

## Initial Risk-Based Prioritization of High Production Volume Chemicals

### Diesters Category

#### Sponsored Chemicals

**Maleic acid, bis(1,3-dimethylbutyl) ester (CASRN 105-52-2)**  
(CA Index Name: 2-Butenedioic acid (2Z)-, 1,4-bis(1,3-dimethylbutyl) ester)  
(9<sup>th</sup> CI Name: 2-Butenedioic acid (2Z)-, bis(1,3-dimethylbutyl) ester)

**Maleic acid, bis(2-ethylhexyl) ester (CASRN 142-16-5)**  
(CA Index Name: 2-Butenedioic acid (2Z)-, 1,4-bis(2-ethylhexyl) ester)  
(9<sup>th</sup> CI Name: 2-Butenedioic acid (2Z)-, bis(2-ethylhexyl) ester)

**Adipic acid, diisopropyl ester (CASRN 6938-94-9)**  
(CA Index Name: Hexanedioic acid, 1,6-bis(1-methylethyl) ester)  
(9<sup>th</sup> CI Name: Hexanedioic acid, bis(1-methylethyl) ester)

**Adipic acid, diisooctyl ester (CASRN 1330-86-5)**  
(CA Index Name: Hexanedioic acid, 1,6-diisooctyl ester)  
(9<sup>th</sup> CI Name: Hexanedioic acid, diisooctyl ester)

**Adipic acid, bis(1-methylheptyl)ester (CASRN 108-63-4)**  
(CA Index Name: Hexanedioic acid, 1,6-bis(1-methylheptyl) ester)  
(9<sup>th</sup> CI Name: Hexanedioic acid, bis(1-methylheptyl) ester)

**Adipic acid, diisononyl ester (CASRN 33703-08-1)**  
(CA Index Name: Hexanedioic acid, 1,6-diisononyl ester)  
(9<sup>th</sup> CI Name: Hexanedioic acid, diisononyl ester)

**Adipic acid, diisodecyl ester (CASRN 27178-16-1)**  
(CA Index Name: Hexanedioic acid, 1,6-diisodecyl ester)  
(9<sup>th</sup> CI Name: Hexanedioic acid, diisodecyl ester)

**Adipic acid, ditridecyl ester (CASRN 16958-92-2)**  
(CA Index Name: Hexanedioic acid, 1,6-ditridecyl ester)  
(9<sup>th</sup> CI Name: Hexanedioic acid, ditridecyl ester)

**Azelaic acid, bis(2-ethylhexyl) ester (CASRN 103-24-2)**  
(CA Index Name: Nonanedioic acid, 1,9-bis(2-ethylhexyl) ester)  
(9<sup>th</sup> CI Name: Nonanedioic acid, bis(2-ethylhexyl) ester)

**Azelaic acid, diisodecyl ester (CASRN 28472-97-1)**  
(CA Index Name: Nonanedioic acid, 1,9-diisodecyl ester)  
(9<sup>th</sup> CI Name: Nonanedioic acid, diisodecyl ester)

**Sebacic acid, dimethyl ester (CASRN 106-79-6)**  
**(CA Index Name: Decanedioic acid, 1,10-dimethyl ester)**  
**(9<sup>th</sup> CI Name: Decanedioic acid, dimethyl ester)**

**Sebacic acid, bis(2-ethylhexyl) ester (CASRN 122-62-3)**  
**(CA Index Name: Decanedioic acid, 1,10-bis(2-ethylhexyl) ester)**  
**(9<sup>th</sup> CI Name: Decanedioic acid, bis(2-ethylhexyl) ester)**

### Supporting Chemicals

**Maleic acid, dibutyl ester (CASRN 105-76-0)**  
**(CA Index Name: 2-Butenedioic acid (2Z)-, 1,4-dibutyl ester)**  
**(9<sup>th</sup> CI Name: 2-Butenedioic acid (2Z)-, dibutyl ester)**

**Adipic acid, dibutyl ester (CASRN 105-99-7)**  
**(CA Index Name: Hexanedioic acid, 1,6-dibutyl ester)**  
**(9<sup>th</sup> CI Name: Hexanedioic acid, dibutyl ester)**

