

Supporting Documents for 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)

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Note: OECD SIDS Initial Assessment Profiles (SIAP) and SIDS Initial Assessment Reports (SIAR) are publicly available through the United Nations Environmental Programme website (<http://www.chem.unep.ch/irptc/sids/oecdsids/sidspub.html>). 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.
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BACKGROUND

Screening-level hazard, exposure and risk characterizations for high production volume chemicals (HPV) are important contributions to the chemicals cooperation work being done in North America¹ through the EPA Chemical Assessment and Management Program (ChAMP)². These screening-level characterizations are developed by EPA for individual chemicals or chemical categories to support initial Risk-Based Prioritizations (RBPs) for HPV chemicals. These screening-level characterizations are technical documents intended primarily to inform the Agency's internal decision-making process. Accordingly, they are written for assessment professionals and assume a degree of technical understanding. Each of the support documents is described below.

The Risk-Based Prioritizations are found in an accompanying document and are written for a general audience. They present EPA's initial thinking regarding the potential risks presented by these chemicals and future possible actions that may be needed.

Hazard Characterizations for HPV Chemicals

EPA's screening-level hazard characterizations are based primarily on the review of the summaries of studies and other information submitted by the chemical sponsor(s) under the HPV Challenge Program³. These studies included in the scope of the HPV Challenge comprise the Screening Information Data Set (SIDS) of the Organization for Economic Cooperation and Development (OECD)⁴, an internationally recognized battery of tests that provides the basic data necessary to make an initial evaluation of a chemical's hazards and fate. In preparing the initial hazard characterizations, EPA also consulted a variety of reliable sources⁵ for additional relevant information and considered its own comments and public comments on the original submission as well as the sponsor's responses to comments and revisions made to the submission. In order to determine whether any new hazard information was developed since the time of an HPV submission, EPA also searched publicly available databases⁶ for information entered from one year prior to the HPV submission through May 2008. The screening-level hazard characterization is performed according to established EPA guidance⁷. A more detailed description of the hazard characterization process is available on the EPA website⁸.

With respect to chemicals for which internationally-accepted OECD SIDS Initial Assessment Profiles (SIAP) and Initial Assessment Reports (SIAR) were available, EPA did not generate its own screening-level hazard characterization, but did check for and incorporate updated information in the risk characterization.

Exposure Characterizations for HPV Chemicals

EPA recently received exposure-related data on chemicals submitted in accordance with the requirements of Inventory Update Reporting (IUR)⁹. The 2006 IUR submissions pertain to chemicals manufactured in

¹ U.S. EPA – U.S. Commitments to North American Chemicals Cooperation: <http://www.epa.gov/hpv/pubs/general/sppframework.htm>.

² U.S. EPA – ChAMP information: <http://www.epa.gov/champ/>.

³ U.S. EPA – HPV Challenge Program information: <http://www.epa.gov/hpv>.

⁴ U.S. EPA – Technical Guidance Document, OECD SIDS Manual Sections 3.4 and 3.5: <http://www.epa.gov/chemrtk/pubs/general/sidsappb.htm>

⁵ U.S. EPA – Public Database Hazard Information: <http://www.epa.gov/hpvis/hazardinfo.htm>

⁶ U.S. EPA – Public Database Update Information: <http://www.epa.gov/chemrtk/hpvis/updateinfo.htm>

⁷ U.S. EPA – Risk Assessment Guidelines: <http://cfpub.epa.gov/ncea/raf/rafguid.cfm>

⁸ U.S. EPA – About HPV Chemical Hazard Characterizations: <http://www.epa.gov/hpvis/abouthc.htm>

⁹ U.S. EPA – Basic IUR Information: <http://www.epa.gov/opptintr/iur/pubs/guidance/basic-information.htm>

(including imported into) the U.S. during calendar year 2005 in quantities of 25,000 pounds or more at a single site. The reports include the identity, the quantity, and the physical form of the chemical manufactured or imported, and the number of workers reasonably likely to be exposed during manufacture of the chemical. For chemicals manufactured or imported in quantities of 300,000 pounds or more at a single site, additional reported information includes: the industrial processing and uses of the chemical; the number of industrial processing sites and workers reasonably likely to be exposed to the chemical at those sites; the consumer and commercial uses of the chemical; and an indication whether the chemical was used in products intended for use by children under 14 years of age.

