer review comments received on the draft risk evaluation and further public comments received on this Draft Supplemental Analysis when it issues the final risk evaluation.

1.1 Scope of this Draft Supplemental Analysis to the Draft Risk Evaluation

This document presents updated sections of the Draft Risk Evaluation for 1,4-Dioxane, appendices, and supplemental files that have been developed based on additional COUs for 1,4-dioxane as a byproduct in consumer products. In addition, the document presents an exposure analysis to the general population from recreational activities (*i.e.*, swimming) in ambient/surface water.

1.1.1 Conditions of Use Included in the Supplemental Analysis to the Draft Risk Evaluation

TSCA (15 U.S.C. § 2602(4)) defines "conditions of use" as ''the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." The conditions of use are described below in Table 1.

As explained in the scope document for 1,4-dioxane, EPA anticipates the production of 1,4-dioxane as a byproduct from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products. In particular, 1,4-dioxane may be produced as a reaction byproduct in chemicals produced through ethoxylation, including alkyl ether sulphates (AES, anionic surfactants) and other ethoxylated substances, such as alkyl, alkylphenol and fatty amine ethoxylates; polyethylene glycols and their esters; and sorbitan ester ethoxylates. 1,4-Dioxane may also be present at residual concentrations in commercial and consumer products that contain ethoxylated chemicals. Examples of products potentially containing 1,4-dioxane as a residual contaminant are paints, coatings, lacquers, ethylene glycol-based antifreeze coolants, spray polyurethane foam, household detergents, cosmetics/toiletries, textile dyes, foods, agricultural and veterinary products (ATSDR, 2012; Canada, 2010; FDA, 2007; ECJRC, 2002). In the Draft Risk Evaluation for 1,4-Dioxane, the manufacture of 1,4-dioxane as a byproduct from ethoxylation of other chemicals, use and disposal of 1,4-dioxane at residual concentrations in industrial, commercial and consumer products containing ethoxylated chemicals were excluded from the scope of the risk evaluation. In response to peer review and public comments, in this Draft Supplemental Analysis, EPA evaluated eight consumer uses of products that contain 1,4-dioxane as a contaminant to determine if there was unreasonable risk of injury to consumers' and bystanders' health. For each of the eight uses, EPA evaluated non-cancer effects to consumers from acute inhalation and dermal exposures. For four of the products, based on the exposure assessment, EPA also evaluated cancer risks to consumers from chronic inhalation and dermal exposures.

In the draft risk evaluation, general population exposures were not evaluated for any condition of use. The exposures to general population via drinking water, ambient air and sediment pathways fall under the jurisdiction of other environmental statutes administered by EPA, *i.e.*, CAA, SDWA, CERCLA, and RCRA. EPA believes it is both reasonable and prudent to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. However, because there is no nationally recommended Ambient Water Quality Criteria under the CWA, EPA included exposures to the general population via ambient surface water in this supplemental analysis. EPA did evaluate hazards or exposures to the general population from ambient surface water for the conditions of use in the draft risk evaluation (see Table 1-2), and the draft unreasonable risk determinations for relevant conditions of use account for exposures to the general population via surface water (EPA, 2018b).

Table 1-1 includes the additional conditions of use included in this supplemental analysis covering consumer exposure pathways for products containing 1,4-dioxane as a byproduct.

Table 1-1 Additional Categories and Subcategories of Conditions of Use Included in the Supplemental Analysis to the Draft Risk Evaluation

Life Cycle Stage	Category	Subcategory	References
Consumer uses	Paints and Coatings	1. Latex Wall Paint or Floor Lacquer	TSCA Work Plan Chemical Problem Formulation and Initial Assessment: 1,4-Dioxane (CASRN 123-91-1) (2015)
	Cleaning and Furniture Care Products	2. Surface Cleaner	
	Laundry and Dishwashing Products	3. Dish Soap 4. Dishwasher Detergent 5. Laundry Detergent	
	Arts, Crafts and Hobby Materials	6. Textile Dye	
	Automotive Care Products	7. Antifreeze	
	Other Consumer Uses	8. Spray Polyurethane Foam (SPF)	

The draft risk evaluation included worker and ONU exposures for Occupational Exposure Scenarios (OES) but did not include associated environmental releases to surface water, which are included in this supplemental analysis for the OES in Table 1-2. These releases to surface water are used in the evaluation of general population exposures via the ambient water pathway and reflect additional pathways of exposure for conditions of use that were presented in the Draft Risk Evaluation.

Table 1-2 Existing Conditions of Use Included in the Supplemental Analysis to the Draft Risk Evaluation to Evaluate Additional Pathways of Exposure

OES	References
Manufacturing	Draft Risk Evaluation for 1,4-Dioxane
Import and Repackaging	
Recycling	
Industrial Uses	
Functional Fluids (Open-System)	
Laboratory Chemical Use	
Film Cement	
Spray Foam Application	
Printing Inks (3D)	
Dry Film Lubricant	
Disposal	

1.1.2 Conceptual Models

The conceptual models for this draft supplemental analysis to the draft risk evaluation are shown in Figure 1-1 and Figure 1-2. EPA considered the potential for hazards to consumers from inhalation and dermal routes and to bystanders from the inhalation route via use of household products containing 1,4-dioxane as a byproduct and hazards from incidental exposure to the general population via releases to ambient water as shown in the conceptual models.

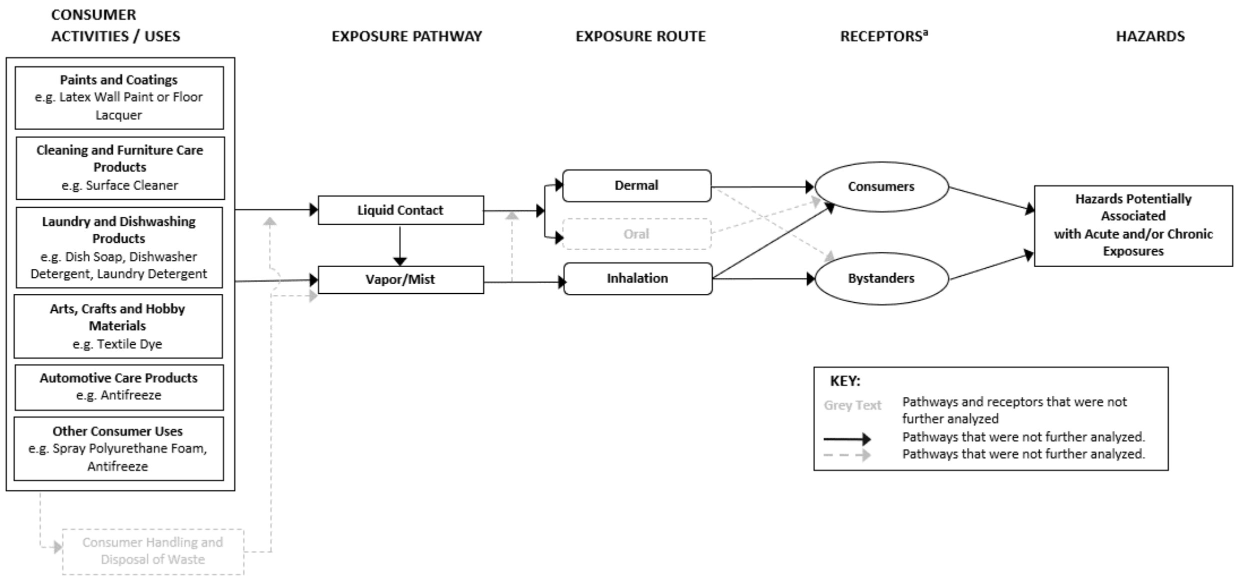


Figure 1-1 1,4-Dioxane Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of 1,4-dioxane in the draft risk evaluation and this supplemental analysis to the draft risk evaluation.

[a] Receptors include potentially exposed or susceptible subpopulations.

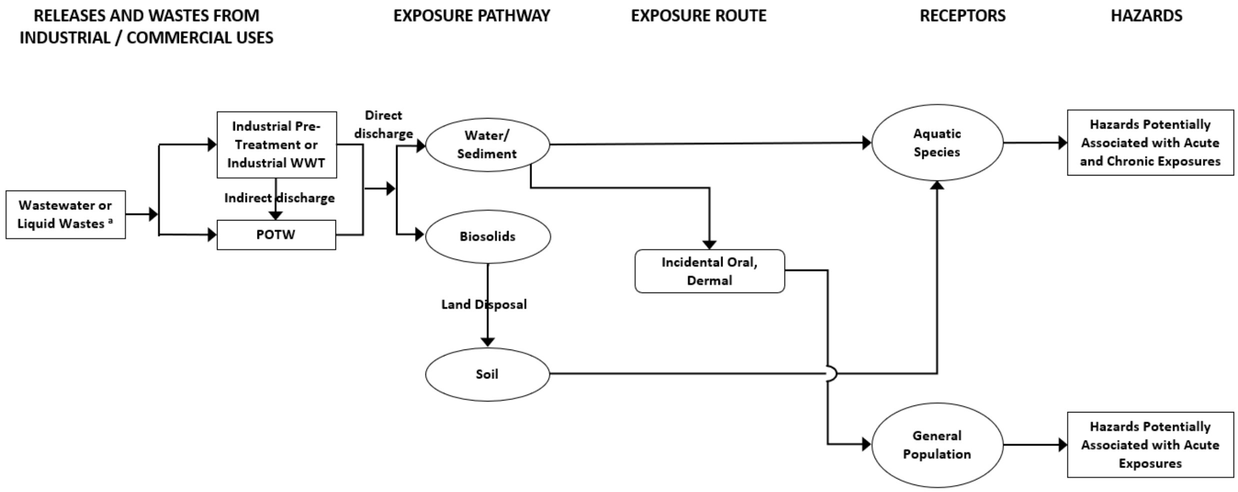


Figure 1-2. 1,4-Dioxane Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of 1,4-dioxane in the draft risk evaluation and this supplemental analysis to the draft risk evaluation.

[a] Industrial wastewater or liquid wastes could be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge).

1.2 Systematic Review

TSCA requires EPA to use scientific information, technical procedures, measures, methods, protocols, methodologies and models consistent with the best available science and base decisions on the weight of the scientific evidence. Within the TSCA risk evaluation context, the weight of the scientific evidence is defined as "*a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance*" (40 C.F.R. 702.33).

To meet the TSCA § 26(h) science standards, EPA used the TSCA systematic review process described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). The process complements the risk evaluation process in that the data collection, data evaluation and data integration stages of the systematic review process are used to develop the exposure and hazard assessments based on reasonably available information. EPA defines "reasonably available information" to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation (40 CFR 702.33).

EPA is implementing systematic review methods and approaches within the regulatory context of the amended TSCA. Although EPA is adopting as many best practices as practicable from the systematic review community, EPA expects modifications to the process to ensure that the identification, screening, evaluation and integration of data and information can support timely regulatory decision making under the aggressive timelines of the statute.

1.2.1 Data and Information Collection

For the risk evaluation, EPA planned and conducted a comprehensive literature search based on chemical descriptors and key words related to the different discipline-specific evidence supporting the risk evaluation (*e.g.,* environmental fate and transport; engineering releases and occupational exposure; exposure to general population, consumers and environmental exposure; and environmental and human health hazard). EPA then developed and applied inclusion and exclusion criteria during the title and abstract screening to identify information potentially relevant for the risk evaluation process. The literature and screening strategy as specifically applied to 1,4-dioxane is described in the *Strategy for Conducting Literature Searches for 1,4-Dioxane: Supplemental File for the TSCA Scope Document* and the results of the title and abstract screening process were published in the *1, 4-Dioxane (CASRN 123-91-1) Bibliography: Supplemental File for the TSCA Scope Document* (U.S. EPA, 2017a). EPA subsequently conducted full-text screening using inclusion/exclusion criteria within population, exposure, comparator, outcome (PECO) or similar statements that are included in Appendix F of *Problem Formulation of the Risk Evaluation for 1,4-Dioxane* (EPA, 2018c).

For the current supplemental analysis, EPA performed an supplemental literature search of peer databases to identify studies related to consumer exposure. EPA conducted a new comprehensive literature search of peer databases based on chemical name and CAS related to exposure to general population, consumers and environmental exposure. EPA filtered the new literature search results of 1,4-dioxane for consumer specific references using Structured Query Language (SQL) querying shown in Table 1-2.

Table 1-2 Categorical Term Sets used in SQL Querying for 1,4-Dioxane Supplemental Consumer Analysis

<table>
<tr><td>carpet|Drapery|curtain|upholstery|furniture|rug|Suede|cleaner|leather|water proofing|starch</td></tr>
<tr><td>anti-static|candle|matches|bleach|laundry|detergent|Insect repellent|litter|Charcoal|briquettes|lighter fluid|Drain cleaner|Dishwasher|dishwashing|dishes|soap|Fabric</td></tr>
<tr><td>dye|softener|Oven cleaner|home|pet|collar|Fertilizer|garden|Fire extinguisher|floor|metal|silver|Food packaging|packaged food</td></tr>
<tr><td>deodorizer|freshener|disinfectant|spot remover|stain remover|Scouring pad|Toilet|Herbicide|patio|Water treatment chemicals|Insecticide|swimming pool|Paint|varnish|remover|thinner|interior|spray|house</td></tr>
<tr><td>exterior|polyurethane|stain|Ceiling|tile|patching|plaster|caulk|sealer|filler|Dry wall|Roofing|Refinishing|wall|wallpaper|Insulation|automobile|car|truck|cycle|van</td></tr>
<tr><td>Antifreeze|Motor oil|Radiator|additives|Automotive paint|Gasoline|diesel fuel|vehicle|Windshield|washer|Clothes|clothing|shoe|Sheets|towels|diaper|games|toys|chew|ingest|jewelry|colorprint|newsprint|newspaper|photograph|consumer|emission</td></tr>
<tr><td>Categorical term sets were derived from the Exposure Factors Handbook. This included Household Furnishings, Garment Conditioning Products, Household Maintenance Products, Home Building & Improvement Products, Automobile-Related Products, and Personal Materials. Cosmetic Hygiene Products, insecticide, food packaging terminology was excluded for the purposes of this assessment per TSCA section 3(2).</td></tr>
</table>

Next, a machine learning model was employed to rank how similar the filtered references were to a pre-determined set of consumer references (positive seeds), and how unsimilar the filtered references were to a pre-determined set of non-consumer references (negative seeds). References that ranked above a relevancy cut-off (0.4 for references with abstracts, 0.1 for references with just titles) were included for data screening. These approaches reduced the number of references from 21,373 to 239. The revised literature flow diagram (Table 3) includes the additional SQL querying and machine learning steps that were used for the consumer assessment.

In addition to the peer database search, EPA utilized previous assessments and performed an additional gray literature search for the supplemental consumer analysis. Previous assessments that were identified in support of the development of EPA's 2015 *TSCA Work Plan Chemical Problem Formulation and Initial Assessment of 1,4-Dioxane* (U.S. EPA, 2015), were screened and evaluated for use in the supplemental consumer assessment. EPA conducted an additional consumer gray literature search to identify references with consumer information related to 1,4-dioxane. Previous assessments and results of the additional gray literature search for consumer uses resulted in 34 data sources. The revised literature flow diagram (Table 3) includes the previous assessments, as well as the additional gray literature results that were used for the consumer assessment.

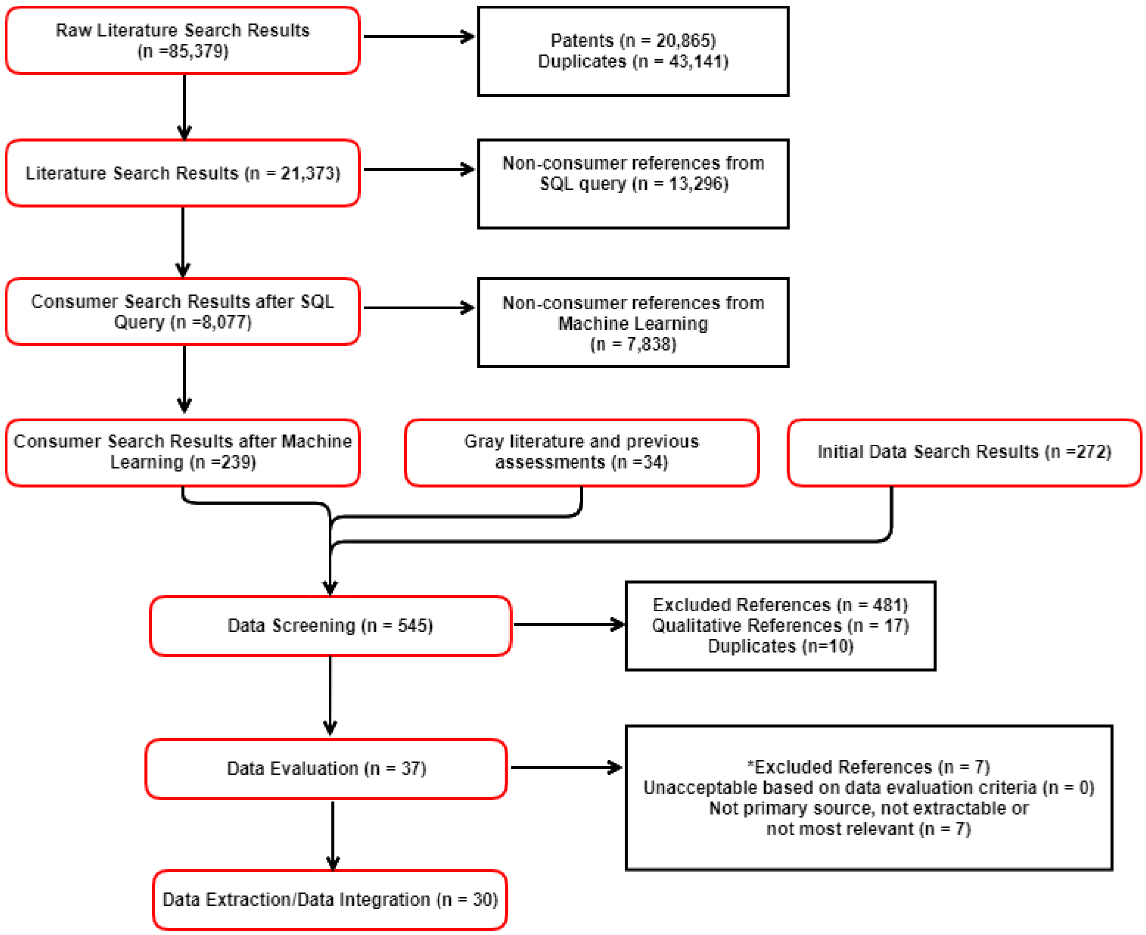
The 239 references as a result of the machine learning efforts and the 34 references from previous assessments and the additional gray literature search underwent data screening. These sources are listed in the Supplemental Analysis File [*Consumer References, Data Screening*].

For the consumer supplemental analysis, EPA modified the inclusion and exclusion criteria for title and abstract screening and full text screening to identify consumer information potentially relevant for the risk evaluation process. The revised PECO is presented in Table 1-3.

Table 1-3 PECO Statement 1,4-Dioxane Consumer Exposure Assessment (September 2020)

PECO Element	Evidence
Population	**Human:** Consumers and bystanders, including children. **Targeted human population groups may be exposed to 1,4-dixoane.**
	Ecological: None.
Exposure	**Expected Primary Exposure Sources, Pathways, Routes** Source: Consumer use of products containing 1,4 dioxane as a byproduct, and associated air emissions and dermal contact. Pathway: Indoor air, contact with products. Routes: Indoor (inhalation), dermal (contact with products)
Comparator (Scenario)	**Human:** Consider use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
	Ecological: None.
Outcomes for Exposure Concentration or Dose	**Human:** A wide range of effects following acute and chronic exposure doses mg/kg/day and concentrations mg/m^3.
	Ecological: None.

The results of the data screening efforts resulted in 37 references that were sent to data evaluation, and 17 references that were evaluated qualitatively. The results of the data evaluation are included in the Supplemental Analysis File [*Data Quality Evaluation on Data Sources on Consumer and Environmental Exposure*] and the list of references evaluated qualitatively are included in the Supplemental Analysis File [*Consumer References, Data Screening*]. Following data evaluation, 30 references were sent forward for data extraction/integration. The process is depicted below in Figure 1-3.



*The quality of data in these sources were acceptable for risk assessment purposes and considered for integration. The sources; however, were not extracted for a variety of reasons, such as they contained only secondary source data, duplicate data, or non-extractable data (i.e., charts or figures). Additionally, some data sources were not as relevant to the PECO as other data sources which were extracted.

Figure 1-3 Literature Flow Diagram for General Population, Consumer and Environmental Exposure Data Sources

In support of this evaluation, EPA undertook an additional raw literature search (n=85,379) to identify, screen, and evaluate literature relevant for a consumer exposure assessment of 1,4-dioxane. Deduplication, SQL querying, and machine learning were employed to reduce the number of references for data screening. The Consumer Supplemental Search Results after Machine Learning (n=239) and the gray literature and previous assessments (n=34) represent the additional sources that were considered for the consumer supplemental analysis, whereas the initial data search results (n=272) refer to the references that were considered in the draft risk evaluation.

2 EXPOSURES

2.1 Environmental Releases

Releases to the environment from conditions of use (*e.g.*, industrial and commercial processes) are one component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

Under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313, 1,4-dioxane has been a Toxics Release Inventory (TRI)-reportable substance since 1987. The TRI database includes information on disposal and other releases of 1,4-dioxane to air, water, and land, in addition to how it is being managed through recycling, treatment, and burning for energy recovery.

2.1.1 Environmental Releases to Water

EPA categorized the conditions of use (COUs) listed in Section 1.4.1 into 12 Occupational Exposure Scenarios (OES). For each OES, a daily water release was estimated based on annual releases, release days, and the number of facilities (Figure 2-1). In this section, EPA describes its approach and methodology for estimating daily water releases, and for each OES provides a summary of release days, number of facilities, and daily water releases (Table 2-1).

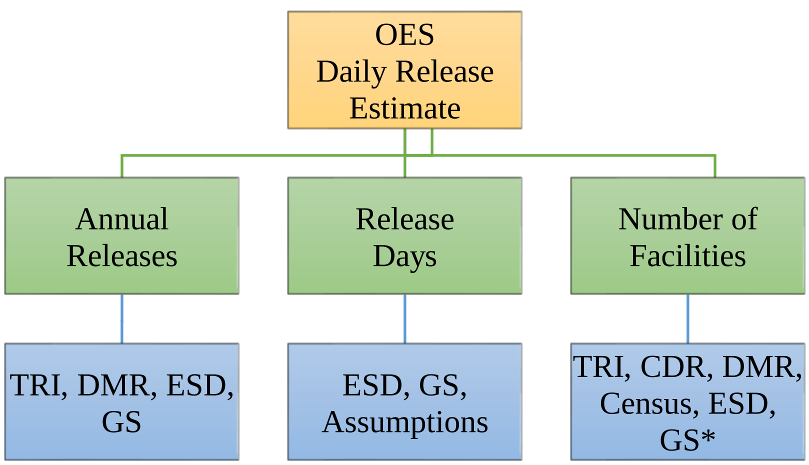


Figure 2-1. An Overview of How EPA Estimated Daily Water Releases for Each OES
* TRI: Toxics Release Inventory; DMR: Discharge Monitoring Report; ESD: Emission Scenario Document; GS: Generic Scenario

2.1.1.1 Results for Daily Release Estimate

EPA combined its estimates for annual releases, release days, and number of facilities to estimate a range for daily water releases for each OES. A summary of these ranges across facilities is presented in Table 2-1. The examples of certain OES where water releases are not expected follows.

Laboratory Uses: EPA expects that releases of 1,4-dioxane from laboratory uses are to air (through volatile releases into the indoor laboratory air and/or through laboratory fume hoods to atmospheric air) and liquid wastes of 1,4-dioxane are handled as hazardous waste. EPA expects commercial and university laboratories to handle their wastes as hazardous waste and not discharge wastes to POTW via pouring the wastes down the drain.

Printing Inks (3D): EPA does not expect water releases from 3D printing ink uses. EPA expects spent printing ink containers, shavings or fragments, or waste scraps to be disposed of as solid waste. There is some uncertainty as to whether and how much 1,4-dioxane may remain in 3D printed products and waste scraps. However, due to the volatility of 1,4-dioxane, EPA expects 1,4-dioxane to evaporate from any printed object, shavings or fragments, or other printed material deposited to the floor or work surface prior to it being cleaned and disposed of as solid waste.

Film Cement: EPA assessed no wastewater discharges for this OES. EPA expects the small glue bottles to be disposed of as solid waste without rinsing them in a sink. There is some uncertainty as to whether and how much 1,4-dioxane may remain in the small glue bottles when disposed. However, due to the small quantities of the glue and high volatility of the 1,4-dioxane, EPA expects any residual 1,4-dioxane to evaporate to the air or remain in the solid waste stream.

