

Initial Risk-Based Prioritization of High Production Volume Chemicals

1,3,5-Trioxane (CASRN 110-88-3)

This document is based on screening-level characterizations done by EPA on the environmental fate, hazard, and exposure of the listed chemical. The information used by EPA includes data submitted under the HPV Challenge Program¹ and the 2006 Inventory Update Reporting (IUR)², and data publicly available through other selected sources³. This screening-level prioritization presents EPA's initial thinking regarding the potential risks presented by this chemical and future possible actions that may be needed. These initial characterization and prioritization documents do not constitute a final Agency determination as to risk, nor do they determine whether sufficient data are available to characterize risk. Rather, they are interim evaluations. Recommended actions may be considered by EPA in the future based on a relative judgment regarding this chemical in comparison with others evaluated under this program, and in light of the uncertainties presented by gaps in the available data that may be determined to exist. These evaluations contribute to meeting U.S. commitments under the chemicals cooperation work being done in North America⁴ through the EPA Chemical Assessment and Management Program (ChAMP)⁵.

Hazard and Fate Summary:

- **Human Health:** The acute oral, inhalation, and dermal toxicity of this chemical is low. Repeated-dose studies showed route-specific toxicity: repeated oral exposure resulted in low toxicity and repeated inhalation exposure resulted in high toxicity. An oral prenatal developmental study in rats showed low developmental and maternal toxicity.
- **Environment:** Available data indicate the acute toxicity of this chemical to fish, aquatic invertebrates, and aquatic plants is low.
- **Persistence and Bioaccumulation:**
 - Available data indicate that this chemical has high persistence.
 - Available data indicate that this chemical has low bioaccumulation potential.

Exposure Summary:

- Both Confidential Business Information (CBI) and non-CBI information from IUR and other sources were used in developing this initial prioritization.
- **Production Volume:** This chemical is an HPV chemical manufactured and/or imported in the U.S. with an aggregated production volume in the range of 100 to 500 million pounds in 2005.
- **Uses:** Non-confidential IUR information for this chemical indicates that it is used as an intermediate in resin and synthetic manufacturing. Other minor uses associated with this chemical are as an adhesive and binding agent in electric lamp bulb and part manufacturing, and other chemical product and preparations. There are no reported

¹ US EPA, HPV Challenge Program information: <http://epa.gov/hpv/>.

² US EPA, IUR information: <http://www.epa.gov/oppt/iur/index.htm>

³ US EPA, Information on additional public databases used: <http://www.epa.gov/hpvis/pubdtsum.htm>

⁴ US EPA, U.S. Commitments to North American Chemicals Cooperation:
<http://www.epa.gov/hpv/pubs/general/sppframework.htm>

⁵ US EPA, ChAMP information: <http://www.epa.gov/champ/>.

commercial or consumer uses. The HPV Challenge Program submission for this chemical stated that it is used primarily as a monomer for production of high-molecular weight polyacetals and secondarily as a chemical intermediate. The Hazardous Substances Data Bank indicates that this chemical is used as an intermediate to make organic chemicals.

- General Population and Environment: EPA identifies a medium potential that the general population and the environment might be exposed to this chemical. There is potential for environmental releases to water and/or air during manufacturing, processing, and use. This chemical is very persistent in the environment, and does not bioaccumulate. It is expected to partition primarily to soil and water. This chemical is highly mobile in soil and moderately volatile from water and moist soil surfaces.
- Workers: EPA identifies a high relative ranking for potential worker exposure. The high ranking is based primarily on the relatively high vapor pressure, which could result in significant worker exposure to vapor, as well as potential for inhalation exposure to solid material. This chemical does not have an OSHA Permissible Exposure Limit (PEL).
- Consumers: EPA identifies a low potential that consumers might be exposed to this chemical from products containing this chemical. IUR submissions indicate no uses in consumer products, nor were any found in other data sources.
- Children: No uses in products specifically intended to be used by children were reported in the IUR, nor were any found in other data sources. Therefore, EPA identifies a low potential that children might be exposed to this chemical.