EPA's screening-level exposure characterizations are based largely on the information submitted under the IUR reporting, although other exposure information submitted to the Agency (for example, in HPV submissions) or readily available through a limited set of publicly accessible databases¹⁰ was also considered. The screening-level exposure characterizations identify a potential (high, medium, or low) that each of five populations – the environment, the general population, workers, consumers, and children – might be exposed to the chemical. In most cases, this potential doesn't address the quantity, frequency, or duration of exposure, but refers only to the likelihood that an exposure could occur.

In many instances EPA is not able to fully disclose to the public all the IUR exposure-related data reviewed or relied upon in the development of the screening-level documents because some of the material was claimed as confidential business information (CBI) when it was submitted to the Agency. These CBI claims do limit the Agency's ability to be completely transparent in presenting some underlying exposure and use data for chemicals in public documents. EPA does consider all data, including data considered to be CBI, in the screening-level exposure and risk characterization process, and endeavors whenever possible to broadly characterize supporting materials claimed as confidential in ways that do not disclose actual CBI.

Risk Characterizations for HPV Chemicals

EPA combines the information from the screening-level exposure characterization with the screening-level hazard characterization to develop a qualitative screening-level risk characterization, as described in the Agency's guidance on drafting risk characterizations¹¹. These screening-level risk characterizations are technical documents intended to support subsequent priority-setting decisions and actions by OPPT. The purpose of the qualitative screening-level risk characterization is two-fold: to support initial risk-based decisions to prioritize chemicals, identify potential concerns, and inform risk management options; and to identify data needs for individual chemicals or chemical categories.

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. Recommended actions reflect EPA's relative judgment regarding this chemical or chemical category in comparison with others evaluated under this program, as well as the uncertainties presented by gaps that may exist in the available data.

¹⁰ U.S. EPA – Summary of Public Databases Routinely Searched: <http://www.epa.gov/chemrtk/hpvis/pubdtsum.htm>.

¹¹ U.S. EPA – Risk Characterization Program: <http://www.epa.gov/osa/spc/2riskchr.htm>

**QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION
OF HIGH PRODUCTION VOLUME CHEMICALS**

CHEMICAL NAME

**Adipic acid, bis(2-ethylhexyl) ester (CAS No. 103-23-1)
(CA Index Name: Hexanedioic acid, bis(2-ethylhexyl) ester)**

September 2008

Prepared by
Risk Assessment Division
Economics, Exposure and Technology Division
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION FOR

Adipic acid, bis(2-ethylhexyl) ester (CAS No. 103-23-1)
(CA Index Name: Hexanedioic acid, bis(2-ethylhexyl) ester)

1. Physical-Chemical Properties and Environmental Fate

Adipic acid, bis (2-ethylhexyl) ester is a colorless to pale straw-colored liquid at room temperature. Its vapor pressure and water solubility are low. The chemical partitions primarily to sediment, soil, and water. It is moderately volatile from water and moist soil surfaces. Soil mobility is expected to be minimal. Atmospheric photodegradation is estimated to occur at moderate rates. Adipic acid, bis (2-ethylhexyl) ester undergoes hydrolysis at rates that are considered negligible. Ready biodegradability tests conducted on adipic acid, bis (2-ethylhexyl) ester indicate that the potential for this compound to persist in the environment is low (P1). Estimated BCF values suggest that this chemical has a low potential to bioaccumulate (B1).

