6. UNREASONABLE RISK DETERMINATION

TSCA section 6(b)(4) requires EPA to conduct a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors. This includes an evaluation of whether a chemical substance presents an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA as relevant to the risk evaluation, under the conditions of use.

EPA has preliminarily determined that 1,4-dioxane presents an unreasonable risk of injury to health under the conditions of use. This determination is based on the information in the 2020 Risk Evaluation and the 2023 Draft Supplement to the Risk Evaluation for 1,4-Dioxane, including the appendices and supporting documents. This draft determination was made in accordance with TSCA section 6(b), as well as TSCA's best available science (TSCA section 26(h)) and weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702.

Table 6-1: Conditions of Use Evaluated in 2020 and 2023, and Associated Unreasonable Risk to Health Determinations

Condition of Use	2020 Unreasonable Risk Determination	2023 Draft Unreasonable Risk Determination
Manufacture: Domestic manufacture	Workers and ONUs[1]	Workers and ONUs[1] **General Population via discharges to surface water sources of drinking water**
Manufacture: Import/repackaging	Workers and ONUs[1]	Workers and ONUs[1] **General Population via discharges to surface water sources of drinking water**
Processing: Repackaging	Workers and ONUs[1]	Workers and ONUs[1] **General Population via discharges to surface water sources of drinking water**
Processing: Recycling	Workers and ONUs[1]	
Processing: Non-incorporative	Workers and ONUs[1]	
Processing: Processing as a reactant	Workers and ONUs[1]	
Processing (including repackaging, recycling, non-incorporative, as a reactant, and as a byproduct)	n/a – added 2023	
Distribution in commerce	No unreasonable risk	Does not contribute to UR
Industrial/commercial use: Intermediate	Workers and ONUs[1]	Workers and ONUs[1] **General Population via discharges to surface water sources of drinking water**

Condition of Use	2020 Unreasonable Risk Determination	2023 Draft Unreasonable Risk Determination
Industrial/commercial use: Processing aid	Workers and ONUs[1]	Workers and ONUs[1] **General Population via discharges to surface water sources of drinking water**
Industrial/commercial use: Laboratory chemicals	Workers	Workers
Industrial/commercial use: Adhesives and sealants	Workers	Workers
Industrial/commercial use: Printing and printing compositions	Workers	Workers
Industrial/commercial use: Dry film lubricant	Workers	Workers
Industrial/commercial use: Functional fluids, open system	No unreasonable risk	**Workers**
Industrial/commercial use: Other uses: Spray polyurethane foam	No unreasonable risk	**Workers**
Industrial use: Other uses: Hydraulic fracturing	n/a – added 2023	Workers
Industrial/commercial use: Arts, crafts, and hobby materials: Textile dye	n/a – added 2023	Workers
Industrial/commercial use: Automotive care products: Antifreeze	n/a – added 2023	Does not contribute to UR
Industrial/commercial use: Cleaning and furniture care products: Surface cleaner	n/a – added 2023	Does not contribute to UR
Industrial/commercial use: Laundry and dishwashing products: Dish soap	n/a – added 2023	Workers
Industrial/commercial use: Laundry and dishwashing products: Dishwasher detergent	n/a – added 2023	Workers
Industrial/commercial use: Laundry and dishwashing products: Laundry soap	n/a – added 2023	Does not contribute to UR
Industrial/commercial use: Paints and coatings: Paint and floor lacquer	n/a – added 2023	Workers
Consumer use: Arts, crafts, and hobby materials: Textile dye	No unreasonable risk	Does not contribute to UR
Consumer use: Automotive care products: Antifreeze	No unreasonable risk	Does not contribute to UR
Consumer use: Cleaning and furniture care products: Surface cleaner	No unreasonable risk	Does not contribute to UR
Consumer use: Laundry and dishwashing products: Dish soap	No unreasonable risk	Does not contribute to UR
Consumer use: Laundry and dishwashing products: Dishwasher detergent	No unreasonable risk	Does not contribute to UR
Consumer use: Laundry and dishwashing products: Laundry detergent	No unreasonable risk	Does not contribute to UR
Consumer use: Paints and coatings: Paint and floor lacquer	No unreasonable risk	Does not contribute to UR
Consumer use: Other uses: Spray polyurethane foam	No unreasonable risk	Does not contribute to UR

Condition of Use	2020 Unreasonable Risk Determination	2023 Draft Unreasonable Risk Determination
Disposal	Workers and ONUs[1]	Workers and ONUs[1] **General Population via discharges to surface water sources of drinking water**

[1] Occupational non-users (ONUs) appear in this table only where ONU risk estimates were found to present an unreasonable risk (2020 Risk Evaluation) or contribute to the unreasonable risk (2023 Draft Supplement). More information on ONU exposures and risk estimates is in Table 6-2.

In the 2020 Risk Evaluation, EPA evaluated 24 conditions of use (COUs) of 1,4-dioxane, including manufacture, processing, distribution in commerce, commercial use, and disposal, as well as consumer use of 1,4-dioxane when it is present as a byproduct in several types of consumer products (Ref. 1). For acute and chronic exposures to workers and occupational non-users, EPA evaluated risks for adverse non-cancer effects based on liver toxicity and effects in the olfactory epithelium, as well as risks of cancer from chronic exposures. For acute exposures to the general population, consumers, and bystanders, EPA evaluated risks for adverse non-cancer effects based on liver toxicity. For chronic exposures to consumers, EPA evaluated risks of cancer.

In the unreasonable risk determinations EPA published in 2020, EPA identified no unreasonable risk to the environment for any COUs, and no unreasonable risks to consumers or bystanders from consumer use of 1,4-dioxane present as a byproduct (a total of eight conditions of use). For workers and occupational non-users, EPA identified unreasonable risk from 13 COUs, based on either worker or occupational non-user risks from acute or chronic inhalation or dermal exposures. EPA identified three occupational COUs as presenting no unreasonable risk.

Regarding the general population, in the 2020 Risk Evaluation, EPA evaluated acute incidental exposures via oral and dermal routes from recreational swimming in ambient water that receives discharges from the industrial and commercial COUs for 1,4-dioxane. EPA determined that this activity presents no unreasonable risk to the general population. In addition, because 1,4-dioxane has low bioaccumulation potential, EPA determined that fish consumption does not present an unreasonable risk to the general population.

The 2020 Risk Evaluation did not evaluate risks from two critical areas: 1) fenceline or general population exposures to 1,4-dioxane in drinking water or air and 2) the full range of exposure that may result from 1,4-dioxane produced as a byproduct. The 2023 Draft Supplement expands on the analysis of COUs in which 1,4-dioxane is present as a byproduct to include additional COUs for which information is reasonably available and to consider associated occupational exposures. This brings the total number of COUs evaluated to 34: 26 industrial and commercial COUs, and 8 consumer COUs. The 2023 Draft Supplement also evaluates risks to fenceline communities and the general population—including potentially exposed or susceptible subpopulations (PESS)—from exposure to 1,4-dioxane through drinking water or ambient air resulting from all industrial releases (including those resulting from 1,4-dioxane produced as a byproduct) as well as down-the-drain releases of consumer and commercial products. In evaluating risks from these additional COUs and exposure pathways, the 2023 Draft Supplement relies on the hazard identification and dose-response analysis presented in the 2020 Risk Evaluation.

EPA's 2023 draft revised unreasonable risk determination includes these additional COUs and exposure pathways, and also proposes to revise the 2020 unreasonable risk determination to incorporate policy changes announced by EPA in June 2021. For 1,4-dioxane, EPA proposes that the appropriate approach is to make an unreasonable risk determination for the whole chemical substance, rather than making unreasonable risk determinations separately on each individual COU evaluated in the risk evaluation. Additionally, EPA proposes that, with regard to occupational risk evaluation and the determination of whether occupational risks are unreasonable, EPA should not rely on assumptions regarding the use of personal protective equipment (PPE); rather, the use of PPE should be considered during risk management. See Table 6-1 earlier in this section for details of how the change in PPE assumptions impacts the draft unreasonable risk determination, including the identification of two additional industrial/commercial COUs as contributing to the unreasonable risk from 1,4-dioxane. Further discussion of the rationale for the whole chemical approach is in the Federal Register notice in the docket accompanying this 2023 draft revised 1,4-dioxane unreasonable risk determination and further discussion of the decision to not rely on assumptions regarding the use of PPE is provided in the Federal Register Notice and in section 6.1.1.3 below.

EPA's 2023 draft revised unreasonable risk determination differs from the 2020 risk determination in other, significant ways. Specifically, EPA proposes to include risks to fenceline communities and the general population from consuming drinking water sourced from surface water contaminated with 1,4-dioxane from industrial discharges and to identify these risks as contributing to the unreasonable risk from 1,4-dioxane. Many conditions of use can contribute to general population and fenceline communities' exposures to 1,4-dioxane in surface water, including industrial releases from a range of conditions of use (including where 1,4-dioxane is produced as a byproduct).