Risk Characterization Summary:

- Potential Risk to Aquatic Organisms from Environmental Releases: *LOW CONCERN*. EPA identifies a medium potential that aquatic organisms might be exposed from environmental releases. This chemical has high persistence but low bioaccumulation potential. These characteristics, in combination with the low toxicity to fish, aquatic invertebrates, and aquatic plants, indicate a low concern for potential risk to these organisms.
- Potential Risk to the General Population from Environmental Releases: *HIGH CONCERN*. EPA identifies a medium potential that the general population may be exposed to this chemical from environmental releases to air and water. The potential human health hazard is low for oral exposure. Therefore, there is a low concern for potential risk to the general population from oral exposure from environmental releases. However, the potential human health hazard is high for inhalation exposure. Therefore, there is a high concern for potential risk to the general population from inhalation exposures from environmental releases.
- Potential Risk to Workers: *HIGH CONCERN*. EPA identifies a high relative ranking for potential worker exposure. The ranking is primarily based on relatively high vapor pressure, which could result in significant worker exposure to vapor, as well as potential for inhalation exposure to solid material. The potential human health hazard is high for inhalation exposure. Therefore, there is a high concern for potential risk to workers.
- Potential Risk to Consumers from Known Uses: *LOW CONCERN*. Available IUR data indicate that there is a low potential that consumers might be exposed to this chemical because it is not used in consumer products. Therefore, there is a low concern for potential risk to consumers.

- Potential Risk to Children: *LOW CONCERN*. Available IUR data indicate that there is a low potential that children might be exposed to this chemical. There are no toxicology studies that specifically address potential toxicity at early life stages. However, this chemical is not present in children's products or consumer products. Therefore, the available information suggests a low concern for potential risk to children.

Regulatory and Related Information Summary:

- This chemical is listed on the TSCA Inventory. It is not otherwise regulated by EPA.
- Canada, as a result of categorization of their Domestic Substances List (DSL), has prioritized this chemical for further consideration based on developmental toxicity data. EPA and Canada use different criteria for this endpoint.

Assumptions and Uncertainties:

- EPA has no information on releases of this chemical, and assumes potential exposures based on reported uses.
- There is uncertainty regarding the extent of personal protective equipment used by workers.
- Given the difference in acute and repeat-dose toxicity between the oral and inhalation routes of exposure, additional route-specific testing may be useful.

Rationale Leading To Prioritization Decision:

- Hazard communications and standard industrial hygiene practices, if properly followed, may be sufficient to address concerns for occupational exposures.
- The high concern for potential risk to the general population from environmental releases and to workers is driven by repeat-dose toxicity data combined with assumptions about the potential for exposures. Information concerning environmental releases and exposures in the workplace would be useful in determining the extent of potential concern.

Prioritization Decision:

- **MEDIUM PRIORITY, POTENTIAL CONCERN:** In order to further evaluate the high concern for potential risk from inhalation exposures to this chemical to the general population and to workers, EPA has identified possible next steps involving efforts to develop a better understanding of exposure to and uses of this chemical. Examples of information that would assist EPA in its analysis include, but are not limited to:
 - Information concerning potential releases to air from manufacturing, use, and disposal of the chemical and products containing the chemical;
 - Information concerning potential exposures in the workplace; and,
 - Other information pertinent to exposures to this chemical.

As an initial step in developing this understanding, companies that manufacture, process, or use this chemical are encouraged to provide available information on a voluntary and non-confidential basis.

- Depending on the exposure information received, additional route-specific toxicity testing might be considered, as appropriate.

Supporting Documentation:

Screening-Level Risk Characterization: September 2008

Screening-Level Hazard Characterization: September 2008

Screening-Level Exposure Characterization: September 2008