2. Hazard Characterization

Adipic acid, bis(2-ethylhexyl) ester has been assessed in the Organization for Economic Cooperation and Development (OECD), High Production Volume (HPV) Programme. The hazard summary below was taken from the OECD document which can be viewed at: <http://www.chem.unep.ch/irptc/sids/OECD/SIDS/103231.pdf>. This hazard summary also includes information that post-dates the SIDS SIAR that was submitted to EPA under the HPV Challenge Program as part of the Diesters Category and for which EPA has prepared a screening-level hazard and risk characterization and a risk-based prioritization (http://iaspub.epa.gov/opthpv/hpv_hc_characterization.get_report?doctype=1).

Aquatic Organism Toxicity: The evaluation of available toxicity data on adipic acid, bis(2-ethylhexyl) ester indicates that the potential acute hazard to fish, aquatic invertebrates, and aquatic plants is low. A chronic daphnid toxicity study indicates chronic hazard to aquatic organisms is low.

Human Health Toxicity: The acute toxicity of adipic acid, bis(2-ethylhexyl) ester is low for the oral, dermal, and inhalation routes. Data indicate that adipic acid, bis(2-ethylhexyl) ester 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 on adipic acid, bis(2-ethylhexyl) ester that included an assessment of postnatal growth and development showed no reproductive toxicity. Repeated-dose toxicity studies in rats with examination of various reproductive organs and endpoints showed no evidence of reproductive toxicity, with the exception of one study, which showed low reproductive toxicity. Adipic acid, bis(2-ethylhexyl) ester did not induce gene mutations or chromosomal aberrations. IARC has classified adipic acid, bis (2-ethylhexyl) ester into Group 3 (substances not classifiable as to its carcinogenicity to humans).

3. Exposure Characterization

Adipic acid, bis(2-ethylhexyl) ester has an aggregated production and/or import volume in the range of 50 million to 100 million pounds. Non-confidential IUR information indicates that this chemical is used as a functional fluid in various manufacturing processes. There were a number of submissions that reported processing activities in various industrial sectors but didn't specify the function. There were also IUR submissions that indicated uses in commercial settings or consumer uses in electrical and electronic products and also in rubber and plastic products. Information in the Hazardous Substances Data Bank (HSDB) indicated that this chemical is used as a plasticizer, solvent, lubricant and as a functional (hydraulic) fluid.

Potential Exposures to the General Population and the Environment: Based on the information considered, including information found from non-confidential public sources, EPA identifies, for the purposes of risk-based prioritization, a high potential that the general population and the environment might be exposed. The Hazardous Substances Data Bank (HSDB) information for this chemical states that there might be potential releases to the environment from various waste streams. Particularly, adipic acid, bis(2-ethylhexyl) ester may be released into the environment from waste incineration and from leaching from plastics where it is used as a plasticizer. This chemical was subject to TRI reporting for reporting years 1987-1994 but was delisted from TRI in 1996 and is no longer subject to reporting.

Persistence and bioaccumulation ratings for this chemical are P1 and B1. These ratings indicate that this chemical is not persistent in the environment; and is not bioaccumulative.

Potential Exposures to Workers: Based on the information considered, including IUR data and the HSDB, and in combination with Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a medium relative ranking for potential worker exposure. The medium relative ranking is based on the physical form of this chemical, potential dermal exposure during industrial processing and use activities and commercial uses, the number of workers potentially exposed, and the relatively high aggregated production volume for this chemical.

Potential Exposures to Consumers: EPA identifies, for the purposes of risk-based prioritization, a high potential that consumers might be exposed based on the use of products containing this chemical. IUR submissions indicate uses in commercial settings or consumer uses. The non-confidential consumer uses for this chemical are: rubber and plastic products, and electrical and electronic products. There is also potential for exposure to consumers from non-TSCA uses based on information from public data sources. This chemical is contained in food-contact wrappings.

Potential Exposures to Children: EPA identifies, for the purposes of risk-based prioritization, a high potential that children might be exposed based on the use of products containing this chemical. The IUR reported uses in products intended to be used by children, as well as reporting that such information was Not Readily Obtainable.

4. Risk Characterization

The statements and rationale provided below are intended solely for the purpose of this qualitative screening-level risk characterization and will be used for prioritizing substances for future work in the Chemical Assessment Management Program (ChAMP).