Table 2-1. Summary of EPA's Daily Water Release Estimates for Each OES and EPA's Overall Confidence in these Estimates

Occupational Exposure Scenario (OES)	Estimated Daily Release Range Across Sites (kg/site-day)		Release Days per Year	Release Media	Overall Confidence	Notes
	Minimum	Maximum				
Manufacturing	0	2.48	250	Surface Water	M	Estimates based on TRI and DMR data.
Import and Repackaging	0	0	0	N/A	M	Estimates based on TRI and DMR data.
Recycling	-	-	-	-	-	EPA evaluated recycling as part of the industrial uses OES.
Industrial Uses	0	67.7	250	Surface Water, POTW, and Non-Public WWT	M	Estimates based on TRI and DMR data.
Functional Fluids (Open-System)	9.92E-4	3.79E-2	247	Surface Water and POTW	M	EPA estimates releases for three sites reported in DMR and for additional, unknown sites not captured in DMR or TRI using the Emission Scenario Document on the Use of Metalworking Fluids.
Laboratory Chemical Use	N/A	N/A	N/A	N/A	H	1,4-Dioxane could be released to air; and wastes disposed of as

Occupational Exposure Scenario (OES)	Estimated Daily Release Range Across Sites (kg/site-day)		Release Days per Year	Release Media	Overall Confidence	Notes
	Minimum	Maximum				
						hazardous waste for this OES.
Film Cement	N/A	N/A	N/A	N/A	H	EPA expects releases of 1,4-dioxane to be to air and wastes disposed of as solid waste for this OES.
Spray Foam Application	3.59E-3		260	Surface Water or POTW	M	Modeled using the Application of Spray Polyurethane Foam Insulation Generic Scenario.
Printing Inks (3D)	N/A	N/A	N/A	N/A	H	EPA expects releases of 1,4-dioxane to be to air and wastes disposed of as solid waste for this OES.
Dry Film Lubricant	N/A	N/A	N/A	N/A	H	Based on conversations with the only known user, EPA expects wastes to be drummed and sent to a waste handler with residual wastes releasing to air or being disposed to landfill.
Disposal	0	0.12	250	Surface Water	M	Estimates based on TRI and DMR data.
N/A: Not applicable. EPA does not expect 1,4-dioxane releases to water from this OES. POTW = Publicly owned treatment works WWT = wastewater treatment						

2.1.1.2 Approach and Methodology

2.1.1.2.1 Water Release Estimates

Where available, EPA used 2018 TRI (U.S. EPA, 2017c) and 2018 DMR (U.S. EPA, 2016) data to provide a basis for estimating releases. Facilities are only required to report to TRI if the facility has 10 or more full-time employees, is included in an applicable NAICS code, and manufactures, processes, or uses the chemical in quantities greater than a certain threshold (25,000 pounds for manufacturers and processors of 1,4-dioxane and 10,000 pounds for users of 1,4-dioxane). Due to these limitations, some sites that manufacture, process, or use 1,4-dioxane may not report to TRI and are therefore not included in these datasets.

For the 2018 Discharge Monitoring Report (DMR) (U.S. EPA, 2016), EPA used the Water Pollutant Loading Tool within EPA's Enforcement and Compliance History Online (ECHO) to query all 1,4-dioxane point source water discharges in 2018. DMR data are submitted by National Pollutant Discharge Elimination System (NPDES) permit holders to states or directly to the EPA according to the monitoring requirements of the facility's permit. States are only required to load major discharger data into DMR and may or may not load minor discharger data. The definition of major versus minor discharger is set by each state and could be based on discharge volume or facility size. Due to these limitations, some sites that discharge 1,4-dioxane may not be included in the DMR dataset.

Where releases are expected but TRI and DMR data were not reasonably available or where EPA determined TRI and DMR data did not sufficiently represent releases of 1,4-dioxane to water for a condition of use, releases were estimated using data from literature, relevant Emission Scenario Documents (ESDs), and Generic Scenarios (GSs).

2.1.1.2.2 Estimates of Number of Facilities

Where available, EPA used 2018 TRI (U.S. EPA, 2017c), and 2018 DMR (U.S. EPA, 2016) data to provide a basis to estimate the number of sites using 1,4-dioxane within a condition of use. Generally, information for reporting sites in CDR was sufficient to accurately characterize each reporting site's condition of use. However, information for determining the condition of use for reporting sites in TRI and DMR is typically more limited.

In TRI, sites submitting a Form R indicate whether they perform a variety of activities related to the chemical, including, but not limited to whether they: produce the chemical; import the chemical; use the chemical as a reactant; use the chemical as a chemical processing aid; and ancillary or other use. In TRI, sites submitting Form A are not required to designate an activity. For both Form R and Form A, TRI sites are also required to report the primary North American Industry Classification System (NAICS) code for their site. For each TRI site, EPA used the reported primary NAICS code and activity indicators to determine the condition of use at the site. For instances where EPA could not definitively determine the condition of use because: 1) the reported NAICS codes could include multiple conditions of use; 2) the site reported multiple activities; and/or 3) the site did not report activities due to submitting a Form A, EPA made an assumption on the condition of use to avoid double counting the site. For these sites, EPA supplemented the NAICS code and activity information with information from company websites, satellite images, and industry data to determine a "most likely" or "primary" condition of use.

In DMR, the only information reported on condition of use is each site's Standard Industrial Classification (SIC) code. EPA could not determine each reporting site's condition of use based on SIC code alone; therefore, EPA supplemented the SIC code information with the same supplementary information used for the TRI.

Where the number of sites could not be determined using CDR/TRI/DMR or where these data sources were determined to insufficiently capture the number of sites within a condition of use, EPA supplemented the available data with U.S. economic data using the following method:

- Identify the North American Industry Classification System (NAICS) codes for the industry sectors associated with these uses.
- Estimate total number of sites using the U.S. Census' Statistics of US Businesses (SUSB) (U.S. Census Bureau, 2015) data on total establishments by 6-digit NAICS.

- Review available ESDs and GSs for established facility estimates for each occupational exposure scenario.
- Combine the data generated in Steps 1 through 3 to produce an estimate of the number of sites using 1,4-dioxane in each 6-digit NAICS code, and sum across all applicable NAICS codes for the condition of use, augmenting as needed with data from the ESDs and GSs, to arrive at a total estimate of the number of sites within the condition of use.

Table 2-2. Summary of EPA's Estimates for the Number of Facilities for Each OES

Occupational Exposure Scenario (OES)	Number of Facilities	Notes
Manufacturing	2	Based on CDR and TRI reporting (see Appendix G.6.1)
Import and Repackaging	3 to 18	Based on TRI and CDR reporting (see Appendix G.6.2)
Recycling	-	Evaluated as a part of Industrial Uses.
Industrial Uses	24	Based on TRI and DMR data (see Appendix G.6.3)
Functional Fluids (Open-System)	89,000	Based on TRI reporting and bounding estimate from the 2011 OECD *Emission Scenario Document on the Use of Metalworking Fluids* (see Appendix G.6.4)
Laboratory Chemicals	6,844	Bounding estimate based on CDR, and U.S. Census Bureau data for NAICS code 541380, Testing Laboratories (see Appendix G.6.5)
Film Cement	211	Bounding estimate based on U.S. Census Bureau data for NAICS code 512199, Other Motion Picture and Video Industries (see Appendix G.6.6)
Spray Foam Application	1,553,559	Bounding estimate based on U.S. Census Bureau data for NAICS code 238310, Drywall and Insulation Contractors and the 2018 EPA generic scenario *Application of Spray Polyurethane Foam Insulation* (see Appendix G.6.7)
Printing Inks (3D)	10,767	Bounding estimate based on U.S. Census Bureau data for NAICS code 339113, Surgical Appliance and Supplies Manufacturing (see Appendix G.6.8)
Dry Film Lubricant	8	Based on conversations with the Kansas City National Security Campus, which is a manufacturer and user (see Appendix G.6.9)
Disposal	14	Based on TRI and DMR data (see Appendix G.6.10)

2.1.1.2.3 Estimates of Release Days

EPA referenced Emission Scenario Documents (ESDs) or needed to make assumptions when estimating release days for each OES. A summary along with a brief explanation is presented in Table 2-3 below.

Table 2-3. Summary of EPA's Estimates for Release Days Expected for Each OES

Occupational Exposure Scenario (OES)	Release Days	Notes
Manufacturing	250	Assumed five days per week and 50 weeks per year with two weeks per year for shutdown activities.
Import and Repackaging	250	Assumed five days per week and 50 weeks per year with two weeks per year for shutdown activities.
Recycling	-	Evaluated as a part of Industrial Uses.
Industrial Uses	250	Assumed five days per week and 50 weeks per year with two weeks per year for shutdown activities.
Functional Fluids (Open-System)	247	2011 OECD *Emission Scenario Document on the Use of Metalworking Fluids*
Laboratory Chemicals	250	Assumed five days per week and 50 weeks per year with two weeks per year for shutdown activities.

Occupational Exposure Scenario (OES)	Release Days	Notes
Film Cement	250	Assumed five days per week and 50 weeks per year with two weeks per year for shutdown activities.
Spray Foam Application	260	Based on the 2018 EPA generic scenario *Application of Spray Polyurethane Foam Insulation,* estimated average of 3 days spent/year at each work site.
Printing Inks (3D)	250	Assumed five days per week and 50 weeks per year with two weeks per year for shutdown activities.
Dry Film Lubricant	56	Facility provided dry film lubricant manufacture and application frequency.
Disposal	250	Assumed 5 days per week and 50 weeks per year.

Table 2-4 shows site-specific 1,4-dioxane releases as per 2018 TRI and DMR documents. For each Occupational Exposure Scenario (OES), annual releases, release media, the type of water body, and water use are also tabulated. These releases were reported to the 2018 TRI or DMR, and these data represent a snapshot in time. Several reported water releases to TRI and DMR are estimated only. Facilities below a requisite size are not required to report in TRI or DMR and therefore this map is likely not representative of all the releases in the U.S. for 2018. There were no releases reported to TRI or DMR for facilities in Alaska or Hawaii during this time period. Additional information available in Supplemental Analysis File [*Exposure Modeling Inputs, Results, and Risk Estimates for Incidental Ambient Water Exposure*].

Table 2-4. 1,4-Dioxane releases in TRI and DMR (2018)

Company Name	City, State	OES	Annual Release (kg/yr)	NPDES Permit Number[1]	Release Media	Sub-Watershed or Waterbody Name[1]	Recreational / Aquatic Life Use[1]
BASF Corp.	Zachary, LA	Manufacturing	620.06	LA0004057	Surface Water	Tchefuncta River: Savannah Branch	Yes / Yes
INEOS Oxide	Plaquemine, LA	Industrial Uses	721.70	LA0115100	Non-POTW WWT	Bayou Bourbeaux	No / No
Microdyn-Nadir Corp	Goleta, CA	Industrial Uses	24.04	CAZ482715	POTW	None Listed	No / No
Union Carbide Corp: St Charles Operations	Hahnville, LA	Industrial Uses	828.26	LA0000191	Surface Water	Bayou Fortier	No / No
Suez Wts Solutions USA Inc	Minnetonka, MN	Industrial Uses	16920.83	MN0059013	POTW	South Fork Ninemile Creek	No / No
The Dow Chemical Co - Louisiana Operations	Plaquemine, LA	Industrial Uses	647.73	LAG530436	Surface Water	Bayou Bourbeaux	No / No
Union Carbide Corp: Institute Facility	Institute, WV	Industrial Uses	3818.80	WVG611765	Surface Water	Rocky Fork	Yes / Yes
Union Carbide Corp: Seadrift Plant	Seadrift, TX	Industrial Uses	503.49	None	Surface Water	Private Surface Water	No / No
BASF Corp.	Monaca, PA	Industrial Uses	2.98	PA0092223	Surface Water	Sixmile Run-Ohio River - Raccoon Creek	No / No

Company Name	City, State	OES	Annual Release (kg/yr)	NPDES Permit Number[1]	Release Media	Sub-Watershed or Waterbody Name[1]	Recreational / Aquatic Life Use[1]
Cherokee Pharmaceuticals LLC	Riverside, PA	Industrial Uses	1.66	PA0008419	Surface Water	Susquehanna River	No / No
Dak Americas LLC	Fayetteville, NC	Industrial Uses	7965.95	NC0003719	Surface Water	Locks Creek-Cape Fear River	Yes / Yes
Institute Plant	Institute, WV	Industrial Uses	6132.57	WV0000086	Surface Water	Tyler Creek-Kanawha River - Rocky Fork	Yes / Yes
Kodak Park Division	Rochester, NY	Industrial Uses	63.88	NY0001643	Surface Water	Round Pond Creek, Paddy Hill Creek	Yes / Yes
Pharmacia & Upjohn (Former)	North Haven, CT	Industrial Uses	1.05	CT0001341	Surface Water	Quinnipiac River	No / No
Philips Electronics Plant	Parker County, TX	Industrial Uses	0.06	TX0113484	Surface Water	Rock Creek	No / No
Sanderson Gulch Drainage Improvements	Denver, CO	Industrial Uses	0.03	COG315474	Surface Water	Bolden Gulch-Muddy Creek	Yes / Yes
Ametek Inc. U.S. Gauge Division	Sellersville, PA	Open System Functional Fluid	2.64	PA0056014	Surface Water	East Branch Perkiomen Creek	No / No
Lake Reg Med/Collegeville	Collegeville, PA	Open System Functional Fluid	0.24	PA0042617	Surface Water	Lower Perkiomen Creek - Donny Brook	No / No
Pall Life Sciences Inc	Ann Arbor, MI	Open System Functional Fluid	5.42	MI0048453	Surface Water	Honey Creek	Yes / Yes
Beacon Heights Landfill	Beacon Falls, CT	Disposal	30.06	CTMIU0161	Surface Water	Bladens River-Naugatuck River	No / No
Ingersoll Rand/Torrington Facility	Walhalla, SC	Disposal	11.49	SC0049093	Surface Water	Cane Creek-Little River	No / No

[1]Further detail on water releases and media of release are available at https://echo.epa.gov/

2.1.1.3 Assumptions and Key Sources of Uncertainty for Environmental Releases

EPA estimated water releases using reported discharges from the 2018 TRI and the 2018 DMR. TRI and DMR data were determined to have a "medium" confidence rating through EPA's systematic review process. Due to reporting requirements for TRI and DMR, the number of sites for a given OES may be underestimated. It is uncertain the extent to which sites not captured in these databases discharge wastewater containing 1,4-dioxane and whether any such discharges would be to surface water, POTW, or non-POTW WWT.

In addition, information on the use of 1,4-dioxane at facilities in TRI and DMR is limited; therefore, there is uncertainty as to whether the number of facilities estimated for a given OES do in fact represent that specific OES. If sites were categorized under a different OES, the annual wastewater discharges for each site would remain unchanged; however, average daily discharges may change depending on the release days expected for the different OES.

Facilities reporting to TRI and DMR only report annual discharges; to assess daily discharges, EPA estimated the release days and averaged the annual releases over these days. There is uncertainty that all sites for a given OES operate for the assumed duration; therefore, the average daily discharges may be higher if sites have fewer release days or lower if they have greater release days. TRI-reporting facilities are required to submit their "best available data" to EPA for TRI reporting purposes. Some facilities are required to measure or monitor emissions or other waste management quantities due to regulations unrelated to the TRI Program (*e.g.*, permitting requirements), or due to company policies. These existing, readily available data are often used by facilities for TRI reporting purposes, as they represent the best available data. When monitoring or direct measurement data are not readily available or are known to be non-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. These reasonable estimates may be obtained through various Release Estimation Techniques, including mass-balance calculations, the use of emission factors, and engineering calculations. There may be greater uncertainty in data resulting from estimates compared to monitoring measurements.

Furthermore, 1,4-dioxane concentrations in wastewater discharges at each site may vary from day-to-day such that on any given day the actual daily discharges may be higher or lower than the estimated average daily discharge.

In some cases, the number of facilities for a given OES was estimated using data from the U.S. Census. In such cases, the average daily release calculated from sites reporting to TRI or DMR was applied to the total number of sites reported in (U.S. Census Bureau, 2015). It is uncertain how accurate this average release is to actual releases at these sites; therefore, releases may be higher or lower than the calculated amount.

2.1.1.3.1 Summary of Overall Confidence in Release Estimates

Table 2-5 provides a summary of EPA's overall confidence in its release estimates for each of the Occupational Exposure Scenarios assessed.

Table 2-5. Summary of Overall Confidence in Release Estimates by OES

Occupational Exposure Scenario (OES)	Overall Confidence in Release Estimates
Manufacturing	Wastewater discharges are assessed using reported discharges from the 2018 TRI for two sites. TRI data were determined to have a "medium" confidence rating through EPA's systematic review process. Facilities reporting to TRI only report annual discharges; to assess daily discharges, EPA assumed 250 days/yr. of operation and averaged the annual discharges over the operating days. There is some uncertainty that all sites manufacturing 1,4-dioxane will operate for this duration; therefore, the average daily discharges may be higher if sites operate for fewer than 250 days/yr. or lower if they operate for greater than 250 days/yr. Furthermore, 1,4-dioxane concentrations in wastewater discharges at each site may vary from day-to-day such that on any given day the actual daily discharges may be higher or lower than the estimated average daily discharge. Based on this information, EPA has a medium confidence in the wastewater discharge estimates for the two sites in the 2018 TRI.
Import and Repackaging	Wastewater discharges are assessed using reported discharges from the 2018 TRI and the 2018 DMR. TRI and DMR data were determined to have a "medium" confidence rating through EPA's systematic review process. Due to reporting requirements for TRI and DMR, the number of sites in this OES may be underestimated. It is uncertain the extent that sites not captured in these databases discharge wastewater containing 1,4-dioxane and whether any such discharges would be to surface

Occupational Exposure Scenario (OES)	Overall Confidence in Release Estimates
	water, POTW, or non-POTW WWT. Additionally, information on the conditions of use of 1,4-dioxane at facilities in TRI and DMR is limited; therefore, there is some uncertainty as to whether all the sites assessed in this section are performing repackaging (of imported or domestically manufactured volumes) rather than a different OES. If the sites were categorized under a different OES, the annual wastewater discharges for each site would remain unchanged; however, average daily discharges may change depending on the number of operating days expected for the OES. Facilities reporting to TRI and DMR only report annual discharges; to assess daily discharges, EPA assumed 250 days/year of operation and averaged the annual discharges over the operating days. There is some uncertainty that all sites importing or repackaging 1,4-dioxane will operate for this duration; therefore, the average daily discharges may be higher if sites operate for fewer than 250 days/yr. or lower if they operate for greater than 250 days/yr. Furthermore, 1,4-dioxane concentrations in wastewater discharges at each site may vary from day-to-day such that on any given day the actual daily discharges may be higher or lower than the estimated average daily discharge. Based on this information, EPA has a medium confidence in the wastewater discharge estimates.
Recycling	Assessed as part of industrial uses.
Industrial Uses	Wastewater discharges are assessed using reported discharges from the 2018 TRI and the 2018 DMR. TRI and DMR data were determined to have a "medium" confidence rating through EPA's systematic review process. Due to reporting requirements for TRI and DMR, the number of sites in this OES may be underestimated. It is uncertain the extent that sites not captured in these databases discharge wastewater containing 1,4-dioxane and whether any such discharges would be to surface water, POTW, or non-POTW WWT. Additionally, information on the conditions of use of 1,4-dioxane at facilities in TRI and DMR is limited; therefore, there is some uncertainty as to whether all the sites assessed in this section are using 1,4-dioxane in an industrial use capacity rather than a different OES. If the sites were categorized under a different OES, the annual wastewater discharges for each site would remain unchanged; however, average daily discharges may change depending on the number of operating days expected for the OES. Facilities reporting to TRI and DMR only report annual discharges; to assess daily discharges, EPA assumed 250 days/yr. of operation and averaged the annual discharges over the operating days. There is some uncertainty that all sites using 1,4-dioxane for industrial uses will operate for this duration; therefore, the average daily discharges may be higher if sites operate for fewer than 250 days/yr. or lower if they operate for greater than 250 days/yr. Furthermore, 1,4-dioxane concentrations in wastewater discharges at each site may vary from day-to-day such that on any given day the actual daily discharges may be higher or lower than the estimated average daily discharge. Based on this information, EPA has a medium confidence in the wastewater discharge estimates.
Functional Fluids (Open-System)	Wastewater discharges are assessed using reported discharges from the 2018 TRI and the 2018 DMR. TRI and DMR data were determined to have a "medium" confidence rating through EPA's systematic review process. Due to reporting requirements, the number of sites reflected in TRI and DMR is assessed as an underestimate. EPA included the estimated 89,000 metal products and machinery facilities estimated by the ESD on the Use of Metalworking Fluids as a conservative bounding estimate for the possible range of sites. It is uncertain the extent that sites not captured in the TRI and DMR databases discharge wastewater containing 1,4-dioxane and whether any such discharges would be to surface water, POTW, or non-POTW WWT. Additionally, information on the conditions of use of 1,4-dioxane at facilities in TRI and DMR is limited; therefore, there is some uncertainty as to whether all the sites assessed in this section are using 1,4-dioxane in an open system functional fluids capacity rather than a different OES. If the sites were categorized under a different OES, the annual wastewater discharges for each site would remain unchanged; however,

Occupational Exposure Scenario (OES)	Overall Confidence in Release Estimates
	average daily discharges may change depending on the number of operating days expected for the OES. Facilities reporting to TRI and DMR only report annual discharges; to assess daily discharges, EPA assumed 247 days/yr. of operation and averaged the annual discharges over the operating days. There is some uncertainty that all sites using 1,4-dioxane for open system functional fluids will operate for this duration; therefore, the average daily discharges may be higher if sites operate for fewer than 247 days/yr. or lower if they operate for greater than 247 days/yr. Furthermore, 1,4-dioxane concentrations in wastewater discharges at each site may vary from day-to-day such that on any given day the actual daily discharges may be higher or lower than the estimated average daily discharge. Based on this information, EPA has a medium confidence in the wastewater discharge estimates.
Laboratory Chemicals	Water releases from laboratory uses are unlikely as laboratories collect and track spent and unspent chemicals prior to hazardous waste disposal. The releases of 1,4-dioxane from laboratory uses are to air (through volatile releases into the indoor laboratory air and/or through laboratory fume hoods to atmospheric air) and liquid wastes of 1,4-dioxane are handled as hazardous waste. The commercial analytical laboratories and university laboratories handle their wastes as hazardous waste and they are not allowed to discharge wastes to POTW via pouring the wastes down the drain. The number of laboratories assessed is based on the U.S. Census Bureau data for NAICS code 541380, Testing Laboratories. This NAICS code was chosen based on the main use of 1,4-dioxane in the laboratory setting: as a reference standard for determination of analytes in bulk pharmaceuticals. There are other types of laboratories, such as university laboratories and analytical laboratories, that may use 1,4-dioxane that are not represented in this NAICS code. However, it is unknown how many of laboratories within each of these categories use 1,4-dioxane. Thus, it is possible that the inclusion of only NAICS code 541380 could overrepresent the number of laboratories that use 1,4-dioxane. The direction of bias, whether the 6,844 number of sites is an underestimate or overestimate of the number of laboratories using 1,4-dioxane, is unknown. However, EPA has high confidence in the assessment of no or negligible releases to water or POTWs. This high confidence in no releases of water mitigates the uncertainties in the estimate of number of sites. Based on this information, EPA has a high confidence in the wastewater discharge estimates.
Film Cement	EPA assessed no wastewater discharges for this OES. The small glue bottles could be disposed of as solid waste without rinsing them in a sink. There is some uncertainty as to whether and what quantity of 1,4-dioxane could remain in the small glue bottles when disposed. However, due to the small quantities of the glue and high volatility of the 1,4-dioxane, EPA expects any residual 1,4-dioxane to evaporate to the air or remain in the solid waste stream. Small amount of film cement could inadvertently be spilled inside a facility, but due to the higher viscosity and small quantities of the substance, it will likely be cleaned up via wiping and disposed of as solid waste. Based on this information, EPA has a high confidence in the release assessment.
Spray Foam Application	Wastewater discharges are assessed using EPA's container residual model. EPA defined operating days, operating days per site, foam thickness, and mass fraction of B-side in final formulation from the Generic Scenario for Application of Spray Polyurethane Foam Insulation. The parameters for average roofing area were defined from homeadvisor.com and houselogic.com. The parameters for density and mass fraction of the 1,4-dioxane in the B-side formulation were defined from a spray foam producer's technical fact sheet. This EPA model addresses residual spray polyurethane foam in the container only and is based on industry averages, such as roof size. As a result of the model limitations and uncertainties due to various activities including container cleaning and product handling could vary dramatically on a site-by-site basis. It is uncertain to the extent these water releases are over- or underestimated.