EPA's proposed determination is based on cancer and non-cancer risks (from liver toxicity and effects in the olfactory epithelium) to workers and occupational non-users (ONUs) from inhalation and dermal exposures, and cancer risks to fenceline communities and the general population from exposures to 1,4-dioxane in drinking water sourced from surface water contaminated with industrial discharges of 1,4-dioxane (including when it is generated as a byproduct). EPA proposes to identify the following conditions of use from the 2020 Risk Evaluation and the 2023 Draft Supplement as contributing to the unreasonable risk from 1,4-dioxane:

- Manufacture (including domestic manufacture and import)
- Processing (including repackaging, recycling, non-incorporative, as a reactant, and as a byproduct)

- Industrial/commercial use: Functional fluids (open and closed system): Metalworking fluid, cutting and tapping fluid, polyalkylene glycol fluid, hydraulic fluid
- Industrial/commercial use: Intermediate
- Industrial/commercial use: Processing aid
- Industrial/commercial use: Laboratory chemicals
- Industrial/commercial use: Adhesives and sealants
- Industrial/commercial use: Other uses: Printing and printing compositions
- Industrial/commercial use: Other uses: Dry film lubricant
- Industrial/commercial use: Other uses: Spray polyurethane foam
- Industrial/commercial use: Other uses: Hydraulic fracturing
- Industrial/commercial use: Arts, crafts, and hobby materials: Textile dye
- Industrial/commercial use: Laundry and dishwashing products: Dish soap
- Industrial/commercial use: Laundry and dishwashing products: Dishwasher detergent
- Industrial/commercial use: Paints and coatings: Paint and floor lacquer
- Disposal

Because the risk estimates for all processing COUs identified and evaluated in the 2020 Risk Evaluation and the 2023 Draft Supplement (including those where 1,4-dioxane is processed as a byproduct) contribute to the unreasonable risk, EPA believes that it is appropriate to conclude that any processing of 1,4-dioxane contributes to the unreasonable risk. This would include circumstances described but not necessarily individually quantified in the 2020 Risk Evaluation or the 2023 Draft Supplement, such as when 1,4-dioxane is generated as a byproduct during sulfonation, sulfation, and esterification processes. EPA also emphasizes that this determination identifies any manufacturing, processing, or disposal of 1,4-dioxane – including as a byproduct – as contributing to the unreasonable risk if the 1,4-dioxane contaminates surface water that is the source of drinking water.

EPA believes that its 2020 Risk Evaluation, the 2023 Draft Supplement, and the risk estimates calculated for the conditions of use of 1,4-dioxane fully support EPA's conclusions that 1,4-dioxane as a whole chemical substance presents an unreasonable risk of injury to health. In the accompanying Federal Register Notice, EPA outlines specific requests for comments regarding this 2023 draft risk determination.

The list of conditions of use (COUs) evaluated for 1,4-dioxane (i.e., the COUs evaluated in the 2020 Risk Evaluation as well as the new COUs evaluated in the 2023 Draft Supplement to the 2020 Risk Evaluation) are presented in Table 6-1 earlier in this section, and in Table D1 of the 2023 Draft Supplement to the Risk Evaluation for 1,4-Dioxane (Ref. 2). Table 6-2 and Table 6-3 summarize the basis for the draft revised determination of unreasonable risk of injury to health presented by 1,4-dioxane.

When EPA finalizes the unreasonable risk determination, EPA would initiate risk management for 1,4-dioxane under TSCA either by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that 1,4-dioxane no longer presents an unreasonable risk or determining pursuant to TSCA sections 9(a) and/or 9(b) that other Federal laws can eliminate or reduce to a sufficient extent the unreasonable risk. Under TSCA section 6(a), EPA is not limited to regulating the specific activities found to contribute to the unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, use, and disposal in order to address the unreasonable risk. For instance, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities contributing to the unreasonable risk (e.g., use) even if the upstream activities do not contribute to the unreasonable risk.

6.1 Background

6.1.1 Background on Policy Changes Relating to the Whole Chemical Risk Determination and Assumption of PPE Use by Workers

From June 2020 to January 2021, EPA published risk evaluations on the first ten chemical substances, including for 1,4-dioxane in December 2020. The risk evaluations included individual unreasonable risk determinations for each condition of use evaluated. The determinations that particular conditions of use did not present an unreasonable risk were issued by order under TSCA section 6(i)(1).

In the unreasonable risk determinations for 1,4-dioxane that EPA published in 2020, EPA identified no unreasonable risk to the environment for any conditions of use, no unreasonable risks to the general population from fish consumption or recreational swimming in ambient water that receives discharges from the industrial and commercial conditions of use, and no unreasonable risks to consumers or bystanders from consumer use of 1,4-dioxane present as a byproduct (a total of eight conditions of use). For workers and occupational non-users, EPA identified unreasonable risk from 13 of the conditions of use, based on either worker or occupational non-user risks from acute or chronic inhalation or dermal exposures. EPA identified three occupational conditions of use as presenting no unreasonable risk.

In accordance with Executive Order 13990 ("Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis") and other Administration priorities (Refs. 3, 4, 5, and 6), EPA reviewed the risk evaluations for the first ten chemical substances to ensure that they met the requirements of TSCA, including the requirement to use the best available science in decision-making.

A key outcome of EPA's review of the initial 10 risk evaluations under E.O. 13990 is EPA's conclusion that the appropriate approach to making the unreasonable risk determination for 1,4-dioxane is to make an unreasonable risk determination for the whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the 2020 Risk Evaluation and 2023 Draft Supplement. A second important outcome of this review is that with regard to occupational risk evaluation and the determination of whether occupational risks are unreasonable, EPA determined that it should not rely on assumptions regarding the use of personal protective equipment (PPE); rather, the use of PPE should be considered during risk management.

As a result of EPA's review under E.O. 13990, EPA announced plans to revise specific aspects of the first ten risk evaluations. This was done in order to ensure that the risk evaluations accurately assess the risks so that EPA's determinations of unreasonable risks are complete and accurate to ensure the protection of health and the environment (Ref. 7).

Further discussion of the rationale for making a risk determination on the whole chemical substance is found in the Federal Register notice in the docket accompanying this draft revised 1,4-dioxane unreasonable risk determination and further discussion of the decision to not rely on assumptions regarding the use of PPE is provided in the Federal Register Notice and in section 6.1.1.3 below. For those conditions of use assessed in the 2020 Risk Evaluation for 1,4-Dioxane, EPA does not intend to amend, nor does a risk determination on the whole chemical substance require amending, the underlying scientific analysis of the 2020 Risk Evaluation as presented in the risk characterization section of that document.

With regard to the specific circumstances of 1,4-dioxane, as further explained below, EPA has found that EPA estimated exposures to 1,4 dioxane would exceed benchmark human health risk levels for multiple conditions of use (spanning across most aspects of the chemical lifecycle– from manufacturing (including import), processing, industrial and commercial use, and disposal). Moreover, the health effects associated with 1,4-dioxane exposures are irreversible. As explained in the Federal Register Notice, the revisions to the unreasonable risk determination would be based on the existing risk characterization sections of the risk evaluation (section 4 of the 2020 Risk Evaluation and section 5.2 of the 2023 Draft Supplement) and would not involve additional technical or scientific analysis beyond the 2020 Risk Evaluation and the 2023 Draft Supplement. The discussion of the issues in this 2023 draft revision to the risk determination (e.g., whether or not a condition of use or exposure pathway contributes to the unreasonable risk from 1,4-dioxane, whether or not a condition of use is within the scope of the risk evaluation) would supersede any conflicting statements in the 2020 Risk Evaluation and the response to comments document (*Summary of External Peer Review and Public Comments and Disposition for 1,4-Dioxane, December 2020*). In addition, in making this risk determination, EPA does not assume the use of PPE. EPA also notes the Correction of Dermal Acute and Chronic Non-Cancer Hazard Values that explained, while the corrections slightly alter occupational dermal risk estimates, they do not appreciably impact the overall risk conclusions (Ref. 9). Because updates are not necessary for the 2020 Risk Evaluation, EPA also views the peer reviewed hazard and exposure assessments and associated risk characterizations as robust and upholding the standards of best available science and weight of the scientific evidence, per TSCA sections 26(h) and (i).

6.1.2 Background on 1,4-Dioxane and the 2023 Draft Supplement to the Risk Evaluation for 1,4-Dioxane

1,4-Dioxane is primarily used as a solvent in commercial and industrial applications. It can also be produced as a byproduct of several common manufacturing processes, including but not limited to ethoxylation processes used in the production of surfactants used in soaps and detergents and production of polyethylene terephthalate (PET) plastics. Even though it is not intentionally added, 1,4-dioxane produced as a byproduct may remain present in consumer and commercial products, including soaps and detergents, cleaning products, antifreeze, textile dyes, and paints/lacquers. 1,4-Dioxane is released to the environment from industrial and commercial releases and from consumer and commercial products that are washed down the drain or disposed of in landfills. People may be exposed to 1,4-dioxane through occupational exposure, consumer products, or contact with water, land, or air where 1,4-dioxane has been released to the environment.

