

Initial Risk-Based Prioritization of High Production Volume Chemicals

Sponsored Chemical

Lactic Acid (CASRN 50-21-5)

(9th CI and CA Index Name: Propanoic acid, 2-hydroxy-)

Supporting Chemical

L(+)-Lactic acid (CASRN 79-33-4)

(9th CI and CA Index Name: Propanoic acid, 2-hydroxy-, (2S)-)

This document is based on screening-level characterizations done by EPA on the environmental fate, hazard, and exposure of the listed chemicals. 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 sources.³ This screening-level prioritization presents EPA's initial thinking regarding the potential risks presented by these chemicals 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:** Acute oral and inhalation toxicity of the sponsored chemical is low in rats, and dermal toxicity is low in rabbits. Repeated oral exposure in rats and developmental toxicity testing in mice produced no toxicity.
- **Environment:** Available data indicate that the potential acute hazard of the supporting chemical is low for fish, aquatic invertebrates and aquatic plants.
- **Persistence and Bioaccumulation:**
 - Available data indicate that these chemicals have low persistence.
 - Available data indicate that these chemicals have 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.

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/>

- Production Volume: These chemicals are HPV chemicals manufactured and/or imported in the U.S. with an aggregated production volume in the range of 51 to 110 million pounds in 2005.
- Uses: Non-confidential information in the Inventory Update Reporting (IUR) indicates that these chemicals are used as solvents, pH-regulating agents or intermediates in a variety of industries, including the manufacturing of basic organic chemicals, paints and coatings, soaps and cleaning agents as well as textiles and fabrics. Both chemicals have IUR submissions that indicate uses in commercial settings or consumer uses. Information from the Hazardous Substances Data Bank (HSDB) indicate that these chemicals are naturally occurring in foods and are used as an acidulant in foods; a mordant in printing woolen goods; a solvent; and in textile, leather, and many other applications.
- General Population and Environment: EPA identifies a high potential for environmental release and subsequent exposure to the general population and the environment.
- Workers: EPA identifies a high relative ranking for potential worker exposure. This relative ranking is based on a relatively high production volume; a number of industrial processing and uses; and the potential for inhalation exposure to vapor and possibly mist. The vapor pressure of these chemicals could result in significant worker exposure to vapors if workers are close to the liquid. Neither of these chemicals have OSHA Permissible Exposure Limits (PELs).
- Consumers: EPA identifies a high potential that consumers might be exposed to these chemicals. Both chemicals have IUR submissions that indicate uses in commercial settings or consumer uses. Information from public data sources also indicates potential for exposure to consumers from the ingestion of foods containing these chemicals.
- Children: EPA identifies a moderate potential that children might be exposed to these chemicals. Most IUR submissions reported no uses in products intended to be used by children, but there is uncertainty in the IUR. HSDB indicates that these chemicals are used in foods and textile finishing which may be used by children. Exposures to children may be expected to occur through household uses of consumer products.

Risk Characterization Summary:

- Potential Risk to Aquatic Organisms from Environmental Releases: *LOW CONCERN*. EPA identifies a high potential that aquatic organisms might be exposed from environmental releases. These chemicals have low persistence and low bioaccumulation. These characteristics in combination with the low toxicity to fish, aquatic invertebrates and plants indicate a low concern for potential risk to these organisms.
- Potential Risk to the General Population from Environmental Releases: *LOW CONCERN*. EPA identifies a high potential that the general population may be exposed to these chemicals from environmental releases to air and water. The potential human health hazard is low. Therefore, there is a low concern for potential risk to the general population from environmental releases.
- Potential Risk to Workers: *LOW CONCERN*. EPA identifies a high relative ranking for potential worker exposure. The potential human health hazard is low. Therefore, there is a low concern for potential risk to workers.
- Potential Risk to Consumers from Known Uses: *LOW CONCERN*. Available data indicate that there is a high potential that consumers might be exposed to these chemicals

in consumer products. These chemicals are also a normal part of human intermediary metabolism, and will be produced naturally. The potential human health hazard is low. Therefore taken together, there is a low concern for potential risk to consumers.

- Potential Risk to Children: *LOW CONCERN*. Available data indicate that there is a moderate potential that children might be exposed to these chemicals from the household use of consumer products. There are no toxicology studies that specifically address potential toxicity at early life stages. However, these chemicals are a normal component of human intermediary metabolism, and the adult animal toxicology studies indicate low toxicity. Therefore, the available information suggests a low concern for potential risks to children.

Regulatory and Related Information Summary:

- These chemicals are listed on the TSCA Inventory. They are not otherwise regulated by EPA.
- The National Institute of Occupational Safety and Health (NIOSH), an institute of the U.S. Centers for Disease Control and Prevention (CDC), includes safe handling recommendations for these chemicals at industrial concentrations in an International Chemical Safety Card (April 09, 1997: <http://www.cdc.gov/niosh/ipcsneng/neng0501.html>).

Assumptions and Uncertainties:

- EPA has no information on releases of this chemical, and assumes potential exposures based on reported uses.

Rationale Leading To Prioritization Decision:

- These chemicals are naturally found in food, primarily in sour milk products. They are also naturally present in humans and animals.
- Available data suggest a low hazard to all potential exposure groups.

Prioritization Decision:

- LOW PRIORITY - Follow-up action not suggested at this time.

Supporting Documentation:

Screening-Level Risk Characterization: August 2008

Screening-Level Hazard Characterization: August 2008

Screening-Level Exposure Characterization: August 2008