Supporting Documents for 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)**

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BACKGROUND

Screening-level hazard, exposure and risk characterizations for high production volume chemicals (HPV) are important contributions to the chemicals cooperation work being done in North America[1] through the EPA Chemical Assessment and Management Program (ChAMP)[2]. These screening-level characterizations are developed by EPA for individual chemicals or chemical categories to support initial Risk-Based Prioritizations (RBPs) for HPV chemicals. These screening-level characterizations are technical documents intended primarily to inform the Agency's internal decision-making process. Accordingly, they are written for assessment professionals and assume a degree of technical understanding. Each of the support documents is described below.

The Risk-Based Prioritizations are found in an accompanying document and are written for a general audience. They present EPA's initial thinking regarding the potential risks presented by these chemicals and future possible actions that may be needed.

Hazard Characterizations for HPV Chemicals

EPA's screening-level hazard characterizations are based primarily on the review of the summaries of studies and other information submitted by the chemical sponsor(s) under the HPV Challenge Program[3]. These studies included in the scope of the HPV Challenge comprise the Screening Information Data Set (SIDS) of the Organization for Economic Cooperation and Development (OECD)[4], an internationally recognized battery of tests that provides the basic data necessary to make an initial evaluation of a chemical's hazards and fate. In preparing the initial hazard characterizations, EPA also consulted a variety of reliable sources[5] for additional relevant information and considered its own comments and public comments on the original submission as well as the sponsor's responses to comments and revisions made to the submission. In order to determine whether any new hazard information was developed since the time of an HPV submission, EPA also searched publicly available databases[6] for information entered from one year prior to the HPV submission through May 2008. The screening-level hazard characterization is performed according to established EPA guidance[7]. A more detailed description of the hazard characterization process is available on the EPA website[8].

With respect to chemicals for which internationally-accepted OECD SIDS Initial Assessment Profiles (SIAP) and Initial Assessment Reports (SIAR) were available, EPA did not generate its own screening-level hazard characterization, but did check for and incorporate updated information in the risk characterization.

Exposure Characterizations for HPV Chemicals

EPA recently received exposure-related data on chemicals submitted in accordance with the requirements of Inventory Update Reporting (IUR)[9]. The 2006 IUR submissions pertain to chemicals manufactured in

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[1] U.S. EPA – U.S. Commitments to North American Chemicals Cooperation: http://www.epa.gov/hpv/pubs/general/sppframework.htm.
[2] U.S. EPA – ChAMP information: http://www.epa.gov/champ/.
[3] U.S. EPA – HPV Challenge Program information: http://www.epa.gov/hpv.
[4] U.S. EPA – Technical Guidance Document, OECD SIDS Manual Sections 3.4 and 3.5: http://www.epa.gov/chemrtk/pubs/general/sidsappb.htm.
[5] U.S. EPA – Public Database Hazard Information: http://www.epa.gov/hpvis/hazardinfo.htm.
[6] U.S. EPA – Public Database Update Information: http://www.epa.gov/chemrtk/hpvis/updateinfo.htm.
[7] U.S. EPA – Risk Assessment Guidelines: http://cfpub.epa.gov/ncea/raf/rafguid.cfm.
[8] U.S. EPA – About HPV Chemical Hazard Characterizations: http://www.epa.gov/hpvis/abouthc.htm.
[9] U.S. EPA – Basic IUR Information: http://www.epa.gov/opptintr/iur/pubs/guidance/basic-information.htm.

(including imported into) the U.S. during calendar year 2005 in quantities of 25,000 pounds or more at a single site. The reports include the identity, the quantity, and the physical form of the chemical manufactured or imported, and the number of workers reasonably likely to be exposed during manufacture of the chemical. For chemicals manufactured or imported in quantities of 300,000 pounds or more at a single site, additional reported information includes: the industrial processing and uses of the chemical; the number of industrial processing sites and workers reasonably likely to be exposed to the chemical at those sites; the consumer and commercial uses of the chemical; and an indication whether the chemical was used in products intended for use by children under 14 years of age.

EPA's screening-level exposure characterizations are based largely on the information submitted under the IUR reporting, although other exposure information submitted to the Agency (for example, in HPV submissions) or readily available through a limited set of publicly accessible databases[10] was also considered. The screening-level exposure characterizations identify a potential (high, medium, or low) that each of five populations – the environment, the general population, workers, consumers, and children – might be exposed to the chemical. In most cases, this potential doesn't address the quantity, frequency, or duration of exposure, but refers only to the likelihood that an exposure could occur.