As previously noted, the 2020 Risk Evaluation did not evaluate risks from fenceline community or general population exposures to 1,4-dioxane in drinking water or air. Nor did it evaluate the full range of exposure that may result from 1,4-dioxane produced as a byproduct. During the development of the 2020 Risk Evaluation, peer reviewers and public commenters raised concerns that failure to consider these exposure pathways could leave portions of the population at risk. These concerns include the fact that 1,4-dioxane has been detected in drinking water and is not readily removed through traditional treatment. In addition, 1,4-dioxane produced as a byproduct results in occupational exposures that were not evaluated in the 2020 RE. Finally, 1,4-dioxane produced as a byproduct also contributes to 1,4-dioxane in drinking water through industrial releases and down-the-drain (DTD) disposal of consumer and commercial products.

The 2023 Draft Supplement to the 2020 Risk Evaluation evaluates risks for the following exposure pathways:

- Occupational exposure, including PESS, to:
  - 1,4-dioxane present as a byproduct in commercial products (consumer products were assessed in the 2020 risk evaluation)
  - 1,4-dioxane produced or present as a byproduct in additional industrial COUs for which information on the presence of 1,4-dioxane is reasonably available, including ethoxylation processing, PET manufacturing, and hydraulic fracturing (Sections 3.1, 5.2.1).
- Fenceline community and general population exposures, including PESS, to
  - 1,4-dioxane present in drinking water sourced from surface water as a result of all direct and indirect industrial releases and DTD releases of consumer and commercial products (Sections 2.3.1, 3.2.2 and 5.2.2.1);
  - 1,4-dioxane present in drinking water sourced from groundwater contaminated as a result of disposals (Sections 2.3.2, 3.2 and 5.2.2); and,
  - 1,4-dioxane released to air from industrial and commercial sources (Sections 2.3.3, 3.2, and 5.2.2.3).

The following conditions of use are added to the 2023 Draft Supplement:

- Processing as a byproduct (including polyethylene terephthalate (PET) byproduct and ethoxylation process byproduct)
- Industrial/commercial use: Other uses: Hydraulic fracturing
- Industrial/commercial use: Arts, crafts, and hobby materials: Textile dye
- Industrial/commercial use: Automotive care products: Antifreeze
- Industrial/commercial use: Cleaning and furniture care products: Surface cleaner
- Industrial/commercial use: Laundry and dishwashing products: Dish soap
- Industrial/commercial use: Laundry and dishwashing products: Dishwasher detergent
- Industrial/commercial use: Laundry and dishwashing products: Laundry detergent

- Industrial/commercial use: Paints and coatings: Paint and floor lacquer

For the 2023 Draft Supplement, EPA relied on the physical and chemical properties information, as well as lifecycle information, environmental fate and transport information, and hazard identification and dose-response analyses presented in the 2020 Risk Evaluation (Sections 1.1, 1.4, 2.1, and 3.2 of the 2020 Risk Evaluation, respectively).

6.1.3 Background on Unreasonable Risk Determination

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. The unreasonable risk determination must not consider costs or other non-risk factors. In making the unreasonable risk determination, 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 also takes into consideration the Agency's confidence in the data used in generating risk estimates. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimates and the risk characterization. This approach is in keeping with the Agency's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017).[1]

This section describes the draft revised unreasonable risk determination for 1,4-dioxane, under the conditions of use in the scope of the 2020 Risk Evaluation for 1,4-dioxane and in section 1.2 of the 2023 Draft Supplement.

6.2 Unreasonable Risk to Human Health

6.2.1 Human Health

EPA's 1,4-dioxane risk evaluation identified adverse non-cancer effects from acute and chronic inhalation and dermal exposures to 1,4-dioxane, and cancer from chronic inhalation and dermal exposures to 1,4-dioxane. The health risk estimates for all conditions of use are in Tables 4-23 through 4-25 of Section 4.6.2 of the 2020 Risk Evaluation and in section 5.2.1, Tables 5-2 through 5-6 of Section 5.2 of the 2023 Draft Supplement, and in the following supplemental files of the 2023 Draft Supplement:

[1] This risk determination is being issued under TSCA section 6(b) and the terms used, such as unreasonable risk, and the considerations discussed are specific to TSCA. Other EPA programs have different statutory authorities and mandates and may involve risk considerations other than those discussed here.

- *Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Occupational Exposure and Risk Estimates*
- *Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Drinking Water Exposure and Risk Estimates for 1,4-Dioxane Release to Surface Water from Individual Facilities*
- *Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Drinking Water Exposure and Risk Estimates for 1,4-Dioxane Surface Water Concentrations Predicted with Probabilistic Modeling*
- *Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Drinking Water Exposure and Risk Estimates for 1,4-Dioxane Land Releases to Landfills*
- *Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Drinking Water Exposure and Risk Estimates for 1,4-Dioxane Land Releases to Surface Impoundments*
- *Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Air Exposures and Risk Estimates for Single Year Analysis*
- *Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Air Exposure and Risk Estimates for 1,4-Dioxane Emissions from Hydraulic Fracturing Operations*
- *Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Air Exposures and Risk Estimates for Industrial Laundry*
- *Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Air Exposures and Risk Estimates for Multi-Year Analysis*

TSCA requires that EPA conduct risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs 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." 15 U.S.C. 605(b)(4)(A). In developing the exposure assessment for 1,4-dioxane, EPA analyzed reasonably available information to ascertain whether some subpopulations of people may have greater exposure or susceptibility than the general population to the hazard posed by 1,4-dioxane. Factors that may contribute to increased exposure or biological susceptibility to a chemical include lifestage, pre-existing disease, lifestyle activities, geographic factors, socio-demographic factors, nutrition, genetics, aggregate exposures, and other chemical and non-chemical stressors. For example, exposures of 1,4-dioxane would be expected to be higher amongst workers who use 1,4-dioxane on a regular basis as part of typical processes and occupational non-users (ONUs) who work in close proximity to such workers. For the 2020 Risk Evaluation, EPA identified the following groups as Potentially Exposed or Susceptible Subpopulations: workers and ONUs (including men and women of reproductive age and adolescents); consumer users (including men, women, and children ages 11 and up) and bystanders of any age group (including infants, toddlers, children, and elderly) (Section 4.4 and Tables 4-23 and 4-24 of the 2020 Risk Evaluation). The 2023 Draft Supplement considers PESS throughout the human health exposure assessment and risk characterization and incorporates all PESS considerations described previously in the 2020 Risk Evaluation. The 2023 Draft Supplement provides a summary of how specific factors contributing to exposure and susceptibility were addressed and identifies remaining sources of uncertainty for PESS (Section 5.2.3 and Table 5-11).

EPA evaluated exposures to workers, occupational non-users (ONUs), consumer users, bystanders, the general population, and people who live in fenceline communities, who may also be considered PESS due to their greater exposure, using reasonably available monitoring and modeling data for inhalation, dermal, and ingestion exposures, as applicable. The description of the data used for human health exposure is in Section 2.4 of the 2020 Risk Evaluation and in Section 3 of the 2023 Draft Supplement. Uncertainties in the analysis are discussed in Section 4.3.2 of the 2020 Risk Evaluation and in Sections 2.2, 2.3, 3.1, 4.3, and 5.2.5 of the 2023 Draft Supplement, and are considered in the unreasonable risk determination.

In the 2020 Risk Evaluation, EPA did not assess exposures from the ambient air, drinking water, and land/disposal pathways because they could fall under the jurisdiction of other environmental statutes administered by EPA, *i.e.*, CAA, SDWA, RCRA, and CERCLA. However, because EPA had not yet developed recommended recreational water quality criteria for the protection of human health for 1,4-dioxane, in the 2020 Risk Evaluation, EPA evaluated the human health risks of potential acute and chronic incidental exposures via oral and dermal routes from recreational swimming in bodies of water that receive discharges from the industrial and commercial conditions of use of 1,4-dioxane. More information on these risks can be found in Sections 2.4.2.1.3, 2.4.2.1.4, and 4.2.4. of the 2020 Risk Evaluation.

As a result of the policy change discussed in Section 1.1 of this document, in the 2023 Draft Supplement, EPA quantitatively evaluated inhalation and ingestion exposures for fenceline communities and the general population via exposure to ambient air, and oral exposures via ingestion of drinking water sourced from surface water or groundwater contaminated with 1,4-dioxane from facility-specific releases, down-the-drain releases of consumer and commercial products that contain 1,4-dioxane as a byproduct, hydraulic fracturing releases, and leaching from landfills (disposal). More information on these risks can be found in Sections 2, 3.2 and 5.2 of the 2023 Draft Supplement.

