Initial Risk-Based Prioritization of High Production Volume Chemicals

Tall Oil and Related Substances Category

Tall oil	**(CASRN 8002-26-4)**
Tall oil, sodium salt	**(CASRN 65997-01-5)**
Tall oil, potassium salt	**(CASRN 68647-71-2)**
Wastewater, tall-oil soap acidulation	**(CASRN 65997-02-6)**
Tall oil, disproportionated	**(CASRN 68152-92-1)**
Tall oil, disproportionated, potassium salt*	**(CASRN 68527-29-7)**
Tall-oil pitch	**(CASRN 8016-81-7)**
Tall-oil pitch, sodium salt	**(CASRN 68140-16-9)**

(*added to the category after the original HPV submission at the sponsor's request because fulfills HPV criteria based on the 2002 IUR)

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[1] and the 2006 Inventory Update Reporting (IUR)[2], and data publicly available through other selected sources[3]. 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[4] through the EPA Chemical Assessment and Management Program (ChAMP)[5].

Hazard and Fate Summary:

- Human Health: Available studies indicate that the acute oral toxicity for several members of this category is low. CASRN 8002-26-4 was selected as representative of this category for testing the remaining endpoints. Repeated oral exposures in animal studies showed low toxicity. There was no developmental toxicity and low reproductive toxicity observed in a combined repeated dose/reproductive/developmental toxicity screening test. CASRN 8002-26-4 did not show mutagenic potential or induce chromosomal effects in *in vitro* tests.
- Environment: Available data indicate that the potential acute hazard to fish, aquatic invertebrates and aquatic plants is low. Based on their environmental fate

[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/.

characterization (generally not persistent or bioaccumulative) the hazard to aquatic organisms under chronic exposure conditions is expected to be low for all category members except for CASRN 8016-81-7 and CASRN 68140-16-9. While CASRN 8016-81-7 and CASRN 68140-16-9 are moderately persistent (but not bioaccumulative), they are semi-solid/solid and virtually insoluble in water which is expected to limit chronic toxicity.

- Persistence and Bioaccumulation:
  - Available data indicate that CASRN 8016-81-7 and CASRN 68140-16-9 have moderate persistence. The other chemicals in this category have low persistence.
  - Available data indicate that the chemicals in 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.
  - Five category members are HPV chemicals:
    - CASRNs 8002-26-4 and 65997-02-6: = 1 billion lbs.
    - CASRN 65997-01-5: = 500 million and < 1 billion lbs.
    - CASRN 8016-81-7: =100 million and < 500 million lbs.
    - CASRN 68140-16-9: = 1 million and < 10 million lbs.
  - Two category members are MPV chemicals:
    - CASRN 68647-71-2: = 0.5 million and < 1 million lbs.
    - CASRN 68152-92-1: < 0.5 million lbs.
  - One category member does not have an IUR submission:
    - CASRN 65997-02-6.
- Uses: Non-confidential information in the IUR indicates that there are 45 manufacturers of crude CASRN 8002-26-4, all of which are paper manufacturers, and fractionators of CASRN 8002-26-4. Most companies and sites use the fractionated product(s) as a reactant or component in formulated products. There may be other companies and sites that are claimed confidential. Six of the eight chemicals in this category have IUR submissions. Non-confidential IUR information indicates a variety of uses for these chemicals including uses as intermediates, flotation agents, fuels, and adhesive and binding agents. All six chemicals have IUR submissions that indicate commercial or consumer uses. Information submitted as part of the HPV Challenge Program also provides information on uses. CASRN 8002-26-4 is used as a feedstock to the fractionation process and separated into rosin, fatty acids, distilled CASRN 8002-26-4, heads, pitch, etc. CASRN 65997-01-5 is used in the production of adhesives and binding agents, flotation agents, pigments, metalworking fluids and lubricants, and soaps and detergents. CASRN 65997-02-6, composed of dilute CASRN 8002-26-4, has no commercial value and is either recycled to the pulping process or diverted to wastewater treatment. CASRN 68140-16-9 is used in the asphalt industry as a bonding agent in paving applications or as a plasticizer in asphalt coatings. CASRN 68152-92-1 is used in the production of rubber and neoprene. CASRN 68647-71-2 is used in the production of soaps and detergents, metal-working fluids and lubricants. CASRN 8016-81-7 is used as a fuel by the CASRN 8002-26-4 processor, and in adhesives. The Hazardous Substances

Data Bank (HSDB) information for CASRN 8002-26-4 lists uses as the manufacturing of soap pastes, flotation agents, greases, paint, rubber formulation, cutting oils and sulfonated oils.

- General Population and Environment: EPA identifies a medium potential that the general population and the environment may be exposed based on information on known uses and environmental fate. There may be potential for environmental releases, although the quantity of releases to various media including water is unknown.
- Workers: EPA identifies a medium relative ranking for potential worker exposure. This relative ranking is based on the relatively non-volatile nature of these chemicals, the relatively high production volume, the industrial processing and use information, the relatively high number of sites, the potential for dermal exposure, and a relatively high number of potentially exposed workers. Members of this category do not have OSHA Permissible Exposure Limits (PELs).
- Consumers: EPA identifies a high potential that consumers may be exposed based on the use of products containing these chemicals. IUR submissions indicate that six of the chemicals have uses in commercial settings or consumer uses such as in paper products, soaps, polishes, and lubricants.
- Children: Based on known uses in products intended for children and that exposures to children may be expected to occur through the household use of some consumer products, EPA identifies a high potential that children might be exposed. Non-confidential IUR information for CASRN 8002-26-4 reported uses in products intended to be used by children. IUR submissions for CASRN 65997-01-5 and CASRN 8016-81-7 reported that such information was Not Readily Obtainable. IUR submissions for CASRN 65997-02-6 reported no uses in products intended to be used by children.

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. All category members have low bioaccumulation potential and six of the eight members have low environmental persistence. These characteristics in combination with the low acute toxicity for fish, invertebrates and aquatic plants, suggest a low concern for potential risk to aquatic organisms.
- 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 minimal toxicity in animals following repeated exposures at high doses. Given the low hazard and the environmental fate characteristics of low persistence (for most category members) and low bioaccumulation (all category members), the available information 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 potential 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*. EPA identifies a high potential that consumers may 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 may be exposed. Uses in products specifically intended to be used by children were reported in the IUR for some category members. Exposures to children may also be expected to occur through the household use of some consumer products. Available toxicity data exist with animals exposed postnatally and no toxicity was observed. The available information suggests a low concern for potential risks to children.

Regulatory and Related Information Summary:

- The members of this category are listed on the TSCA Inventory. They are not otherwise regulated under TSCA.
- CASRN 8002-26-4 is listed as an inert substance of unknown toxicity under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Assumptions and Uncertainties:

- EPA has no information on releases of these chemicals, and assumes potential exposures based on reported uses.

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.

Supporting Documentation:

Screening-Level Risk Characterization: September 2008
Screening-Level Hazard Characterization: September 2008
Screening-Level Exposure Characterization: September 2008