

Initial Risk-Based Prioritization of High Production Volume Chemicals

Rosin Esters Category

Rosin, pentaerythritol ester (CASRN 8050-26-8)

(9th CI and CA Index Name: Resin acids and Rosin acids, esters with pentaerythritol)

Rosin, glycerol ester (CASRN 8050-31-5)

(9th CI and CA Index Name: Resin acids and Rosin acids, esters with glycerol)

Rosin, diethylene glycol ester (CASRN 68153-38-8)

(9th CI and CA Index Name: Resin acids and Rosin acids, esters with diethylene glycol)

Rosin, methyl ester (CASRN 68186-14-1)

(9th CI and CA Index Name: Resin acids and Rosin acids, Me esters)

Rosin, hydrogenated, glycerol ester (CASRN 65997-13-9)

(9th CI and CA Index Name: Resin acids and Rosin acids, hydrogenated, esters with glycerol)

Rosin, hydrogenated, pentaerythritol ester (CASRN 64365-17-9)

(9th CI and CA Index Name: Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol)

Rosin, partially hydrogenated, methyl ester (CASRN 8050-15-5)

(9th CI and CA Index Name: Resin acids and Rosin acids, hydrogenated, Me esters)

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 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 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 these chemicals 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

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>

work being done in North America⁴ through the EPA Chemical Assessment and Management Program (ChAMP)⁵.

Hazard and Fate Summary:

- **Human Health:** Results from acute oral toxicity studies in rodents indicate that these chemicals have low hazard potential. Systemic toxicity in oral repeated-dose studies in rats is low. Two combined oral reproductive/developmental toxicity studies showed low developmental, reproductive and systemic toxicity. The category members were shown to be negative in genetic toxicity tests.
- **Environment:** Available acute toxicity data for fish, aquatic invertebrates and aquatic plants indicate the acute hazard to aquatic organisms is low based on no effects observed at the water solubility limit (saturation) of CASRNs 64365-17-9 and 8050-15-5. While the acute testing did not show toxicity in aquatic organisms, the physical-chemical properties and fate characteristics of the substances in this category indicate they are soluble or dispersible in water at concentrations that raise uncertainty regarding the potential to have chronic effects.
- **Persistence and Bioaccumulation:**
 - Available data indicate the persistence of CASRNs 68186-14-1, 8050-15-5, and 65997-13-9 to be moderate and the remaining four category members to be high.
 - Available data indicate the potential for bioconcentration in aquatic organisms for all category members is low.

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:** Non-confidential IUR information indicates that the category members were manufactured and/or imported at numerous companies and sites. There may be other companies and sites that are claimed as confidential. The ranges reported below are based on 2006 IUR submissions. Five category members were HPV chemicals:
 - CASRN 8050-26-8: = 50 - < 100 million lbs.
 - CASRNs 8050-31-5 and 65997-13-9: = 10 - < 50 million lbs.
 - CASRNs 64365-17-9 and 8050-15-5: = 1 - < 10 million lbs.Two category members were moderate production volume (MPV) chemicals:
 - CASRNs 68153-38-8, 68186-14-1: < 500,000 lbs.
- **Uses:** Non-confidential IUR information indicates the primary uses of these chemicals are as adhesives and binding agents. Six of the seven chemicals also reported commercial or consumer uses. The HPV Challenge Program submission indicates uses in hot melt adhesives, pressure sensitive adhesives, and chewing gum. Additionally, public data from the National Institutes of Health (NIH) Household Products Database identifies specific uses as adhesives for CASRNs 64365-17-9, 8050-26-8, and 8050-31-5.
- **General Population and Environment:** EPA identifies a high potential that the general population and the environment might be exposed to the chemicals in this category.

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/>.