6.2.2 Non-Cancer Risk Estimates

The risk estimates of non-cancer effects (expressed as margins of exposure or MOEs) refer to adverse health effects associated with health endpoints other than cancer, including to other organ systems and function, such as adverse 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)) and the corresponding human equivalent concentration (HEC) or human equivalent dose (HED) for a specific health endpoint divided by the estimated exposure for the specific scenario of concern. Section 3.2.6 of the 2020 Risk Evaluation presents the PODs for acute and chronic non-cancer effects for 1,4-dioxane and Section 4.2 of the 2020 Risk Evaluation presents the MOEs for acute and chronic non-cancer effects. Section 4.2 of the 2023 Draft Supplement provides information on how some of the exposure scenarios included in the 2023 Draft

Supplement required duration adjustments to the previously established PODs. For example, to evaluate risks from ambient air exposures for fenceline communities, EPA assumed continuous exposure to air for 24 hours/day, 7 days/week.

To characterize risk from non-cancer endpoints, the estimated endpoint-specific MOEs are compared to their respective benchmark MOE. The benchmark MOE accounts for the total uncertainty in a POD, including, as appropriate: (1) the variation in sensitivity among the members of the human population (i.e., intrahuman/intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (i.e., interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating from a lowest observed adverse effect level (LOAEL) rather than from a NOAEL. A lower benchmark MOE (e.g., 30) indicates greater certainty in the data (because fewer of the default uncertainty factors (UFs) relevant to a given POD as described above were applied). A higher benchmark MOE (e.g., 1000) would indicate more extrapolation uncertainty for specific hazard endpoints and scenarios. However, these are often not the only uncertainties in a risk evaluation. The benchmark MOE for the most robust and sensitive acute non-cancer risks for 1,4-dioxane is 300 (accounting for intraspecies, interspecies variability, and LOAEL to NOAEL variability). The benchmark MOE for the most robust and sensitive chronic non-cancer risks for 1,4-dioxane is 30 (accounting for interspecies and intraspecies variability). Additional information regarding the non-cancer hazard identification is in Section 3.2.3.1 and the benchmark MOE is in Section 3.2.6. of the 2020 Risk Evaluation. The non-cancer benchmarks are unchanged in the 2023 Draft Supplement.

6.2.3 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 example, in the 2020 Risk Evaluation, EPA used $1x10^{-6}$ as the benchmark for the cancer risk to consumers and bystanders from consumer use of products containing 1,4-dioxane as a byproduct, such as dishwashing detergent and antifreeze, and used $1x10^{-4}$ as the benchmark for the cancer risk to individuals in industrial and commercial workplaces. These benchmarks are the same in the 2020 Risk Evaluation and the 2023 Draft Supplement. In the 2020 Risk Evaluation, EPA used $1x10^{-6}$ as the benchmark for exposures to surface water from recreational swimming. For the 2023 Draft Supplement, EPA considers the range of $1x10^{-6}$ to $1x10^{-4}$ as the appropriate benchmark for increased cancer risk for the general population, including fenceline communities. These benchmarks are not bright lines and EPA has discretion to make an unreasonable risk determination for the chemical substance based on other benchmarks as appropriate. Additional information regarding the cancer benchmark is in Sections 3.2.6.2 and 4.2.1 of the 2020 Risk Evaluation and in Sections 4.2.3 and 5.1.2 of the 2023 Draft Supplement.

6.2.4 Determining Unreasonable Risk of Injury to Health

Calculated risk estimates (MOEs or cancer risk estimates) can provide a risk profile of 1,4-dioxane 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 noncancer 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. These calculated risk estimates alone are not bright-line indicators of unreasonable risk. Whether EPA makes a determination of unreasonable risk for the chemical substance 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.

When making a determination of unreasonable risk for the chemical substance, the Agency has a higher degree of confidence where uncertainty is low. The 2020 Risk Evaluation and the 2023 Draft Supplement discuss major assumptions and key uncertainties by major topic: human and environmental hazards, occupational exposure, general population/consumer exposure, and environmental exposure. Important assumptions and key sources of uncertainty in the risk characterization are described in more detail in Section 4.3 of the 2020 Risk Evaluation and in Sections 2.2, 2.3, 3.1, 4.3, and 5.2.5 of the 2023 Draft Supplement.

When determining the unreasonable risk for 1,4-dioxane, EPA considered the central tendency and high-end exposure levels in occupational settings and in environmental media, moderate and high intensity of use for consumer uses, and central tendency and high-end exposure levels for fenceline community and general population exposures. Risk estimates based on high-end exposure levels or high intensity use scenarios (e.g., 95th percentile) are generally intended to cover individuals or sub-populations with greater exposure (PESS) as well as to capture individuals with sentinel exposure, and risk estimates at the central tendency exposure are generally estimates of average or typical exposure.

<u>Unreasonable Risk in Occupational Settings</u>

As shown in Section 4 of the 2020 Risk Evaluation and Section 5 of the 2023 Draft Supplement, when characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where no mitigation measures are assumed to be in place.[2] This approach considers the risk to potentially exposed or susceptible subpopulations of workers who may not be covered by Occupational Safety and Health Administration (OSHA) standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. In addition, EPA believes it is appropriate to also include in the risk evaluation the levels of risk present in

[2] It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

scenarios considering applicable OSHA requirements (e.g., chemical-specific permissible exposure limits (PELs) and/or chemical-specific PELs with additional substance-specific standards) as well as scenarios considering industry or sector-based best practices for industrial hygiene that are clearly articulated to the Agency. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform future potential risk management actions by providing information to risk managers that could be useful during risk management to tailor risk mitigation appropriately to address any unreasonable risk identified.

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, EPA does not assume as a general matter that an applicable OSHA requirement or industry practice is consistently and always properly applied. Mitigation scenarios included in the 2020 1,4-dioxane Risk Evaluation (e.g., scenarios considering use of various personal protective equipment (PPE)) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities will have adopted these practices for the purposes of making the TSCA unreasonable risk determination. Although the 2020 RE did provide information to risk managers on the occupational risks using scenarios that reflected different levels of mitigation, the 2023 Draft Supplement does not include PPE use in any of the occupational scenarios. This is because EPA did not find suitable available information on the extent of PPE use in the assessed industries.

Therefore, for 1,4-dioxane and other chemicals undergoing risk evaluation, EPA conducts baseline assessments of risk and makes its determination of unreasonable risk from a baseline scenario that does not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location or that there is widespread noncompliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health," (Ref. 9) or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

For most of the conditions of use with occupational exposures in the 2020 Risk Evaluation and the 2023 Draft Supplement, high-end cancer risk estimates were above 1 in 10,000 ($1x10^{-4}$). Cancer risk estimates for both central tendency and high-end dermal and inhalation exposures exceeded cancer risk benchmarks and were greater than 1 in 10,000 ($1x10^{-4}$) for occupational exposures associated with numerous conditions of use (COUs), including manufacturing, processing (including repackaging, recycling, processing as a reactant, non-incorporative processing, and processing as a byproduct), industrial use as an intermediate, industrial use as a processing aid, industrial/commercial use in film cement, and disposal. Additionally, cancer risk estimates for both central tendency and high-end dermal exposures exceeded cancer risk benchmarks and were above $1x10^{-4}$ for several additional COUs, including industrial/commercial use in a laboratory, industrial/commercial use as a functional fluid, industrial/commercial use in printing inks, industrial/commercial use in spray foam, industrial/commercial use as a dry film lubricant, and industrial/commercial use in hydraulic fracturing. For non-cancer risks, for numerous COUs, calculated acute and chronic central tendency and high-end MOEs are less than the benchmark MOE for inhalation and dermal exposures (indicating risk), including manufacturing (including importing), processing (including repackaging, recycling, processing as a reactant, and non-incorporative processing), industrial use as an intermediate, industrial use as a processing aid, industrial/commercial use in film cement, and disposal. More information on occupational risk estimates is in Section 4.2.2 of the 2020 Risk Evaluation and Section 5.2.1 of the 2023 Draft Supplement. Complete risk calculations and results for occupational COUs from the 2020 Risk Evaluation and the 2023 Draft Supplement are in *Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Occupational Exposure and Risk Estimates.*

Overall, EPA has moderate to high confidence in the occupational risk estimates from the 2020 Risk Evaluation. EPA used monitoring data to assess inhalation exposures and modeled dermal exposures. EPA has moderate confidence in the dermal exposure estimates, and low confidence in the occupational non-user (ONU) inhalation estimates, which were based on central tendency parameters for worker inhalation exposure estimates. Uncertainties in the representativeness of the monitoring data for all of the industries within the particular occupational exposure scenario (OES), and the extent to which the modeled dermal exposures represent actual exposures. With respect to health endpoints, as discussed in Section 3.2.7, EPA has medium confidence in the PODs for acute exposure scenarios, high confidence in the non-cancer PODs chronic exposure scenarios, high confidence in the cancer inhalation unit risk, and medium-high confidence in the oral and dermal cancer slope factors. More information on EPA's confidence in these estimates and the uncertainties associated with them is in Section 4.3.1 of the 2020 Risk Evaluation. EPA has similar confidence in the occupational risk estimates in the 2023 Draft Supplement. Inhalation monitoring data was available for most of the occupational exposure scenarios, which were used to derive the worker risk estimates for each condition of use. For three of the occupational exposure scenarios (antifreeze, laundry detergent, and hydraulic fracturing), inhalation exposures were modeled. The modeling incorporates Monte Carlo simulation to allow for variation in the model input data, thus increasing the representativeness of the approach. However, EPA was unable to develop distributions for all input parameters, increasing the uncertainty in the parameterization and applicability. More information on EPA's confidence in these estimates and the uncertainties associated with them can be found in Section 5.2.5.1 of the 2023 Draft Supplement.

