Understanding the Risk Evaluation of 1,4-Dioxane

Ensuring the safety of chemicals is part of EPA's mission of protecting public health and the environment. Under the Toxic Substances Control Act (TSCA) EPA reviews the potential risks of chemicals being used in the market.

This factsheet provides the public, businesses, and stakeholders with a clear picture of where EPA is in the risk evaluation process for 1,4-dioxane, whether the Agency has found any unreasonable risks and what that means for chemical safety, and what EPA's next steps are.

Chemical Description

- Used primarily as a solvent in a variety of commercial and industrial applications like in the manufacture of other chemicals, as a processing aid, in laboratory chemicals, and in adhesives and sealants.
- No consumer uses for 1,4-dioxane were reported in the United States in the 2016 Chemical Data Reporting (CDR). EPA did not find evidence of consumer uses besides presence as a contaminant in consumer products, and as explained in the problem formulation document for 1,4-dioxane, such activities will be considered in the scope of the risk evaluation for ethoxylated chemicals.
- 2016 CDR data shows only two manufacturers were producing or importing more than 1 million pounds of 1,4-dioxane in the U.S. in 2015.

Conditions of Use Identified for Risk Evaluation

In the draft risk evaluation, EPA looked at 14 conditions of use associated with the manufacturing (including import), processing, distribution, use, and disposal of 1,4-dioxane, including the following:

- Processing aids (not otherwise listed) (270,000 lbs.)
- Functional fluids in open and closed systems (<150,000 lbs.)
- Laboratory chemicals (<150,000 lbs.)
- Adhesives and sealants (professional film cement)
- Spray polyurethane foam
- Printing and printing compositions
- Disposal of waste materials containing 1,4-dioxane
- Dry film lubricant

Draft Risk Evaluation

TSCA requires EPA to evaluate chemicals for unreasonable risks through a new risk evaluation process. In determining whether there is unreasonable risk, EPA weighs a variety of factors including, but not limited to, the effects of the chemical substance on health under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment under the conditions of use; the population exposed (including potentially exposed or susceptible populations); the severity of hazard; and the uncertainties.

It is important to note that for the general population, including children, environmental statutes administered by EPA such as the Clean Air Act, the Safe Drinking Water Act, the Clean Water Act, and the Resource Conservation and Recovery Act, adequately assess and effectively manage risks from 1,4-dioxane.

In the June 2019 draft risk evaluation of 1,4-dioxane, EPA made the following initial determinations on risk. These initial determinations may change as our assessment becomes more refined through the public and peer review process.

- **No unreasonable risks to occupational non-users**. EPA found no unreasonable risks to workers in the general area of 1,4-dioxane use but not directly in contact with the chemical.
- **Unreasonable risks to workers in certain circumstances**. These initial determinations are based on a draft assessment of the reasonably available information and are not EPA's final determinations on whether this chemical presents unreasonable risks under the conditions of use. The Agency will use feedback received from the public and peer review processes to inform the final risk evaluations.
- **No unreasonable risk to the environment**. For all the conditions of use included in the draft risk evaluation, EPA found no unreasonable risks to the environment from 1,4-dioxane.

Public Participation

The draft risk evaluation will be available for public comment for 60 days in docket EPA-HQ-OPPT-2019-0238. This public comment period is an opportunity for you to submit any additional information to assist EPA in completing the final risk evaluation for 1,4-dioxane. EPA will consider all comments submitted on the draft risk evaluation when developing a final risk evaluation.

Next Steps

This draft risk evaluation and the initial risk determinations are not a final action. This draft represents the Agency's initial review of the scientific information on 1,4-dioxane and will be peer reviewed by independent scientific experts.

EPA is committed to being open and transparent as the Agency follows the process required by the law for evaluating potential risks from chemicals. EPA will continue to keep the public updated as the Agency moves through this process. Following the comprehensive risk evaluation process required by TSCA ensures that EPA has confidence in our final conclusions about whether a chemical poses any unreasonable risks, so the public can have confidence in the safety of chemicals on the market.

The next step in the risk evaluation process is public participation. EPA is asking the public and peer reviewers to provide input on the draft risk evaluations to ensure that the Agency is using the best available science.

EPA's risk findings may change in response to comments from scientific experts conducting a peer review and from the public on the draft risk evaluation. If EPA's final risk evaluation for 1,4-dioxane finds unreasonable risks associated with this chemical under specific conditions of use, the Agency will propose actions to address those risks within the timeframe required by TSCA.