- Workers: EPA identifies a high relative ranking for potential worker exposure. This relative ranking is based on the large number of industrial processing uses, potential dermal and inhalation exposure to solids and mist during industrial processing and use including commercial uses, substantially high production volume, and a relatively high number of potentially exposed workers. These chemicals do not have OSHA Permissible Exposure Limits (PELs).
- Consumers: EPA identifies a high potential that consumers might be exposed to these chemicals based on the use of products containing these chemicals. Six of the seven chemicals have IUR submissions that indicate uses in commercial settings or consumer uses. Non-confidential IUR information for many of these chemicals indicates that they are used in adhesives and binding agents.
- Children: EPA identifies a high potential that children might be exposed to these chemicals based on the use of products containing these chemicals. Non-confidential IUR information for CASRNs 8050-26-8 and 8050-31-5 reported uses in products intended to be used by children. Additional consumer uses, which may include products intended to be used by children, have been reported but were claimed to be CBI. CASRNs 68153-38-8 and 68186-14-1 reported no use in children's products.

Risk Characterization Summary:

- Potential Risk to Aquatic Organisms from Environmental Releases: *LOW CONCERN*. EPA identifies a high potential that aquatic organisms might be exposed to the chemicals in this category. Despite their moderate to high persistence, a low acute hazard to fish, invertebrates and plants considered in combination with low bioaccumulation suggest a low concern for potential risk of acute toxicity to these aquatic organisms from environmental releases.
- Potential Risk to the General Population from Environmental Releases: *LOW CONCERN*. EPA identifies a high potential that the general population might be exposed to the chemicals in this category. The potential human health hazard is expected to be low due to the lack of specific toxicity to animals following exposure to high doses. Despite the moderate to high persistence, the low hazard and low bioaccumulation suggest a low concern for potential risk to the general population from environmental releases.
- Potential Risk to Workers: *LOW CONCERN*. EPA identifies a high relative ranking for potential worker exposure. Overall, the potential health hazard of the category members is low. Therefore the available information suggests a low overall 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 these chemicals based on the use of products containing these chemicals. 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, the available information suggests a low concern for potential risks to consumers.
- Potential Risk to Children: *LOW CONCERN*. EPA identifies a high potential for exposures to children based on the use of products containing these chemicals. The potential human health hazard is expected to be low due to the lack of specific toxicity to

young animals following exposure to high doses. Therefore, the available information suggests a low concern for potential risks to children.

Regulatory and Related Information Summary:

- All of the chemicals appear on the TSCA Inventory. CASRNs 68153-38-8, 68186-14-1, 65997-13-9, and 8050-26-8 are not otherwise regulated.
- CASRNs 8050-31-5, 64365-17-9, and 8050-15-5 are considered as inert ingredients permitted for use in non-food use pesticide products under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).
- Canada, as a result of initial categorization of their Domestic Substances List (DSL), has designated two category members, CASRNs 65997-13-9 and 64365-17-9, as persistent, bioaccumulative and inherently toxic (PBiT) and has prioritized them for further consideration in proposed Batch10 under their Challenge program. If these chemicals are retained in Batch 10, the analyses supporting the PBiT determinations will be published for comment in spring 2009. In the meantime, EPA will share the information supporting its decisions with Canada.

Assumptions and Uncertainties:

- EPA has no information on releases of this chemical, and assumes potential exposures based on reported uses.
- Chronic aquatic toxicity data were identified as a data gap under the HPV Challenge Program. Given the physical-chemical properties and fate characteristics of these chemicals, additional information on environmental releases could be useful in determining whether or not it would be appropriate to conduct chronic aquatic toxicity studies.

Rationale Leading To Prioritization Decision:

- Available data suggest a low hazard to the environment and to humans in all potential exposure groups.

Prioritization Decision:

- LOW PRIORITY – Follow-up action not suggested at this time.
- Information on environmental releases and studies on chronic toxicity to aquatic organisms could help resolve the remaining uncertainty concerning potential environmental risk concerns.

Supporting Documentation:

Screening-Level Risk Characterization: September 2008

Screening-Level Hazard Characterization: September 2008

Screening-Level Exposure Characterization: September 2008