Occupational Exposure Scenario (OES)	Overall Confidence in Release Estimates
	EPA determined that there were 17,857 establishments that fell into NAICS code 238310, for Drywall and Insulation Contractors. The GS estimates that a contractor spends three days at a job site before moving to the next job site and further estimates that a contractor works 260 days per year. Assuming a contractor works at only a single job site at a time, EPA calculates that a contractor works at approximately 87 job sites per year (260 working days divided by three days per job site). EPA multiplied the number of contractors by 87 to determine a bounding limit for the number of job sites in a year at which all contractors could potentially discharge container residuals down a drain to a POTW or directly on the ground, which could eventually reach surface waters. Based on this information, EPA has a low confidence in the release assessment.
Printing Inks (3D)	EPA assessed no wastewater discharges for this OES. EPA expects spent printing ink containers, shavings or fragments, or waste scraps to be disposed of as solid waste. There is some uncertainty as to whether and how much 1,4-dioxane may remain in 3D printed products and waste scraps. However, due to the volatility of 1,4-dioxane, EPA expects 1,4-dioxane to evaporate from any printed object, shavings or fragments, or other printed material deposited to the floor or work surface prior to it being cleaned and disposed of. EPA acknowledges that some 3D printing inks may be inadvertently spilled inside a facility prior to printing and some quantities may not be properly captured through spill containment techniques, resulting in printing ink being discharged to POTW (through floor or sink drains. Due to the high volatility of 1,4-dioxane, EPA expects any spilled printing ink not captured by spill containment materials to primarily be released to air. Based on this information, EPA has a high confidence in the release assessment.
Dry Film Lubricant	EPA assessed no wastewater discharges for this OES based on conversations with the only known facility to use the product. All dry film lubricant materials are mixed and handled in a laboratory setting underneath a fume hood. The material is sprayed onto components in a spray booth with ventilation. Wastes are containerized and handled as wastes for removal by a waste handler. There is some uncertainty as to whether and how much 1,4-dioxane may be deposited on the floor or other surfaces as a result of overspray or spills. However, due to the volatility of 1,4-dioxane and expected spill clean-up methods of the laboratory setting, EPA expects deposited overspray or spilled 1,4-dioxane to evaporate to the air or be contained in spill containment materials and handled as waste. Based on this information, EPA has a high confidence in the release assessment.
Disposal	Wastewater discharges are assessed using reported discharges from the 2018 TRI and the 2018 DMR. TRI and DMR data were determined to have a “medium” confidence rating through EPA’s systematic review process. Due to reporting requirements for TRI and DMR, the number of sites in this OES may be underestimated. It is uncertain the extent that sites not captured in these databases discharge wastewater containing 1,4-dioxane and whether any such discharges would be to surface water, POTW, or non-POTW WWT. Additionally, information on the conditions of use of 1,4-dioxane at facilities in TRI and DMR is limited; therefore, there is some uncertainty as to whether all the sites assessed in this section are using 1,4-dioxane in a disposal capacity rather than a different OES. If the sites were categorized under a different OES, the annual wastewater discharges for each site would remain unchanged; however, average daily discharges may change depending on the number of operating days expected for the OES. Facilities reporting to TRI and DMR only report annual discharges; to assess daily discharges, EPA assumed 250 days/yr. of operation and averaged the annual discharges over the operating days. There is some uncertainty that all sites using 1,4-dioxane for disposal will operate for this duration; therefore, the average daily discharges may be higher if sites operate for fewer than 250 days/yr. or lower if they operate for greater than 250 days/yr. Furthermore, 1,4-dioxane concentrations in wastewater discharges at each site may vary from day-to-day such that on any given day the actual daily discharges may be higher or lower than the estimated average daily discharge. Based on this information, EPA has a medium confidence in the wastewater discharge estimates.

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2.4 Human Exposures

2.1.2 General Population Exposure

1,4-Dioxane does not currently have established water quality criteria to protect human health under the CWA Section 304(a). Therefore, in this evaluation, EPA considers potential general population exposures via the ambient water pathway through evaluating incidental oral and dermal exposures related to recreational activities such as swimming. 1,4-Dioxane is not expected to accumulate in fish tissues; therefore, exposures to the general population via fish ingestion are not expected. The EPI Suite™ BCFBAF model estimates 1,4-dioxane's bioaccumulation factor (BAF) to be 0.9. The BAF indicates the concentration in fish tissues relative to the surrounding water, with concentrations in fish tissues resulting from partitioning from water and dietary sources and reduced by metabolism. A BAF < 1 indicates that concentrations in fish tissues are expected to be lower than aqueous concentrations and supports the expectation that fish ingestion is not a primary pathway of human exposure for 1,4-dioxane. This is consistent with human and rat toxicokinetic data suggesting a short half-life (approximately 1 hour) for 1,4-dioxane following uptake. Given its hydrophilic properties and short half-life, 1,4-dioxane is not expected to accumulate in tissue .

2.1.2.1 General Population Exposure Approach

Both estimated (*i.e.*, modeled) and measured levels of 1,4-dioxane in ambient water/surface water, were used to estimate incidental oral and dermal exposures during recreational activities such as swimming. Based on the incidental nature of such exposures, this supplemental analysis focuses on only acute exposures.

2.1.2.1.1 Modeling Surface Water Concentrations

In Section 2.2.1, Environmental Releases to Water, EPA estimates annual releases, release days, and number of facilities to provide a range of daily water releases for each OES based on 2018 TRI and DMR. Some OES had no predicted releases to surface water (see Table 2-1). Therefore, included in this evaluation of general population exposures via ambient water include discharging sites involved in the following OES: manufacturing, industrial uses, functional fluids (open-system), spray foam application, and disposal. Table 2-1 shows the range of surface water release estimates across these OES; however, site-specific discharges are provided and used in this exposure analysis (see Supplemental File [*Exposure Modeling Inputs, Results, and Risk Estimates for Incidental Ambient Water Exposure*]).

Using the described site-specific water release information (kg/site/day) and days of release based on OES categories and assumptions, environmental modeling was conducted using EPA's Exposure and Fate Assessment Screening Tool (E-FAST 2014) to predict surface water concentrations in near-facility ambient water bodies (U.S. EPA, 2014c). For more on the operation and inputs of the E-FAST model, refer to the Estimating Surface Water Concentrations Section of Appendix E and the E-FAST 2014 Documentation Manual (U.S. EPA, 2007).

In this evaluation, site-specific stream flows were applied within E-FAST, where available, and no wastewater treatment removal was applied. E-FAST does not incorporate degradation or volatilization once released and estimates concentrations at the point of release (not downstream).

Modeled Surface Water Concentrations

Table 2-6 displays the modeled surface water concentrations obtained from E-FAST, as well as the site-specific water release inputs. Refer to the Supplemental Files [*Exposure Modeling Inputs, Results, and*

Risk Estimates for Incidental Ambient Water Exposure and *Ambient Water Exposure Modeling Output from E-FAST*].

Table 2-6. Modeled Surface Water Concentrations

Occupational Exposure Scenario (OES)	Facility	SIC Code or NPDES[1]	Daily Release (kg/site/day)	Days of Release	30Q5[2] Surface Water Concentration (µg/L)
Manufacturing	BASF	LA0004057	2.48	250	9.67E+01
Industrial Uses	Ineos Oxide	Industrial POTW	2.89	250	2.17E+02
	Microdyn-Nadir Corp	Industrial POTW	0.10	250	7.24E+00
	St Charles Operations (Taft/Star) Union Carbide Corp	LA0000191	3.31	250	1.11E-02
	SUEZ Water Technologies & Solutions	Industrial POTW	67.68	250	5.09E+03
	The Dow Chemical Co - Louisiana Operations	LA0003301	2.59	250	8.70E-03
	Union Carbide Corp Institute Facility	WV0000078	15.28	250	3.33E+00
	Union Carbide Corp Seadrift Plant	TX0002844	2.01	250	2.41E+01
	BASF Corp	PA0092223	0.01	250	3.40E-01
	Cherokee Pharmaceuticals LLC	PA0008419	0.01	250	2.63E-03
	DAK Americas LLC	NC0003719	31.86	250	2.78E+01
	Institute Plant	WV0000086	24.53	250	5.27E+00
	Kodak Park Division	NY0001643	0.256	250	1.70E-01
	Pharmacia & Upjohn (Former)	CT0001341	0.00	250	2.74E-02
	Philips Electronics Plant	TX0023779	0.00	250	1.00E-01
	Sanderson Gulch Drainage Improvements	Industrial POTW	0.00	250	1.00E-02
Open System Functional Fluids	Ametek Inc. U.S. Gauge Div	PA0020460	0.01	247	4.00E-01
	Lake Reg Med/Collegeville	PA0042617	0.00	247	1.31E-02

Occupational Exposure Scenario (OES)	Facility	SIC Code or NPDES[1]	Daily Release (kg/site/day)	Days of Release	30Q5[2] Surface Water Concentration (µg/L)
	Pall Life Sciences Inc	MI0024066	0.02	247	4.30E-02
	Modeled Release Estimates	Industrial POTW	0.038	247	2.85E+00
Spray Foam Application	Modeled Release Estimates	Industrial POTW	0.00	260	2.70E-01
Disposal	Beacon Heights Landfill	CT0101061	0.12	250	5.30E-01
	Ingersoll Rand/Torrington Fac	Industrial POTW	0.05	250	3.46E+00

[1] Some of the site-specific OES release estimates were unable to be associated with a specific NPDES code and receiving water body within the E-FAST model. These sites were modeled using a generic, sector-specific SIC code.
[2] Predicted 30Q5 surface water concentrations are the concentrations predicted using a 30Q5 stream flow. The 30Q5 stream flow is the lowest 30-day mean stream flow for a recurrence interval of five years. For sites modeled using a generic SIC code, the values in this column correspond to concentrations predicted using the low-end (*i.e.*, 10th percentile) of the 30Q5 stream flow distribution for that SIC code. Receiving stream flow distributions for direct discharges within a given SIC code are used to apply the 10th percentile flow. The 30Q5 concentrations are used in this evaluation over the mean or 7Q10 concentrations based on alignment with the E-FAST guidance for assessing acute drinking water exposures; this is noted to be consistent with EPA's Office of Water Technical Support Document for Water Quality-Based Toxics Control (U.S. EPA, 2007).

2.1.2.1.2 Measured Surface Water Concentrations

Surface water monitoring data were discussed and submitted during the public comment for 1,4-dioxane. These submitted sources are briefly summarized below and were utilized in this evaluation of general population exposures via ambient water.

A report from the North Carolina Department of Environmental Quality identified 1,4-dioxane in surface water in the Deep, Haw, and Cape Fear Rivers at levels as high as 1,030 ug/L (mean 42.6-350.5 ug/L) (EPA-HQ-OPPT-2019-0238-0042; EPA-HQ-OPPT-2019-0238-0060; EPA-HQ-OPPT-2019-0238-0061). Sun et al. (2016) reported detections in North Carolina's Cape Fear watershed of 154 to 1,405 µg/L. The Minnesota Department of Environmental Quality reported 1,4-dioxane in state surface waters at levels ranging from 0.05 to 4.4 µg/L (EPA-HQ-OPPT-2019-0238-0043). The upper ends of these ranges were also used to estimate incidental oral and dermal exposures from swimming.

2.1.2.1.3 Estimating Incidental Oral Exposures from Swimming

Predicted stream concentrations were used to estimate incidental acute incidental oral exposure from swimming. Predicted surface water concentrations range from 2.63E-03 µg/L to 5.09E+03 µg/L (see Table 2-6); this range of predicted concentrations encompasses the full range of the surface water monitoring data submitted during the public comment period.

Additional inputs/exposure factors used to estimate these acute oral exposures are included in

Table **2-7**. Supplemental Analysis File [*Exposure Modeling Inputs, Results, and Risk Estimates for Incidental Ambient Water Exposure*] for additional details on inputs and assumptions. This evaluation focused on children 11-15 years, as they present most conservative conditions when considering the age-specific ingestion rate, body weight, and duration of exposure.

Table 2-7 Incidental Oral Exposure Factors

Description	Value	Notes
Age Class	11-15	Selected based on having highest incidental oral ingestion rate during swimming from the Exposure Factors Handbook, Table 3-7 (EPA, 2019b)
Incidental Ingestion Rate	152 mL/hr	Upper-percentile hourly incidental ingestion rate from the Exposure Factors Handbook, Table 3-7 (EPA, 2019b)
Body Weight	56.8 kg	Recommended, mean body weight for children 11-15 from the Exposure Factors Handbook Table 8-1 (U.S. EPA, 2011)
Duration of Exposure	2 hrs/day	High-end default short-term duration default from EPA Swimmer Exposure Assessment Model (SWIMODEL); based on competitive swimmers in the child 11-15 age class (EPA, 2015)
Daily Incidental Ingestion Rate	0.304 L/day	0.152 L/day * 2 hrs

The equation used to estimate the acute daily dose rate (ADR) for incidental oral ingestion is shown below (U.S. EPA, 2007):

$$ADR = \frac{SW\ x\ IR\ x\ CF}{BW}$$

Where,

SWC = Surface water concentration (µg/L)
IR = Daily ingestion rate (L/day)
CF = 0.001 mg/µg
BW = Body weight (kg)

2.1.2.1.4 Estimating Dermal Exposures from Swimming

Predicted stream concentrations were used to estimate incidental acute and incidental dermal exposure from swimming. Predicted surface water concentrations ranges from 2.63E-03 µg/L to 5.09E+03 µg/L (see Table 2-6). Additional inputs/exposure factors used to estimate these acute dermal exposures are included in

Table 2-8. Supplemental Analysis File [*Exposure Modeling Inputs, Results, and Risk Estimates for Incidental Ambient Water Exposure*] for additional details on inputs and assumptions. This evaluation focused on the adult age class, as they present the most conservative exposure conditions when considering the age-specific surface area to body weight ratio and duration of exposure. Default parameterization from OPP's SWIMODEL were utilized for most inputs as shown in Table 2-8 (EPA, 2015).

Table 2-8 Dermal Exposure Factors

Description	Value	Notes
Age Class	Adult	Selected based on having highest dose based on permeability-based dermal exposure equation used in SWIMODEL, considering exposed surface area, duration, and body weight
Skin Surface Area	19,500 cm^2	Default dermal contact surface area for the adult age class in SWIMODEL(EPA, 2015)
Body Weight	80 kg	Recommended, mean body weight for adult age class (EFH, Table 8-1)

Description	Value	Notes
Exposure Duration	3 hrs/day	High-end, short-term default duration from EPA Swimmer Exposure Assessment Model (SWIMODEL); based on competitive swimmers in the adult age class (EPA, 2015)
Permeability Coefficient (Kp)	5.05E-04 cm/hr	Estimated using IHSkinPerm© for 1,4-dioxane dermally absorbed into the stratum corneum from water

The equation used to estimate the acute daily dose rate for dermal exposure from swimming shown below (EPA, 2015):

$$ADR = \frac{CW\ x\ Kp\ x\ SA\ x\ ET\ x\ CF}{BW}$$

Where,

CW = Chemical concentration in water (mg/L)
Kp = Permeability coefficient (cm/hr)
SA = Skin surface area exposed (cm^2)
ET = Exposure time (hrs/day)
CF = Conversion factor (0.001 L/cm^3)
BW = Body Weight (kg)

2.1.2.2 General Population Exposure Results

Estimated acute incidental oral exposures range from 1.41E-08 to 2.73E-02 mg/kg/day, while estimated acute dermal exposures range from 9.71E-10 to 1.88E-03 mg/kg/day. The highest doses are associated with releases from the industrial uses OES. This range of exposure estimates cover acute oral and dermal doses estimated using both modeled and measured surface water concentrations. Refer to the Supplemental File [*Exposure Modeling Inputs, Results, and Risk Estimates for Incidental Ambient Water Exposure*] and Section 4.2.2 for the full set of results for all releasing sites and submitted monitoring data.

2.1.2.3 Assumptions and Key Sources of Uncertainty Uncertainties for General Population Exposure

EPA's approach recognizes the need to include uncertainty analysis. One important distinction for such an analysis is variability versus uncertainty – both aspects need to be addressed. Variability refers to the inherent heterogeneity or diversity of data in an assessment. It is a quantitative description of the range or spread of a set of values and is often expressed through statistical metrics, such as variance or standard deviation, that reflect the underlying variability of the data. Uncertainty refers to a lack of data or an incomplete understanding of the context of the risk evaluation decision. Variability cannot be reduced, but it can be better characterized. Uncertainty can be reduced by collecting more or better data. Quantitative methods to address uncertainty include non-probabilistic approaches such as sensitivity analysis and probabilistic or stochastic methods. Uncertainty can also be addressed qualitatively, by including a discussion of factors such as data gaps and subjective decisions or instances where professional judgment was used. Uncertainties associated with approaches and data used in the evaluation of general population exposures are described below.

Modeling Inputs and Assumptions

Releases modeled using E-FAST 2014 were predicted based on engineering site-specific estimates based on DMR and TRI reporting databases. These data that form the basis for engineering estimates are self-reported by facilities subject to minimum reporting thresholds; therefore, they may not capture releases from certain facilities not meeting reporting thresholds (*i.e.*, environmental releases may be underestimated). These release estimates, however, are described as having a medium level of confidence in Section 2.2.1.3.1.

E-FAST 2014 estimates surface water concentrations at the point of release, without accounting for post-release environmental fate or degradation processes such as volatilization, biodegradation, photolysis, hydrolysis, or partitioning. Additionally, E-FAST does not estimate stream concentrations based on the potential for downstream transport and dilution. These considerations tend to lead to higher predicted surface water concentrations. Dilution is incorporated, but it is based on the stream flow applied. Therefore, there is uncertainty regarding the level of 1,4-dioxane that would be predicted downstream of a releasing facility or after accounting for potential volatilization from the water surface, which is dependent on the degree of mixing in a receiving water body.

The ambient water analysis assumes that members of the general population are incidentally exposed via swimming in ambient waters, but there is uncertainty surrounding the likelihood that such recreation and contact would occur at or near the point of release. If such activities occurred further from the point of release, this analysis may overestimate the water concentrations that swimmers would be exposed to.

EPA's SWIMODEL was used as the source for exposure duration. This model is intended to assess exposure from swimming in pools, not ambient water bodies, so there is uncertainty about the application of swimming pool duration data in this analysis.

Aggregate Exposure

Background levels of 1,4-dioxane from other sources are not considered or aggregated in this analysis; therefore, there is a potential for underestimating exposures, particularly for populations living near a facility emitting 1,4-dioxane or living in a home with other sources of 1,4-dioxane, such as other 1,4-dioxane-containing products stored and/or used in the home such as personal care products that are not covered under TSCA. Similarly, there was no aggregation of incidental oral and dermal exposures from swimming, which would be expected to be concurrent.

2.1.2.4 Confidence in General Population Exposure Estimates

Confidence ratings for general population ambient water exposure scenarios are informed by uncertainties surrounding inputs and approaches used in modeling surface water concentrations and estimating incidental oral and dermal doses. In Section 2.2.1.3.1, confidence ratings are assigned to these estimated daily releases (kg/site-day) on a per occupational exposure scenario (OES) basis and reflect moderate confidence.

Other considerations that impact confidence in the ambient water exposure scenarios include the model used (E-FAST 2014) and its associated default and user-selected values and related uncertainties. As described, there are uncertainties related to the ability of E-FAST 2014 to incorporate downstream fate and transport. Of note, as stated on the EPA's E-FAST 2014 website, "modeled estimates of concentrations and doses are designed to reasonably overestimate exposures, for use in an exposure assessment in the absence of or with reliable monitoring data." Regarding the assumption that members of the general population could reasonably be expected to swim at or near the point of release, there is relatively low confidence due to uncertainty.

EPA utilized the SWIMODEL default duration parameters to estimate incidental dermal and oral exposures to the general population from swimming in ambient water bodies. The model's default duration inputs were based on swimming pool use patterns rather than freshwater bodies, so there is low to moderate confidence that these parameters accurately reflect the ambient water body recreation activities covered in this supplemental analysis.

There are surface water monitoring data available that reflect ambient water exposure levels in the United States (see Section 2.4.2.3). These data were submitted from only two states (NC and MN) and may reflect multiple sources of 1,4-dioxane in surface water that may or may not be related to within-scope occupational exposure scenarios. Because these monitoring data reflect surface water conditions at specific sampling sites during a specific sampling period, they may not reflect current levels of 1,4-dioxane in surface water. The modeled surface water concentration ranges obtained from E-FAST modeling (2.63E-03 - 5.09E+03 µg/L) encompass the full range of the surface water monitoring data submitted during public comment period.

Based on the above considerations, the general population ambient water exposure assessment scenarios have an overall low to moderate confidence.

2.1.3 Consumer Exposures

As explained in the scope document, 1,4-dioxane may be found as a contaminant in consumer products that are readily available for public purchase.

2.1.3.1 Consumer Conditions of Use and Routes of Exposure Evaluated

Eight consumer conditions of use are evaluated based on the uses identified in EPA's 2015 TSCA Work Plan Chemical Problem Formulation and Initial Assessment of 1,4-Dioxane (U.S. EPA, 2015). An additional systematic review effort was undertaken for consumer exposures to identify, screen, and evaluate relevant data sources. These conditions of use include surface cleaner, antifreeze, dish soap, dishwasher detergent, laundry detergent, paint and floor lacquer, textile dye, and spray polyurethane foam (SPF). 1,4-Dioxane may be found in these products at low levels (0.0009 to 0.02%) based on its presence as a byproduct of other formulation ingredients, *i.e.*, ethoxylated chemicals.

Inhalation exposures to 1,4-dioxane are estimated for household consumers (*i.e.*, product users – receptors who use a product directly) and bystanders (*i.e.*, receptors who are a non-user that may be incidentally exposed to the product). Acute inhalation exposures are presented for all conditions of use, while chronic inhalation exposures are only presented for conditions of use that are reasonably expected to involve daily use intervals (*i.e.*, surface cleaner, dish soap, dishwasher detergent, and laundry detergent). Other conditions of use (*i.e.*, SPF, antifreeze, textile dye, and paint and floor lacquer) are not evaluated over chronic exposure durations based on expected infrequent and intermittent use frequencies.

Dermal exposures to 1,4-dioxane are estimated for household consumers, or users. Users are assumed to include adults (21+ years) and children (11-20 years). As with inhalation, acute dermal exposures are presented for all conditions of use, while chronic inhalation exposures are only presented for conditions of use that are reasonably expected to involve daily use intervals (*i.e.*, surface cleaner, dish soap, dishwasher detergent, and laundry detergent). Other conditions of use (*i.e.*, SPD, antifreeze, textile dye, and paint and floor lacquer) are not evaluated over chronic exposure durations based on expected infrequent and intermittent use frequencies. Generally, individuals that have contact with liquid 1,4-dioxane would be users and not bystanders. Therefore, direct dermal exposures are not expected for bystanders and are only estimated for users.

2.1.3.2 Potentially Exposed or Susceptible Subpopulations

Consumers and bystanders are potentially exposed or susceptible subpopulations (PESS) due to their greater exposure. Additionally, high-intensity users (*i.e.*, those using consumer products for longer durations or in great amounts) are evaluated. Consumers are considered to include children and adults, ages 11 and up, while bystanders in the home exposed via inhalation could include children and adults of all ages.

2.1.3.3 Consumer Exposure Modeling Approach

Modeling was conducted to estimate exposure from the identified consumer conditions of use. Exposures via inhalation and dermal contact to consumer products were estimated using EPA's Consumer Exposure Model (CEM) Version 2.1 (U.S. EPA, 2019a), along with consumer behavioral pattern data (*i.e.*, use patterns) and product-specific inputs. An older version of CEM, available within E-FAST 2014, was used to estimate chronic inhalation exposures and obtain lifetime average daily concentration outputs (U.S. EPA, 2014c). EPA's Multi-Chamber Concentration and Exposure Model (MCCEM) was used to estimate inhalation exposures related to use of SPF based on the availability of measured emission rate data for that scenario (EPA, 2010). Table 2-9 displays the models used to estimate inhalation and dermal exposures across the consumer conditions of use.

Table 2-9 Models Used Across Consumer Conditions of Use and Routes of Exposure

Consumer Condition of Use	Acute Inhalation Exposure	Chronic Inhalation Exposure	Acute Dermal Exposure	Chronic Dermal Exposure
Surface Cleaner	CEM 2.1	CEM	CEM 2.1	CEM 2.1
Antifreeze	CEM 2.1	---	CEM 2.1	---
Dish Soap	CEM 2.1	CEM	CEM 2.1	CEM 2.1
Dishwasher Detergent	CEM 2.1	CEM	CEM 2.1	CEM 2.1
Laundry Detergent	CEM 2.1	CEM	CEM 2.1	CEM 2.1
Paint and Floor Lacquer	CEM 2.1	---	CEM 2.1	---
Textile Dye	CEM 2.1	---	CEM 2.1	---
SPF	MCCEM	---	CEM 2.1	---

Emission data were identified and evaluated through systematic review. For some conditions of use, emission data were used to support estimated exposures and to model emissions of SPF (see Appendix A.1.2.1).

2.1.3.3.1 Modeling Air Concentrations and Inhalation Exposure

Consumer Exposure Model

CEM 2.1 and CEM predict indoor air concentrations from consumer product use by implementing a deterministic, mass-balance calculation utilizing an emission profile determined by applying appropriate emission scenarios. The model uses a two-zone representation of the building of use (*e.g.,* residence, school, office), with Zone 1 representing the room where the consumer product is used (*e.g.,* a utility room) and Zone 2 being the remainder of the building. The product user is placed within Zone 1 for the duration of use, while a bystander is placed in Zone 2 during product use. Otherwise, product users and bystanders follow prescribed activity patterns throughout the simulated period.

For acute exposure scenarios, emissions from each incidence of product usage are estimated over a period of 72 hours using the following approach that accounts for how a product is used or applied, the total applied mass of the product, the weight fraction of the chemical in the product, and the molecular weight and vapor pressure of the chemical. Time weighted averages (TWAs) were then computed based on these user and bystander concentration time series per available human health hazard data. For 1,4-dioxane, 8-hour TWAs were quantified for use in risk evaluation based on alignment of relevant acute human health hazard endpoints. For additional details on CEM 2.1's underlying emission models, assumptions, and algorithms, please see the User Guide Section 3: Detailed Descriptions of Models within CEM 2.1 (U.S. EPA, 2019a), also summarized in Appendix A. The emission models used have been compared to other model results and measured data; see Appendix D: Model Corroboration of the User Guide Appendices for the results of these analyses (U.S. EPA, 2019b).

For chronic exposure scenarios, CEM within E-FAST 2014 was used to obtain lifetime average daily concentrations (LADCs) for the scenarios involving chronic exposures. Emissions are estimated over a period of 60 days. For cases where the evaporation time estimated exceeds 60 days, the model will truncate the emissions at 60 days. Conversely, for cases where the evaporation time is less than 60 days, emissions will be set to zero between the end of the evaporation time and 60 days. For more information on this version of CEM and its chronic inhalation estimates, refer to the E-FAST 2014 Documentation Manual (U.S. EPA, 2007).