In many instances EPA is not able to fully disclose to the public all the IUR exposure-related data reviewed or relied upon in the development of the screening-level documents because some of the material was claimed as confidential business information (CBI) when it was submitted to the Agency. These CBI claims do limit the Agency's ability to be completely transparent in presenting some underlying exposure and use data for chemicals in public documents. EPA does consider all data, including data considered to be CBI, in the screening-level exposure and risk characterization process, and endeavors whenever possible to broadly characterize supporting materials claimed as confidential in ways that do not disclose actual CBI.

Risk Characterizations for HPV Chemicals

EPA combines the information from the screening-level exposure characterization with the screening-level hazard characterization to develop a qualitative screening-level risk characterization, as described in the Agency's guidance on drafting risk characterizations[11]. These screening-level risk characterizations are technical documents intended to support subsequent priority-setting decisions and actions by OPPT. The purpose of the qualitative screening-level risk characterization is two-fold: to support initial risk-based decisions to prioritize chemicals, identify potential concerns, and inform risk management options; and to identify data needs for individual chemicals or chemical categories.

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. Recommended actions reflect EPA's relative judgment regarding this chemical or chemical category in comparison with others evaluated under this program, as well as the uncertainties presented by gaps that may exist in the available data.

[10] U.S. EPA – Summary of Public Databases Routinely Searched: http://www.epa.gov/chemrtk/hpvis/pubdtsum.htm.
[11] U.S. EPA – Risk Characterization Program: http://www.epa.gov/osa/spc/2riskchr.htm

QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION OF HIGH PRODUCTION VOLUME CHEMICALS

CHEMICAL CATEGORY NAME
Tall Oil Fatty Acids and Related Substances

SPONSORED CHEMICALS

Fatty acids, tall oil	**CAS No. 61790-12-3**
Fatty acids, tall oil, sodium salts	**CAS No. 61790-45-2**
Fatty acids, tall oil, potassium salts	**CAS No. 61790-44-1**
Fatty acids, tall oil, low boiling	**CAS No. 65997-03-7**
Fatty acids, C16-C18 and C18 unsaturated, branched and linear	**CAS No. 68955-98-6**
Octadecanoic acid, branched and linear	**CAS No. 68201-37-6**

SUPPORTING CHEMICALS

Fatty acids, C16-C18 and C18 unsaturated, branched and linear, sodium salt (Monomer acid, sodium salt)	**No CAS No.**
Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt (Monomer acid, calcium salt)	**No CAS No.**

September 2008

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QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION FOR Tall Oil Fatty Acids and Related Substances

1. Category Justification

The six members of the tall oil fatty acids and related substances category are all derived from or are closely related to tall oil fatty acids (TOFA). TOFA is a substance obtained by the fractional distillation of crude tall oil, a by-product from the pulping of pine trees. The substances in this category are complex mixtures, also called Class 2 substances, which means that they are composed of several chemicals at concentrations that vary depending on their source or methods of derivation. Although each species of pine tree yields a somewhat different mix of TOFA, all members of this category are similar in chemical composition. The sponsor reported that a typical tall oil fatty acid is composed of 86% fatty acids, 4 % other acids and 2% unsaponifiable matter.

Tall oil fatty acid (TOFA) is the raw material from which all the other group members, except "fatty acids, tall oil, low boiling," are derived. TOFA was selected as representative of this category for testing purposes because all the substances in the tall oil fatty acids category are similar in chemical composition, being predominantly C18 unsaturated and saturated fatty acids, or their salts. Consequently, test results obtained on TOFA are most representative of the category.

In comments on the original test plan EPA requested that additional information on the category members be provided and the sponsor did supply the information (details may be found in the Hazard Characterization). This category is considered acceptable and reasonable for the purposes of the HPV Challenge Program and ChAMP.

Additional data are available in the following related categories: Tall oils and related substances, Rosin and rosin salts, Rosin esters, Rosin adducts and adducts salts.

2. Physical-Chemical Properties and Environmental Fate

Tall oil fatty acids and the other non-salts in this grouping category are liquids at room temperature; fatty acids tall oil sodium and potassium salts are solids. The members of this category have moderate to negligible vapor pressure and moderate solubility except for the salts which are dispersible in water. The members of this category have low mobility. They are expected to degrade at moderate rates by biodegradation and by atmospheric photooxidation, and negligible rates by hydrolysis. The persistence and bioaccumulation ranking for the members of this category are low (P1 and B1).

3. Hazard Characterization

Tall oil, fatty acid (CAS# 61790-12-3) was selected as representative of this category for testing purposes.

Aquatic Organism Toxicity: The evaluation of available toxicity data for fish and aquatic invertebrates and aquatic plants indicates the potential acute hazard to aquatic organisms is low based primarily on no effects observed at the water solubility limit (saturation) of category members.

