

Initial Risk-Based Prioritization of High Production Volume Chemicals

6-*tert*-Butyl-3-(chloromethyl)-2,4-xylenol (CASRN 23500-79-0) (CA Index Name: Phenol, 3-(chloromethyl)-6-(1,1-dimethylethyl)-2,4-dimethyl-)

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.

This chemical was considered in 2003 to have met the HPV Challenge Program guidance for a closed-system intermediate, a chemical manufactured and processed only in closed systems to produce other chemicals. Because closed-system intermediates have a limited potential for exposure generally attributable only to isolated accidental releases, toxicity testing elements in the HPV Challenge Program were reduced for those chemicals, and consisted of the Screening Information Data Set (SIDS) minus the tests for repeated dose toxicity and reproductive toxicity, but including a developmental toxicity test⁶. For this chemical, the sponsor provided a complete SIDS data set.

Hazard and Fate Summary:

- **Human Health:** Acute oral and dermal toxicity of this chemical is low in rats and rabbits, respectively. It is highly irritating to rabbit skin and eyes. A combined oral repeated-dose/ reproductive/ developmental toxicity study in rats showed high systemic and reproductive toxicity in the parental females. There was no developmental toxicity. Gene mutations were not observed in bacteria. Chromosomal aberrations were observed *in vitro* but not *in vivo*.
- **Environment:** The acute toxicity of this chemical is low to fish and aquatic invertebrates and moderate to aquatic plants.

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/>.

⁶ US EPA, Guidance for Testing Closed System Intermediates:
<http://www.epa.gov/chemrtk/pubs/general/closed9.htm>.

- Persistence and Bioaccumulation:
 - Available data indicate that this chemical has low persistence.
 - Available data indicate that this chemical has low bioaccumulation potential.

Exposure Summary:

- Both Confidential Business Information (CBI) and non-confidential information from IUR and other sources were used in developing this initial prioritization.
- Production Volume: This chemical is an HPV with an aggregated production and/or import volume in the United States of 1 to 10 million pounds in 2005.
- Uses: Non-confidential IUR information for this chemical indicates that it is used as an intermediate. No commercial/consumer uses were reported in the IUR submissions or in the Hazardous Substances Data Bank. Information submitted as part of the HPV Challenge Program indicates that it is used in the chemical industry for synthesis.
- General Population and Environment: EPA identifies a low potential that the general population or the environment might be exposed to this chemical.
- Workers: EPA identifies a low relative ranking for potential worker exposure.
- Consumers: EPA identifies a low potential that consumers might be exposed.
- Children: EPA identifies a low potential that children might be exposed.

Risk Characterization Summary:

EPA reviewed the information in the HPV submission for this chemical in 2003, and determined that it met the guidance for a closed-system intermediate. Therefore, there is a low concern for potential risk to aquatic organisms and the general population from environmental releases, and also to workers, consumers, and children.

- Potential Risk to Aquatic Organisms from Environmental Releases: *LOW CONCERN.*
- Potential Risk to the General Population from Environmental Releases: *LOW CONCERN.*
- Potential Risk to Workers: *LOW CONCERN.*
- Potential Risk to Consumers from Known Uses: *LOW CONCERN.*
- Potential Risk to Children: *LOW CONCERN.*

Regulatory and Related Information Summary:

- This chemical is listed on the TSCA Inventory. It is not otherwise regulated under TSCA.

Assumptions and Uncertainties:

- EPA assumes that potential exposures are very limited, based on the reported use.
- The high skin and eye irritation of this chemical could pose a concern if workers were accidentally exposed.

Rationale Leading To Prioritization Decision:

- The manufacture and processing of this chemical only as an intermediate to produce other chemicals in systems that may significantly reduce the potential for worker exposure and environmental releases lead to a low concern for risk.

Prioritization Decision:

- LOW PRIORITY – Follow-up action not suggested at this time.
- EPA will share information on this chemical with other Agencies, including the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH), given the concerns that may be presented by its high skin and eye irritation potential.

Supporting Documentation:

Screening-Level Risk Characterization: September 2008

Screening-Level Hazard Characterization: September 2008

Screening-Level Exposure Characterization: September 2008