Initial Risk-Based Prioritization of High Production Volume Chemicals

Tall Oil Fatty Acids and Related Substances Category

Sponsored Chemicals

Fatty acids, tall-oil	**(CASRN 61790-12-3)**
Fatty acids, tall-oil, sodium salts	**(CASRN 61790-45-2)**
Fatty acids, tall-oil, potassium salts	**(CASRN 61790-44-1)**
Fatty acids, tall-oil, low-boiling	**(CASRN 65997-03-7)**
Fatty acids, C16-18 and C18-unsatd., branched and linear	**(CASRN 68955-98-6)**
Octadecanoic acid, branched and linear	**(CASRN 68201-37-6)**

Supporting Chemicals

Fatty acids, C16-C18 and C18-unsatd., branched and linear, sodium salts (also known as Monomer acid, sodium salt)	**(CASRN 252363-93-2)**
Fatty acids, C16-C18 and C18-unsatd., branched and linear, calcium salt (Monomer acid, calcium salt)	**(No CASRN)**

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:

- CASRN 61790-12-3 was selected as representative of this category for testing purposes.
- Human Health: Available studies indicate that the acute oral toxicity for the members of this category is low. Repeated exposures to CASRN 61790-12-3 via the oral route did not produce any signs of toxicity in animal studies. No reproductive or developmental

[1] US EPA, HPV Challenge Program information: http://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/.

toxicity was observed in rats exposed to CASRN 61790-12-3 in the diet for two generations. Mutagenicity data with *in vitro* tests for the category member CASRN: 61790-12-3 and the supporting chemical, monomer acid, sodium salt, showed no effects. Other *in vitro* tests with CASRN 61790-12-3 and the supporting chemical, monomer acid, calcium salt (no CASRN), did not induce chromosomal effects.

- Environment: Available studies indicate that the potential acute hazard to fish, aquatic invertebrates, and aquatic plants is low.
- Persistence and Bioaccumulation:
  - Available data indicate that the 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:
    - CASRN 61790-45-2: = 500 million and < 1 billion lbs.
    - CASRN 61790-12-3: = 100 million and < 500 million lbs.
    - CASRN 65997-03-7: = 50 million and < 100 million lbs.
    - CASRNs 61790-44-1 and 68955-98-6: = 1 million and < 50 million lbs.
  - One category member did not have IUR submissions in 2006:
    - CASRN 68201-37-6
- Uses: Non-confidential IUR information indicates a variety of uses for the six members of this category, including uses as intermediates, lubricants, surfactants, flotation agents, viscosity adjustors, fuels, and adhesives.
- General Population and Environment: EPA identifies a medium potential that the general population and the environment might be exposed based on environmental fate and known uses. Based on use information, 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 based on the non-volatile nature of these chemicals, high production volume, industrial processing and use information, high number of sites, potential for dermal exposure, and a high number of potentially exposed workers. Category members do not have OSHA Permissible Exposure Limits (PELs).
- Consumers: EPA identifies a high potential that consumers might be exposed to these chemicals in consumer products. The substances in this category are consumed mostly as industrial intermediates, where they are reacted or further distilled to produce other chemicals. However, five of the six members of this category have IUR submissions that indicate commercial/consumer uses.
- Children: EPA identifies a high potential that children might be exposed to these chemicals in household products. Non-confidential IUR information for CASRN 61790-44-1 includes uses in products intended to be used by children. IUR submissions for the remainder of the category members reported no uses in products intended to be used by children. Exposures to children, however, may be expected to occur through the household use of some consumer products.

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 both low persistence and low bioaccumulation potential. These characteristics, in combination with the low acute toxicity for fish, aquatic 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 no adverse effects observed in animals following repeated exposures at high doses. Given the low hazard and the environmental fate characteristics of low persistence and low bioaccumulation potential for all category members, the available information suggests a low concern for potential risk to the general population from environmental releases.
- Potential Risk to Workers: *LOW CONCERN*. EPA identifies a medium potential for worker exposure. The potential human health hazard is expected to be low. Therefore, the available information suggests a low concern for potential risk 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. Therefore, the available information suggests a low concern for potential risk to consumers.
- Potential Risk to Children: *LOW CONCERN*. EPA identifies a high potential that children may be exposed. Use in products specifically intended to be used by children were reported in the IUR for one category member. Exposures to children may also be expected to occur through the household use of some consumer products. Available hazard data in which animals were exposed to the test substance both pre- and post-natally showed no adverse effects. Therefore, the available information suggests a low concern for potential risk to children.

Regulatory and Related Information Summary:

- The members of the category are listed on the TSCA Inventory. They are not otherwise regulated under TSCA.
- CASRN 61790-12-3 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