Human Health Toxicity: The acute oral toxicity for the members of this category is low, based on testing of the category member, TOFA, and the supporting chemicals, monomer acid, sodium and calcium salts. Repeated exposures to TOFA via the oral route did not produce any signs of toxicity in animal studies. No reproductive or developmental toxicity was observed in rats exposed to TOFA in the diet for two-generations. Mutagenicity data with *in vitro* tests for the category member TOFA and the supporting chemical, monomer acid, sodium salt, showed no effects. Other *in vitro* tests with TOFA and the supporting chemical, monomer acid, calcium salt, did not induce effects on the chromosome.

4. Exposure Characterization

Five of the six chemicals in the tall oil and related substances category (CAS # 61790-12-3; 61790-44-1; 61790-45-2; 65997-03-7; and 68955-98-6) have aggregated production and/or import volume in the United States of 650 million to 1.7 billion pounds. The sixth, octadecanoic acid, branched and linear (CAS # 68201-37-6), does not have an Inventory Update Reporting (IUR) submission.

Non-confidential information in the IUR indicates that these chemicals were manufactured and/or imported at numerous companies and sites. Most companies and sites use the fractionated product(s) as a reactant or component in formulated products. Non-confidential IUR information indicates a variety of uses for the chemicals in the tall oil fatty acids category, including uses as intermediates, lubricants, surfactants, flotation agents, viscosity adjustors, fuels, and adhesives.

Information submitted as part of the HPV Challenge Program provides information on manufacturing, processing, and use. Tall oil fatty acid (TOFA) is a distillation fraction of crude tall oil. Crude tall oil is fractionally distilled to yield several fractions, two of which are included in this category: TOFA (CAS # 61790-12-3) and fatty acids, tall oil, low boiling (CAS # 65997-03-7). The remaining members of this group are all derived from TOFA.

The HPV submission indicates that TOFA and the other substances in this category are consumed almost entirely as industrial intermediates where they are reacted or further distilled to produce other chemicals. Of the various TOFA distillation and reaction products, it is estimated that greater than 75% are marketed and consumed in non-dispersive commercial applications in the production of dimer acids, polyamide adhesive resins, alkyd resins for paint, polyester lubricants, plasticizers, and metal working fluids. The main use of TOFA is as a raw material for the production of a wide variety of other chemicals. The largest single use of TOFA is for the production of dimer acids that are then converted into coatings, adhesives, and printing inks. Another important end use for tall oil fatty acids is in the production of alkyd resins that go into paints and printing inks. The tall oil fatty acid sodium or potassium salts are used as surfactants in liquid soaps for both industrial and household cleaning and disinfectant products. They also find uses in metal working fluids and in lubricants. Octadecanoic acid, branched and linear

(hydrogenated monomer) is an intermediate in the production of isostearic acid from monomer acid and does not have any other specific commercial use.

Potential Exposures to the General Population and the Environment: Based on use information, there may be potential for environmental releases, although the quantity of releases to various media including water is unknown. These chemicals are not expected to be persistent in the environment (P1) and their bioaccumulation potential (B1) is low. Based on the information considered, including environmental fate, known uses, and the Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a medium potential that the general population and the environment might be exposed.

Potential Exposures to Workers: Based on the information considered and in combination with the Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, 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 relatively high number of potentially exposed workers. Tall oil fatty acids do not have OSHA Permissible Exposure Limits (PELs).

Potential Exposures to Consumers: EPA identifies, for the purposes of risk-based prioritization, a high potential that consumers might be exposed based on the use of products containing these chemicals. Though the substances in this category are reported to be consumed mostly as industrial intermediates, where they are reacted or further distilled to produce other chemicals, five of the six TOFAs, have IUR submissions that indicate commercial/consumer uses. Public information from the National Institutes of Health Household Products Database indicates that fatty acids, tall oil (CAS # 61790-12-3) is used in several consumer products, including car wax, hand cleaner, metal polish, and heavy-duty disinfectant cleaner, and that fatty acids, tall oil, sodium salts (CAS # 61790-45-2) is used in hand cleaners.

Potential Exposures to Children: EPA identifies, for the purposes of risk-based prioritization, a high potential that children might be exposed. Specifically, non-confidential IUR information for tall oil fatty acid potassium salts (CAS # 61790-44-1) reported uses in products intended to be used by children. Though IUR submissions for the remainder of the tall oil fatty acids category reported no uses in products intended to be used by children, exposures to children, may be expected to occur through the household use of some consumer products.

