

Supporting Documents for Initial Risk-Based Prioritization of High Production Volume Chemicals

Maleic acid, dibutyl ester (CASRN 105-76-0)
(CA Index Name: 2-Butenedioic acid (2Z)-, 1,4-dibutyl ester)
(9th CI Name: 2-Butenedioic acid (2Z)-, dibutyl 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 qualitative risk characterization conducted under ChAMP.
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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

**Maleic acid, dibutyl ester (CAS No. 105-76-0)
(9th CI Name: 2-Butanedioic acid (2Z)-, dibutyl ester)**

September 2008

Prepared by
Risk Assessment Division
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**QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION FOR
Maleic acid, dibutyl ester (CAS No. 105-76-0)
(9th CI Name: 2-Butanedioic acid (2Z)-, dibutyl ester)**

1. Physical-Chemical Properties and Environmental Fate

Maleic acid, dibutyl ester is a colorless to pale straw-colored liquid at room temperature. Its vapor pressure and water solubility are moderate. The chemical partitions primarily to soil and water. It is moderately volatile from water and moist soil surfaces. Soil mobility is expected to be moderate. Atmospheric photodegradation is estimated to occur at moderate rates. Maleic acid, dibutyl ester undergoes hydrolysis at rates that are considered negligible. Ready biodegradability tests conducted on maleic acid, dibutyl 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

Maleic acid, dibutyl ester has been assessed in the Organization for Economic Cooperation and Development (OECD) High Production Volume (HPV) program. The hazard summary below was taken from the OECD document which can be viewed at:

<http://www.chem.unep.ch/irptc/sids/OECDSEIDS/105760.pdf>

Maleic acid, dibutyl ester also supports the hazard and risk characterizations for the Diesters Category submitted under the U.S. HPV Challenge Program.

Aquatic Organism Toxicity: The evaluation of available toxicity data for maleic acid, dibutyl ester indicates that the potential acute hazard to fish is moderate, the potential acute hazard to aquatic invertebrates is low, and the potential acute hazard to aquatic plants is moderate.

Human Health Toxicity: The acute toxicity of maleic acid, dibutyl ester is low for the oral, dermal, and inhalation routes. Data indicate that maleic acid, dibutyl ester is a strong dermal sensitizer and a mild dermal and eye irritant. A combined repeated-dose/reproductive/developmental toxicity screening study in rats showed low systemic toxicity, low maternal toxicity, and no developmental or reproductive toxicity. Maleic acid, dibutyl ester did not induce gene mutations *in vitro* or *in vivo*.

3. Exposure Characterization

Maleic acid, dibutyl ester has an aggregated production and/or import volume of 500,000 pounds. Non-confidential IUR information indicates that this chemical is used in non-incorporative activities in the manufacturing of other basic organic chemicals. The OECD SIDS dossier for maleic acid, dibutyl ester indicates that this chemical is mainly used as an inner softening agent for watery dispersions of co-polymers with vinyl acetate in closed systems.

Potential Exposures to the General Population and the Environment: Based on the information considered, including information found in 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 OECD use information noted above (as an inner softening agent for watery dispersions of co-polymers with vinyl acetate in closed systems) would indicate that releases of this chemical to water could be possible. Also, the moderate vapor pressure of 0.0075 torr at 20^o C could result in potential releases to air due to volatilization.

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 SIDS, and in combination with the Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a low relative ranking for potential worker exposure. The low relative ranking is based on the moderate vapor pressure of 0.0075 torr at 20°C, potential inhalation exposure to vapor only, low number of potentially exposed workers, and limited industrial uses. This chemical does not have an OSHA Permissible Exposure Limit (PEL).

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 do not indicate uses in commercial settings or consumer uses. However, there is potential for exposure to consumers from uses based on information from public data sources. This chemical is contained in fragrances.

Potential Exposures to Children: No uses in products intended to be used by children are reported in the IUR, nor are any found in other data sources. However, there may be potential exposure of children through the use of some consumer products. Therefore, EPA identifies, for the purposes of risk-based prioritization, a medium potential that children might be exposed.