The general steps of the calculation engine within the CEM 2.1 and CEM models include:

- Introduction of the chemical (*i.e.*, 1,4-dioxane into the room of use (Zone 1) through two possible pathways: (1) overspray of the product or (2) evaporation from a thin film;
- Transfer of the chemical to the rest of the house (Zone 2) due to exchange of air between the different rooms;
- Exchange of the house air with outdoor air; and
- Compilation of estimated air concentrations in each zone as the modeled occupant (*i.e.*, user or bystander) moves about the house per prescribed activity patterns.

Multi-Chamber Concentration and Exposure Model

The Multi-Chamber Concentration and Exposure Model (MCCEM) estimated indoor air concentrations of chemicals released from household products (EPA, 2010). It uses air infiltration and interzonal air flow rates with user-input emission rates to calculate time-varying concentrations in several zones or chambers within a residence. Four types of source models are available in MCCEM – constant, single exponential, incremental, and data entry. For additional details, see the MCCEM User Guide (EPA, 2019c).

Within MCCEM, the incremental source model is specifically designed for products that are applied to a surface (as SPF is) rather than products that are placed in an environment (*e.g.*, an air freshener). This distinction is important because the incremental source model considers the time or duration of application or use in its calculations of emissions and concentrations, while the single exponential source model does not. The incremental model assumes a constant application rate over time, coupled with an emission rate for each instantaneously applied segment that declines exponentially.

The incremental model can be populated using data derived from the experimental data and proposed model of emission rates in Karlovich et al. (2011). See Appendix A for details on the underlying equations and applying these data to estimate the emission rate for this scenario.

2.1.3.3.2 Modeling Dermal Exposure

CEM 2.1 contains dermal modeling components that estimate absorbed dermal doses resulting from dermal contact with chemicals found in consumer products: P_DER2a: Dermal Dose from a Product Applied to Skin, Fraction Absorbed Model and P_DER2b: Dermal Dose from Product Applied to Skin, Permeability Model. The selection of the appropriate dermal model was based on whether an evaluated condition of use is expected to involve dermal contact with impeded or unimpeded evaporation. For scenarios that are more likely to involve dermal contact with impeded evaporation (*e.g.*, wiping or cleaning with a chemical soaked rag), the permeability model is applied. In contrast, for scenarios less likely to involve impeded evaporation, the fraction absorbed model is applied. For acute exposure scenarios, dermal acute dose rates (ADRs) are estimated and, for chronic exposure scenarios, lifetime average daily doses (LADDs) are estimated. See Appendix A for a more detailed comparison of these dermal models.

The permeability model estimates the mass of a chemical absorbed and dermal flux based on a permeability coefficient (K_p) and is based on the ability of a chemical to penetrate the skin layer once contact occurs. It assumes a constant supply of chemical directly in contact with the skin throughout the exposure duration. K_p is a measure of the rate of chemical flux through the skin. The parameter can either be specified by the user (if measured data are reasonably available) or be estimated within CEM using a chemical's molecular weight and octanol-water partition coefficient (K_{OW}). The permeability model does not inherently account for evaporative losses (unless the available flux or K_p values are based on non-occluded, evaporative conditions), which can be considerable for volatile chemicals in scenarios where evaporation is not impeded. While the permeability model does not explicitly represent exposures involving such impeded evaporation, the model assumptions make it the preferred model for an such a scenario. For 1,4-dioxane, an estimated aqueous dermal permeability coefficient (K_p, 5.05E-04 cm/hr) is used, based on IHSkinPerm© predictions. For additional details on this model, please see Appendix A and the CEM User Guide Section 3: Detailed Descriptions of Models within CEM (U.S. EPA, 2019a).

The fraction absorbed model estimates the mass of a chemical absorbed through the applicational of a fractional absorption factor to the mass of chemical present on or in the skin following a use event. The initial dose or amount retained on the skin is determined using a film thickness approach. A fractional absorption factor is then applied the initial dose to estimate absorbed dose. The fraction absorbed is essentially the measure of two competing processes, evaporation of the chemical from the skin surface and penetration deeper into the skin. It can be estimated using an empirical relationship based on Frasch and Bunge (2015). Due to the model's consideration of evaporative processes, it was considered more representative of dermal exposure under unimpeded exposure conditions. For additional details on this model, please see Appendix A and the CEM User Guide Section 3: Detailed Descriptions of Models within CEM (U.S. EPA, 2019a).

2.1.3.4 Consumer Exposure Scenarios and Modeling Inputs

Based on the combination of high-end and central tendency inputs, modeling results are presented for "high-intensity users" or "moderate-intensity users." High-intensity user scenarios are characterized by high-end (*i.e.*, 95th percentile or maximum) inputs governing key user behavior pattern inputs (duration of use, mass of product used). Moderate-intensity user scenarios are characterized by central tendency (*i.e.*, 50th percentile) inputs governing the key user behavior pattern inputs of duration of use and mass of product used. Although key inputs represent high-end or central tendencies, this was a deterministic assessment and exposure results are not reflective of a distribution.

For acute exposure scenarios, only high-intensity user scenarios that incorporate high-end mass, duration, and weight fraction inputs are presented. For chronic exposure scenarios, both high-end and moderate-intensity user scenarios are presented based on model documentation and the understanding that central tendency parameters may more accurately represent lifetime exposures. CEM and CEM 2.1 are designed to use central tendency inputs for mass, duration, use frequency, and weight fraction when estimating lifetime exposures (U.S. EPA, 2007; U.S. EPA, 2019a). Chronic high-intensity user scenarios, unlike the acute high-intensity user scenarios, utilize central tendency weight fraction inputs, where possible.

Some modeling inputs such as the room of use (*i.e.*, Zone 1 volume) and surface area to body weight ratio exposed in dermal exposure scenarios were held constant across the multiple iterations of a single product scenario but differed across product scenarios based on their product-specific nature. Other parameters such as chemical properties, building volume, air exchange rate, interzonal ventilation rate, and user and bystander activity patterns (*i.e.*, movements around the home) were held constant across all exposure scenarios and reflect central tendency inputs (*i.e.*, median or mean values; see Table 2-10).

For details on default modeling inputs and a sensitivity analysis, see Appendix B and Appendix C, respectively, of the CEM 2.1 user guide appendices (U.S. EPA, 2019b). The sensitivity analysis is also summarized in Appendix A.

Table 2-10 Default Modeling Input Parameters

Parameter Type	Modeling Parameter	Default Value Modeled	Value Characterization	Reference
Building Characteristic[1]	Building Volume (m^3)	492	Central Tendency (Mean)	(U.S. EPA, 2011)
	Air Exchange Rate (hr^{-1})	0.45	Central Tendency (Median)	(U.S. EPA, 2011)
	Interzonal Ventilation Rate[2] (m^3/hr)	107	NA	Defaults (U.S. EPA, 2019a, b)
Emission Characteristics	Background Air Concentration (mg/m^3)	0	Minimum	
	Gas Phase Mass Transfer Coefficient (m/hr)	Based on chemical properties and estimated within CEM (for SPF scenario modeled with MCCEM, see Appendix A)		
	Emission Factor (ug/m^2/hr)			
	Saturation Concentration in Air (mg/m^3)	1.89E+05	Based on chemical properties and estimated within CEM	
Use Patterns and Exposure Factors	Receptor Activity Pattern	Stay at home[3]	NA	Default (U.S. EPA, 2019a, b)
	Use Start Time	9 AM[4]	NA	NA
	Frequency of Use	1 event per day	NA	Defaults (U.S. EPA, 2019a, b)
	Acute Exposure Duration	1 day	NA	

	Acute Averaging Time	1 day	NA	
	Chronic Exposure Duration	57 years	NA	
	Chronic Averaging Time	78 years	NA	
	Surface Area to Body Weight Ratio	Face, Hands, Arms		
		Adult (21+): 15.8	Central tendency (mean)	
		Children (16-20): 14.9		
		Children (11-15): 16.4		
		Both Hands		
		Adult (21+): 12.4	Central tendency (mean)	
		Children (16-20): 11.6		
		Children (11-15): 12.7		
		Inside of One Hand		
		Adult (21+): 3.10	Central tendency (mean)	
		Children (16-20): 2.90		
		Children (11-15): 3.17		
		10% of Hands		
		Adult (21+): 1.24	Central tendency (mean)	
		Children (16-20): 1.16		
		Children (11-15): 1.27		

[1] An overall residential building volume of 492 m^3 is used to calculate air concentrations in Zone 2 and room volume is used to calculate air concentrations in Zone 1. The volume of the near-field bubble in Zone 1 was assumed to be 1 m^3 in all cases, with the remaining volume of Zone 1 comprising the far-field volume.
[2] The default interzonal air flows are a function of the overall air exchange rate and volume of the building, as well as the "openness" of the room itself. Kitchens, living rooms, garages, schools, and offices are considered more open to the rest of the home or building of use; bedrooms, bathrooms, laundry rooms, and utility rooms are usually accessed through one door and are considered more closed.
[3] The activity pattern (*i.e.*, zone location throughout the simulated exposure period) for user and bystander was the default "stay-at-home" resident, which assumes the receptors are primarily in the home (in either Zone 1 or 2) throughout the day. These activity patterns in CEM were developed based on Consolidated Human Activity Database (CHAD) data of activity patterns (Isaacs, 2014).
[4] Product use was assumed to start at 9 AM in the morning; as such, the user was assumed to be in the room of use (Zone 1) at that time, regardless of the default activity pattern at 9 AM.

Key product scenario-specific modeling inputs for inhalation modeling are shown in Table 2-11. For scenarios with both acute and chronic exposure estimates, the table includes both high-end and central tendency inputs for duration, mass, and frequency of use. Please refer to the Supplemental Analysis File [*Consumer Exposure Assessment Modeling Input Parameters*] for a detailed listing of all inputs and associated sources.

Table 2-11 Key Product-Specific Inputs for Inhalation Modeling

Consumer Product Scenario	Form	Range of Product Conc. (ppm)	Max [1] Weight Fraction	Room of Use (volume, m^3)	Duration of Use (min)	Mass of Product Used (g)	Frequency of Use (days/year)
Surface Cleaner	Liquid	0.36 – 9	9.00E-06	Bathroom (15)	30	300	365
					15	200	300
Antifreeze	Liquid	0.01 – 86	8.60E-05	Garage (90)	15	150	NA
Dish Soap	Liquid	0.7 – 204	2.04E-04	Kitchen (24)	20	84	365
					10	48	300
Dishwasher Detergent	Liquid/ Gel	0.86 – 9.7	9.70E-06		50	40	365
					45	20	300
Laundry Detergent	Liquid	0.05 – 14	1.40E-05	Utility Room (20)	50	60	365
					45	40	300
Paint and Floor Lacquer	Liquid	0.02 – 30	3.00E-05	Bedroom (36)	810	26025	NA
Textile Dye	Aqueous	NA	4.70E-06	Utility Room (20)	20	100	NA
SPF [2]	Foam	500 [3]	5.00E-04	Attic (123)	360	4.5 [4]	NA
				Basement (246)		4.5 [4]	
				Garage (118)	180	2.2 [4]	

[1] The use of "Max" (*i.e.*, maximum) here does not indicate use of a theoretical maximum or upper limit but refers to the highest identified weight fraction for a given product type based on the available data. Mean weight fractions were used, where possible, for chronic exposure estimates. See the Supplemental Analysis File [*Consumer Exposure Assessment Modeling Input Parameters*].
[2] The SPF scenario was modeled using MCCEM to estimate inhalation exposures. Please refer to the Supplemental Analysis File [*Consumer Exposure Assessment Modeling Input Parameters*] for additional, distinct modeling inputs for this scenario.
[3] The applied 500 ppm concentration aligns with the related OES, which assumed 50% blending (parts A and B).
[4] Mass of use was not an input in MCCEM as it was in the CEM model. These masses instead reflect the total mass of chemical released in each exposure setting. These were estimated using loading ratios, application surface areas, emission rate per square inch, and decay rate per hour. Please refer to the Supplemental Analysis File [*Consumer Exposure Assessment Modeling Input Parameters*] and Appendix A for more details.

Key product scenario-specific modeling inputs for dermal modeling are shown in Table 2-12. For scenarios with both acute and chronic exposure estimates, the table includes both high-end and central tendency inputs for duration, mass, and frequency of use. Please refer to the Supplemental Analysis File [*Consumer Exposure Assessment Modeling Input Parameters*] for a detailed listing of all inputs and associated sources.

Table 2-12 Key Product-Specific Inputs for Dermal Modeling

Consumer Product Scenario	Form	Max [1] Weight Fraction	Exposed Surface Area	Duration of Use [2] (min)	Absorption Fraction [3]	Film Thickness (cm)	Permeability Coefficient (Kp, cm/hr)	Frequency of Use (days/year)
Surface Cleaner	Liquid	9.00E-06	Inside of one hand	30	0.32	0.00214	5.05E-04	365
				15	0.26			300
Antifreeze	Liquid	8.60E-05		15	0.26	0.00655		NA
Dish Soap	Liquid	2.04E-04 [4]	Both hands	20	0.29	0.00655		365
				10	0.21			300
Dishwasher Detergent	Liquid/ Gel	9.70E-06	10% of hands	1	0.038	0.00655		365
								300
Laundry Detergent	Liquid	1.40E-05 [4]	Both hands	20	0.29	0.00655		365
				10	0.21			300
Paint and Floor Lacquer	Liquid	3.00E-05	Face, hands, arms	810	0.34	0.00981		NA
Textile Dye	Aqueou s	4.70E-06 [4]	Both hands	20	0.29	0.00655		NA
SPF	Foam	5.00E-04	Face, hands, arms	Attic 360	0.34	0.01		NA
				Basement 360				
				Garage 180				

[1] The use of "Max" (*i.e.*, maximum) here does not indicate use of a theoretical maximum or upper limit but refers to the highest identified weight fraction for a given product type based on the available data. See the Supplemental Analysis File [*Consumer Exposure Assessment Modeling Input Parameters*].
[2] Durations of use were adjusted for dermal exposure for two scenarios: dishwashing detergent and laundry detergent. The model default durations listed in Table 2-11 above are based on machine run times and would not be appropriate for dermal contact duration.
[3] Absorption fractions are estimated using duration of exposures; therefore, distinct absorption fractions are estimated and applied for high-end vs. central tendency durations. This term is only used in estimation of dose using the fraction absorbed model.
[4] Dilution fractions were applied to three scenarios: dish soap (3%), laundry detergent (1.6%), and textile dye (10%). See the Supplemental Analysis File [*Consumer Exposure Assessment Modeling Input Parameters*] for details.

2.1.3.5 Consumer Exposure Results

Estimated inhalation and dermal exposures are presented below for all consumer conditions of use. Scenarios that involve frequent (*i.e.*, daily) exposure intervals present acute and chronic exposure estimates for consumer users and acute exposure estimates for users and bystanders. Scenarios that involve intermittent or infrequent exposure intervals present acute exposure estimates only for users and bystanders.

2.1.3.5.1 Surface Cleaner

Acute and chronic inhalation and dermal exposures to 1,4-dioxane present as a byproduct in surface cleaner were evaluated. Concentrations of 1,4-dioxane in surface cleaners range from 0.36 to 9 ppm (up to 0.0009%). CEM 2.1 default inputs for all-purpose liquid cleaner were used as the basis for duration of use and mass of product used. The room of use (Zone 1) is a bathroom and the dermal surface area reflects the inside of one hand. This scenario assumes dermal contact during wiping/cleaning activities and may involve inhibited evaporation from the skin surface.

Inhalation exposure estimates are presented below. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates.

Table 2-13 Estimated Inhalation Exposure: Surface Cleaner

Scenario Description	Duration of Use (min)	Weight Fraction	Mass Used (g)	Product User or Bystander	8-hr Max TWA (mg/m^3)	LADC (mg/m^3)
Acute						
High-Intensity User	High End (30)	Max (9.0E-06)	High End (300)	User	5.0E-03	---
				Bystander	9.5E-04	---
Chronic						
High-Intensity User	High End (30)	Max [1] (9.0E-06)	High End (300)	User	---	1.0E-03
Moderate-Intensity User	Central Tendency (15)	Max (9.0E-06)	Central Tendency (200)	User	---	5.6E-04

[1]Although, generally, mean weight fractions were utilized in all chronic modeling (high-intensity and moderate-intensity user scenarios), a mean could not be estimates for this scenario based on source information.

Dermal exposure estimates are presented below and are based on the permeability model within CEM 2.1. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates, including those based on the fraction absorbed model within CEM 2.1.

Table 2-14 Estimated Dermal Exposure: Surface Cleaner

Scenario Description	Duration of Use (min)	Weight Fraction (%)	Receptor	ADR (mg/kg/day)	LADD (mg/kg/day)
Acute					
High-Intensity User	High End (30)	Max (9.0E-06)	Adult (≥21 years)	7.7E-06	---
			Children (16-20 years)	7.2E-06	---
			Children (11-15 years)	7.9E-06	---
Chronic					
High-Intensity User	High End (30)	Max[1] (9.0E-06)	Adult (≥21 years)	---	5.6E-06
Moderate-Intensity User	Central Tendency (15)	Max (9.0E-06)	Adult (≥21 years)	---	2.3E-06

[1]Although, generally, mean weight fractions were utilized in all chronic modeling (high-intensity and moderate-intensity user scenarios), a mean could not be estimates for this scenario based on source information.

2.1.3.5.2 Antifreeze

Acute inhalation and dermal exposures to 1,4-dioxane present as a byproduct in antifreeze were evaluated. Concentrations of 1,4-Dioxane in antifreeze range from 0.01 to 86 ppm (up to 0.0086%). CEM 2.1 default inputs for anti-freeze liquid were used as the basis for duration of use and mass of product used. The room of use (Zone 1) is a garage and the dermal surface area reflects the inside of one hand. This scenario assumes dermal contact during pouring activities and is not expected to involve inhibited evaporation from the skin surface.

Inhalation exposure estimates are presented below. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates.

Table 2-15 Estimated Inhalation Exposure: Antifreeze

Scenario Description	Duration of Use (min)	Weight Fraction	Mass Used (g)	Product User or Bystander	8-hr Max TWA (mg/m^3)
Acute					
High-Intensity User	High End (15)	Max (8.6E-05)	High End (150)	User	1.6E-02
				Bystander	4.0E-03

Dermal exposure estimates are presented below and are based on the fraction absorbed model within CEM 2.1. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates, including those based on the permeability model within CEM 2.1.

Table 2-16 Estimated Dermal Exposure: Antifreeze

Scenario Description	Duration of Use (min)	Weight Fraction (%)	Receptor	ADR (mg/kg/day)
Acute				
High-Intensity User	High End (15)	Max (150)	Adult (≥21 years)	5.12E-04
			Children (16-20 years)	4.80E-04
			Children (11-15 years)	5.24E-04

2.1.3.5.3 Dish Soap

Acute and chronic inhalation and dermal exposures to 1,4-dioxane present as a byproduct in dish soap were evaluated. Concentrations of 1,4-dioxane in dish soap range from 0.7 to 204 ppm (up to 0.02%). CEM 2.1 default inputs for hand dishwashing soap/liquid serves as the basis for duration of use and an American Cleaning Institute exposure and risk screening methods document serves as the basis for mass of product used during hand dishwashing. The room of use (Zone 1) is a kitchen and the dermal surface area reflects both hands. A 0.7% dilution factor is applied. This scenario assumes immersive dermal contact in the 0.7% dish soap solution during washing activities and may involve inhibited evaporation from the skin surface.

Inhalation exposure estimates are presented below. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates.

Table 2-17 Estimated Inhalation Exposure: Dish Soap

Scenario Description	Duration of Use (min)	Weight Fraction	Mass Used (g)	Product User or Bystander	8-hr Max TWA (mg/m^3)	LADC (mg/m^3)
Acute						
High-Intensity User	High End (20)	Max (2.04E-04)	High End (84)	User	3.0E-02	---
				Bystander	5.4E-03	---
Chronic						
High-Intensity User	High End (20)	Central Tendency (2.40E-05)	High End (84)	User	---	7.1E-04
Moderate-Intensity User	Central Tendency (10)	Central Tendency (2.40E-05)	Central Tendency (48)	User	---	3.3E-04

Dermal exposure estimates are presented below and are based on the permeability model within CEM 2.1. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates, including those based on the fraction absorbed model within CEM 2.1.

Table 2-18 Estimated Dermal Exposure: Dish Soap

Scenario Description	Duration of Use (min)	Weight Fraction (%)	Receptor	ADR (mg/kg/day)	LADD (mg/kg/day)
Acute					
High-Intensity User	High End (20)	Max (2.04E-04)	Adult (≥21 years)	3.1E-06	---
			Children (16-20 years)	2.9E-06	---
			Children (11-15 years)	3.1E-06	---
Chronic					
High-Intensity User	High End (20)	Central Tendency (2.40E-05)	Adult (≥21 years)	---	2.6E-07
Moderate-Intensity User	Central Tendency (10)	Central Tendency (2.40E-05)	Adult (≥21 years)	---	1.1E-07

2.1.3.5.1 Dishwashing Detergent

Acute and chronic inhalation and dermal exposures to 1,4-dioxane present as a byproduct in dishwashing detergent were evaluated. Concentrations of 1,4-dioxane in dishwashing detergent range from 0.86 to 9.7 ppm (up to 0.001%). CEM 2.1 default inputs for on machine dishwashing detergent (liquid/gel) were used as the basis for duration of use and mass of product used. The room of use (Zone 1) is a kitchen and the dermal surface area reflects 10% of hands. This scenario assumes brief dermal contact during loading activities and is not expected to involve inhibited evaporation from the skin surface.

Inhalation exposure estimates are presented below. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates.

Table 2-19 Estimated Inhalation Exposure: Dishwasher Detergent

Scenario Description	Duration of Use (min)	Weight Fraction	Mass Used (g)	Product User or Bystander	8-hr Max TWA (mg/m^3)	LADC (mg/m^3)
Acute						
High-Intensity User	High End (50)	Max (9.7E-06)	High End (40)	User	6.9E-04	---
				Bystander	1.2E-04	---
Chronic						
High-Intensity User	High End (50)	Central Tendency (5E-06)	High End (40)	User	---	7.1E-05
Moderate-Intensity User	Central Tendency (45)	Central Tendency (5E-06)	Central Tendency (20)	User	---	2.9E-05

Dermal exposure estimates are presented below and are based on the fraction absorbed model within CEM 2.1. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates, including those based on the permeability model within CEM 2.1.

Table 2-20 Estimated Dermal Exposure: Dishwasher Detergent

Scenario Description	Duration of Use [1] (min)	Weight Fraction (%)	Receptor	ADR (mg/kg/day)	LADD (mg/kg/day)
Acute					
High-Intensity User	(1)	Max (9.7E-06)	Adult (≥21 years)	3.2E-06	---
			Children (16-20 years)	3.0E-06	---
			Children (11-15 years)	3.3E-06	---
Chronic					
High-Intensity User [2]	(1)	Central Tendency (5E-06)	Adult (≥21 years)	---	1.2E-06
Moderate-Intensity User [2]	(1)	Central Tendency (5E-06)	Adult (≥21 years)	---	9.9E-07

[1] The exposure duration applied for dermal exposures to dishwashing detergent were adjusted to 1 minute, as the scenario default exposure duration is based on the run time of a dishwasher, not on expected dermal contact time.
[2] For this scenario, the distinct chronic dermal estimates are a result of a difference in frequency of use (365 days/yr for high-intensity users and 300 days/yr for moderate-intensity users).

2.1.3.5.2 Laundry Detergent

Acute and chronic inhalation and dermal exposures to 1,4-dioxane present as a byproduct in laundry detergent were evaluated. Concentrations of 1,4-dioxane in laundry detergent range from 0.05 to 14 ppm (up to 0.0014%). CEM 2.1 default inputs for laundry detergent (liquid) were used as the basis for duration of use and mass of product used. The room of use (Zone 1) is a utility room and the dermal surface area reflects both hands. A 1.6% dilution factor is applied. This scenario assumes immersive dermal contact in the 1.6% laundry detergent solution during hand washing activities and may involve inhibited evaporation from the skin surface.

Inhalation exposure estimates are presented below. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates.

Table 2-21 Estimated Inhalation Exposure: Laundry Detergent

Scenario Description	Duration of Use (min)	Weight Fraction	Mass Used (g)	Product User or Bystander	8-hr Max TWA (mg/m^3)	LADC (mg/m^3)
Acute						
	High End	Max	High End	User	1.5E-03	---

Scenario Description	Duration of Use (min)	Weight Fraction	Mass Used (g)	Product User or Bystander	8-hr Max TWA (mg/m³)	LADC (mg/m³)
High-Intensity User	(50)	(1.4E-05)	(20)	Bystander	2.7E-04	---
Chronic						
High-Intensity User	High End (50)	Central Tendency (6E-06)	High End (20)	User	---	1.3E-04
Moderate-Intensity User	Central Tendency (45)	Central Tendency (6E-06)	Central Tendency (10)	User	---	7.1E-05

Dermal exposure estimates are presented below and are based on the permeability model within CEM 2.1. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates, including those based on the fraction absorbed model within CEM 2.1.

Table 2-22 Estimated Dermal Exposure: Laundry Detergent

Scenario Description	Duration of Use [1] (min)	Weight Fraction (%)	Receptor	ADR (mg/kg/day)	LADD (mg/kg/day)
Acute					
High-Intensity User	High End (20)	Max (1.4E-05)	Adult (≥21 years)	4.8E-07	---
			Children (16-20 years)	4.5E-07	---
			Children (11-15 years)	4.9E-07	---
Chronic					
High-Intensity User	High End (20)	Central Tendency (6E-06)	Adult (≥21 years)	---	1.5E-07
Moderate-Intensity User	Central Tendency (10)	Central Tendency (6E-06)	Adult (≥21 years)	---	6.2E-08

[1] The exposure duration applied for dermal exposures to laundry detergent were adjusted to equal the default exposures times for dish soap, as this dermal exposure scenario is intended to approximate dermal contact from hand washing of clothing, whereas the default exposure durations for the laundry detergent scenario are based on run times of the washing machine.