Based on the occupational risk estimates and EPA's confidence in them, EPA finds that risks to workers and ONUs from all but four occupational conditions of use contribute to the unreasonable risk from 1,4-dioxane. More details are in Table 6-1 and Table 6-2.

<u>Consumer Uses</u>

In the 2020 Risk Evaluation, EPA evaluated eight consumer uses of products that contain 1,4-dioxane as a byproduct. For each of the eight conditions of use, EPA evaluated non-cancer effects to consumers and bystanders from acute inhalation and dermal exposures (for consumer users). For four of the conditions of use, based on the exposure assessment, EPA also evaluated cancer risks to consumers from chronic inhalation and dermal exposures. EPA did not estimate chronic inhalation exposures to bystanders because bystanders would be exposed to lower levels than the users 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. EPA's overall confidence in the consumer inhalation exposure estimates ranges from moderate to high, while confidence in the consumer dermal exposure estimates ranges from low to moderate. More information on the consumer and bystander analysis can be found in Sections 2.4.3.4, 4.2.3, and 4.3.2.1. of the 2020 Risk Evaluation.

Based on the consumer and bystander risk estimates, which do not exceed applicable benchmarks, and EPA's confidence in them, EPA finds that the consumer use alone of products that contain 1,4-dioxane does not contribute to the unreasonable risk.

<u>Unreasonable Risk to Fenceline Communities and the General Population</u>

Drinking water. In the 2023 Draft Supplement, EPA evaluated oral exposures via ingestion of drinking water sourced from surface water or groundwater contaminated with 1,4-dioxane from facility-specific releases, down-the-drain (DTD) releases of consumer and commercial products that contain 1,4-dioxane as a byproduct, hydraulic fracturing releases, and leaching from landfills. 1,4-Dioxane is not readily removed through typical wastewater or drinking water treatment processes. Sources of 1,4-dioxane in surface water include direct and indirect industrial releases from COUs where 1,4-dioxane is manufactured, processed, or used, industrial COUs where 1,4-dioxane is present due to production as a byproduct (including PET manufacturing, ethoxylation processes and hydraulic fracturing operations), and down-the-drain releases of 1,4-dioxane present in consumer and commercial products.

EPA considered risks from these sources individually and in aggregate. The relative contribution from different sources varies under different conditions and is likely to be driven by site-specific factors including the amounts released from each source, flow rates of receiving water bodies, and proximity of releases to drinking water intakes. In general, drinking water risk estimates related to surface water are highest where there are high releases (whether from industrial facilities or large populations (DTD)) and low flow. Similarly, EPA's drinking water risk estimates associated with groundwater indicate that higher hydraulic fracturing releases or landfill leachate concentrations and loadings are associated with higher risks.

For facility-specific releases to surface water, EPA used release data reported to the Toxics Release Inventory (TRI) and the Discharge Monitoring Report (DMR) as model inputs to estimate concentrations in receiving waterbodies for manufacturing, processing, disposal, and most industrial use COUs. Because 1,4-dioxane is not readily removed through typical wastewater or drinking water treatment processes, EPA evaluated a range of potential downstream dilutions from 1% of modeled initial concentration to 100% (no dilution). Risk estimates were also compared to available drinking water monitoring data and, where monitoring data are available near release sites, the comparisons demonstrate strong concordance between modeled concentrations and monitoring data where available. The facility-specific analysis supports the unreasonable risk finding for 1,4-dioxane because the median lifetime cancer risk estimate is 2.32×10^{-6} and the 95th percentile risk estimate is 4.92×10^{-3}. For nearly all COUs, the mean cancer risk estimates exceed $1\text{x}10^{-6}$.[3] These risk estimates rely on the assumption that concentrations at drinking water intakes are the same as concentrations estimated near the point of release. To evaluate the validity of that assumption, EPA considered the proximity of release sites to downstream drinking water intake locations for community and non-community non-transient public water systems. Of the 69 facilities with cancer risks within or greater than the benchmark range of 1×10^{-6} to 1×10^{-4}, 4 have a downstream drinking water intake within 10 kilometers. As discussed in section 5.2.2.1.2 of the 2023 Draft Supplement, based on available site-specific information for each facility, the mean modeled dilution predicted at downstream drinking water intakes is one percent of original concentrations estimated in receiving water bodies near the point of release. Assuming that drinking water intake concentrations were diluted to 1% of initial receiving water body concentrations, the median lifetime cancer risk estimate is 8.51×10^{-9} and the 95th percentile cancer risk estimate is 4.92×10^{-5}. Even after accounting for additional dilution, cancer risk estimates are within or exceed the benchmark range of 1×10^{-6} to 1×10^{-4} for 27 percent of the public water systems evaluated, serving a combined population of over 2 million people. Overall confidence in the overall distribution of risk estimates for drinking water exposures resulting from facility releases is medium-high. Based on this analysis, EPA proposes to find that risks to fenceline communities due to exposure to drinking water sourced from surface water that is contaminated by 1,4-dioxane released from industrial facilities contributes to the unreasonable risk from 1,4-dioxane.

EPA's analysis indicates that other sources of 1,4-dioxane in surface water contribute less to drinking water exposure and risk than facility-specific releases. EPA evaluated the potential contribution of DTD releases of consumer and commercial products that contain 1,4-dioxane as a byproduct to drinking water exposure and risk. EPA's drinking water exposure estimates correspond to surface water concentrations estimated by probabilistic modeling of DTD releases under varying population and stream flow conditions. Surface water concentrations at the point of DTD releases via publicly-owned treatment works are primarily determined by the size of the population contributing to DTD releases and the flow rates of receiving water bodies. Assuming no dilution between the point of release and the drinking water intake, the estimated risks range from 2.04×10^{-11} to 6.11×10^{-5}, with the risks increasing as population increases and stream flow decreases (Table 5-4, Ref. 1). Overall confidence in risk estimates for drinking water exposures resulting from DTD releases is medium. Based on this analysis, EPA proposes to find that general population exposures to drinking water contaminated with 1,4-dioxane from DTD releases do not contribute to the unreasonable risk from 1,4-dioxane.

[3] 1,4-Dioxane Supplemental Information File_Drinking Water Exposure and Risk Estimates for 1,4-Dioxane Release to Surface Water from Individual Facilities.

EPA also evaluated the contribution of 1,4-dioxane to surface water by hydraulic fracturing. EPA incorporated information from reports on 1,4-dioxane use reported by hydraulic fracturing wells and reasonably available hydrologic information to generate a distribution of modeled releases and pair them with hydrologic flows, resulting in a distribution of possible surface water concentrations. Water concentrations of 1,4-dioxane resulting from disposal of hydraulic fracturing produced water vary substantially across sites. The median lifetime cancer risk estimate is 3.57×10^{-8} and the 95th percentile lifetime cancer risk estimate is 1.45×10^{-6}. Overall confidence in risk estimates for drinking water exposures resulting from hydraulic fracturing releases is medium. Based on this analysis, EPA proposes to find that general population exposures to drinking water contaminated with 1,4-dioxane from hydraulic fracturing do not contribute to the unreasonable risk from 1,4-dioxane.

Finally, because multiple sources may contribute to 1,4-dioxane concentrations in drinking water sourced from surface water in a single location, EPA estimated aggregate general population exposures and risks that could occur as a result of combined contributions from multiple sources. To do this, EPA used probabilistic modeling to predict aggregate surface water concentrations that could occur when accounting for direct industrial releases, indirect industrial releases to wastewater treatment plants, and DTD releases. High-end cancer risk estimates in this analysis are very similar to high-end risk estimates for individual facility releases alone, indicating that high-end estimates are driven primarily by high-end industrial releases. Overall confidence in distributions of risk estimates for drinking water exposures resulting from aggregate surface water concentrations predicted by probabilistic modeling varies across COU. Uncertainties common to all drinking water analyses involving surface water include the proximity of releases to drinking water intake locations and the extent to which 1,4-dioxane is further diluted prior to reaching intake locations.