**Adipic acid, di-C7-9 branched and linear alkyl ester (CASRN 68515-75-3)**  
**(9<sup>th</sup> CI and CA Index Name: Hexanedioic acid, di-C7-9-branched and linear alkyl esters)**

**Adipic acid, bis(2-ethylhexyl) ester (CASRN 103-23-1)**  
**(CA Index Name: Hexanedioic acid, 1,6-bis(2-ethylhexyl) ester)**  
**(9<sup>th</sup> 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 chemicals. The information used by EPA includes data submitted under the HPV Challenge Program<sup>1</sup> and the 2006 Inventory Update Reporting (IUR)<sup>2</sup>, and data publicly available through other selected sources<sup>3</sup>. This screening-level prioritization presents EPA's initial thinking regarding the potential risks presented by these chemicals 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<sup>4</sup> through the EPA Chemical Assessment and Management Program (ChAMP)<sup>5</sup>.

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<sup>1</sup> US EPA, HPV Challenge Program information: <http://www.epa.gov/hpv/>.

<sup>2</sup> US EPA, IUR information: <http://www.epa.gov/oppt/iur/index.htm>

<sup>3</sup> US EPA, Information on additional public databases used: <http://www.epa.gov/hpvis/pubdtsum.htm>

<sup>4</sup> US EPA, U.S. Commitments to North American Chemicals Cooperation:  
<http://www.epa.gov/hpv/pubs/general/sppframework.htm>.

<sup>5</sup> US EPA, ChAMP information: <http://www.epa.gov/champ/>.

### **Hazard and Fate Summary:**

- **Human Health:** Acute oral and dermal toxicity of category members is low. Repeated-dose studies on various category members indicated low systemic toxicity, and no to low reproductive and developmental toxicity. Data indicate that the maleic acid esters would be strong dermal sensitizers and mild dermal and eye irritants.
- **Environment:** Available data indicate that the potential acute hazard to fish and aquatic plants is moderate for the maleic acid esters (CASRN 105-52-2 and 142-16-5) and the C12 adipic acid and sebacic acid esters (CASRN 6938-94-9 and 106-79-6) and low for the other category members. Available data indicate that the potential acute hazard to aquatic invertebrates is low for all category members. Available data for supporting chemical (CASRN 103-23-1) indicate chronic toxicity hazard of the C22 and above diester category members is low.
- **Persistence and Bioaccumulation:**
  - Available data indicate that these chemicals have low persistence.
  - Available data indicate that these chemicals have 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:** The ranges reported below are based on 2006 IUR submissions.
  - Eight category chemicals were HPV chemicals in 2005:

<u>CASRN</u>	<u>Production Volume (pounds)</u>
105-52-2	1-10 million
142-16-5	10-50 million
1330-86-5	1-10 million
33703-08-1	1-10 million
27178-16-1	10-50 million
16958-92-2	1-10 million
103-24-2	1-10 million
122-62-3	1-10 million
  - Three chemicals were moderate production volume (MPV) chemicals in 2005:

<u>CASRN</u>	<u>Production Volume (pounds)</u>
6938-94-9	< 500,000
28472-97-1	> 500,000 and < 1 million
106-79-6	< 500,000
  - One chemical did not have IUR submissions in 2005:  
CASRN 108-63-4.
- **Uses:** Non-confidential IUR information for many of the chemicals in the category indicates that they are used as lubricants in the manufacturing of basic organic chemicals and other chemical products and preparations and as intermediates, or functional fluids in various manufacturing processes. Ten of the eleven chemicals with IUR submissions are indicated to have uses in commercial settings or consumer uses. Information submitted as part of the HPV Challenge Program indicates that diester category chemicals have widespread applications as lubricants, solvents and plasticizers.
- **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. Some of these chemicals may be released to the environment from various waste streams.

- Workers: EPA identifies a medium relative ranking for potential worker exposure based on the vapor pressure and physical forms of these chemicals, potential dermal exposure during industrial processing and use activities and commercial uses, the number of workers, and the relatively high aggregated production volumes for all chemicals in this category.
- Consumers: EPA identifies a high potential that consumers may be exposed from using products containing these chemicals. Many category members have reported uses in commercial settings or consumer uses, including rubber and plastic products and electrical and electronic products.
- Children: EPA identifies a high potential that children might be exposed to chemicals in this category based on the use of products containing these chemicals. Two of these chemicals (CASRN 142-16-5, 33703-08-1) had reported uses in products intended to be used by children. Three chemicals (CASRN 27178-16-1, 103-24-2, and 122-62-3) reported that such information was Not Readily Obtainable.