2.1.3.5.3 Paints and Floor Lacquer

Acute inhalation and dermal exposures to 1,4-dioxane present as a byproduct in paints or floor lacquer were evaluated. Concentrations of 1,4-dioxane in paints and floor lacquer range from 0.02 to 30 ppm (up to 0.003%). Westat Survey data on latex paint were used as the basis for duration of use and mass of product used. The room of use (Zone 1) is a bedroom and the dermal surface area reflects the face, hands, and arms. This scenario assumes dermal contact during painting activities and is not expected to involve inhibited evaporation from the skin surface.

Inhalation exposure estimates are presented below. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates.

Table 2-23 Estimated Inhalation Exposure: Paints and Floor Lacquer

Scenario Description	Duration of Use (min)	Weight Fraction	Mass Used (g)	Product User or Bystander	8-hr Max TWA (mg/m^3)
Acute					
High-Intensity User	95th Percentile (810)	Max (3E-05)	95th Percentile (26025)	User	2.0E-02
				Bystander	7.5E-03

Dermal exposure estimates are presented below and are based on the fraction absorbed model within CEM 2.1. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates, including those based on the permeability model within CEM 2.1.

Table 2-24 Estimated Dermal Exposure: Paints and Floor Lacquer

Scenario Description	Duration of Use (min)	Weight Fraction (%)	Receptor	ADR (mg/kg/day)
Acute				
High-Intensity User	95th Percentile (810)	Max (3E-05)	Adult (≥21 years)	1.96E-03
			Children (16-20 years)	1.85E-03
			Children (11-15 years)	2.03E-03

2.1.3.5.4 Textile Dye

Acute inhalation and dermal exposures to 1,4-dioxane present as a byproduct in textile dye were evaluated. An identified concentration of 1,4-dioxane in textile dye is 4.7 ppm (up to 0.00047%). CEM 2.1 default inputs for textile and fabric dyes were used as the basis for duration of use and mass of product used. The room of use (Zone 1) is a utility room and the dermal surface area reflects both hands. A 10% dilution factor is applied. This scenario assumes immersive dermal contact in the 10% dye solution during dyeing activities and may involve inhibited evaporation from the skin surface.

Inhalation exposure estimates are presented below. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates.

Table 2-25 Estimated Inhalation Exposure: Textile Dye

Scenario Description	Duration of Use (min)	Weight Fraction	Mass Used (g)	Product User or Bystander	8-hr Max TWA (mg/m^3)
Acute					
High-Intensity User	High End (20)	Max (4.7E-06)	High End (100)	User	8.5E-04
				Bystander	1.5E-04

Dermal exposure estimates are presented below and are based on the permeability model within CEM 2.1. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates, including those based on the fraction absorbed model within CEM 2.1.

Table 2-26 Estimated Dermal Exposure: Textile Dye

Scenario Description	Duration of Use (min)	Weight Fraction[1] (%)	Receptor	ADR (mg/kg/day)
Acute				
High-Intensity User	High End (20)	Max (4.7E-06)	Adult (≥21 years)	6.4E-07
			Children (16-20 years)	6.0E-07
			Children (11-15 years)	6.5E-07

2.1.3.5.5 Spray Polyurethane Foam

Acute inhalation and dermal exposures to 1,4-dioxane present as a byproduct in SPF were evaluated. Concentrations of 1,4-dioxane in SPF range from <0.5 to 500 ppm (up to 0.05% in mixed SPF) and the selected weight fraction aligns with that used in the occupational exposure assessment. Three rooms of use (Zone 1) were assumed: the basement, the attic, and the garage. The dermal surface area reflects the face, hands, and arms. Duration of use is based on loading rate and application surface area, but it aligns well with the durations assumed in the occupational exposure assessment (see Appendix A for more details). This scenario assumes dermal contact during application activities and are not expected to involve inhibited evaporation from the skin surface.

While application of SPF insulation products may primarily be occupational, a “do it yourself” or DIY installation of SPF is possible. There are consumer products available that may expose consumers (users and bystanders) to 1,4-dioxane.

Inhalation exposure estimates are presented below. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates.

Table 2-27 Estimated Inhalation Exposure: SPF

Scenario Description	Duration of Use (min)	Weight Fraction	Mass Used (g)	Product User or Bystander	8-hr Max TWA (mg/m^3)
Acute					
Basement[1]	(360)[2]	Max (5.0E-04)	4.5 [3]	User	8.9E-01
				Bystander	7.4E-01
Attic[1]	(360)[2]	Max (5.0E-04)	4.5 [3]	User	1.9E-01
				Bystander	7.1E-02
Garage[1]	(180)[2]	Max (5.0E-04)	2.5 [3]	User	1.6E-01
				Bystander	1.2E-01

[1] SPF scenarios are not described in the same manner as the other product scenarios, as they are based on home application areas: basement, attic, and garage, each with distinct air exchange rates and interzonal ventilation rates.
[2] Durations of use are not described as "high-end" in these scenarios because they are not based on a distribution; however, they are based on loading rates and application surface areas and align with occupational exposure scenario durations (excluding time for set-up and without considering multiple jobs per day).
[3] Mass of use was not an input in MCCEM as it was in the CEM model. These masses instead reflect the total mass of chemical released in each exposure setting. These were estimated using loading ratios, application surface areas, emission rate per square inch, and decay rate per hour. Please refer to the Supplemental Analysis File [*Consumer Exposure Assessment Modeling Input Parameters*] for more details.

Dermal exposure estimates are presented below and are based on the fraction absorbed model within CEM 2.1. See the Supplemental Analysis File [*Exposure Modeling Results and Risk Estimates for Consumer Exposures*] for exposure results and associated risk estimates, including those based on the permeability model within CEM 2.1.

Table 2-28 Estimated Dermal Exposure: SPF

Scenario Description	Duration of Use (min)	Weight Fraction (%)	Receptor	ADR (mg/kg/day)
Acute				
Basement, Attic, Garage[1]	(360, 360, 180)[2]	Max (5.0E-04)	Adult (≥21 years)	1.0E-03
			Children (16-20 years)	9.7E-04
			Children (11-15 years)	1.0E-03

[1] SPF scenarios are not described in the same manner as the other product scenarios, as they are based on home application areas: basement, attic, and garage, each with distinct air exchange rates and interzonal ventilation rates. For dermal exposures, there is no difference across these scenarios, as the maximum fraction absorbed is estimated and applied for either duration (360 or 180 minutes).
[2] Durations of use are not described as "high-end" in these scenarios because they are not based on a distribution; however, they are based on loading rates and application surface areas and align with occupational exposure scenario durations (excluding time for set-up and without considering multiple jobs per day).

2.1.3.6 Assumptions and Key Sources of Uncertainty for Consumer Exposures

EPA's approach recognizes the need to include uncertainty analysis. One important distinction for such an analysis is variability versus uncertainty – both aspects need to be addressed.

Variability refers to the inherent heterogeneity or diversity of data in an assessment. It is a quantitative description of the range or spread of a set of values and is often expressed through statistical metrics, such as variance or standard deviation, that reflect the underlying variability of the data. Uncertainty refers to a lack of data or an incomplete understanding of the context of the risk evaluation decision. Variability cannot be reduced, but it can be better characterized. Uncertainty can be reduced by collecting more or better data. Quantitative methods to address uncertainty include non-probabilistic approaches such as sensitivity analysis and probabilistic or stochastic methods. Uncertainty can also be addressed qualitatively, by including a discussion of factors such as data gaps and subjective decisions or instances where professional judgment was used. Uncertainties associated with approaches and data used in the evaluation of consumer exposures are described below.

Deterministic vs. Stochastic

With deterministic approaches like the one applied in this evaluation of consumer exposure, the output of the model is fully determined by the choices of parameter values and initial conditions. Stochastic approaches feature inherent randomness, such that a given set of parameter values and initial conditions can lead to an ensemble of different model outputs.

Aggregate Exposure

Background levels of 1,4-dioxane in indoor and outdoor air are not considered or aggregated in this analysis; therefore, there is a potential for underestimating consumer inhalation exposures, particularly for populations living near a facility emitting 1,4-dioxane or living in a home with other sources of 1,4-dioxane, such as other 1,4-dioxane-containing products stored and/or used in the home such as personal care products that are not covered under TSCA. Similarly, inhalation and dermal exposures were evaluated on a product-specific basis and are based on use of a single product type within a day, not multiple products. There was no aggregation of dermal and inhalation exposure to single products either.

Dermal Exposure Approach

For dermal exposure scenarios using the permeability model that may involve dermal contact with impeded evaporation based on professional considerations of the formulation type and likely use pattern, there is uncertainty surrounding the application of exposure durations for such scenarios. The exposure durations modeled are based on reported durations of product use, unless otherwise specified, and may not reflect reasonable durations of dermal contact with impeded evaporation. The exposure duration modeled could exceed a reasonable duration of such dermal contact with a wet rag, for example.

For scenarios using the absorption fraction model that are less likely to involve dermal contact with impeded evaporation, there is uncertainty surrounding the assumption that the entire mass present in the thin film is absorbed and retained in the stratum corneum following a use event. The fractional absorption factor estimated based on Frasch and Bunge (2015) is intended to be applied to the mass retained in the stratum corneum after exposure; it does not account for evaporation from the skin surface during the exposure event. Therefore, the assumption that the entire amount of chemical present in the thin film on the skin surface is retained in the stratum corneum may lead to uncertainty in the absorbed dose estimate.

Product Concentration Data

The products evaluated are largely based on EPA's 2015 TSCA Work Plan Chemical Problem Formulation and Initial Assessment of 1,4-Dioxane (U.S. EPA, 2015). EPA conducted an additional systematic review focused on identifying data on 1,4-dioxane presence in consumer products and associated exposures and/or emissions. Because 1,4-dioxane is present in consumer products as a byproduct and not as an ingredient, there is more uncertainty than typical when identifying and using concentration information. Unlike other chemicals that are ingredients in consumer products with readily available reported concentration ranges in SDSs for each product category, 1,4-dioxane concentrations have been sourced from a variety of primary and secondary sources such as governmental risk assessments, SDSs, literature reviews, emission studies, etc. There are limited reasonably available data and they are not necessarily complete or consistently updated and general internet searches cannot guarantee entirely comprehensive product identification. Therefore, it is possible that the entire universe of products that contain 1,4-dioxane as a byproduct may not have been identified, or that certain changes in the universe of products may not have been captured, due to market changes or research limitations. Maximum identified weight fractions were used in acute high-intensity user scenarios and mean weight fractions were used in chronic high-intensity and moderate-intensity user scenarios, where possible. While weight fractions are described as "maximum" in tables, these reflect only the maximum levels identified from available literature and other sources and may not capture the true maximum in specific products or batches. There is uncertainty about how these means and maximums broadly reflect typical products and there is also uncertainty about whether the true upper end is captured in the ranges identified through the available sources. For the range of weight fractions identified, see the Supplemental Analysis File [*Consumer Exposure Assessment Modeling Input Parameters*].

Emission Rate

The higher-tier Multi-Chamber Concentration and Exposure Model (MCCEM) is used in the estimation of inhalation exposures from SPF application only. For other product scenarios, key data (*i.e.,* chamber emission data) were not reasonably available. Therefore, the model used (CEM 2.1) estimates emission rate based on chemical properties and emission profiles matching the formulation type and use method.

The emission rate data derived from Karlovich et al. (2011) is based on occupational-grade products, so there is some uncertainty surrounding the application to consumers. The product for which 1,4-dioxane emission data were collected is an open-cell foam. The initial emission rate and decay constant estimates were based on a modeled relationship, as measured emission data were not available during application.

Dilution Factor

For most product scenarios, the dilution factor is not considered. For dish soap, laundry detergent, and textile dye, all of which are expected to be used in aqueous solutions during hand washing or dyeing activities, dilution factors are incorporated. For dish soap, a dilution factor of 0.7% is applied based on assuming a mass of 28 g (~1 oz) is used in one gallon of water for hand washing of dishes. For laundry detergent, a dilution factor of 1.6% is applied based on assuming a high-end mass of 60 g (oz) is used in one gallon of water for hand washing of laundry. These estimations incorporate a conservative water use assumption.

Chronic Exposure Estimations

Chronic (lifetime) inhalation and dermal exposures were estimated for four product scenarios: surface cleaner, dish soap, dishwasher detergent, and laundry detergent. The inclusion of lifetime exposure estimates for these conditions of use is based on the anticipated daily or near-daily use of these products. This differs from expected intermittent exposure pattern associated with the other evaluated consumer conditions of use. Lifetime exposure estimates are calculated assuming the exposure event occurs for 365 or 300 days per year for high-end or central tendency frequencies, respectively, for 57 years. The exposure scenarios still assume one exposure event per day and therefore may not capture users that continuously use products throughout the day. This exposure is averaged over a period of 78 years. The models employed (CEM 2.1 and CEM) typically utilize central tendency inputs for weight fraction, duration, frequency, and mass when estimating lifetime exposures (U.S. EPA, 2019a; U.S. EPA, 2007). Central tendency inputs for weight fraction were used in estimating chronic exposures, across high- and moderate-intensity user scenarios.

2.1.3.7 Confidence in Consumer Exposure Estimates

The considerations and overall confidence ratings for the inhalation consumer exposure scenarios are displayed in Table 2-29. Ratings are based on the strength of the models employed, as well as the quality and relevance of the modeling parameterization. CEM, CEM 2.1, and MCCEM are peer reviewed, publicly available, and were designed to estimate inhalation and dermal exposures from household uses of products and articles.

Systematic review identified several studies reporting emission rates or chamber concentrations of 1,4-dioxane from spray foam and paint products and findings as they relate to the current evaluation are summarized in Appendix A.3. Although measured chamber or test room concentrations are not directly comparable to the 8-hr TWAs estimated for the various consumer exposure scenarios, on the whole, these emission studies bolster confidence in the predicted air concentrations for the SPF and paint and floor lacquer conditions of use.

The predicted 8-hr TWAs for SPF range from 160 to 890 $\mu g/m^3$ for users. These predicted estimates fall within the range predicted in Karlovich et al. (2011) for samples measured at four and 12 hours. Peppendieck et al. (2017) also reported measured air concentrations that encompass the modeled consumer exposure estimates, with concentrations from non-ideal closed-cell spray foam ranging from 500 to 1,000 $\mu g/m^3$ over the first 48 hours. Won et al. (2014) reported levels of 1,4-dioxane well below the CEM 2.1 predictions, from 0.25 to 44.68 $\mu g/m^3$ at six hours for various insulation products including foam board and two-component open- and closed-cell spray foams.

The predicted 8-hr TWAs for paint and floor lacquer is 20 $\mu g/m^3$ for users, which is roughly one order of magnitude greater than concentrations measured in Won et al. (2014) (0.8 – 1.74 $\mu g/m^3$ at six hours), but aligns with the measured air concentration five hours after application of the two-component epoxy floor paint (21 $\mu g/m^3$). The predicted TWA also falls within the range of air concentrations taken five hours after application in the Danish EPA’s 2020 Follow-Up study, which reported levels from 7 to 460 $\mu g/m^3$ at five hours.

Table 2-29 Overall Confidence Ratings for Consumer Inhalation Exposure Estimates

Consumer Product Scenario	Overall Confidence Acute	Overall Confidence Chronic	Scenario-Specific Considerations	Overarching Considerations
Surface Cleaner	Moderate to High	Moderate	• Duration and mass inputs obtained from the Westat Survey from its solvent-type cleaning fluids and degreasers category. • Weight fraction range obtained from few sources.	• There is uncertainty regarding how the maximum and mean from identified weight fraction sources reflects the existing range or captures actual maximum concentrations. • Use of CEM (not CEM 2.1) to estimate lifetime inhalation exposures (LADCs) did not estimate exposure to bystanders; however, bystanders would be exposed to lower levels than the presented user exposures based on their placement in the home during use (Zone 2). • Use of central tendency weight fractions for chronic exposure scenarios bolsters confidence, as it does not assume use of the highest identified concentration daily or near-daily intervals over 57 years.
Antifreeze	Moderate to High	NA	• Duration and mass inputs obtained from CEM 2.1 scenario-specific defaults. • Weight fraction range obtained from few sources.	
Dish Soap	Moderate to High	Moderate	• Duration and mass inputs obtained from CEM 2.1 scenario-specific defaults. • Weight fraction range obtained from several sources.	
Dishwasher Detergent	Moderate to High	Moderate	• Duration and mass inputs obtained from CEM 2.1 scenario-specific defaults. • Exposure duration assumes user is in the room of use (kitchen) during the machine's run time (50 min). • Weight fraction range obtained from several sources.	
Laundry Detergent	Moderate to High	Moderate	• Duration and mass inputs obtained from CEM 2.1 scenario-specific defaults. • Exposure duration assumes user is in the room of use (utility) during the machine's run time (50 min). • Weight fraction range obtained from several sources.	
Paint and Floor Lacquer	High	NA	• Duration and mass inputs obtained from the Westat Survey from its latex paint category. • Weight fraction data obtained from American Coatings Association public submission (Nekoomaram and Wieroniey, 2015). • Measured emission data align with 8-hr TWA for users.	

Consumer Product Scenario	Overall Confidence Acute	Overall Confidence Chronic	Scenario-Specific Considerations	Overarching Considerations
Textile Dye	Moderate	NA	• Duration and mass inputs obtained from CEM 2.1 scenario-specific defaults. • Single weight fraction source.	
SPF	High	NA	• Initial emission rate and decay constant are based on a modeled relationship. • No emission or concentration data were available for 1,4-dioxane during application. • Emission data on 1,4-dioxane from Karlovich et al (2012) is from open cell foam. • Duration inputs based on the SPF occupational exposure assessment. • Application area specific air exchange rates and ventilation rates applied. • Product and chemical specific emission rate applied. • Used higher-tier MCCEM model to estimate air concentrations. • Weight fraction based on occupational exposure assessment. • Measured and predicted emission data encompass predicted range of 8-hr TWAs for users.	

The considerations and overall confidence ratings for the dermal consumer exposure scenarios are displayed in Table 2-30. Ratings are based on the strength of the models employed, as well as the quality and relevance of the modeling parameterization. CEM 2.1is peer reviewed, publicly available, and was designed to estimate inhalation and dermal exposures from household uses of products and articles.

Table 2-30 Overall Confidence Ratings for Consumer Dermal Exposure Estimates

Consumer Product Scenario	Overall Confidence Acute	Overall Confidence Chronic	Scenario-Specific Considerations	Overarching Considerations
Surface Cleaner	Moderate	Low to Moderate	• Duration input obtained from the Westat Survey from its solvent-type cleaning fluids and degreasers category. • Exposure duration assumes dermal contact may occur during the entire activity duration. • Weight fraction range obtained from few sources.	• There is uncertainty regarding how the maximum and mean from identified weight fraction sources reflects the existing range or captures actual maximum concentrations. • An estimated permeability coefficient is used in dermal modeling. • There are uncertainties associated with both dermal models applied (see Section 2.4.3.6). • Use of central tendency weight fractions for chronic exposure scenarios bolsters confidence, as it does not assume use of the highest identified concentration daily or near-daily intervals over 57 years.
Antifreeze	Moderate	NA	• Duration input obtained from CEM 2.1 scenario-specific defaults. • Exposure duration assumes dermal contact may occur during the entire activity duration. • Weight fraction range obtained from few sources.	
Dish Soap	Moderate	Low to Moderate	• Duration input obtained from CEM 2.1 scenario-specific defaults. • Dilution fraction of 3% may be a conservative assumption. • Weight fraction range obtained from several sources.	
Dishwasher Detergent	Moderate	Low to Moderate	• Duration input obtained from CEM 2.1 scenario-specific defaults. • Exposure duration adjusted to one minute to approximate contact time during loading of liquid detergent. • Weight fraction range obtained from several sources.	
Laundry Detergent	Moderate	Low to Moderate	• Duration input obtained from CEM 2.1 scenario-specific defaults. • Exposure duration adjusted to equal dish soap exposure durations to approximate contact time during hand washing of laundry.	

Consumer Product Scenario	Overall Confidence Acute	Overall Confidence Chronic	Scenario-Specific Considerations	Overarching Considerations
			• Chronic exposure scenario assumes hand washing of laundry daily or near daily. • Weight fraction range obtained from several sources.	
Paint and Floor Lacquer	Moderate	NA	• Duration and mass inputs obtained from the Westat Survey from its latex paint category. • Exposure duration assumes dermal contact may occur during the entire activity duration. • Weight fraction data obtained from American Coatings Association public comment submission (Nekoomaram and Wieroniey, 2015).	
Textile Dye	Moderate	NA	• Duration and mass inputs obtained from CEM 2.1 scenario-specific defaults. • Dilution fraction of 10% likely a conservative assumption. • Single weight fraction source.	
SPF	Moderate	NA	• Duration inputs based on the SPF occupational exposure assessment. • Exposure duration assumes dermal contact may occur during the entire activity duration. • Weight fraction based on occupational exposure assessment.	

3 HAZARDS (EFFECTS)

Several of the points of departure (PODs) for human health hazard presented in the draft risk evaluation were revised in response to peer review and public comment. The PODs identified through dose-response analysis in the draft risk evaluation are summarized below. These revised PODs are the basis for risk estimates presented in the risk characterization section.

3.1.1 Summary of Human Health Hazards

The results of the hazard identification and dose-response are summarized in Table 3-1.

Table 3-1. Summary of Hazard Identification and Dose-Response Values

Exposure Route	Endpoint Type	Hazard POD/HEC/Slope Factor[a]	Value	Units	Benchmark MOE[b]	Basis for Selection	Key Study
Inhalation	Short-term	Acute inhalation POD_{HEC}	283.5	mg/m^3	300 (UF_L= 10; UF_A = 3; UF_H = 10)	Systemic liver effect; Study duration relevant to worker short-term exposures	(Mattie et al., 2012)
Dermal	Short-term	Acute dermal POD_{HED} extrapolated from an inhalation study	35.4	mg/kg/day	300 (UF_L= 10; UF_A = 3; UF_H = 10)		
Inhalation	Non-Cancer	Human Equivalent Concentration (HEC)	12.8	mg/m^3	30 (UF_A 3= 3; UF_H = 10)	POD relevant for olfactory epithelium effects (*i.e.*, metaplasia and atrophy)	(Kasai et al., 2009)
	Cancer	Inhalation Unit Risk (IUR)	1.18E-06	$(\mu g/m^3)^{-1}$	N/A	Result of combined cancer modeling for male rats (including liver)	(Kasai et al., 2009)
			1.03E-06	$(\mu g/m^3)^{-1}$	N/A	Result of combined cancer modeling for male rats (excluding liver)	(Kasai et al., 2009)

Exposure Route	Endpoint Type	Hazard POD/HEC/Slope Factor[a]	Value	Units	Benchmark MOE[b]	Basis for Selection	Key Study
Dermal	Non-Cancer	Human Equivalent Dose (HED) extrapolated from an inhalation study	1.6	mg/kg/day	30 (UF_A = 3; UF_H = 10)	POD for systemic effects in the nasal cavity (respiratory metaplasia of the olfactory epithelium) in male rats	(Kociba et al., 1974) (Kasai et al., 2009)
		Human Equivalent Dose (HED) extrapolated from oral studies	2.6	mg/kg/day	30 (UFA = 3; UFH = 10)	PODs for hepatocellular and renal toxicity (degeneration and necrosis of renal tubular cells and hepatocytes; hepatocellular mixed cell foci) following drinking water exposure in male rats[c]	(Kano et al., 2009); Kociba et al. (1974)
	Cancer	Cancer Slope Factor (CSF) extrapolated from an oral study	1.2E-01	$(mg/kg\text{-}d)^{-1}$	N/A	Cancer model for liver tumors in female mice (the most sensitive sex/species);	(Kano et al., 2009)
		Cancer Slope Factor (CSF) extrapolated from an inhalation study	1.4E-02	$(mg/kg\text{-}d)^{-1}$	N/A	Result of combined cancer modeling for male rats (including liver)	(Kasai et al., 2009)
			1.2E-02	$(mg/kg\text{-}d)^{-1}$	N/A	Result of combined cancer modeling for male rats (excluding liver)	(Kasai et al., 2009)

[a] HECs are adjusted from the study conditions as described above in Section 3.2.6
[b] UF_S = subchronic to chronic UF; UF_A = interspecies UF; UF_H = intraspecies UF; UF_L = LOAEL to NOAEL UF (U.S. EPA, 2002)
[c] Data from both drinking water studies independently arrived at the same POD for liver effects
N/A is shown in the benchmark MOE column for cancer endpoints because EPA did not use MOEs for cancer risks, see Section 3.2.6 for more information.

4 RISK CHARACTERIZATION

4.1 Human Health Risk

4.1.1 Risk Estimate for Exposures from Incidental Exposure to 1,4-Dioxane in Surface Water

The following sections present the risk estimates for acute dermal and inhalation exposures that may occur from incidental contact with surface water. Calculated MOE values below the benchmark MOE (300) would indicate a potential safety concern.