EPA estimated risks from general population exposures that could occur if groundwater containing 1,4-dioxane is used as a source of drinking water. These risk estimates are not tied to known releases at specific locations. Rather, the analysis defines the conditions under which 1,4-dioxane disposal to landfills or from hydraulic fracturing operations could result in varying levels of risk based on concentrations of 1,4-dioxane in groundwater.

For potential groundwater concentrations resulting from landfill leachate, EPA estimated risks under varying combinations of leachate concentrations and landfill loading rates. While estimated risks exceed EPA's benchmark range of 1×10^{-6} to 1×10^{-4} at the highest leachate concentrations and loading rates, the overall confidence in these risk estimates is low to medium. The modeling methodology that was used is robust, but the release information relied on as model input data is supported by slight to moderate strength of the evidence. The drinking water exposure scenario relies on the assumption that modeled groundwater concentrations reflect the actual groundwater concentrations that occur at well locations. Based on this analysis, EPA proposes that general population exposures to drinking water sourced from groundwater contaminated with 1,4-dioxane from landfill leachate do not contribute to the unreasonable risk from1,4-dioxane.

EPA also calculated risks for groundwater concentrations resulting from disposal of hydraulic fracturing produced water. While the estimated risks exceed $1x10^{-6}$ for 95th percentile modeled releases, mean estimated risk is $4.0x10^{-7}$, and overall confidence in the risk estimates is low to medium. The modeling methodology is robust and the release information relied on as model input data is supported by moderate evidence, but no monitoring data are available to confirm detection of 1,4-dioxane in groundwater near hydraulic fracturing operations. Again, this exposure scenario relies on the assumption that modeled groundwater concentrations reflect the actual groundwater concentrations that occur at well locations. Based on this analysis, EPA proposes that general population exposures to drinking water sourced from groundwater contaminated with 1,4-dioxane from the disposal of hydraulic fracturing produced water do not contribute to the unreasonable risk from 1,4-dioxane.

In summary, EPA proposes that exposure to drinking water sourced from surface water that is contaminated by 1,4-dioxane released from industrial facilities contributes to the unreasonable risk from 1,4-dioxane. EPA proposes that other exposures to drinking water contaminated with 1,4-dioxane do not contribute to the unreasonable risk for 1,4-dioxane. This is based primarily on the risk estimates for facility-specific releases of 1,4-dioxane, the extent to which those high-end risk estimates exceed the range of applicable benchmarks, EPA's higher confidence in the facility-specific risk estimates versus other drinking water risk estimates, and the fact that the aggregate analysis for drinking water sourced from surface water indicates that the high-end risk analysis is driven primarily by high-end industrial releases.

Ambient Air: EPA estimated risks from fenceline community exposures to 1,4-dioxane released to air. Risks were evaluated for air releases from industrial COUs, hydraulic fracturing operations, and industrial and institutional laundry facilities. EPA estimated risks from fenceline exposures that could occur in communities immediately neighboring releases from industrial COUs by modeling either facility-specific chemical releases reported to TRI or, when TRI data was not available, alternative release estimates representing a generic facility. Cancer and non-cancer risk estimates for fenceline exposures within 10,000 meters of industrial releases were calculated for the modeled exposure concentrations. Acute and chronic non-cancer risk estimates do not indicate risk relative to the benchmark MOEs for any of the estimated exposure concentrations at any facilities evaluated. Cancer risk estimates for 95th percentile exposure concentrations within 1,000 meters of the facilities with the greatest risk in each COU, ranging from 1.05×10^{-10} to 1.1×10^{-4}.[4] The COUs with estimated risks exceeding 1×10^{-6} include manufacturing, processing as an ethoxylation byproduct, processing as a byproduct of polyethlene terephtalate production, processing as a reactant, non-incorporative processing, industrial use as an intermediate, laboratory chemical use, and disposal. For the screening level analysis locations where lifetime cancer risk is estimated to be within the benchmark range of

[4] The facility with the highest risk estimate at 1.1×10^{-4} ceased manufacture of 1,4-dioxane in 2018.

1×10^{-6} to 1×10^{-4}, EPA evaluated land use patterns to determine whether fenceline community exposures are reasonably anticipated. Based on this characterization of land use patterns, fenceline community exposures for the screening level analysis are reasonably anticipated at 50 percent of facilities where cancer risk is within the benchmark range based on modeled air concentrations.

EPA's confidence in the risk estimates for ambient air exposures for those COUs identified in the previous paragraph is medium to high, with the exception of the laboratory chemical use. The modeling methodology used for this analysis is robust and relied primarily on release data reported to TRI via Form R. Because the laboratory chemical analysis relied on surrogate or modeled release data, EPA's confidence in those risk estimates is low to medium. For most COUs, the analysis is limited to facilities that report to TRI, so other sources of 1,4-dioxane releases are not directly captured.

EPA also evaluated potential risks from aggregate ambient air exposures from multiple neighboring facilities in these COUs using a conservative screening methodology. EPA identified five groups of two to four facilities reporting 1,4-dioxane releases in proximity to each other, *i.e.*, within 10 km. Aggregated risks estimated for these groups of facilities were generally dominated by the facility with the greatest risk. This aggregate analysis did not identify locations with cancer risk greater than 1×10^{-6} that did not already have cancer risk above that level from an individual facility.

For two COUs without site-specific data, modeling was used to estimate high-end and central tendency 1,4-dioxane concentrations in ambient air at three distance zones from an emitting facility (100, 100 to 1,000, and 1,000 meters). This methodology was applied for hydraulic fracturing and for industrial and institutional laundry facilities. Environmental releases (fugitive and stack) along with other data (like days of release) for these COUs were estimated using Monte Carlo modeling. These release estimates were then used to estimate ambient air concentrations. Lifetime cancer risk estimates for distances within 1,000 meters of hydraulic fracturing operations range from 3.9×10^{-7} to 7.1×10^{-5} for high end release estimates and 2.2×10^{-8} to 4.1×10^{-6} for central tendency release estimates across a range of model scenarios. Lifetime cancer risk estimates for distances within 1,000 meters of industrial and institutional laundry facilities range from 1.5×10^{-11} to 3.8×10^{-8} across a range of high end and central tendency exposure scenarios. Acute and chronic non-cancer risk estimates do not indicate risk relative to benchmark MOEs for any exposure concentrations estimated for hydraulic fracturing operations or industrial and institutional laundry facilities.

Overall confidence in risk estimates from inhalation exposures resulting from hydraulic fracturing and industrial and institutional laundries is medium. The modeling methodologies are robust. The distribution of air releases used as model input data were estimated using Monte Carlo modeling and rely on assumptions. No air monitoring data were reasonably available to determine whether 1,4-dioxane is detected near hydraulic fracturing operations or industrial and institutional laundry facilities. Because the air concentrations underlying this analysis are based on probabilistic modeling, they are not tied to specific locations that can be evaluated for land use patterns.

Based on the risk estimates for cancer, acute effects, and non-cancer chronic effects, the fact that the risk estimates are within the applicable benchmark range, and EPA's confidence in the risk estimates, EPA does not find that fenceline community exposure to 1,4-dioxane in ambient air from releases from industrial conditions of use, including hydraulic fracturing and industrial laundry facilities, and institutional laundry facilities contributes to the unreasonable risk from 1,4-dioxane.

6.3 Unreasonable Risk to the Environment

6.3.1 Environment

EPA used environmental fate parameters, physical-chemical properties, modelling, and monitoring data to assess ambient water exposure to aquatic organisms. Further analysis was not conducted for biosolids, soil and sediment pathways based on a qualitative assessment of the physical-chemical properties and fate of 1,4-dioxane in the environment. However, a quantitative comparison of hazards and exposures for aquatic organisms in surface water was evaluated. EPA calculated a risk quotient (RQ) to compare environmental concentrations against an effect level in surface water for the most biological relevant species. Exposures of 1,4-dioxane to aquatic organisms from surface water were assessed and presented in the 2020 risk evaluation and used to inform the risk determination. Th ese analyses are described in Sections 2.1, 2.3, and 4.1 of the 2020 risk evaluation. Uncertainties in the analysis are discussed in Section 4.3.4 of the 2020 risk evaluation.

6.3.2 Determining Unreasonable Risk of Injury to the Environment

Calculated risk quotient (RQs) can provide a risk profile by presenting a range of estimates for different environmental hazard effects for different conditions of use. An RQ equal to 1 indicates that the exposures are the same as the concentration that causes effects. An RQ less than 1, when the exposure is less than the effect concentration, generally indicates that there is not risk of injury to the environment that would support a determination of unreasonable risk for the chemical substance. An RQ greater than 1, when the exposure is greater than the effect concentration, generally indicates that there is risk of injury to the environment that would support a determination of unreasonable risk for the chemical substance. Consistent with EPA's human health evaluations, the RQ is not treated as a bright line and other risk-based factors may be considered (*e.g.*, confidence in the hazard and exposure characterization, duration, magnitude, uncertainty) for purposes of making an unreasonable risk determination.

