

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

### Rosin Adducts and Adduct Salts Category

#### Rosin, fumarated (CASRN 65997-04-8)

**Rosin, fumarated, sodium salt (CASRN 68201-59-2)**  
(CA Index Name: Resin acids and Rosin acids, fumarated, sodium salts)

**Rosin, fumarated, potassium salt (CASRN 68649-83-2)**  
(CA Index Name: Resin acids and Rosin acids, fumarated, potassium salts)

#### Rosin, maleated (CASRN 8050-28-0)

**Rosin, maleated, potassium salt (CASRN 85409-27-4)**  
(CA Index Name: Resin acids and Rosin acids, maleated, potassium salts)

**Rosin, maleated/fumarated (CASRN 68554-16-5)**  
(CA Index Name: Rosin, fumarated maleated)

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 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 work being done in North America<sup>4</sup> through the EPA Chemical Assessment and Management Program (ChAMP)<sup>5</sup>.

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

**Human Health:** Acute oral toxicity of members of the rosin adducts and adduct salts category is low. In a combined repeated-dose/reproductive/developmental toxicity study in rats, systemic,

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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/>.

developmental and reproductive toxicity were low. CASRN 65997-04-8 did not induce gene mutations or chromosomal aberrations *in vitro*.

- Environment: Available data indicate the acute hazard is low to fish, aquatic invertebrates, and aquatic plants based on no effects observed at the water solubility limit (saturation) of CASRN 65997-04-8. 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 uncertainties regarding the potential to have chronic effects.
- Persistence and Bioaccumulation:
  - Available data indicate that the salts in this category appear to have moderate persistence while the non-salts appear to have high persistence.
  - Available data indicate that all members of this category 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. Three of the chemicals are HPV chemicals:
  - CASRN 65997-04-8 and CASRN 68649-83-2: = 10 and < 50 million lbs.
  - CASRN 8050-28-0: = 1 and < 10 million lbs.One category member is a moderate production volume (MPV) chemical:
  - CASRN 68201-59-21: < 500,000 lbs.No IUR report was submitted for two chemicals:
  - CASRNs 68554-16-5 and 85409-27-4 had no 2006 IUR submissions.
- Uses: Non-confidential IUR information for the category members indicate that some of these chemicals are used as fixing agents in the manufacturing of other basic organic chemicals. Some other chemicals are used in the paper mill industry, or as intermediates in the manufacturing of soap and cleaning compounds. All four of the chemicals that have IUR submissions also have commercial or consumer uses. Information submitted to the HPV Challenge Program indicates the chemicals in this category are typically used as chemical intermediates to form derivatives that go into printing inks and a variety of surface coatings. CASRNs 68201-59-2, 68649-83-2, and 85409-27-4 are used in paper sizing to improve the final finish of the paper and to provide water resistance.
- General Population and Environment: Based on environmental fate and known uses, EPA identifies a medium potential that the general population and the environment might be exposed.
- Workers: EPA identifies a high relative ranking for potential worker exposure. This relative ranking is based on the potential for 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 (> 1,000 workers for each of three chemicals). These chemicals do not have OSHA Permissible Exposure Limits (PELs).
- Consumers: EPA identifies a high potential that consumers might be exposed based on the use of products containing the chemicals in this category. All four of the chemicals

that contain IUR submissions have commercial or consumer uses. Non-confidential IUR information for many of these chemicals indicates that they are used in paper products.

- **Children:** EPA identifies a medium potential that children might be exposed. All non-confidential IUR information indicates no uses in products intended to be used by children; however, children may be exposed through the household use of consumer products containing these chemicals.

#### **Risk Characterization Summary:**

- **Potential Risk to Aquatic Organisms from Environmental Releases:** *LOW CONCERN.* EPA identifies a medium potential that aquatic organisms might be exposed from environmental releases. Although these chemicals have moderate to high persistence, the low acute hazard to fish, aquatic invertebrates and aquatic plants, and low bioaccumulation suggest a low concern for potential risk of acute toxicity to aquatic organisms from environmental releases.
- **Potential Risk to the General Population from Environmental Releases:** *LOW CONCERN.* EPA identifies a medium 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. 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, 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 products containing the chemicals in this category. The potential human health hazard is expected to be low. Therefore, 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. 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:**

- The chemicals in this category are listed on the TSCA Inventory but are otherwise unregulated.

#### **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 Characterizations: September 2008**