Risks from acute oral exposure through incidental ingestion of surface water are shown in **Table 4-1.** and risks from acute dermal exposure through swimming in surface water are shown in **Table 4-2.**

Table 4-1. Risk from Acute Oral Exposure Through Incidental Ingestion of Water; Benchmark MOE = 300

OES	Facility/Data Source	Surface Water Concentration (µg/L)	Drinking Water Acute Dose, Child 11-15 (mg/kg/day)[a]	MOE (Oral POD 35.4 mg/kg/day)
Site-Specific Modeling – Estimated Surface Water Concentrations				
Manufacturing	BASF	9.7E+01	5.2E-04	6.8E+04
Industrial Uses	Ineos Oxide	2.2E+02	1.2E-03	3.0E+04
Industrial Uses	Microdyn-Nadir Corp	7.2E+00	3.9E-05	9.1E+05
Industrial Uses	St Charles Operations (Taft/Star) Union Carbide Corp	1.1E-02	5.9E-08	6.0E+08
Industrial Uses	SUEZ Water Technologies & Solutions	5.1E+03	2.7E-02	1.3E+03
Industrial Uses	The Dow Chemical Co - Louisiana Operations	8.7E-03	4.7E-08	7.6E+08
Industrial Uses	Union Carbide Corp Institute Facility	3.3E+00	1.8E-05	2.0E+06
Industrial Uses	Union Carbide Corp Seadrift Plant	2.4E+01	1.3E-04	2.7E+05
Industrial Uses	BASF Corp	3.4E-01	1.8E-06	2.0E+07
Industrial Uses	Cherokee Pharmaceuticals LLC	2.6E-03	1.4E-08	2.5E+09
Industrial Uses	DAK Americas LLC	2.8E+01	1.5E-04	2.4E+05
Industrial Uses	Institute Plant	5.3E+00	2.8E-05	1.3E+06

OES	Facility/Data Source	Surface Water Concentration (µg/L)	Drinking Water Acute Dose, Child 11-15 (mg/kg/day)[a]	MOE (Oral POD 35.4 mg/kg/day)
Industrial Uses	Kodak Park Division	1.7E-01	9.1E-07	3.9E+07
Industrial Uses	Pharmacia & Upjohn (Former)	2.7E-02	1.5E-07	2.4E+08
Industrial Uses	Philips Electronics Plant	1.0E-01	5.4E-07	6.6E+07
Industrial Uses	Sanderson Gulch Drainage Improvements	1.0E-02	5.4E-08	6.6E+08
Open System Functional Fluids	Ametek Inc. U.S. Gauge Div	4.0E-01	2.1E-06	1.7E+07
Open System Functional Fluids	Lake Reg Med/Collegeville	1.3E-02	7.0E-08	5.1E+08
Open System Functional Fluids	Pall Life Sciences Inc	4.3E-02	2.3E-07	1.5E+08
Open System Functional Fluids	Modeled Release Estimates	2.9E+00	1.5E-05	2.3E+06
Spray Foam Application	Modeled Release Estimates	2.7E-01	1.5E-06	2.5E+07
Disposal	Beacon Heights Landfill	5.3E-01	2.8E-06	1.3E+07
Disposal	Ingersoll Rand/Torrington Fac	3.5E+00	1.9E-05	1.9E+06
High-End of Submitted Monitoring Data – Measured Surface Water Concentrations				
---	STORET	1.0E+02	5.4E-04	6.6E+04
---	Sun et al. 2016	1.4E+03	7.5E-03	4.7E+03
---	North Carolina Department of Environmental Quality	1.0E+03	5.5E-03	6.4E+03
---	Minnesota Department of Environmental Quality	4.4E+00	2.4E-05	1.5E+06
[a]Dose is based on high end incidental intake rate				

Table 4-2. Risk from Acute Dermal Exposure from Swimming; Benchmark MOE = 300

OES	Facility/Data Source	Surface Water Concentration (µg/L)	Dermal Acute Dose, Adult (mg/kg/day)	MOE (Dermal POD 35.4 mg/kg/day)
Site-Specific Modeling – Estimated Surface Water Concentrations				
Manufacturing	BASF	9.7E+01	3.6E-05	9.9E+05
Industrial Uses	Ineos Oxide	2.8E+02	8.0E-05	4.4E+05
Industrial Uses	Microdyn-Nadir Corp	7.2E+00	2.7E-06	1.3E+07
Industrial Uses	St Charles Operations (Taft/Star) Union Carbide Corp	1.1E-02	4.1E-09	8.6E+09
Industrial Uses	SUEZ Water Technologies & Solutions	5.1E+03	1.9E-03	1.9E+04
Industrial Uses	The Dow Chemical Co - Louisiana Operations	8.7E-03	3.2E-09	1.1E+10
Industrial Uses	Union Carbide Corp Institute Facility	3.3E+00	1.2E-06	2.9E+07
Industrial Uses	Union Carbide Corp Seadrift Plant	2.4E+01	8.9E-06	4.0E+06
Industrial Uses	BASF Corp	3.4E-01	1.3E-07	2.8E+08
Industrial Uses	Cherokee Pharmaceuticals LLC	2.6E-03	9.7E-10	3.6E+10
Industrial Uses	DAK Americas LLC	2.8E+01	1.0E-05	3.4E+06
Industrial Uses	Institute Plant	5.3E+00	2.0E-06	1.8E+07
Industrial Uses	Kodak Park Division	1.7E-01	6.3E-08	5.6E+08
Industrial Uses	Pharmacia & Upjohn (Former)	2.7E-02	1.0E-08	3.5E+09
Industrial Uses	Philips Electronics Plant	1.0E-01	3.7E-08	9.6E+08
Industrial Uses	Sanderson Gulch Drainage Improvements	1.00E-02	3.7E-09	9.6E+09
Open System Functional Fluids	Ametek Inc. U.S. Gauge Div	4.0E-01	1.5E-07	2.4E+08
Open System Functional Fluids	Lake Reg Med/Collegeville	1.3E-02	4.8E-09	7.3E+09
Open System Functional Fluids	Pall Life Sciences Inc	4.3E-02	1.6E-08	2.2E+09
Open System Functional Fluids	Modeled Release Estimates	2.9E+00	1.1E-06	3.4E+07
Spray Foam Application	Modeled Release Estimates	2.7E-01	10.0E-08	3.6E+08

OES	Facility/Data Source	Surface Water Concentration (µg/L)	Dermal Acute Dose, Adult (mg/kg/day)	MOE (Dermal POD 35.4 mg/kg/day)
Disposal	Beacon Heights Landfill	5.3E-01	2.0E-07	1.8E+08
Disposal	Ingersoll Rand/Torrington Fac	3.5E+00	1.3E-06	2.8E+07
High-End of Submitted Monitoring Data – Measured Surface Water Concentrations				
---	STORET	1.0E+02	3.7E-05	9.6E+05
---	Sun et al. 2016	1.4E+03	5.2E-04	6.8E+04
---	North Carolina Department of Environmental Quality	1.0E+03	3.8E-04	9.3E+04
---	Minnesota Department of Environmental Quality	4.4E+00	1.6E-06	2.2E+07

4.1.2 Risk Estimates for Exposures from Consumer Use of 1,4-Dioxane

The following sections present risk estimates for acute and chronic dermal and inhalation exposures following consumer use of products containing 1,4-dioxane.

4.1.2.1 Risk Estimation for Inhalation Exposures to 1,4-Dioxane as a byproduct in Consumer Products

Risks from acute and chronic inhalation exposure to 1,4-dioxane in consumer products are shown in Table 4-3., and Table 4-4, respectively.

EPA evaluated risk from acute inhalation exposure using a POD of 283.5 mg/m^3 based on liver toxicity reported in Mattie *et al*. (2012). Calculated MOE values below the benchmark MOE of 300 would indicate a consumer safety concern for acute exposures.

Table 4-3. Risks from Acute Inhalation Exposure to 1,4-Dioxane in Consumer Products; Benchmark MOE= 300

Consumer Condition of Use	Scenario	Receptor	8 hr Max TWA (mg/m^3)	MOE
Surface Cleaner	High-Intensity User	User	5.0E-03	5.7E+04
		Bystander	9.5E-04	3.0E+05
Antifreeze	High-Intensity User	User	1.6E-02	1.8E+04
		Bystander	4.0E-03	7.2E+04
Dish Soap	High-Intensity User	User	3.0E-02	9.3E+03
		Bystander	5.4E-03	5.2E+04

Dishwasher Detergent	High-Intensity User	User	6.9E-04	4.1E+05
		Bystander	1.2E-04	2.3E+06
Laundry Detergent	High-Intensity User	User	1.5E-03	1.9E+05
		Bystander	2.7E-04	1.1E+06
Paint and Floor Lacquer	High-Intensity User	User	2.1E-02	1.4E+04
		Bystander	7.5E-03	3.8E+04
Textile Dye	High-Intensity User	User	8.5E-04	3.3E+05
		Bystander	1.5E-04	1.9E+06
Spray Polyurethane Foam	Basement	User	8.9E-01	317
		Bystander	7.4E-01	384
	Attic	User	1.9E-01	1.5E+03
		Bystander	7.1E-02	4.0E+03
	Garage	User	1.6E-01	1.7E+03
		Bystander	1.2E-01	2.5E+03

For consumer products that are used regularly, EPA also evaluated chronic cancer risks. EPA evaluated cancer risk from chronic inhalation exposure using an inhalation unit risk of 1.0E-06 $(\mu g/m^3)^{-1}$. Calculated MOE values for chronic exposure above the cancer benchmark for consumers (1×10^{-6}) would indicate a consumer safety concern.

Table 4-4. Risks from Chronic Inhalation Exposure to 1,4-Dioxane in Consumer Products. Benchmark Cancer Risk = 1×10^{-6}

Consumer Condition of Use	Scenario	Lifetime Average Daily Concentration (LADC, mg/m^3)	Cancer Risk
Surface Cleaner	High-Intensity User	1.0E-03	**1.0E-06**
	Moderate-Intensity User	5.6E-04	5.6E-07
Dish Soap	High-Intensity User	7.1E-04	7.1E-07
	Moderate-Intensity User	3.3E-04	3.3E-07
Dishwasher Detergent	High-Intensity User	7.1E-05	7.1E-08
	Moderate-Intensity User	2.9E-05	2.9E-08
Laundry Detergent	High-Intensity User	1.3E-04	1.3E-07
	Moderate-Intensity User	7.1E-05	7.1E-08

Bold: Cancer risk exceeds the benchmark of 1×10^{-6}.

4.1.2.2 Risk Estimation for Dermal Exposure to 1,4-Dioxane in Consumer Products

Risks from acute and chronic dermal exposure to 1,4-dioxane in consumer products are shown in Table 4-5., and Table 4-6, respectively.

EPA evaluated risk from acute dermal exposure using a POD of 35.4 mg/kg/day based on liver toxicity reported in Mattie *et al*. (2012). Calculated MOE values below the benchmark MOE of 300 would indicate a consumer safety concern for acute exposures.

Table 4-5. Risks from Acute Dermal Exposure to 1,4-Dioxane in Consumer Products; Benchmark MOE=300

Consumer Condition of Use	Scenario	Receptor	Acute Dose Rate (mg/kg/day)	MOE
Surface Cleaner	High-Intensity User	Adult (≥21 years)	7.7E-06	4.6E+06
		Child (16-20 years)	7.2E-06	4.9E+06
		Child (11-15 years)	7.9E-06	4.5E+06
Antifreeze	High-Intensity User	Adult (≥21 years)	5.1E-04	6.9E+04
		Child (16-20 years)	4.8E-04	7.4E+04
		Child (11-15 years)	5.2E-04	6.8E+04
Dish Soap	High-Intensity User	Adult (≥21 years)	3.1E-06	1.2E+07
		Child (16-20 years)	2.9E-06	1.2E+07
		Child (11-15 years)	3.1E-06	1.1E+07
Dishwasher Detergent	High-Intensity User	Adult (≥21 years)	3.2E-06	1.1E+07
		Child (16-20 years)	3.0E-06	1.2E+07
		Child (11-15 years)	3.3E-06	1.1E+07
Laundry Detergent	High-Intensity User	Adult (≥21 years)	4.8E-07	7.4E+07
		Child (16-20 years)	4.5E-07	7.9E+07
		Child (11-15 years)	4.9E-07	7.2E+07
Paint and Floor Lacquer	High-Intensity User	Adult (≥21 years)	2.0E-03	1.8E+04
		Child (16-20 years)	1.9E-03	1.9E+04
		Child (11-15 years)	2.0E-03	1.7E+04
Textile Dye	High-Intensity User	Adult (≥21 years)	6.4E-07	5.6E+07
		Child (16-20 years)	6.0E-07	5.9E+07
		Child (11-15 years)	6.5E-07	5.4E+07
Spray Polyurethane Foam	Basement, Attic or Garage	Adult (≥21 years)	1.0E-03	3.5E+04
		Child (16-20 years)	9.7E-04	3.7E+04
		Child (11-15 years)	1.1E-03	3.3E+04

For consumer products that are used regularly, EPA also evaluated chronic cancer risks. EPA evaluated cancer risk from chronic inhalation exposure using a dermal cancer slope factor of 0.12 $(mg/kg\text{-}d)^{-1}$. Calculated MOE values for chronic exposure above the cancer benchmark for consumers (1 x 10-6) would indicate a consumer safety concern.

Table 4-6. Risks from Chronic Dermal Exposure to 1,4-Dioxane in Consumer Products. Benchmark Cancer Risk = 1 x 10^{-6}

Consumer Condition of Use	Scenario	Lifetime Average Daily Dose (mg/kg/day)	Cancer Risk (Cancer Slope Factor = 0.12)
Surface Cleaner	High-Intensity User	5.6E-06	6.7E-07
	Moderate-Intensity User	2.3E-06	2.8E-07
Dish Soap	High-Intensity User	2.6E-07	3.2E-08
	Moderate-Intensity User	1.1E-07	1.3E-08
Dishwasher Detergent	High-Intensity User	1.2E-06	1.4E-07
	Moderate-Intensity User	9.9E-07	1.2E-07
Laundry Detergent	High-Intensity User	1.5E-07	1.8E-08
	Moderate-Intensity User	6.2E-08	7.4E-09

4.2 Risk Conclusions

4.2.1 Summary of Human Health Risk

4.2.1.1 Summary of Risk for the General Population

EPA considered reasonably available information to characterize general population exposures and risk.

Table 4-7. summarizes potential risks from acute exposures from incidental ingestion of or dermal contact with 1,4-dioxane in surface water. Calculated MOE values below the benchmark MOE (300) would indicate a potential safety concern. None of the surface water concentration estimates indicate risks from acute exposures to the general population. EPA did not identify releases to surface waters from OESs that are not included in this table (including for import/repackaging, recycling, film cement, printing inks, dry film lubricants, and laboratory chemical use).

Table 4-7. Summary of Human Health Risks from Incidental Exposure to 1,4-Dioxane in Surface Waters

OES	Facility/Data Source	Acute MOE Oral Exposure *Benchmark= 300*	Acute MOE Dermal Exposure *Benchmark = 300*
Site-Specific Modeling – Estimated Surface Water Concentrations			
Manufacturing	BASF	6.8E+04	9.9E+05
Industrial Uses	Ineos Oxide	3.0E+04	4.4E+05
Industrial Uses	Microdyn-Nadir Corp	9.1E+05	1.3E+07
Industrial Uses	St Charles Operations (Taft/Star) Union Carbide Corp	6.0E+08	8.6E+09
Industrial Uses	SUEZ Water Technologies & Solutions	1.3E+03	1.9E+04

OES	Facility/Data Source	Acute MOE Oral Exposure *Benchmark= 300*	Acute MOE Dermal Exposure *Benchmark = 300*
Industrial Uses	The Dow Chemical Co - Louisiana Operations	7.6E+08	1.1E+10
Industrial Uses	Union Carbide Corp Institute Facility	2.0E+06	2.9E+07
Industrial Uses	Union Carbide Corp Seadrift Plant	2.7E+05	4.0E+06
Industrial Uses	BASF Corp	2.0E+07	2.8E+08
Industrial Uses	Cherokee Pharmaceuticals LLC	2.5E+09	3.6E+10
Industrial Uses	DAK Americas LLC	2.4E+05	3.4E+06
Industrial Uses	Institute Plant	1.3E+06	1.8E+07
Industrial Uses	Kodak Park Division	3.9E+07	5.6E+08
Industrial Uses	Pharmacia & Upjohn (Former)	2.4E+08	3.5E+09
Industrial Uses	Philips Electronics Plant	6.6E+07	9.6E+08
Industrial Uses	Sanderson Gulch Drainage Improvements	6.6E+08	9.6E+09
Open System Functional Fluids	Ametek Inc. U.S. Gauge Div	1.7E+07	2.4E+08
Open System Functional Fluids	Lake Reg Med/Collegeville	5.1E+08	7.3E+09
Open System Functional Fluids	Pall Life Sciences Inc	1.5E+08	2.2E+09
Open System Functional Fluids	Modeled Release Estimates	2.3E+06	3.4E+07
Spray Foam Application	Modeled Release Estimates	2.5E+07	3.6E+08
Disposal	Beacon Heights Landfill	1.3E+07	1.8E+08
Disposal	Ingersoll Rand/Torrington Fac	1.9E+06	2.8E+07
High-End of Submitted Monitoring Data – Measured Surface Water Concentrations			
---	STORET	6.6E+04	9.6E+05
---	Sun et al. 2016	4.7E+03	6.8E+04
---	North Carolina Department of Environmental Quality	6.4E+03	9.3E+04
---	Minnesota Department of Environmental Quality	1.5E+06	2.2E+07

4.2.1.2 4.6.2.2 Summary of Risk for Consumer Users and Bystanders

Table 4-8. summarizes risk estimates for inhalation and dermal exposures for all consumer exposure scenarios. Risk estimates that indicate potential risk (*i.e.*, MOEs less than the benchmark MOE or cancer risks greater than the cancer risk benchmark) are highlighted by bolding the number and shading the cell in gray. The consumer exposure assessment and risk characterization are described in more detail in Sections 2.4.3 and 4.2.3, respectively.

Table 4-8. Summary of Human Health Risks from Consumer Exposures

Category	Assessed Condition of Use	Scenario Descriptor	Receptor	Dermal Risk Estimates		Inhalation Risk Estimates	
				Acute MOE *Benchmark = 300*	**Chronic Cancer Risk**[a] *Benchmark = 1E-06*	**Acute MOE HEC = 284 mg/m^3** *Benchmark = 300*	**Chronic Cancer Risk**[a] *Benchmark = 1E-06*
Paints and Coatings	Paint and Floor Lacquer	High-Intensity User	Adult (≥21 years)	1.8E+04	NA	1.4E+04	NA
		High-Intensity User	Child (16-20 years)	1.9E+04	NA	NA	NA
		High-Intensity User	Child (11-15 years)	1.7E+04	NA	NA	NA
		High-Intensity User	Bystander	NA	NA	3.8E+04	NA
Cleaning and Furniture Care Products	Surface Cleaner	High-Intensity User	Adult (≥21 years)	4.6E+06	6.7E-07	5.7E+04	**1.0E-06**
		Moderate-Intensity User	Adult (≥21 years)	NA	2.8E-07	NA	5.6E-07
		High-Intensity User	Child (16-20 years)	4.9E+06	NA	NA	NA
		High-Intensity User	Child (11-15 years)	4.5E+06	NA	NA	NA
		High-Intensity User	Bystander	NA	NA	3.0E+05	NA
Laundry and Dishwashing Products	Dish Soap	High-Intensity User	Adult (≥21 years)	1.2E+07	3.2E-08	9.3E+03	7.1E-07
		Moderate-Intensity User	Adult (≥21 years)	NA	1.3E-08	NA	3.3E-07
		High-Intensity User	Child (16-20 years)	1.2E+07	NA	NA	NA
		High-Intensity User	Child (11-15 years)	1.1E+07	NA	NA	NA
		High-Intensity User	Bystander	NA	NA	5.2E+04	NA
	Dishwasher Detergent	High-Intensity User	Adult (≥21 years)	1.1E+07	1.4E-07	4.1E+05	7.1E-08

Category	Assessed Condition of Use	Scenario Descriptor	Receptor	Dermal Risk Estimates		Inhalation Risk Estimates	
				Acute MOE *Benchmark = 300*	**Chronic Cancer Risk[a]** *Benchmark = 1E-06*	**Acute MOE HEC = 284 mg/m³** *Benchmark = 300*	**Chronic Cancer Risk[a]** *Benchmark = 1E-06*
		Moderate-Intensity User	Adult (≥21 years)	NA	1.2E-07	NA	2.9E-08
		High-Intensity User	Child (16-20 years)	1.2E+07	NA	NA	NA
		High-Intensity User	Child (11-15 years)	1.1E+07	NA	NA	NA
		High-Intensity User	Bystander	NA	NA	2.3E+06	NA
	Laundry Detergent	High-Intensity User	Adult (≥21 years)	7.4E+07	1.8E-08	1.9E+05	1.3E-07
		Moderate-Intensity User	Adult (≥21 years)	NA	7.4E-09	NA	7.8E-08
		High-Intensity User	Child (16-20 years)	7.9E+07	NA	NA	NA
		High-Intensity User	Child (11-15 years)	7.2E+07	NA	NA	NA
		High-Intensity User	Bystander	NA	NA	1.1E+06	NA
Arts, Crafts, and Hobby Materials	Textile Dye	High-Intensity User	Adult (≥21 years)	5.6E+07	NA	3.4E+05	NA
		High-Intensity User	Child (16-20 years)	5.9E+07	NA	NA	NA
		High-Intensity User	Child (11-15 years)	5.4E+07	NA	NA	NA
		High-Intensity User	Bystander	NA	NA	1.9E+06	NA
Other Consumer Uses	Spray Polyurethane Foam	Basement	Adult (≥21 years)	3.5E+04	NA	317	NA
			Bystander	NA	NA	384	NA
			Child (16-20 years)	3.7E+04	NA	NA	NA

Category	Assessed Condition of Use	Scenario Descriptor	Receptor	Dermal Risk Estimates		Inhalation Risk Estimates	
				Acute MOE *Benchmark = 300*	**Chronic Cancer Risk[a]** *Benchmark = 1E-06*	**Acute MOE HEC = 284 mg/m³** *Benchmark = 300*	**Chronic Cancer Risk[a]** *Benchmark = 1E-06*
			Child (11-15 years)	3.3E+04	NA	NA	NA
		Attic	Adult (≥21 years)	3.5E+04	NA	1.5E+03	NA
			Bystander	NA	NA	4.0E+03	NA
			Child (16-20 years)	3.7E+04	NA	NA	NA
			Child (11-15 years)	3.3E+04	NA	NA	NA
		Garage	Adult (≥21 years)	3.5E+04	NA	1.7E+03	NA
			Bystander	NA	NA	2.5E+03	NA
			Child (16-20 years)	3.7E+04	NA	NA	NA
			Child (11-15 years)	3.3E+04	NA	NA	NA
	Antifreeze	High-Intensity User	Adult (≥21 years)	6.9E+04	NA	1.8E+04	NA
		High-Intensity User	Child (16-20 years)	7.4E+04	NA	NA	NA
		High-Intensity User	Child (11-15 years)	6.8E+04	NA	NA	NA
		High-Intensity User	Bystander	NA	NA	7.2E+04	NA

NA= Not Applicable
[a] Risks from chronic exposure were evaluated only for consumer products that are used regularly

5 RISK DETERMINATION

5.1 Overview

In each risk evaluation under TSCA Section 6(b), EPA determines whether a chemical substance presents an unreasonable risk of injury to health or the environment, under the conditions of use. These determinations do not consider costs or other non-risk factors. In making these determinations, EPA considers relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations (PESS)); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties. EPA takes into consideration the Agency's confidence in the data used in the risk estimate. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization.

This section describes the draft unreasonable risk determinations for the conditions of use in this supplemental analysis.

5.1.1 Human Health

EPA identified cancer and non-cancer adverse effects from acute and chronic inhalation and dermal exposure to 1,4-dioxane from the conditions of use described in this supplemental analysis. The health risk estimates for the conditions of use in this supplemental analysis are in Section 4 (Table 4.8).

For this supplemental analysis, EPA identified as Potentially Exposed or Susceptible Subpopulations: consumers and bystanders, including men, women, and children of any age.

EPA evaluated exposures to consumer users and bystanders using reasonably available modeling data of inhalation and dermal exposures, as applicable. For example, EPA assumed that bystanders do not have direct contact with 1,4-dioxane; therefore, non-cancer effects and cancer from dermal exposures to 1,4-dioxane are not expected and were not evaluated for bystanders. Also, EPA did not estimate chronic inhalation exposures to bystanders; however, bystanders would be exposed to lower levels than the user based on the model bystander placement in the home during the product's use. The description of the data used for human health exposure is in Section 2. Uncertainties in the analysis are discussed above and are considered in the draft unreasonable risk determination for each condition of use presented below.

EPA considered reasonably available information and environmental fate properties to characterize general population exposure from surface water via the oral and dermal routes. EPA does not expect general population exposure from fish consumption. EPA's draft unreasonable risk determination for the general population is presented below. EPA did not evaluate risks to the general population from ambient air, drinking water, and sediment pathways for any conditions of use, and the draft unreasonable risk determinations do not account for exposures to the general population from ambient air, drinking water, and sediment pathways.

5.1.1.1 Non-Cancer Risk Estimates

The risk estimates of non-cancer effects (MOEs) refers to adverse health effects associated with health endpoints other than cancer, including to the body's organ systems, such as reproductive/developmental effects, cardiac and lung effects, and kidney and liver effects. The MOE is the point of departure (POD) (an approximation of the no-observed adverse effect level (NOAEL) or benchmark dose level (BMDL)) for a specific health endpoint divided by the exposure concentration for the specific scenario of concern.