Risk Statement and Rationale

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, bis(2-ethylhexyl) ester has low persistence and low bioaccumulation. For fish, aquatic invertebrates, and aquatic plants, these characteristics, in combination with the low acute toxicity indicates 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)¹². Furthermore, adipic acid, bis(2-ethylhexyl) ester has been shown to undergo extensive metabolism and rapid excretion in biota¹³, 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 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 and the environmental fate characteristics of 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 due to the lack of specific toxicity to animals following exposure to high doses. Therefore, taken together, the available information suggests a low concern for potential risks to workers.

Potential Risk to Consumers from Known Uses (LOW CONCERN). EPA identifies a high potential that consumers might be exposed to products containing this chemical. The potential human health hazard is expected to be low due to the lack of specific toxicity to animals following exposure to high doses. Taken together, the available information suggests a low concern for potential risks to consumers.

¹² Chronic daphnid study described in Robust Summary for Diesters Category submitted under HPV Challenge Program: <http://www.epa.gov/chemrtk/pubs/summaries/alipestr/c13466tc.htm>

¹³ Bioconcentration study presented in the SIAR indicates extensive metabolism and excretion (half-life < 1 day) occurs in bluegill sunfish.

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 use of some consumer products. Animal toxicity data that assessed postnatal growth and development indicated a low concern for potential toxicity to young animals. Taken together, the available information suggests a low concern for potential risks to children.

Screening Level Exposure Characterization for HPV Challenge Chemical

Adipic acid, bis (2-ethylhexyl) ester

CAS # 103-23-1

September 2008

Prepared by

Exposure Assessment Branch
Chemical Engineering Branch
Economics, Exposure and Technology Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Screening Level Exposure Characterization Adipic acid, bis(2-ethylhexyl) ester (CAS# 103-23-1)

Non-CBI Executive Summary

Adipic acid, bis(2-ethylhexyl) ester (CAS# 103-23-1) has an aggregated production and/or import volume in the range of 50 million to 100 million pounds. Non-confidential information in the Inventory Update Reporting (IUR) indicates that this chemical was manufactured and/or imported by the following companies:

- Charkit Chemical Corporation
- DynaChem Inc.
- Eastman Chemical Company
- Ester Solutions
- GNC Corporation, Incorporated
- LG Chem America, Inc.
- PolyOne Corporation
- Sunoco, Inc.
- Teknor Apex
- Velsicol Chemical Corporation

There may be other company names that are claimed confidential. Non-confidential IUR information indicates that this chemical is used as a functional fluid in various manufacturing processes. There were a number of submissions that reported processing activities in various industrial sectors but didn't specify the function. There were also IUR submissions that indicated uses in commercial settings or consumer uses in electrical and electronic products and also in rubber and plastic products.

Information in the Hazardous Substances Data Bank (HSDB) indicated that this chemical is used as a plasticizer, solvent, lubricant and as a functional (hydraulic) fluid¹⁴.

Potential Exposures to the General Population and the Environment: Based on the information considered, including information found from non-confidential public sources, EPA identifies, for the purposes of risk-based prioritization, a high potential that the general population and the environment might be exposed. The Hazardous Substances Data Bank (HSDB) information for this chemical states that there might be potential releases to the environment from various waste streams. Particularly, adipic acid, bis(2-ethylhexyl) ester may be released into the environment from waste incineration and from leaching from plastics where it is used as a plasticizer¹⁵.

This chemical was subject to TRI reporting for reporting years 1987-1994 but was delisted from TRI in 1996 and is no longer subject to reporting¹⁶.

¹⁴ HSDB, 2008. Hazardous Substances Data Bank. Bis(2-ethylhexyl) adipate. <http://toxnet.nlm.nih.gov>. Accessed, 8/13/08.

¹⁵ HSDB, 2008. Hazardous Substances Data Bank. Diesters Category. <http://toxnet.nlm.nih.gov>. Accessed, 6/12/08.

¹⁶ USEPA, 2006. Toxics Release Inventory. Accessed, 6/12/08. <http://www.epa.gov/tri/>.