EPA considered the effects on the aquatic and terrestrial organisms. In the 2020 Risk Evaluation, EPA found that there were no exceedances of benchmarks to aquatic organisms from exposures to 1,4-dioxane. The RQ values for acute and chronic risks are 0.2 and 0.397, respectively, based on the best available science. The high volatility, high water solubility and low Log Koc of 1,4-dioxane suggest that 1,4-dioxane will only be present at low concentrations in sediment and land-applied biosolids.

EPA considered uncertainties in its determination of unreasonable risk for 1,4-dioxane. Key assumptions and uncertainties in the environmental risk estimation are related to data used for the characterization of environmental exposure (*e.g.,* model input parameters, inability to directly relate monitoring sites to conditions of use) and environmental hazard (*e.g.,* selection of representative organisms, allometric-scaling to estimate hazard thresholds for other organisms). Additionally, the reasonably available environmental monitoring data was limited temporally and geographically. Assumptions and key sources of uncertainty in the risk characterization are detailed in Section 4.3.1. of the 2020 Risk Evaluation.

Therefore, based on the 2020 Risk Evaluation, EPA did not identify risk of injury to the environment that would contribute to the unreasonable risk from 1,4-dioxane.

6.4 Unreasonable Risk Determination

EPA has preliminarily determined that 1,4-dioxane presents an unreasonable risk of injury to health under the conditions of use. This draft determination is based on the information in the 2020 Risk Evaluation and the 2023 Draft Supplement, including the appendices and supporting documents. This draft determination was made in accordance with TSCA section 6(b), as well as TSCA's best available science (TSCA section 26(h)) and weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702.

EPA's proposed unreasonable risk determination for 1,4-dioxane as a whole chemical is based on cancer and non-cancer risks to workers from inhalation and dermal exposures, and cancer risks to fenceline communities from exposures to 1,4-dioxane in drinking water sourced from surface water contaminated by industrial discharges of 1,4-dioxane (including when it is generated as a byproduct). EPA proposes to identify as contributing to this determination the following:

- Manufacture (including domestic manufacture and import)
- Processing (including repackaging, recycling, non-incorporative, as a reactant, and as a byproduct)
- Industrial/commercial use: Functional fluids (open and closed system): Metalworking fluid, cutting and tapping fluid, polyalkylene glycol fluid, hydraulic fluid
- Industrial/commercial use: Intermediate
- Industrial/commercial use: Processing aid
- Industrial/commercial use: Laboratory chemicals
- Industrial/commercial use: Adhesives and sealants
- Industrial/commercial use: Other uses: Printing and printing compositions
- Industrial/commercial use: Other uses: Dry film lubricant
- Industrial/commercial use: Other uses: Spray polyurethane foam
- Industrial/commercial use: Other uses: Hydraulic fracturing
- Industrial/commercial use: Arts, crafts, and hobby materials: Textile dye
- Industrial/commercial use: Laundry and dishwashing products: Dish soap

- Industrial/commercial use: Laundry and dishwashing products: Dishwasher detergent
- Industrial/commercial use: Paints and coatings: Paint and floor lacquer
- Disposal

EPA proposes to identify the following as not contributing to the unreasonable risk from 1,4-dioxane[5]:

- Distribution in commerce
- Industrial/commercial use: Automotive care products: Antifreeze
- Industrial/commercial use: Cleaning and furniture care products: Surface cleaner
- Industrial/commercial use: Laundry and dishwashing products: Laundry soap
- 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

Because the risk estimates for all processing COUs evaluated in the 2020 Risk Evaluation and the 2023 Draft Supplement (including those where 1,4-dioxane is processed as a byproduct) contribute to the unreasonable risk determination, EPA is proposing that any processing of 1,4-dioxane contributes to the unreasonable risk from 1,4-dioxane. This would include circumstances described but not evaluated in the 2020 Risk Evaluation or the 2023 Draft Supplement, such as when 1,4-dioxane is generated as a byproduct during sulfonation, sulfation, and esterification processes. EPA also emphasizes that this determination identifies any manufacturing, processing, or disposal of 1,4-dioxane – including as a byproduct – as contributing to the unreasonable risk if the 1,4-dioxane contaminates surface water that is the source of drinking water.

[5] EPA is not proposing to make a condition-of-use-specific risk determination for these conditions of use, is not planning to issue a final order under TSCA section 6(i)(1) for these conditions of use that do not contribute to the unreasonable risk, and does not intend to consider the revised risk determination for 1,4-dioxane to constitute a final agency action.

Consistent with the statutory requirements of TSCA, EPA would initiate risk management either by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that 1,4-dioxane no longer presents an unreasonable risk or by determining pursuant to TSCA sections 9(a) and/or 9(b) that other Federal laws can eliminate or reduce to a sufficient extent the unreasonable risk. EPA expects to focus a risk management action on the conditions of use that contribute to the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to contribute to unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) driving unreasonable risk, even if the upstream activities do not contribute to the unreasonable risk.

Table 6-2 and Table 6-3 summarize the basis for the draft revised determination of unreasonable risk of injury to health presented by 1,4-dioxane. In these tables, a checkmark indicates the type of effect and the exposure route to the population evaluated for each condition of use that contribute to the draft unreasonable risk determination. As explained in Section 6.2, for the draft revised unreasonable risk determination, EPA considered the effects on human health and the environment of exposure to 1,4-dioxane at the central tendency and high-end (or moderate and high intensity use), the exposures from the condition of use, the risk estimates, and the uncertainties in the analysis. See Section 4.6 of the 2020 Risk Evaluation and Sections 5.2.1 and 5.2.2 of the 2023 Draft Supplement for summaries of risk estimates.

Table 6-2. Supporting Basis for the Unreasonable Risk Determination for Human Health (Occupational Conditions of Use)[6]

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects							
					Acute Non-cancer		Chronic Non-cancer		Cancer		General Population/ Fenceline Communities	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency	Ambient Air [c]	Drinking Water [d]
Manufacture	Domestic manufacture	Domestic manufacture	Worker	Inhalation	✓		✓		✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation						✓		
Manufacture	Import	Import/ Repackaging (Bottle and Drum)	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		
Processing	Repackaging	Repackaging (Bottle and Drum)	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		
Processing	Recycling	Recycling	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		
Processing	Non-incorporative	Basic organic chemical manufacturing (process solvent)	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		

[6] The checkmarks indicate the type of effect and the exposure route to the population evaluated for each condition of use that contributes to the draft revised unreasonable risk from 1,4-dioxane. If a check mark is not noted that effect or exposure route does not contribute to the unreasonable risk.

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects							
					Acute Non-cancer		Chronic Non-cancer		Cancer		General Population/ Fenceline Communities	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency	Ambient Air [c]	Drinking Water [d]
Processing	Processing as a reactant	Polymerization catalyst	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		
Processing	Byproduct	Polyethylene terephthalate (PET) byproduct	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal			✓		✓	✓		
			ONU[e]	Inhalation								
Processing	Byproduct	Ethoxylation process byproduct	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal			✓		✓	✓		
			ONU[e]	Inhalation								
Distribution in Commerce												
Industrial Use	Intermediate use	Agricultural chemical and plasticizer intermediate; Catalysts and reagents for anhydrous acid reactions, brominations and sulfonations	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects							
					Acute Non-cancer		Chronic Non-cancer		Cancer		General Population/ Fenceline Communities	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency	Ambient Air [c]	Drinking Water [d]
Industrial Use	Processing aids, not otherwise listed	Wood pulping, extraction of animal and vegetable oils, wetting and dispersing agent in textile processing, purification of process intermediates, and etching of fluoropolymers	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		
Industrial Use	Functional Fluids	Metalworking fluid, cutting and tapping fluid, polyalkalene glycol fluid	Worker	Inhalation								
				Dermal					✓	✓		
			ONU	Inhalation								
Industrial Use	Functional Fluids	Hydraulic Fracturing	Worker	Inhalation	✓	✓	✓	✓	✓	✓		
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU[e]	Inhalation								

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects							
					Acute Non-cancer		Chronic Non-cancer		Cancer		General Population/ Fenceline Communities	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency	Ambient Air [c]	Drinking Water [d]
Industrial Use and Commercial Use	Laboratory Use	Chemical reagent, Reference material, spectroscopic and photometric measurement, liquid scintillation counting medium, stable reaction medium, cryoscopic solvent for molecular mass determination, preparation of histological sections for microscopic examination	Worker	Inhalation	✓		✓		✓			
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU[e]	Inhalation								
Industrial and Commercial Use,	Adhesives and Sealants	Film cement	Worker	Inhalation	✓	✓	✓	✓	✓	✓		
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation								

