

Initial Risk-Based Prioritization of High Production Volume Chemicals

Sponsored Chemical

Adipic acid, di-C7-9 branched and linear alkyl ester (CASRN 68515-75-3)

(9th CI and CA Index Name: Hexanedioic acid, di-C7-9-branched and linear alkyl esters)

Supporting Chemicals

Di(*n*-hexyl) adipate (CASRN 110-33-8)

(CA Index Name: Hexanedioic acid, 1,6-dihexyl ester)

(9th CI Name: Hexanedioic acid, dihexyl ester)

Adipic acid, bis(2-ethylhexyl) ester (CASRN 103-23-1)

(CA Index Name: Hexanedioic acid, 1,6-bis(2-ethylhexyl) ester)

(9th CI Name: Hexanedioic acid, bis(2-ethylhexyl) ester)

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:** Acute oral and dermal toxicity are low. A repeated dose study showed no systemic toxicity. Studies on both the sponsored and supporting chemicals showed no to low reproductive toxicity, and low developmental toxicity. The sponsored chemical did not induce gene mutation, and the supporting chemicals did not induce chromosomal aberrations either *in vivo* or *in vitro*.
- **Environment:** Adequate acute toxicity data for fish, aquatic invertebrates, and aquatic plants were not submitted. EPA used ECOSAR estimates and the hazard information available in the Diesters Category to conclude that acute toxicity of the sponsored chemical to aquatic organisms is low. The evaluation of chronic toxicity data for aquatic

¹ US EPA, HPV Challenge Program information: <http://www.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/>.

invertebrates for a supporting chemical (CASRN 103-23-1) indicates that the potential chronic hazard to aquatic organisms is low.

- 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 was a moderate production volume (MPV) chemical in 2005, with an aggregated production and/or import volume in the U.S. in the range of 500,000 to 1 million pounds. It was an HPV chemical in earlier reporting years.
- Uses: Non-confidential IUR information reported use of this chemical in processing activities in various unspecified industrial sectors and use in commercial settings or consumer products as a component of transportation products. Information submitted as part of the HPV Challenge Program indicates that this chemical is used as a plasticizer.
- General Population and Environment: Based on use information, EPA identifies a high potential that the general population and the environment may be exposed through releases to air, water, and land. The Hazardous Substances Data Bank information for this chemical states that there might be potential release to the environment from various waste streams.
- Workers: EPA identifies a medium relative ranking for potential worker exposure based on the potential dermal exposure during industrial processing and use activities and commercial uses, and the number of workers potentially exposed.
- Consumers: EPA identifies a high potential that consumers may be exposed from using products containing this chemical based on commercial and consumer uses identified in IUR submissions as well as the use of this chemical in non-TSCA uses, such as food packaging.
- Children: IUR submissions reported that information on products intended for use by children is Not Readily Obtainable. Based on this uncertainty and the potential that exposures to children may be expected to occur through the use of some consumer products, EPA identifies a high potential that children might be exposed.

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. Adipic acid, di-C7-9 branched and linear alkyl ester has low persistence and low bioaccumulation. Although adequate acute toxicity data for adipic acid, di-C7-C9 branched and linear alkyl ester was not submitted, EPA used ECOSAR estimates and hazard information available in the Diesters Category to conclude that acute toxicity is expected to be low. The evaluation of chronic toxicity data for aquatic invertebrates for the supporting chemical, adipic acid, bis(2-ethylhexyl) ester, indicates that the potential chronic hazard of hexanedioic acid, diC7 – C9 branched and linear alkyl ester to aquatic organisms is low. The combination of low toxicity, low persistence and low bioaccumulation potential suggest a low concern for potential risk to aquatic organisms.

- Potential Risk to the General Population from Environmental Releases: *LOW CONCERN*. EPA identifies a high potential that the general population might be exposed from environmental releases. The potential human health hazard is expected to be low due to the lack of specific toxicity to animals following exposure to high doses. The low hazard, low persistence, and low bioaccumulation together suggest a low concern for potential risk to the general population from environmental releases.
- Potential Risk to Workers: *LOW CONCERN*. EPA identifies a moderate relative ranking for potential worker exposure. The potential human health hazard is expected to be low. Therefore, the available information suggests a low concern for potential risks to workers.
- Potential Risk to Consumers from Known Uses: *LOW CONCERN*. Available information indicates a high potential that consumers might be exposed. The potential human health hazard is expected to be low. The available information suggests a low concern for potential risks to consumers.
- Potential Risk to Children: *LOW CONCERN*. EPA identifies a high potential that children might be exposed. Postnatal animal toxicity data indicated a low concern for potential toxicity to young animals. The available information suggests a low concern for potential risks to children.

Regulatory and Related Information Summary:

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

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:

- Available data suggest a low hazard to aquatic organisms and to humans in all potentially exposed groups.

Prioritization Decision:

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

Supporting Documentation:

Screening-Level Risk Characterization: September 2008

Screening-Level Hazard Characterization: September 2008

Screening-Level Exposure Characterization: September 2008