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/MEDIUM CONCERN). EPA identifies a high potential that aquatic organisms might be exposed from environmental releases. Maleic acid, dibutyl ester has low persistence and low bioaccumulation. For fish and aquatic plants, these characteristics, in combination with the moderate acute toxicity for the maleic acid, dibutyl ester indicates a medium concern for potential risks. For aquatic invertebrates, these characteristics, in combination with the low acute toxicity for maleic acid, dibutyl ester indicates a low concern for potential risks.

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 low 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. 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.

Potential Risk to Children (LOW CONCERN). EPA identifies a high potential that children might be exposed. Postnatal developmental toxicity data on maleic acid, dibutyl ester 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

Maleic acid, dibutyl ester

CAS # 105-76-0

September 2008

Prepared by

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Screening Level Exposure Characterization Maleic acid, dibutyl ester (CAS# 105-76-0)

Non-CBI Executive Summary

Maleic acid, dibutyl ester (CAS# 105-76-0) has an aggregated production and/or import volume of < 500,000 pounds¹². Non-confidential information in the Inventory Update Reporting (IUR) indicates that this chemical was manufactured and/or imported by the following companies:

- BASF Construction Chemicals
- Boehme Filatex Inc.
- Lynx Chemical Group, LLC

There may be other companies that are claimed confidential. Non-confidential IUR information indicates that this chemical is used in non-incorporative activities in the manufacturing of other basic organic chemicals.

The Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) dossier for maleic acid, dibutyl ester indicates that this chemical is mainly used as an inner softening agent for watery dispersions of co-polymers with vinyl acetate in closed systems¹³.

Potential Exposures to the General Population and the Environment: Based on the information considered, including information found in non-confidential public sources, EPA identifies, for purposes of risk-based prioritization, a high potential that the general population and the environment might be exposed. The OECD use information noted above (as an inner softening agent for watery dispersions of co-polymers with vinyl acetate in closed systems) would indicate that releases of this chemical to water could be possible. Also, the moderate vapor pressure of 0.0075 torr at 20°C¹³ could result in potential releases to air due to volatilization. Maleic acid, dibutyl ester (CAS# 105-76-0) is not on the Toxics Release Inventory¹⁴.

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 SIDS, and in combination with Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a low relative ranking for potential worker exposure. The low relative ranking is based on the moderate vapor pressure of 0.0075 torr at 20°C¹³, potential inhalation exposure to vapor only, low number of potentially exposed workers, and limited industrial uses. This chemical does not have an OSHA Permissible Exposure Limit (PEL)¹⁵.

¹² USEPA, 2006. Partial Updating of TSCA Chemical Inventory.

¹³ OECD 2007. Organization for Economic Cooperation and Development.

<http://www.chem.unep.ch/irptc/sids/OECD/SIDS/105760.pdf>. Accessed, 8/13/2008.

¹⁴ USEPA, 2006. Toxics Release Inventory. <http://www.epa.gov/tri/>. Accessed, 6/12/08.

¹⁵ NIOSH, 1988. OSHA PEL Project Documentation. <http://www.cdc.gov/niosh/pel88/npelcas.html>. Accessed, 6/12/08.

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 do not indicate uses in commercial settings or consumer uses. However, there is potential for exposure to consumers from uses based on information from public data sources. This chemical is contained in fragrances¹⁶.

Potential Exposures to Children: No uses in products intended to be used by children are reported in the IUR, nor are any found in other data sources. However, there may be potential exposure of children through the use of some consumer products. Therefore, EPA identifies, for the purposes of risk-based prioritization, a medium potential that children might be exposed.

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.

¹⁶ OECD 2007. Organization for Economic Cooperation and Development.
<http://www.chem.unep.ch/irptc/sids/OECDSEIDS/105760.pdf>. Accessed 8/13/2008.

Non Confidential IUR Data Summary: Maleic acid, dibutyl ester (105-76-0)

Manufacturing/Import Information

Production and import volume: < 500,000 pounds
 List of non-CBI companies*: BASF Construction Chemicals
 Boehme Filatex Inc.
 Lynx Chemical Group, LLC

Maximum number of potentially exposed workers**: less than 100 (including those of manufacturing, industrial processing and use)

Highest non-CBI maximum concentration: up to 100% by weight
 Non-CBI physical forms*: 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 |
| Use-non-incorporative activities | Other Basic Organic Chemical Manufacturing | Other |
| 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 |
| None reported | | |