

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)

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:** The acute toxicity of this chemical is low by oral, dermal, and inhalation routes. A repeated-dose study showed low systemic, developmental, and reproductive toxicity. This chemical is a strong dermal sensitizer and a mild dermal and eye irritant.
- **Environment:** Available data indicate that the potential acute hazard of this chemical is moderate to fish and aquatic plants and low to aquatic invertebrates.
- **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. of less than 500,000 pounds. It was an HPV chemical in earlier reporting years.
- **Uses:** Non-confidential IUR information for this chemical indicates that it is used in non-incorporative activities in the manufacturing of other basic organic chemicals. The OECD SIDS dossier for this chemical indicates that it is mainly used as an inner

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/>.

softening agent for watery dispersions of co-polymers with vinyl acetate in closed systems.

- General Population and Environment: EPA identifies a high potential that the general population and the environment may be exposed. The OECD use information indicates that water releases are possible. The moderate vapor pressure of 0.0075 torr at 20°C could result in potential air releases from volatilization.
- Workers: EPA identifies a low relative ranking for potential worker exposure based on the moderate vapor pressure, potential inhalation exposure to vapor only, the low number of potentially exposed workers, and limited industrial uses.
- Consumers: EPA identifies a high potential that consumers may be exposed from using products containing these chemicals. Although the IUR submissions do not indicate consumer uses in the U.S., public data sources in the OECD SIDS document indicate potential exposure from consumer products such as fragrances.
- Children: EPA identifies a medium potential that children might be exposed from using products containing this chemical. Although no uses in products specifically intended to be used by children were reported, there is potential for exposure through the use of household consumer products containing this chemical.

Risk Characterization Summary:

- 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. Although this chemical has low persistence and bioaccumulation, its moderate acute toxicity to fish and aquatic plants combined with a high exposure potential indicates a medium concern for potential risks to fish and aquatic plants. However, this chemical's low toxicity to aquatic invertebrates suggests a low concern for potential risks to aquatic invertebrates.
- 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 low 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 suggests that there is 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 medium potential that children might be exposed. Postnatal developmental toxicity data on this chemical indicated a low concern for potential toxicity to young animals. This 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.
- The absence of chronic aquatic toxicity information noted in EPA's comments on the HPV Challenge Program test plan on the Diesters Category adds uncertainty to the characterization of environmental hazard and risk.

Rationale Leading To Prioritization Decision:

- Because this chemical is a strong dermal sensitizer, hazard communication and adherence to good industrial hygiene practices (protective clothing, goggles) would be expected to manage risk in occupational settings that could involve direct skin contact with the chemical.
- Although this chemical may be found in household consumer products, because it is a strong dermal sensitizer and a mild irritant, it is expected that the chemical would not be present in concentrations sufficient to elicit these reactions.
- The concern for potential risks to fish and aquatic plants is driven by acute toxicity data combined with assumptions about the potential for environmental exposures. Information concerning releases to water and resultant exposures would be useful in determining the extent of potential concern for fish and aquatic plants.

Prioritization Decision:

- **MEDIUM PRIORITY, POTENTIAL CONCERN:** In order to further evaluate the medium concern for potential risk to aquatic organisms from this chemical, EPA has identified next steps involving efforts to develop a better understanding of hazard, exposure and use of this chemical. Examples of information that would assist EPA in its analysis include, but are not limited to:
 - Chronic aquatic data to clarify the trend from acute to chronic toxicities for this chemical;
 - Information concerning potential releases to water from manufacturing, use and disposal of the chemical and products containing the chemical; and
 - Other information pertinent to environmental exposures to this chemical.As an initial step in developing this understanding, companies that manufacture, process, or use this chemical are encouraged to provide available information on a voluntary and non-confidential basis.

Supporting Documentation:

Screening-Level Risk Characterization: September 2008

Screening-Level Hazard Characterization: OECD SIDS Initial Assessment Report, 10/1998, <http://www.chem.unep.ch/irptc/sids/OECD/SIDS/105760.pdf>

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.

Screening-Level Exposure Characterization: September 2008