The MOEs are compared to a benchmark MOE. The benchmark MOE accounts for the total uncertainty in a POD. The benchmark MOE for 1,4-dioxane for acute exposures is 100 (accounting for interspecies and intraspecies variability and LOAEL-to-NOAEL uncertainty), while the benchmark MOE for chronic exposures is 30 (accounting for interspecies and intraspecies variability).

5.1.1.2 Cancer Risk Estimates

Cancer risk estimates represent the incremental increase in probability of an individual in an exposed population developing cancer over a lifetime (excess lifetime cancer risk (ELCR)) following exposure to the chemical. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (*i.e.*, $1x10^{-6}$ to $1x10^{-4}$) depending on the subpopulation exposed. For this supplemental analysis, EPA used $1x10^{-6}$ as the benchmark for the cancer risk to consumers from consumer use of cleaning and furniture care products and laundry and dishwashing products.

The benchmark of $1x10^{-6}$ is not a bright line and EPA has discretion to make unreasonable risk determinations based on other benchmarks as appropriate.

5.1.1.3 Determining Unreasonable Risk to Injury Health

Calculated risk estimates (MOEs or cancer risk estimates) can provide a risk profile by presenting a range of estimates for different health effects for different conditions of use. A calculated MOE that is less than the benchmark MOE supports a determination of unreasonable risk of injury to health, based on non-cancer effects. Similarly, a calculated cancer risk estimate that is greater than the cancer benchmark supports a determination of unreasonable risk of injury to health from cancer. Whether EPA makes a determination of unreasonable risk depends upon other risk-related factors, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (*e.g.*, duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values.

EPA may make a determination of no unreasonable risk for conditions of use where the substance's hazard and exposure potential, or where the risk-related factors described previously, lead the Agency to determine that the risks are not unreasonable.

5.2 Detailed Draft Unreasonable Risk Determinations by Condition of Use

Table 5-1. Categories and Subcategories of Conditions of Use Included in the Supplemental Analysis

Life Cycle Stage	Category [a]	Subcategory [b]	Unreasonable Risk
Consumer uses	Arts, Crafts, and Hobby Materials	Textile dye	No
	Automotive care products	Antifreeze	No
	Cleaning and furniture care products	Surface cleaner	No
	Laundry and dishwashing products	Dish soap	No
		Dishwasher detergent	No
		Laundry detergent	No
	Paints and coatings	Paint and floor lacquer	No
	Other uses	Spray polyurethane foam	No

5.2.1 Consumer use – Arts, crafts and hobby materials – Textile dye

Section 6(b)(4)(A) unreasonable risk determination for the consumer use of 1,4-dioxane in textile dye: Does not present an unreasonable risk of injury to health (consumers and bystanders).

For consumers, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation or dermal exposures at the high-intensity use. For bystanders, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation exposures at the high intensity use.

EPA's determination that the consumer use of 1,4-dioxane in textile dye does not present an unreasonable risk is based on the comparison of the risk estimates for non-cancer effects to the benchmarks (Table 4.8) and other considerations. As explained in Section 5.1., EPA considered the health effects of 1,4-dioxane, the exposures from the condition of use, and the uncertainties in the analysis (Section 4):

- Chronic exposures were not evaluated for this condition of use because daily use intervals are not reasonably expected to occur.
- Inhalation exposures to consumers and bystanders were evaluated with the Consumer Exposure Model Version 2.1 (CEM 2.1). The magnitude of inhalation exposures to consumers and bystanders depends on several factors, including the concentration of 1,4-dioxane in products used, use patterns (including frequency, duration, amount of product used, room of use, and local ventilation), and application method.

- Dermal exposures to consumers were evaluated with the CEM (Fraction Absorbed). Dermal exposures to consumers result from dermal contact not involving impeded evaporation while using the product. The magnitude of dermal exposures depends on several factors, including skin surface area, film thickness, concentration of 1,4-dioxane in product used, dermal exposure duration, and estimated fractional absorption.

In summary, the risk estimates, the health effects of 1,4-dioxane, the exposures, and consideration of uncertainties support EPA's determination that there is no unreasonable risk of injury to health (consumers and bystanders) from the consumer use of 1,4-dioxane in textile dye.

5.2.2 Consumer use – Automotive care products – Antifreeze

Section 6(b)(4)(A) unreasonable risk determination for the consumer use of 1,4-dioxane in antifreeze: Does not present an unreasonable risk of injury to health (consumers and bystanders).

For consumers, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation or dermal exposures at the high-intensity use. For bystanders, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation exposures at the high intensity use.

EPA's determination that the consumer use of 1,4-dioxane in antifreeze does not present an unreasonable risk is based on the comparison of the risk estimates for non-cancer effects to the benchmarks (Table 4.8) and other considerations. As explained in Section 5.1., EPA considered the health effects of 1,4-dioxane, the exposures from the condition of use, and the uncertainties in the analysis (Section 4):

- Chronic exposures were not evaluated for this condition of use because daily use intervals are not reasonably expected to occur.
- Inhalation exposures to consumers and bystanders were evaluated with the Consumer Exposure Model Version 2.1 (CEM 2.1). The magnitude of inhalation exposures to consumers and bystanders depends on several factors, including the concentration of 1,4-dioxane in products used and use patterns (including frequency, duration, amount of product used, and local ventilation).
- Dermal exposures to consumers were evaluated with the CEM (Fraction Absorbed). Dermal exposures to consumers result from dermal contact not involving impeded evaporation while using the product. The magnitude of dermal exposures depends on several factors, including skin surface area, film thickness, concentration of 1,4-dioxane in product used, dermal exposure duration, and estimated fractional absorption.

In summary, the risk estimates, the health effects of 1,4-dioxane, the exposures, and consideration of uncertainties support EPA's determination that there is no unreasonable risk of injury to health (consumers and bystanders) from the consumer use of 1,4-dioxane in antifreeze.

5.2.3 Consumer use – Cleaning and furniture care products -- Surface cleaner

Section 6(b)(4)(A) unreasonable risk determination for the consumer use of 1,4-dioxane in general purpose cleaners: Does not present an unreasonable risk of injury to health (consumers and bystanders).

For consumers, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation or dermal exposures or of cancer from chronic inhalation or dermal exposures at the high intensity use. For bystanders, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation exposures at the high intensity use.

EPA's determination that the consumer use of 1,4-dioxane in surface cleaner does not present an unreasonable risk is based on the comparison of the risk estimates for non-cancer effects and cancer to the benchmarks (Table 4.8) and other considerations. As explained above, EPA considered the health effects of 1,4-dioxane, the exposures from the condition of use, and the uncertainties in the analysis (Section 4):

- Inhalation exposures to consumers and bystanders were evaluated with the Consumer Exposure Model Version 2.1 (CEM 2.1). The magnitude of inhalation exposures to consumers and bystanders depends on several factors, including the concentration of 1,4-dioxane in products used and use patterns (including frequency, duration, amount of product used, and local ventilation).
- Dermal exposures to consumers were evaluated with the CEM (Fraction Absorbed). Dermal exposures to consumers result from dermal contact not involving impeded evaporation while using the product. The magnitude of dermal exposures depends on several factors, including skin surface area, film thickness, concentration of 1,4-dioxane in product used, dermal exposure duration, and estimated fractional absorption.

In summary, the risk estimates, the health effects of 1,4-dioxane, the exposures, and consideration of uncertainties support EPA's determination that there is no unreasonable risk of injury to health (consumers and bystanders) from the consumer use of 1,4-dioxane in surface cleaner.

5.2.4 Consumer use – Laundry and dishwashing products – Dish soap

Section 6(b)(4)(A) unreasonable risk determination for the consumer use of 1,4-dioxane in dish soap: Does not present an unreasonable risk of injury to health (consumers and bystanders).

For consumers, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation or dermal exposures or of cancer from chronic inhalation or dermal exposures at the high intensity use. For bystanders, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation exposures at the high intensity use.

EPA's determination that the consumer use of 1,4-dioxane in dish soap does not present an unreasonable risk is based on the comparison of the risk estimates for non-cancer effects and cancer to the benchmarks (Table 4.8) and other considerations. As explained above, EPA considered the health effects of 1,4-dioxane, the exposures from the condition of use, and the uncertainties in the analysis (Section 4):

- Inhalation exposures to consumers and bystanders were evaluated with the Consumer Exposure Model Version 2.1 (CEM 2.1). The magnitude of inhalation exposures to consumers and bystanders depends on several factors, including the concentration of 1,4-dioxane in products used and use patterns (including frequency, duration, amount of product used, and local ventilation).
- Dermal exposures to consumers were evaluated with the CEM (Fraction Absorbed). Dermal exposures to consumers result from dermal contact not involving impeded evaporation while using the product. The magnitude of dermal exposures depends on several factors, including

skin surface area, film thickness, concentration of 1,4-dioxane in product used, dermal exposure duration, and estimated fractional absorption.

In summary, the risk estimates, the health effects of 1,4-dioxane, the exposures, and consideration of uncertainties support EPA's determination that there is no unreasonable risk of injury to health (consumers and bystanders) from the consumer use of 1,4-dioxane in dish soap.

5.2.5 Consumer use – Laundry and dishwashing products – Dishwasher detergent

Section 6(b)(4)(A) unreasonable risk determination for the consumer use of 1,4-dioxane in dishwasher detergent: Does not present an unreasonable risk of injury to health (consumers and bystanders).

For consumers, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation or dermal exposures or of cancer from chronic inhalation or dermal exposures at the high intensity use. For bystanders, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation exposures at the high intensity use.

EPA's determination that the consumer use of 1,4-dioxane in dishwasher detergent does not present an unreasonable risk is based on the comparison of the risk estimates for non-cancer effects and cancer to the benchmarks (Table 4.8) and other considerations. As explained above, EPA considered the health effects of 1,4-dioxane, the exposures from the condition of use, and the uncertainties in the analysis (Section 4):

- Inhalation exposures to consumers and bystanders were evaluated with the Consumer Exposure Model Version 2.1 (CEM 2.1). The magnitude of inhalation exposures to consumers and bystanders depends on several factors, including the concentration of 1,4-dioxane in products used and use patterns (including frequency, duration, amount of product used, and local ventilation).
- Dermal exposures to consumers were evaluated with the CEM (Fraction Absorbed). Dermal exposures to consumers result from dermal contact not involving impeded evaporation while using the product. The magnitude of dermal exposures depends on several factors, including skin surface area, film thickness, concentration of 1,4-dioxane in product used, dermal exposure duration, and estimated fractional absorption.

In summary, the risk estimates, the health effects of 1,4-dioxane, the exposures, and consideration of uncertainties support EPA's determination that there is no unreasonable risk of injury to health (consumers and bystanders) from the consumer use of 1,4-dioxane in dishwasher detergent.

5.2.6 Consumer use – Laundry and dishwashing products – Laundry detergent

Section 6(b)(4)(A) unreasonable risk determination for the consumer use of 1,4-dioxane in laundry detergent: Does not present an unreasonable risk of injury to health (consumers and bystanders).

For consumers, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation or dermal exposures or of cancer from chronic inhalation or dermal exposures at the high intensity use. For bystanders, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation exposures at the high intensity use.

EPA's determination that the consumer use of 1,4-dioxane in laundry detergent does not present an unreasonable risk is based on the comparison of the risk estimates for non-cancer effects and cancer to the benchmarks (Table 4.8) and other considerations. As explained in Section 5.1., EPA considered the health effects of 1,4-dioxane, the exposures from the condition of use, and the uncertainties in the analysis (Section 4):

- Inhalation exposures to consumers and bystanders were evaluated with the Consumer Exposure Model Version 2.1 (CEM 2.1). The magnitude of inhalation exposures to consumers and bystanders depends on several factors, including the concentration of 1,4-dioxane in products used and use patterns (including frequency, duration, amount of product used, and local ventilation).
- Dermal exposures to consumers were evaluated with the CEM (Fraction Absorbed). Dermal exposures to consumers result from dermal contact not involving impeded evaporation while using the product. The magnitude of dermal exposures depends on several factors, including skin surface area, film thickness, concentration of 1,4-dioxane in product used, dermal exposure duration, and estimated fractional absorption.

In summary, the risk estimates, the health effects of 1,4-dioxane, the exposures, and consideration of uncertainties support EPA's determination that there is no unreasonable risk of injury to health (consumers and bystanders) from the consumer use of 1,4-dioxane in laundry detergent.

5.2.7 Consumer use – Paints and coatings – Paint and floor lacquer

Section 6(b)(4)(A) unreasonable risk determination for the consumer use of 1,4-dioxane in paint and floor lacquer: Does not present an unreasonable risk of injury to health (consumers and bystanders).

For consumers, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation or dermal exposures at the high-intensity use. For bystanders, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation exposures at the high intensity use.

EPA's determination that the consumer use of 1,4-dioxane in paint and floor lacquer does not present an unreasonable risk is based on the comparison of the risk estimates for non-cancer effects to the benchmarks (Table 4.8) and other considerations. As explained in Section 5.1., EPA considered the health effects of 1,4-dioxane, the exposures from the condition of use, and the uncertainties in the analysis (Section 4):

- Chronic exposures were not evaluated for this condition of use because daily use intervals are not reasonably expected to occur.
- Inhalation exposures to consumers and bystanders were evaluated with the Consumer Exposure Model Version 2.1 (CEM 2.1). The magnitude of inhalation exposures to consumers and bystanders depends on several factors, including the concentration of 1,4-dioxane in products used and use patterns (including frequency, duration, amount of product used, and local ventilation).
- Dermal exposures to consumers were evaluated with the CEM (Fraction Absorbed). Dermal exposures to consumers result from dermal contact not involving impeded evaporation while using the product. The magnitude of dermal exposures depends on several factors, including skin surface area, film thickness, concentration of 1,4-dioxane in product used, dermal exposure duration, and estimated fractional absorption.

In summary, the risk estimates, the health effects of 1,4-dioxane, the exposures, and consideration of uncertainties support EPA's determination that there is no unreasonable risk of injury to health (consumers and bystanders) from the consumer use of 1,4-dioxane in paint and floor lacquer.

5.2.8 Consumer use – Other uses – Spray Polyurethane Foam

Section 6(b)(4)(A) unreasonable risk determination for the consumer use of 1,4-dioxane in spray polyurethane foam: Does not present an unreasonable risk of injury to health (consumers and bystanders).

For consumers, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation and dermal exposures at the high-intensity use. For bystanders, EPA found that there was no unreasonable risk of non-cancer effects (liver toxicity) from acute inhalation exposures at the high intensity use.

EPA's determination that the consumer use of 1,4-dioxane in spray polyurethane foam does not present an unreasonable risk is based on the comparison of the risk estimates for non-cancer effects to the benchmarks (Table 4.8) and other considerations. As explained in Section 5.1., EPA considered the health effects of 1,4-dioxane, the exposures from the condition of use, and the uncertainties in the analysis (Section 4):

- Chronic exposures were not evaluated for this condition of use because daily use intervals are not reasonably expected to occur.
- Inhalation exposures to consumers and bystanders were evaluated with the Consumer Exposure Model Version 2.1 (CEM 2.1). The magnitude of inhalation exposures to consumers and bystanders depends on several factors, including the concentration of 1,4-dioxane in products used and use patterns (including frequency, duration, amount of product used, and local ventilation).
- Dermal exposures to consumers were evaluated with the CEM (Fraction Absorbed). Dermal exposures to consumers result from dermal contact not involving impeded evaporation while using the product. The magnitude of dermal exposures depends on several factors, including skin surface area, film thickness, concentration of 1,4-dioxane in product used, dermal exposure duration, and estimated fractional absorption.

In summary, the risk estimates, the health effects of 1,4-dioxane, the exposures, and consideration of uncertainties support EPA's determination that there is no unreasonable risk of injury to health (consumers and bystanders) from the consumer use of 1,4-dioxane in spray polyurethane foam.

5.2.9 General Population

Section 6(b)(4)(A) unreasonable risk determination from **any of the conditions of use** of 1,4-dioxane: Does not present an unreasonable risk of injury to health (general population). EPA did not assess exposures from ambient air, drinking water, and sediment pathways because they fall under the jurisdiction of other environmental statutes administered by EPA, *i.e.,* CAA, SDWA, RCRA, and CERCLA. However, EPA has not developed recommended ambient water quality criteria for the protection of human health for 1,4-dioxane. Exposure to the general population via surface water can occur through recreational activities (*e.g.,* swimming) and through consuming fish. EPA considered reasonably available information and environmental fate properties to characterize general population exposure through the surface water pathway. EPA evaluated the human health risks of potential acute and chronic incidental exposures via oral and dermal routes from recreational swimming and determined that these risks are not unreasonable. In addition, because 1,4-dioxane has low bioaccumulation potential, EPA has determined that the human health risks from fish ingestion are not unreasonable. This unreasonable risk determination does not account for exposures to the general population from ambient air, drinking water, and sediment pathways.

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APPENDICES

Appendix A CONSUMER EXPOSURES

For additional consumer modeling support files, please see the following supplemental documents: *Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane - Consumer Exposure Assessment Model Input Parameters; Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane - Exposure Modeling Results and Risk Estimates for Consumer Exposures*.

A.1 Consumer Inhalation Exposure

A.1.1 CEM 2.1 and CEM

The Consumer Exposure Models (CEM 2.1 and CEM within E-FAST 2014) predict indoor air concentrations from consumer product use by implementing a deterministic, mass-balance calculation utilizing an emission profile determined by implementing appropriate emission scenarios. The model uses a two-zone representation of the building of use (*e.g.*, residence, school, office), with Zone 1 representing the room where the consumer product is used (*e.g.*, a utility room) and Zone 2 being the remainder of the building. The product user is placed within Zone 1 for the duration of use, while a bystander is placed in Zone 2 during product use. Otherwise, product users and bystanders follow prescribed activity patterns throughout the simulated period. Each zone is considered well-mixed. Product users are exposed to airborne concentrations estimated within the near-field during the time of use and otherwise follow their prescribed activity pattern. Bystanders follow their prescribed activity pattern and are exposed to far-field concentrations when they are in Zone 1. Background concentrations can be set to a non-zero concentration if desired.

The general steps of the calculation engine within the CEM models include:

- Introduction of the chemical (*i.e.*, 1,4-dioxane) into the room of use (Zone 1) through two possible pathways: (1) overspray of the product or (2) evaporation from a thin film;
- Transfer of the chemical to the rest of the house (Zone 2) due to exchange of air between the different rooms;
- Exchange of the house air with outdoor air; and
- Compilation of estimated air concentrations in each zone as the modeled occupant (*i.e.*, user or bystander) moves about the house per prescribed activity patterns.

For acute exposure scenarios, emissions from each incidence of product usage are estimated over a period of 72 hours using the following approach that accounts for how a product is used or applied, the total applied mass of the product, the weight fraction of the chemical in the product, and the molecular weight and vapor pressure of the chemical. Time weighted averages (TWAs) were then computed based on these user and bystander concentration time series per available human health hazard data. For 1,4-dioxane, 8-hour TWAs were quantified for use in risk evaluation based on alignment of relevant acute human health hazard endpoints. For additional details on CEM 2.1's underlying emission models, assumptions, and algorithms, please see the User Guide Section 3: Detailed Descriptions of Models within CEM 2.1 (U.S. EPA, 2019a). The emission models used have been compared to other model results and measured data; see Appendix D: Model Corroboration of the User Guide Appendices for the results of these analyses (U.S. EPA, 2019b).

For chronic exposure scenarios, CEM within E-FAST 2014 was used to obtain lifetime average daily concentrations (LADCs) for the scenarios involving chronic exposures. Emissions are estimated over a period of 60 days. For cases where the evaporation time estimated exceeds 60 days, the model will truncate the emissions at 60 days. Conversely, for cases where the evaporation time is less than 60 days, emissions will be set to zero between the end of the evaporation time and 60 days. For more information on this version of CEM and its chronic inhalation estimates, refer to the E-FAST 2014 Documentation Manual (U.S. EPA, 2007).

Emission Models in CEM 2.1

Based on the suite of product scenarios developed to evaluate the 1,4-dioxane consumer conditions of use, the specific emission models applied for the purposes of this evaluation include: E1: Emission from Product Applied to a Surface Indoors Incremental Source Model and E4: Emission from Product Added to Water.

Product Scenarios in CEM

Based on the suite of product scenarios developed to evaluate the 1,4-dioxane consumer conditions of use, the specific models applied for the purposes of this evaluation include: Product Applied to Surface – Incremental Source Model and Product Added to Water – Constant Rate Model.

CEM 2.1’s E1 model and CEM’s Product Applied to Surface – Incremental Source Model are analogous and are generally applicable for liquid products applied to a surface such as cleaners. These emission models assume a constant application rate over a user-specified duration of use and an emission rate that declines exponentially over time, at a rate that depends on the chemical molecular weight and vapor pressure.

CEM 2.1’s E4 model and CENM’s Product Added to Water – Constant Rate Model assume emission at a constant rate over a duration that depends on the chemical’s molecular weight and vapor pressure. If this estimated duration is longer than the user-specified duration of use, chemical emissions are truncated at the end of the product use period and the remaining chemical mass is assumed to go down the drain. These emission models are applied for use scenarios such as laundry and dishwashing detergent, dish soap, and textile dye.

A.1.2 MCCEM

The Multi-Chamber Concentration and Exposure Model (MCCEM) estimates indoor air concentrations of chemicals released from household products (EPA, 2010). It uses air infiltration and interzonal air flow rates with user-input emission rates to calculate time-varying concentrations in several zones or chambers within a residence. Four types of source models are available in MCCEM – constant, single exponential, incremental, and data entry. For additional details, see the MCCEM User Guide (EPA, 2019c).

Within MCCEM, the incremental source model is specifically designed for products that are applied to a surface (as SPF is) rather than products that are placed in an environment (*e.g.*, an air freshener). This distinction is important because the incremental source model considers the time or duration of application or use in its calculations of emissions and concentrations, while the single exponential source model does not. The incremental model assumes a constant application rate over time, coupled with an emission rate for each instantaneously applied segment that declines exponentially. The equation for the time-varying emission rate resulting from the combination of constant application and exponentially declining emissions (Evans, 1996) utilized in the single exponential incremental model is shown below. This is a simplification of the overall incremental model in MCCEM that considers two emission decay constants and rates to capture emissions from both the evaporation and diffusion phases. However, the SPF scenario is better modeled by a single decay constant after application.

$$ER(t) = \frac{M \times WF \times CF}{t_a} \times \left[\left(1 - e^{-k(t-t_{start})}\right) - \left(\left(1 - e^{-k(t-(t_{start}+t_a))}\right) \times H(t)\right)\right]$$

Where:

$ER(t)$	=	Emission rate at time t (mg/min)
M	=	Mass of product used (g)
WF	=	Weight fraction of chemical in product (unitless)
CF	=	Conversion factor (1000 mg/g)
t_{start}	=	Time of start of application (min)
t_a	=	Application time (min)
k	=	First-order rate constant for emissions decline (min^{-1})
t	=	Time (min)
$H(t)$	=	0/1 value used to indicate if product is actively in use
	=	0 if $t - (t_{start} + t_a) < 0$
	=	1 if $t - (t_{start} + t_a) > 0$

The incremental model can be populated using experimental data and proposed model of emission rates in Karlovich et al. (2011). In this study, the authors measured air concentrations of 1,4-dioxane after taking samples from an open-cell SPF product applied to a cardboard box and placed in a small-scale environmental chamber. These concentrations were used to develop a mathematical relationship between the emission factor and loading factor based on the volume and airflow of the chamber.

$$EF = \frac{C_{chamber}}{LF \times ACH}$$

Where:

EF	=	Emission Factor (µg/m^2-hr)
$C_{chamber}$	=	Chamber concentration (µg/m^3)
LF	=	Loading factor (m^2/m^3)
ACH	=	air changes per hour

Based on the chamber air flow rate, foam sample surface area, and indoor air assumptions, the above equation can be reworked to find predicted air concentrations:

$$C_{air,\ predicted} = \frac{EF \times 0.5}{0.3}$$

The concentration data can be used to determine decay rates by fitting the data to a time series concentration function associated with MCCEM's incremental model. The general mass-balance equation for a test chamber can be integrated assuming an initial concentration of zero to the following:

$$C(t) = \frac{E_0}{V\left(\frac{Q}{V} - k\right)} \times \left(e^{-kt} - e^{\frac{-Q}{V}t}\right)$$

Where:

$C(t)$ = Concentration (µg/m^3)
E_0 = Initial emission rate (µg/hr)
V = Volume of the chamber (m^3)
Q = Airflow rate into and out of the chamber (m^3/hr)
k = First-order rate constant (hr^{-1})
t = Time (hr)

Karlovich et al. (2011) collected air samples 4, 12, 24, and 48 hours after placing the sample in the chamber. Predicted indoor air concentrations (1,479, 663, 201, and 40 µg/m^3, respectively) were fitted to the concentration equation above to identify the initial emission rate and decay constant, 73.868 µg/hr and 0.1 hr^{-1}, respectively. The emission rate was normalized to the applied surface area of SPF in the study (25 square inches) to find an emission rate per square inch of SPF applied, 2.955 µg/in^2/hr. This initial emission rate and decay constant can then be scaled appropriately to find the total mass applied in each application setting (attic, basement, and garage).

A.1.2.1 MCCEM Inputs for SPF Scenario

Product and Exposure Settings

The suggested values for house volume (492 m^3) and air exchange rate (0.45 ACH) are central values from the Exposure Factors Handbook (EPA, 2011). A two-story house is assumed for all cases. The attic volume is assumed to be half the volume of one story, or 123 m^3. The basement volume is assumed to be the volume of one story, or 246 m^3. The assumed garage volume (118 m^3) is the average volume of one- and two-car garages in 15 single-family homes with attached garages, as reported by Batterman et al. 2007. The attic and garage are assumed to be outside of the standard house volume as they are not modeled to be conditioned or finished.

