

1,4-Dioxane Final Risk Evaluation Non-technical Summary

ACTION

- EPA is releasing the final risk evaluation on 1,4-dioxane. After evaluating 24 conditions of use (COUs) of 1,4-dioxane, EPA has determined that 1,4-dioxane presents an unreasonable risk under 13 conditions of use. This includes an unreasonable risk to workers and occupational non-users (ONUs) when domestically manufacturing or importing the chemical; processing the chemical for a variety of uses; and when used in certain industrial and commercial applications. The Agency has also evaluated eight conditions of use of 1,4-dioxane present as a by-product in consumer products. EPA determined that these consumer uses do not present an unreasonable risk. EPA has also evaluated exposures to the general population through surface water and determined that 1,4-dioxane does not present an unreasonable risk to the general population based on that exposure.
- This final risk evaluation is conducted pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to prioritize and evaluate the safety of existing chemicals to determine whether a chemical presents an unreasonable risk of injury to health or the environment under the conditions of use. If a chemical is determined to present an unreasonable risk, then EPA must regulate the substance to address the unreasonable risk.
- The final risk evaluation and supplemental materials can be found in docket EPA-HQ-OPPT-2019-0238 on www.regulations.gov.
- 1,4-Dioxane was selected in 2016 as one of the first 10 chemicals for risk evaluation under section 6 of TSCA.
- Public comments and external scientific peer review informed the development of the 1,4-dioxane final risk evaluation. EPA published the 1,4-dioxane supplemental analysis in November 2020, the draft risk evaluation in June 2019, the problem formulation document in June 2018, and the scope document in June 2017.

KEY POINTS

- After evaluating 24 conditions of use of 1,4-dioxane, EPA determined that 1,4-dioxane presents an unreasonable risk under 13 conditions of use. There are health risks to workers and occupational non-users (ONUs) from exposures during occupational use.
- The unreasonable risks of injury to health include liver toxicity from acute exposures, and olfactory epithelium effects and increased risk of cancer from chronic exposures.
- The conditions of use with unreasonable risks include domestic manufacturing and import;; repackaging and recycling; non-incorporative processing; processing as a reactant; industrial and commercial uses as an intermediate, as a processing aid, in laboratory applications, in adhesives and sealants, in film cement, in printing and printing composition, and as a dry film lubricant; and disposal.
- In response to public comments and scientific peer review on the draft risk evaluation, EPA evaluated eight conditions of use, all of which are consumer uses where 1,4-dioxane is present as a byproduct in consumer products, in the supplemental analysis. The consumer uses included in the final risk evaluation are use in arts, crafts and hobby materials;

automotive care products; cleaning and furniture care products; laundry and dishwashing products; paints and coatings; and spray polyurethane foam. No unreasonable risks for these consumer uses were identified.

- Overall, those uses that do not present an unreasonable risk include distribution in commerce; industrial and commercial uses in functional fluids; use in spray polyurethane foam; and use in consumer products.

BACKGROUND

- 1,4-Dioxane is a clear volatile liquid used primarily as a solvent and is subject to federal and state regulations and reporting requirements. 1,4-Dioxane is currently manufactured (including import), processed, distributed, and used in industrial and commercial processes, found as a by-product in commercial and consumer cleaning products, and disposed. 1,4-Dioxane has been reportable as a Toxics Release Inventory (TRI) chemical under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) since 1987. It is designated a Hazardous Air Pollutant (HAP) under the Clean Air Act (CAA), and is a hazardous substance under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). It was listed on the Safe Drinking Water (SDWA) fourth Candidate Contaminant List (CCL4) and identified in the third Unregulated Contaminant Monitoring Rule (UCMR3).
- The total annual production volume reported for 1,4-dioxane in 2015 under the Chemical Data Reporting Rule is approximately 1 million pounds.
- Evaluation and risk management steps for the 1,4-dioxane final risk evaluation:
 - EPA has issued the final risk evaluation for 1,4-dioxane, meeting the requirements set forth in TSCA section 6. EPA is now initiating the process to address the unreasonable risks identified. EPA has two years following the issuance of the final risk evaluation to address, by rule, the unreasonable risk identified.