Initial Risk-Based Prioritization of High Production Volume Chemicals

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 Program[1] 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 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 America[4] through the EPA Chemical Assessment and Management Program (ChAMP)[5].

Hazard and Fate Summary:

- Human Health: The acute toxicity of this chemical is low for the oral, dermal, and inhalation routes. It is not a dermal sensitizer or a skin or eye irritant. Systemic toxicity in oral repeated-dose toxicity studies in rats is low. A prenatal developmental toxicity study showed low maternal and developmental toxicity. A one-generation reproductive toxicity study that included an assessment of postnatal growth and development showed no reproductive toxicity. It did not induce gene mutations or chromosomal aberrations.
- Environment: Available toxicity data on this chemical indicate that the acute hazard to fish, aquatic invertebrates, and aquatic plants is low. A chronic daphnid toxicity study indicates 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.

[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/.

- 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 50 to 100 million pounds in 2005.
- Uses: According to non-confidential IUR submissions, this chemical is used as a functional fluid in various manufacturing processes and is used in commercial settings or consumer uses in electrical and electronic products and in rubber and plastic products. Information from the Hazardous Substances Data Bank (HSDB) indicates that this chemical is used as a plasticizer, solvent, lubricant and as a functional (hydraulic) fluid.
- 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 HSDB information for this chemical states that there might be potential release to the environment from various waste streams, especially from waste incineration and leaching from plastics.
- Workers: EPA identifies a medium relative ranking for potential worker exposure based on the physical form of this chemical, potential dermal exposure during industrial processing and use and commercial uses, the number of workers, and the relatively high aggregated production volume for this chemical.
- 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 contact wrappings.
- Children: EPA identifies a high potential that children might be exposed based on the use of products intended to be used by children as well as consumer products containing this chemical.

Risk Characterization Summary:

- Potential Risk to Aquatic Organisms from Environmental Releases: *LOW CONCERN*. EPA identifies a high potential for exposures to aquatic organisms from environmental releases. This chemical has low persistence and low bioaccumulation. For fish, aquatic invertebrates, and aquatic plants, these characteristics in combination with the low acute toxicity indicate a low concern for risk of acute toxicity. Chronic toxicity to daphnia as reported in the SIDS dossier indicates toxicity was seen, but the study was conducted above the water solubility limit of the chemical. Another chronic daphnia study, conducted subsequent to publication of the SIDS dossier, indicates chronic toxicity was not observed at the water solubility limit (measured concentrations). Furthermore, adipic acid, bis(2-ethylhexyl) ester has been shown to undergo extensive metabolism and rapid excretion in biota, which would be expected to mitigate any potential for chronic toxicity. This information along with the low persistence and bioaccumulation of adipic acid, bis(2-ethylhexyl) suggest a low concern for risk of chronic toxicity 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 medium 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 risk to workers.
- Potential Risk to Consumers from Known Uses: *LOW CONCERN*. Available IUR data indicate that there is a high potential that consumers might be exposed. The potential human health hazard is expected to be low. Therefore, 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 through the use of products specifically intended to be used by children, as well as through the household use of some consumer products. Animal toxicity data that assessed postnatal growth and development indicated a low concern for potential toxicity to young animals. Therefore, 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.
- This chemical is included on the list of Inert Ingredients Permitted for Use in Nonfood Pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), see http://www.epa.gov/opprd001/inerts/lists.htm.
- This chemical was subject to Toxics Release Inventory (TRI) reporting for reporting years 1987-1994 but was delisted from TRI in 1996 and is no longer subject to reporting.
- This chemical is subject to a maximum contaminant level (MCL) under the Safe Drinking Water Act's National Primary Drinking Water Regulations (contaminant source is discharge from chemical factories).
- This chemical is on Canada's Domestic Substances List and was identified as a high priority for risk assessment based on categorization by Health Canada as a high human health hazard and presenting a high likelihood of exposure. It is listed in proposed Batch 11 of Canada's Challenge program. EPA will share its data and conclusions with Canada.

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: OECD SIDS Initial Assessment Report, 08/2005, document available at:

http://www.chem.unep.ch/irptc/sids/oecdsids/sidspub.html.
Note: OECD SIDS Initial Assessment Profiles (SIAP) and SIDS Initial Assessment Reports (SIAR) are publicly available through the United Nations Environmental Programme website. These documents are presented in an international forum that involves review and endorsement by governmental authorities around the world. The U.S. EPA is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments for the purpose of the U.S. HPV Challenge qualitative risk characterization process.

Screening-Level Exposure Characterization: September 2008