- For the attic scenario, interzonal airflow rates were applied based on measured air change rates at a variety of temperatures and wind speeds for vented and unvented attics (Walker et al. 2005). The central measured value at wind speeds of 2-3 m/s was about 1.5 air changes per hour (ACH) for the unvented attic and about 6.0 ACH for the vented. The latter case is used in this scenario as most US homes are assumed to have vented attics. When multiplied by the volume of the attic, this 6.0 ACH rate corresponds to an interzonal airflow rate of 738 m^3/hr between the attic and outdoors. Walker et al. also considered the airflow between unconditioned attics and the remainder of the houses, measuring an average of about 0.125 ACH at standard temperatures of 20-25°C. This corresponds to an interzonal airflow rate of 61.5 m^3/hr between the attic and the rest of the house (ROH). The suggested value of 0.45 ACH was applied for the rest of the house and outdoors, corresponding to an interzonal airflow rate of 221.4 m^3/hr.
- For the basement scenario, interzonal airflow rates were applied using an algorithm developed in a study estimating the distributions for residential air exchange rates (Koontz and Rector, 2005). The estimated interzonal airflow rate between both basements and garages is estimated at 109 m^3/hr. The suggested value of 0.45 ACH was applied for the rest of the house and outdoors, corresponding to an interzonal airflow rate of 110.7 m^3/hr.
- For the garage scenario, interzonal airflow rates were informed by the results of a study measuring the airtightness of garages on a variety of homes under induced pressurized conditions (Emmerich et al. 2003). The average airtightness measured with the blower door was 48 ACH at 50 Pa, which corresponds to an air exchange rate of about 2.5 ACH and 295 m^3/hr under normal conditions. The

suggested value of 0.45 ACH was applied for the rest of the house and outdoors, corresponding to an interzonal airflow rate of 221.4 m^3/hr.

A typical floor or ceiling loading ratio of 0.41 m^2/ m^3 (*i.e.*, for a ceiling height of 2.44 m; EPA, 2011), when multiplied by the upstairs volume of 246 m^3, gives an estimated attic floor area of 100.9 m^2 (1086 sq. feet or 156,384 sq. inches). The same ratio applies to the garage ceiling, giving an estimated area of 48.4 m^2 (521 sq. feet or 75,024 sq. inches) when multiplied by the garage volume of 118 m^3. The basement volume (246 m^3) and ceiling height (2.44 m) indicate a floor area of 100.8 m^2, corresponding to dimensions of 7.9 m by 12.8 m. The wall area is 2.44 m x (7.9 m x 2 + 12.8 m x 2) = 101 m^2 or 1087 sq. ft. or 156,528 sq. inches. These areas of application surface were multiplied by the emission rate per square inch over the decay rate per hour to determine the total mass of 1,4-dioxane released in each setting: 4523.752659 mg in the attic, 4527.918177 mg in the basement, and 2170.234931 mg in the garage.

Use Patterns and Exposure Factors

An installation rate of 3 sq. ft./min or 180 sq. ft./hour is assumed, based on an instructional video for DIY spray foam insulation installation. Corresponding estimates for the duration of installation are 6 hours for the attic floor, 6 hours for basement walls, and 3 hours for the garage ceiling. Each application was modeled to start at 9 AM. It is assumed that the user would be in the room of use during the time of application and in the rest of the house for the remainder of the model run. This assumption of staying at home produces a conservative estimate of exposure. Bystander exposure is based on the assumption that the bystander is home during the application period but spends the entire time in the rest of the house and no time in the room of use.

In MCCEM, a breathing rate of 15.083 m^3/day was estimated based on the recommended mean long-term exposure inhalation values in the 2011 Exposure Factors Handbook (EPA, 2011).

A.2 Consumer Dermal Exposure

Two models were used to evaluate consumer dermal exposures, the Fraction Absorbed model (P_DE2a within CEM) and the Permeability model (P_DER2b within CEM). A brief comparison of these two dermal models through the calculation of acute dose rates (ADRs) is provided below. They have been applied to distinct exposure conditions, with the permeability model applied to scenarios likely to involve occluded dermal contact where evaporation may be inhibited and the fraction absorbed model applied to scenarios less likely to involve occluded dermal contact.

The dermal models described below were run for all consumer conditions of use to provide a comparison between the two results while recognizing each model is unique in its approach to estimating dermal exposure and may not be directly comparable. Keeping these limitations in mind, the full suite of exposure results from both models is shown for all conditions of use in *Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane - Exposure Modeling Results and Risk Estimates for Consumer Exposures.xlsx*.

Because neither model considers the mass of chemical as an input in the absorbed dose equations, both have the potential to overestimate the dermal absorption by modeling a mass which is larger than the mass used in a scenario. Therefore, when utilizing either of the CEM models for dermal exposure estimations, a mass check is necessary outside of the CEM model to make sure the mass absorbed does not exceed the typical mass used for a given scenario.

CEM Absorption Fraction Model (P_DER2a)

The fraction absorbed model estimates the mass of a chemical absorbed through the applicational of a fractional absorption factor to the mass of chemical present on or in the skin following a use event. The initial dose or amount retained on the skin is determined using a film thickness approach. A fractional absorption factor is then applied to estimate the absorbed dose from the initial dose. The fraction absorbed is essentially the measure of two competing processes, evaporation of the chemical from the skin surface and penetration deeper into the skin. It can be estimated using an empirical relationship based on Frasch and Bunge (2015). Due to the model's consideration of evaporative processes, dermal exposure under unimpeded exposure conditions was considered to be more representative. For additional details on this model, please see Appendix A and the CEM User Guide Section 3: Detailed Descriptions of Models within CEM (U.S. EPA, 2019a).

The acute form of the absorption fraction model is given below:

$$ADR = \frac{AR \times F_{abs} \times \frac{SA}{BW} \times FQ_{ac} \times Dil \times WF \times ED_{ac} \times CF_1}{AT_{ac}}$$

Where:

ADR = Acute daily dose rate (mg/kg-day)
AR = Amount retained in the skin (g/cm^2, film thickness [cm] multiplied by product density)
F_{abs} = Absorption fraction (see below)
D_{ac} = Duration of use (min/event)
SA/BW = Surface area to body weight ratio (cm^2/kg)
FQ_{ac} = Frequency of use (events/day, 1 for acute exposure scenarios)
Dil = Product dilution fraction (unitless)
WF = Weight fraction of chemical in product (unitless)
ED_{ac} = Exposure duration (1 day for acute exposure scenarios)
CF1 = Conversion factor (1,000 mg/g)
AT_{cr} = Averaging time (1 day for acute exposure scenarios)

The fraction absorbed (F_{abs}) term is estimated using the ratio of evaporation from the stratum corneum to the dermal absorption rate through the stratum corneum, as informed by gas phase mass transfer coefficient, vapor pressure, molecular weight, water solubility, real gas constant, and permeability coefficient.

$$FR_{abs} = \frac{3 + \chi\left[1 - \exp(-a\frac{D_{ac}}{t_{lag} x\ CF_1})\right]}{3(1+\chi)}$$

Where:

χ = Ratio of the evaporation rate from the stratum corneum (SC) to the dermal absorption rate
ɑ = Constant (2.906)
D_{ac} = Duration of use (min/event)
t_{lag} = Lag time for chemical transport through SC (hr)
CF_1 = Conversion factor (60 min/hr)

The chronic form of the dermal absorption fraction model is given below:

$$LADD = \frac{AR \times F_{abs} \times \frac{SA}{BW} \times FQ_{cr} \times Dil \times WF \times ED_{cr} \times CF_1}{AT_{cr} \times CF_2}$$

Where:

LADD = Lifetime average daily dose (mg/kg-day)
D_{cr} = Duration of use (min/event)
FQ_{cr} = Frequency of use (events or days/year)
ED_{cr} = Exposure duration (57 years)
CF2 = Conversion factor (365 days/yr)
AT_{cr} = Averaging time (78 years)

CEM Permeability Model (P_DER2b)

The permeability model estimates the mass of a chemical absorbed and dermal flux based on a permeability coefficient (K_p) and is based on the ability of a chemical to penetrate the skin layer once contact occurs. It assumes a constant supply of chemical directly in contact with the skin throughout the exposure duration. K_p is a measure of the rate of chemical flux through the skin. The parameter can either be specified by the user (if measured data are reasonably available) or be estimated within CEM using a chemical's molecular weight and octanol-water partition coefficient (K_{OW}). The permeability model does not inherently account for evaporative losses (unless the available flux or K_p values are based on non-occluded, evaporative conditions), which can be considerable for volatile chemicals in scenarios where evaporation is not impeded. While the permeability model does not explicitly represent exposures involving such impeded evaporation, the model assumptions make it the preferred model for an such a scenario. For additional details on this model, please see Appendix A and the CEM User Guide Section 3: Detailed Descriptions of Models within CEM (U.S. EPA, 2019a).

The acute form of the dermal permeability model is given below:

$$ADR = \frac{K_p \times D_{ac} \times \rho \times \frac{SA}{BW} \times FQ_{ac} \times Dil \times WF \times ED_{ac} \times CF_1}{AT_{ac} \times CF_2}$$

Where:

ADR = Potential acute dose rate (mg/kg-day)
K_p = Permeability coefficient (cm/hr)
D_{ac} = Duration of use (min/event)
ρ = Density of formulation (g/cm^3)
SA/BW = Surface area to body weight ratio (cm^2/kg)
FQ_{ac} = Frequency of use (events/day, 1 for acute exposure scenarios)
Dil = Product dilution fraction (unitless)
WF = Weight fraction of chemical in product (unitless)
ED_{ac} = Exposure duration (1 day for acute exposure scenarios)
CF1 = Conversion factor (1,000 mg/g)
CF2 = Conversion factor (60 min/hr)
AT_{ac} = Averaging time (1 day for acute exposure scenarios)

The chronic form of the dermal permeability model is given below:

$$LADD = \frac{K_p \times D_{cr} \times \rho \times \frac{SA}{BW} \times FQ_{cr} \times Dil \times WF \times ED_{cr} \times CF_1}{AT_{cr} \times CF_2 \times CF_3}$$

Where:

LADD = Lifetime average daily dose (mg/kg-day)
D_{cr} = Duration of use (min/event)
FQ_{cr} = Frequency of use (events or days/year)
ED_{cr} = Exposure duration (57 years)
CF3 = Conversion factor (365 days/yr)

AT_{cr} = Averaging time (78 years)

A.3 Measured Emission Data

Systematic review identified several studies reporting emission rates or chamber emission concentrations of 1,4-dioxane from spray foam and paint samples. These emission data are summarized below. These data are not directly comparable to the predicted 8-hr TWAs presented for consumer exposure scenarios, as the 8-hr TWAs are zone-integrated to account for the activity patterns of the user or bystander (*i.e.*, the presented TWAs account for a user or bystander's movement throughout the house – Zones 1 and 2 – for the 8-hr period).

As described above, Karlovich et al. (2011) identified 1,4-dioxane in emissions from a two-component open-cell SPF hours and days after application. Chamber concentrations and emission factors were calculated from these sampling results. The emission factors were then used to predict indoor air concentrations (1,479, 663, 201, and 40 µg/m^3 for samples measured at 4, 12, 24, and 48 hours, respectively).

Naldzhiev et al. (2019) analyzed volatile organic compound presence in and emissions from three spray foam insulation products. Authors measured 1,4-dioxane in a two-component closed-cell SPF product, both in the raw material (*i.e.*, mixed spray foam, pre-application) and in the headspace from the cured foam. Air concentrations were not reported, but findings confirm 1,4-dioxane's presence in closed-cell SPF products. 1,4-Dioxane was not detected in the other two products tested including a commercially available, two-component closed-cell spray foam and a commercially available, one-component spray foam.

Poppendieck et al. (2017) reported concentrations of 1,4-dioxane in micro-chamber air sampling of a high-pressure closed-cell spray foam. Initial concentrations (*i.e.*, at sampling time 0) were just above 100 µg/m^3 and fell below 50 µg/m^3 after roughly 48 hours of sampling. In the authors' related final report (Poppendieck, 2017), additional 1,4-dioxane chamber concentrations were reported for a "non-ideal" closed-cell spray foam. The non-ideal foam samples were submitted by the Consumer Product Safety Commission (CPSC) to reflect non-ideal preparation or application conditions such as off-ratio mixing of two-component foams, low substrate temperature, and incorrect nozzle pressure or temperature. Chamber concentrations measured from the non-ideal closed-cell foam were higher, falling between 500 and 1,000 µg/m^3 at sampling time 0, ~500 µg/m^3 at 48 hours, and falling below 250 µg/m^3 around 175 hours.

Won et al. (2014) tested 30 building materials for 121 VOCs and reported measured chamber concentrations and emission factors for 1,4-dioxane in two of the product types covered in this consumer evaluation: foam insulation and paint. Chamber concentrations of 1,4-dioxane from various insulation products ranged from 0.25 to 44.68 µg/m^3 at six hours, with the highest level measured from a two-component, closed-cell foam. Chamber concentrations of 1,4-dioxane from various paint products ranged from 0.80 to 1.74 µg/m^3 at six hours, with the highest level measured from an interior latex paint. Study authors cite mean emission rates of 15.72 µg/m^2/hr and 1.97 µg/m^2/hr for insulation and paint, respectively.

The Danish EPA's 2018 Survey and Risk Assessment of Chemical Substances in Chemical Products Used for "Do-It-Yourself" Projects in the Home (EPA, 2018a) measured respiratory zone concentrations during a realistic use of specific products in a test room and then measured subsequent emissions in a climate chamber after five hours, three days, and 28 days. During application of water-based, two-component epoxy floor paint, respiratory zone levels of 1,4-dioxane were 220 μg/m^3. At five hours, levels decreased to 21 μg/m^3. In a 2020 follow-up survey, the Danish EPA (2019a) tested additional products and reported chamber concentrations of 1,4-dioxane from two-component paint and lacquer ranging from 7 to 460 μg/m^3 at five hours. Following application of floor polish, levels of 1,4-dioxane were measured at 68-70 μg/m^3 at five hours.

Although measured chamber or test room concentrations are not directly comparable to the 8-hr TWAs estimated for the various consumer exposure scenarios, on the whole, these emission studies bolster confidence in the predicted air concentrations for the SPF and paint and floor lacquer conditions of use.

The predicted 8-hr TWAs for SPF range from 160 to 890 μg/m^3 for users. These predicted estimates fall within the range predicted in Karlovich et al., (2011) for samples measured at four and 12 hours. Peppendieck et al. (2017) also reported measured air concentrations that encompass the modeled consumer exposure estimates, with concentrations from non-ideal closed-cell spray foam ranging from 500 to 1,000 μg/m^3 over the first 48 hours. Won et al. (2014) reported levels of 1,4-dioxane well below the CEM 2.1 predictions, from 0.25 to 44.68 μg/m^3 at six hours for various insulation products including foam board and two-component open- and closed-cell spray foams.

The predicted 8-hr TWA for paint and floor lacquer is 20 μg/m^3 for users, which is roughly one order of magnitude greater than concentrations measured in Won et al. (2014) (0.8 – 1.74 μg/m^3 at six hours), but aligns with the Danish EPA's measured air concentration five hours after application of the two-component epoxy floor paint (21 μg/m^3) (EPA, 2018a). The predicted TWA also falls within the range of air concentrations taken five hours after application in the Danish EPA's 2020 Follow-Up study, which reported levels from 7 to 460 μg/m^3 at five hours.

A.4 CEM Model Sensitivity Analysis Summary

The CEM 2.1 developers conducted a detailed sensitivity analysis for CEM, as described in Appendix C of the CEM User Guide (U.S. EPA, 2019b). The CEM developers included results of model corroboration analysis in Appendix D of the CEM User Guide (U.S. EPA, 2019b).

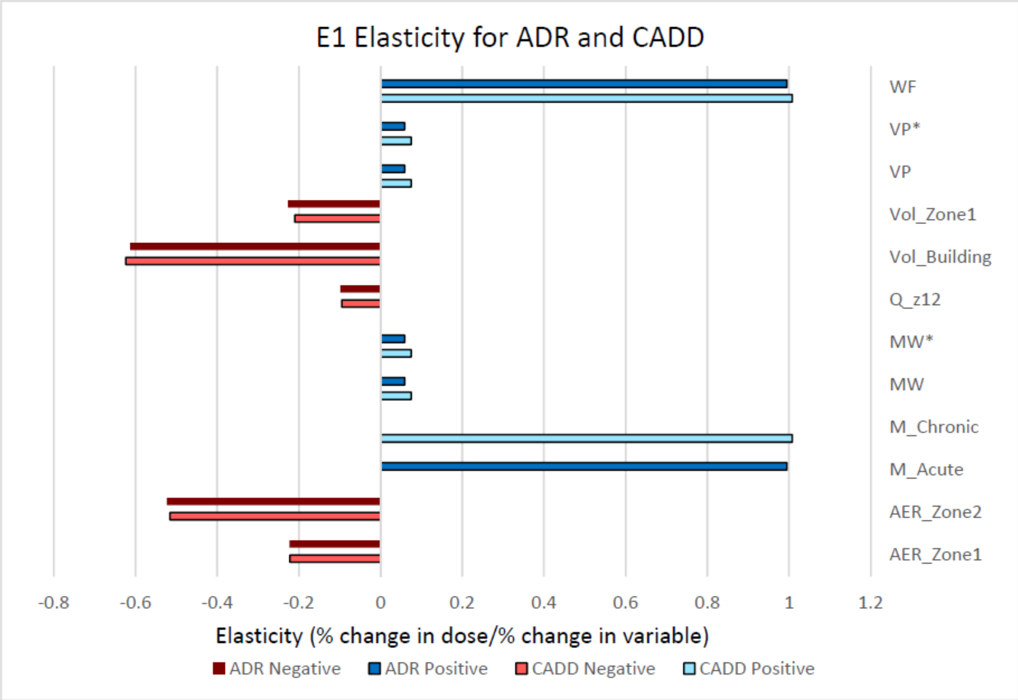
In brief, the analysis was conducted on continuous variables and categorical variables that were used in CEM emission or dermal models. A base run of different CEM models using various product or article categories, along with CEM defaults, was used. Individual variables were modified, one at a time, and the resulting Acute Dose Rate (ADR) and Chronic Average Daily Dose (CADD) were compared to the corresponding results for the base run. Benzyl alcohol, a VOC, was used as an example for product models such as those applied in this evaluation of 1,4-dioxane.

The tested model parameters were increased by 10%. The measure of sensitivity for continuous variables such as mass of product used, weight fraction, and air exchange rate was "elasticity," defined as the ratio of percent change in each result to the corresponding percent change in model input. A positive elasticity indicates that an increase in the model parameter resulted in an increase in the model output, whereas a parameter with negative elasticity is associated with a decrease in the model output. For categorical variables such as receptor activity pattern (*i.e.*, work schedule) and room of use, the percent difference in model outputs for different category pairs was used as the measure of sensitivity.

The results are summarized below for the inhalation and dermal models used to evaluate consumer exposures to 1,4-dioxane (*i.e.*, emission models E1 and E3 and the dermal permeability model P_DER2b. For full results and additional background, refer to Appendix C of the CEM User Guide (U.S. EPA, 2017b).

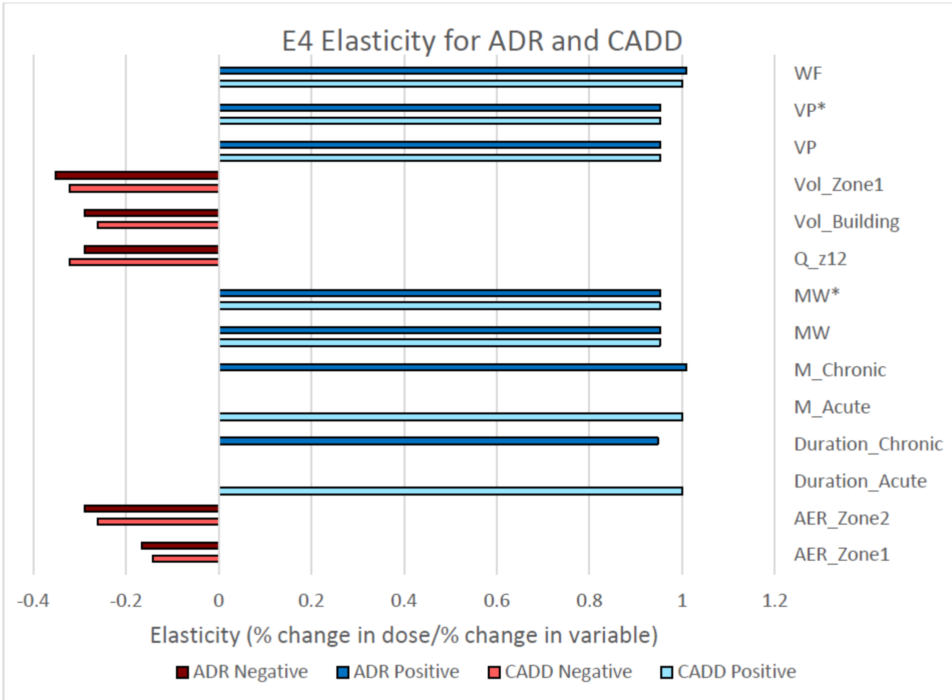
A.4.1 Continuous Variables

For acute exposures generated from emission model E1, WF (weight fraction) and M_acute (mass of product used) have the greatest positive elasticities of the tested parameters. The next most sensitive parameters demonstrate negative elasticity and include: Vol_Building (building volume); AER_Zone2 (air exchange rate in Zone 2); AER_Zone1 (air exchange rate in Zone 1); Vol_Zone1 (room of use, or Zone 1 volume). Inhalation exposures from liquid products applied to surface such as surface cleaner were modeled using E1.



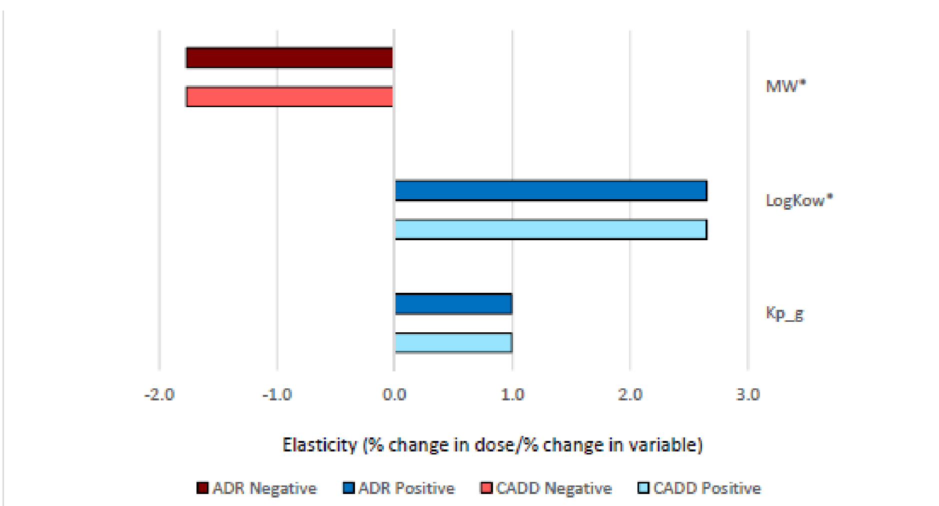
Figure_Apx A-1. Elasticities (≥ 0.05) for Parameters Applied in E1

For acute exposures generated from emission model E4, WF (weight fraction), M_acute (mass of product used), VP (vapor pressure), and MW (molecular weight) have the greatest positive elasticities of the tested parameters. The next most sensitive parameters demonstrate negative elasticity and include: Vol_Zone1 (room of use volume); Qz12 (interzonal ventilation rate); Vol_Building (building volume); AER_Zone2 (air exchange rate in Zone 2); AER_Zone1 (air exchange rate in Zone 1). Inhalation exposures from products added to water such as laundry detergent and dish soap were modeled using E4.



Figure_Apx A-2. Elasticities (≥ 0.05) for Parameters Applied in E4

For acute exposures generated from the dermal permeability model, the chemical properties that inform absorption rate, or absorption rate estimates, have the greatest elasticities. For 1,4-dioxane, dermal exposures from consumer product formulations were modeled using a measured Kp (permeability coefficient). Therefore, $LogK_{OW}$ (octanol/water partition coefficient) and MW (molecular weight) were not used to estimate skin penetration.



Figure_Apx A-3. Elasticities (≥ 0.05) for Parameters Applied in P_DER2b

A.4.2 Categorical Variables

For categorical variables there were multiple parameters that affected other model inputs. For example, varying the room type changed the ventilation rates, volume size and the amount of time per day that a person spent in the room. Thus, each modeling result was calculated as the percent difference from the base run. Among the categorical variables, the most sensitive parameters included receptor type (adult vs. child), room of use (Zone 1) selection, and application of the near-field bubble within Zone 1. However, these types of variables were held constant within a given product modeling scenario and were applied using consistent assumptions across all modeling scenarios.

Supplemental Analysis and Systematic Review Files:

Consumer Exposure:

- Supplemental Systematic Review to the Draft Risk Evaluation for 1,4-Dioxane: *Data Quality Evaluation for Data Sources on Consumer Exposure*
- Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane: *Exposure Modeling Results and Risk Estimates for Consumer Exposures*
- Supplemental Information File: *Consumer Exposure Assessment Modeling Input Parameters*

General Population/Ambient Water Exposure:

- Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane: *Ambient Water Exposure Modeling Outputs from E-FAST*
- Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane: *Modeling Inputs, Results, and Risk Estimates for Incidental Ambient Water Exposures*