#### **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. Chemicals in the diesters category have low persistence and low bioaccumulation. For fish, these characteristics, in combination with the moderate acute toxicity for the maleic acid esters (CASRN 105-52-2 and 142-16-5) and the C12 adipic acid and sebacic acid esters (CASRN 6938-94-9 and 106-79-6) (based on C14 supporting chemical data), indicate a medium concern for potential risk from the C12-C20 category members; and the potential exposure in combination with the low acute toxicity for esters above C20 indicate a low concern for potential risk. For aquatic invertebrates, these characteristics, in combination with the low acute toxicity for the diester category members, indicate a low concern for potential risk. For aquatic plants, the potential exposure in combination with the moderate acute toxicity to the C12 to C20 range indicates a medium concern for potential risks; the potential exposure in combination with the low acute toxicity for C20 and above indicates a low concern for potential risk. The low persistence and low bioaccumulation potential combined with the low chronic toxicity for C22 and above category members indicates a low risk of chronic toxicity for these category members.
- Potential Risk to the General Population from Environmental Releases: *LOW CONCERN*. EPA identifies a high potential that the general population may 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 worker exposure. The potential human health hazard is expected to be low. The available information suggests a low concern for potential risks 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. 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 for the supporting chemicals (CASRN 103-23-1 and 105-76-0). The available information suggests a low concern for potential risk to children for the category members.
- **Regulatory and Related Information Summary:**
- The category chemicals are listed on the TSCA Inventory. They are not otherwise currently regulated under TSCA.
- Three category members (CASRN 6938-94-9, 108-63-4, 103-24-2) are 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>.
- Additional regulatory information on supporting chemical CASRN 103-23-1 is provided in the individual RBP for that chemical.

#### **Assumptions and Uncertainties:**

- EPA has no information on releases of these chemicals, 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 adds uncertainty to the characterization of environmental hazard and risk.

#### **Rationale Leading To Prioritization Decision:**

- Available data suggest a medium concern for potential risk to fish and aquatic plants from four category members (CASRN 105-52-2, 142-16-5, 6938-94-9 and 106-79-6). This concern is driven by acute toxicity data combined with assumptions about the potential for environmental exposures. Information concerning chronic aquatic toxicity, releases to water, and resultant exposures would be useful in determining the extent of potential concern for fish and aquatic plants.
- Two category members (CASRN 105-52-2 and 142-16-5) could also be strong dermal sensitizers. Hazard communication and adherence to good industrial hygiene practices (protective clothing, goggles, engineering controls) would be expected in occupational settings that could involve direct skin contact with these chemicals.
- The hazard profiles are low for the other category members.

#### **Prioritization Decision:**

- **For CASRN 105-52-2, 142-16-5, 6938-94-9 and 106-79-6:** **MEDIUM PRIORITY, POTENTIAL CONCERN** – In order to further evaluate the medium concern for potential risk to fish and aquatic plants from the C12-C20 diesters (CASRN 105-52-2, 142-16-5, 6938-94-9 and 106-79-6), EPA has identified next steps involving efforts to develop a better understanding of hazard, exposure, and use of these

chemicals. 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 these chemicals;
- Information concerning potential releases to water from manufacturing, use and disposal of these chemicals and products containing these chemicals; and
- Other information pertinent to environmental exposures to these chemicals.

As an initial step in developing this understanding, companies that manufacture, process, or use these chemicals are encouraged to provide available information on a voluntary and non-confidential basis.

- **For CASRNs 1330-86-5, 108-63-4, 33703-08-1, 27178-16-1, 16958-92-2, 103-24-2, 28472-97-1 and 122-62-3:**  
LOW PRIORITY – Follow-up action not suggested at this time on the remaining members of the category.

**Supporting Documentation:**

**Screening-Level Risk Characterization: September 2008**

**Screening-Level Hazard Characterization: September 2008**

**Screening-Level Exposure Characterization: September 2008**