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects							
					Acute Non-cancer		Chronic Non-cancer		Cancer		General Population/ Fenceline Communities	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency	Ambient Air [c]	Drinking Water [d]
Industrial Use	Other uses	Spray polyurethane foam	Worker	Inhalation								
				Dermal					✓	✓		
			ONU	Inhalation								
Industrial Use	Other uses	Printing and printing compositions	Worker	Inhalation								
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation								
Industrial Use	Other uses	Dry film lubricant	Worker	Inhalation	✓				✓			
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation								
Commercial Use	Arts, crafts, and hobby materials	Textile dye	Worker	Inhalation	✓		✓		✓			
				Dermal								
			ONU[e]	Inhalation								
Commercial Use	Automotive care products	Antifreeze	Worker	Inhalation								
				Dermal								
			ONU[e]	Inhalation								
Commercial Use	Cleaning and furniture care products	Surface cleaner	Worker	Inhalation								
				Dermal								
			ONU[e]	Inhalation								

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects							
					Acute Non-cancer		Chronic Non-cancer		Cancer		General Population/ Fenceline Communities	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency	Ambient Air [c]	Drinking Water [d]
Commercial Use	Laundry and dishwashing products	Dish soap	Worker	Inhalation	✓	✓	✓	✓	✓	✓		
				Dermal					✓			
			ONU[e]	Inhalation								
Commercial Use	Laundry and dishwashing products	Dishwasher detergent	Worker	Inhalation	✓	✓	✓	✓	✓	✓		
				Dermal								
			ONU[e]	Inhalation								
Commercial Use	Laundry and dishwashing products	Laundry detergent (industrial) (institutional)	Worker	Inhalation								
				Dermal								
			ONU[e]	Inhalation								
Commercial Use	Paints and coatings	Paint and floor lacquer	Worker	Inhalation	✓		✓		✓			
				Dermal								
			ONU[e]	Inhalation								
Disposal	Disposal	Wastewater, underground injection, landfill, recycling, incineration	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects							
					Acute Non-cancer		Chronic Non-cancer		Cancer		General Population/ Fenceline Communities	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency	Ambient Air [c]	Drinking Water [d]

a. These categories of conditions of use appear in the Life Cycle Diagrams in the 2020 Risk Evaluation and the 2023 Draft Supplement, reflect CDR codes, and broadly represent additional information regarding all conditions of use of 1,4-dioxane.
b. These subcategories reflect more specific information regarding the conditions of use of 1,4-dioxane.
c. The general population cancer risks from chronic inhalation exposures associated with the listed conditions of use are highly dependent on release amounts, stack heights, topography, and meteorological conditions as discussed further in Section 5.2.2.3.1 in the 2023 Draft Supplement.
d. The general population cancer risks from chronic exposures to drinking water sourced from surface water associated with the listed conditions of use are highly dependent on the amount of 1,4-dioxane released and the flow of the receiving water body. Exposure and risk estimates are also influenced by whether there is a drinking water intake downstream of a release and the degree of dilution that occurs between the point of release and the drinking water intake. See Sections 3.2.2 and 5.2.2.1 in the 2023 Draft Supplement. Similarly, as discussed in Section 5.2.2.2 in the 2023 Draft Supplement, EPA's drinking water risk estimates associated with groundwater indicate that higher hydraulic fracturing releases or landfill leachate concentrations and loadings are associated with higher risks. As noted in Section 5.2.2.1, cancer risk is the primary risk driver in most exposure scenarios.
e. Monitoring data and modeling approaches were not available to estimate occupational inhalation exposures for ONUs. The ONU exposures are anticipated to be lower than worker exposures since ONUs do not typically directly handle the chemical.

Table 6-3. Supporting Basis for the Unreasonable Risk Determination for Human Health (Consumer Conditions of Use)

Lifecycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-Cancer		Chronic Cancer		General Population/ Fenceline Communities	
					Moderate Intensity Use	High Intensity Use	Moderate Intensity Use	High Intensity Use	Ambient Air [c]	Drinking Water [d]
Consumer use	Arts, crafts, and hobby materials	Textile dye	Adult ≥21 years	Inhalation						
				Dermal						
			Child 16-20 years	Inhalation						
				Dermal						
			Child 11-15 years	Inhalation						
				Dermal						
			Bystander	Inhalation						
Consumer use	Automotive care products	Antifreeze	Adult ≥21 years	Inhalation						
				Dermal						
			Child 16-20 years	Inhalation						
				Dermal						
			Child 11-15 years	Inhalation						
				Dermal						
			Bystander	Inhalation						
Consumer use	Cleaning and furniture care products	Surface cleaner	Adult ≥21 years	Inhalation						
				Dermal						
			Child 16-20 years	Inhalation						
				Dermal						
			Child 11-15 years	Inhalation						
				Dermal						

Lifecycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-Cancer		Chronic Cancer		General Population/ Fenceline Communities	
					Moderate Intensity Use	High Intensity Use	Moderate Intensity Use	High Intensity Use	Ambient Air [c]	Drinking Water [d]
Consumer use	Cleaning and furniture care products (cont.)	Surface cleaner (cont.)	Bystander	Inhalation						
Consumer use	Laundry and dishwashing products	Dish soap	Adult ≥21 years	Inhalation						
				Dermal						
			Child 16-20 years	Inhalation						
				Dermal						
			Child 11-15 years	Inhalation						
				Dermal						
			Bystander	Inhalation						
Consumer use	Laundry and dishwashing products	Dishwasher detergent	Adult ≥21 years	Inhalation						
				Dermal						
			Child 16-20 years	Inhalation						
				Dermal						
			Child 11-15 years	Inhalation						
				Dermal						
			Bystander	Inhalation						
Consumer use	Laundry and dishwashing products	Laundry detergent	Adult ≥21 years	Inhalation						

Lifecycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-Cancer		Chronic Cancer		General Population/ Fenceline Communities	
					Moderate Intensity Use	High Intensity Use	Moderate Intensity Use	High Intensity Use	Ambient Air [c]	Drinking Water [d]
Consumer use	Laundry and dishwashing products (cont.)	Laundry detergent (cont.)	Adult ≥21 years (cont.)	Dermal						
			Child 16-20 years	Inhalation						
				Dermal						
			Child 11-15 years	Inhalation						
				Dermal						
			Bystander	Inhalation						
Consumer use	Paints and coatings	Paint and floor lacquer	Adult ≥21 years	Inhalation						
				Dermal						
			Child 16-20 years	Inhalation						
				Dermal						
			Child 11-15 years	Inhalation						
				Dermal						
			Bystander	Inhalation						
Consumer use	Other consumer uses	Spray polyurethane foam	Adult ≥21 years	Inhalation						
				Dermal						
			Child 16-20 years	Inhalation						
				Dermal						
			Child 11-15 years	Inhalation						
				Dermal						
			Bystander	Inhalation						

Lifecycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-Cancer		Chronic Cancer		General Population/ Fenceline Communities	
					Moderate Intensity Use	High Intensity Use	Moderate Intensity Use	High Intensity Use	Ambient Air [c]	Drinking Water [d]

a. These categories of conditions of use appear in the Life Cycle Diagrams in the 2020 Risk Evaluation and the 2023 Draft Supplement, reflect CDR codes, and broadly represent additional information regarding all conditions of use of 1,4-dioxane.
b. These subcategories reflect more specific information regarding the conditions of use of 1,4-dioxane.
c. The general population cancer risks from chronic inhalation exposures associated with the listed conditions of use are highly dependent on release amounts, stack heights, topography, and meteorological conditions as discussed further in Section 5.2.2.3.1 in the 2023 Draft Supplement.
d. The general population cancer risks from chronic exposures to drinking water sourced from surface water associated with the listed conditions of use are highly dependent on the amount of 1,4-dioxane released and the flow of the receiving water body. Exposure and risk estimates are also influenced by whether there is a drinking water intake downstream of a release and the degree of dilution that occurs between the point of release and the drinking water intake. See Sections 3.2.2 and 5.2.2.1 in the 2023 Draft Supplement. Similarly, as discussed in Section 5.2.2.2 in the 2023 Draft Supplement, EPA's drinking water risk estimates associated with groundwater indicate that higher hydraulic fracturing releases or landfill leachate concentrations and loadings are associated with higher risks. As noted in Section 5.2.2.1, cancer risk is the primary risk driver in most exposure scenarios.

6.5 References

1. EPA. Risk Evaluation for 1,4-Dioxane. December 2020. EPA-HQ-OPPT-2019-0238-0092.

2. EPA. Draft Supplemental Risk Evaluation. July 2023. EPA Document #EPA-740-D-23-001.

3. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register* (86 FR 7009, January 25, 2021).

4. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register* (86 FR 7037, of January 25, 2021).

5. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal Register* (86 FR 7619, February 1, 2021).

6. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. *Federal Register* (86 FR 8845, February 10, 2021).

7. EPA Press Release. EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 30, 2021. https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations

8. Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels

9. EPA. Correction of Dermal Acute and Chronic Non-Cancer Hazard Values Used to Evaluate Risks from Occupational Exposures in the Final Risk Evaluation for 1,4-dioxane. June 26, 2023.