Persistence and bioaccumulation ratings for this chemical are P1 and B1. These ratings indicate that this chemical is not persistent in the environment; and is not bioaccumulative.

Potential Exposures to Workers: Based on the information considered, including IUR data and the HSDB, and in combination with Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a medium relative ranking for potential worker exposure. The medium relative ranking is based on the physical form of this chemical, potential dermal exposure during industrial processing and use activities and commercial uses, the number of workers potentially exposed, and the relatively high aggregated production volume for this chemical.

Potential Exposures to Consumers: EPA identifies, for the purposes of risk-based prioritization, a high potential that consumers might be exposed based on the use of products containing this chemical. IUR submissions indicate uses in commercial settings or consumer uses. The non-confidential consumer uses for this chemical are: rubber and plastic products, and electrical and electronic products. There is also potential for exposure to consumers from non-TSCA uses based on information from public data sources. This chemical is contained in food-contact wrappings¹⁷.

Potential Exposures to Children: EPA identifies, for the purposes of risk-based prioritization, a high potential that children might be exposed based on the use of products containing this chemical. The IUR reported uses in products intended to be used by children, as well as reporting that such information was Not Readily Obtainable.

Below is a summary of non-confidential information in the IUR for this chemical.

This exposure characterization was completed using both public, non-confidential sources, and one or more IUR submissions that were available as of this writing.

¹⁷ SIDS Initial Assessment Report. March 2000. <http://www.chem.unep.ch/irptc/sids/OECD/SIDS/103231.pdf>.

Non Confidential IUR Data Summary: Adipic acid, bis(2-ethylhexyl) ester (103-23-1)

Manufacturing/Import Information

Production and import volume: 50 million to 100 million pounds
 List of non-CBI companies*: Charkit Chemical Corporation
 DynaChem Inc.
 Eastman Chemical Company
 Ester Solutions
 GNC Corporation, Incorporated
 LG Chem America, Inc.
 PolyOne Corporation
 Sunoco, Inc.
 Teknor Apex
 Velsicol Chemical Corporation

Maximum number of potentially exposed workers**: 1,000 or greater (including those of manufacturing, industrial processing and use)
 Highest non-CBI maximum concentration: up to 100% by weight
 Non-CBI physical forms*: pellets or large crystals; liquid

* There may be other companies and physical forms that are claimed confidential.

** There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

Table 1 Industrial Processing and Use Information Reported in 2006 IUR		
Processing Activity	Industrial Sector	Function in Industrial Sector
Processing--incorporation into article	All Other Chemical Product and Preparation Manufacturing	Other
Processing--incorporation into formulation, mixture, or reaction product	All Other Chemical Product and Preparation Manufacturing	Other
Processing--incorporation into formulation, mixture, or reaction product	Other Basic Organic Chemical Manufacturing	Other
Processing--incorporation into formulation, mixture, or reaction product	Other Plastics Product Manufacturing	Other
Processing--incorporation into formulation, mixture, or reaction product	Resin and Synthetic Rubber Manufacturing	Functional fluids
Processing--incorporation into formulation, mixture, or reaction product	Resin and Synthetic Rubber Manufacturing	Other

Table 1 Industrial Processing and Use Information Reported in 2006 IUR		
Processing Activity	Industrial Sector	Function in Industrial Sector
product		
Processing--repackaging	Other Basic Organic Chemical Manufacturing	Other
Processing--repackaging	Other Chemical and Allied Products Merchant Wholesalers	Functional fluids
Processing--repackaging	Other Plastics Product Manufacturing	Other
Not Readily Obtainable	Not Readily Obtainable	Not Readily Obtainable
Additional line item(s) may be claimed as CBI		

Table 2 Commercial/ Consumer Uses Reported in 2006 IUR		
Commercial/ Consumer Product Category Description	Highest Maximum Concentration Range	Use in Children's Products
Electrical and electronic products	1% - 30%	NRO
Rubber and plastic products	Greater than 90%	Yes
Not readily obtainable	NRO	NRO
Additional line item(s) may be claimed as CBI		