5. Risk Characterization

The statements and rationale provided below are intended solely for the purpose of this screening-level and qualitative risk characterization and will be used for prioritizing substances for future work in the Chemical Assessment and Management Program (ChAMP).

Risk Statement and Rationale

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 bioaccumulation potential and 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 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 for 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 due to no adverse effects observed in animals following repeated exposures at high doses. Therefore, taken together, 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 due to no adverse effects observed in animals following repeated exposures at high doses. Taken together, 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. 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 postnatally showed no adverse effects. Taken together, the available information suggests a low concern for potential risks to children.

SCREENING-LEVEL HAZARD CHARACTERIZATION OF HIGH PRODUCTION VOLUME CHEMICALS

CHEMICAL CATEGORY NAME
Tall Oil Fatty Acids and Related Substances

SPONSORED CHEMICALS

Fatty acids, tall oil	**CAS No. 61790-12-3**
Fatty acids, tall oil, sodium salts	**CAS No. 61790-45-2**
Fatty acids, tall oil, potassium salts	**CAS No. 61790-44-1**
Fatty acids, tall oil, low boiling	**CAS No. 65997-03-7**
Fatty acids, C16-C18 and C18 unsaturated, branched and linear	**CAS No. 68955-98-6**
Octadecanoic acid, branched and linear	**CAS No. 68201-37-6**

SUPPORTING CHEMICALS

Fatty acids, C16-C18 and C18 unsaturated, branched and linear, sodium salt (Monomer acid, sodium salt)	**CAS No. not assigned**
Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt (Monomer acid calcium salt)	**CAS No. not assigned**

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SCREENING-LEVEL HAZARD CHARACTERIZATION
Tall Oil Fatty Acids and Related Substances Category

Introduction

The sponsor, Pine Chemicals Association, submitted a Test Plan and Robust Summaries to EPA for the Tall Oil Fatty Acids and Related Substances Category on May 23, 2001. EPA posted the submission on the ChemRTK Web site on June 14, 2001 (http://www.epa.gov/chemrtk/pubs/summaries/tofars/c13055tc.htm). EPA comments on the original submission were posted to the website on December 3, 2001. Public comments were also received and posted to the website. The sponsor submitted revised/final documents on March 5, 2002 and August 9, 2004, which were posted to the ChemRTK website on September 24, 2002 and September 20, 2004, respectively. The Tall Oil Fatty Acids and Related Substances category consists of the following substances:

Sponsored Chemicals

Fatty acids, tall oil	CAS No. 61790-12-3
Fatty acids, tall oil, sodium salts	CAS No. 61790-45-2
Fatty acids, tall oil, potassium salts	CAS No. 61790-44-1
Fatty acids, tall oil, low boiling	CAS No. 65997-03-7
Fatty acids, C16-C18 and C18 unsaturated, branched and linear	CAS No. 68955-98-6
Octadecanoic acid, branched and linear	CAS No. 68201-37-6

Supporting Chemicals

Fatty acids, C16-C18 and C18 unsaturated, branched and linear, sodium salt (Monomer acid, sodium salt)	CAS No. not assigned
Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt (Monomer acid, calcium salt)	CAS No. not assigned

This screening-level hazard characterization is based primarily on the review of the Test Plan and Robust Summaries of studies submitted by the sponsor(s) under the HPV Challenge Program. In preparing the hazard characterization, EPA considered its own comments and public comments on the original submission as well as any sponsor responses to comments and revisions made to the submission. In order to determine whether any new hazard information was developed since the time of the HPV submission, a search of the following databases was made from 2004 to April 2008: the NLM databases (ChemID to locate available data sources including Medline/PubMed, Toxline, HSDB, ATSDR, EPA SRS, etc.), STN/CAS online databases (Registry file for locators, ChemAbs for toxicology data, RTECS, Merck, etc.) and Science Direct. The structures of the sponsored chemicals are included in the appendix. Summary tables of SIDS endpoint data are included in the document. The screening-level hazard characterization for environmental and human health toxicity is based largely on SIDS endpoints and is described according to established EPA or OECD effect level definitions and hazard assessment practices.

Category Justification

The six members of the tall oil fatty acids and related substances category are all derived from or are closely related to tall oil fatty acids (TOFA). TOFA is a substance obtained by the fractional distillation of crude tall oil, a by-product from the pulping of pine trees. The substances in this category are complex mixtures, also called Class 2 substances, which means that they are composed of several chemicals with concentrations that vary depending on their source or methods of derivation. Although each species of pine tree yields a somewhat different mix of TOFA, all members of this category are similar in chemical composition. The sponsor reported that a typical tall oil fatty acid is composed of 86% fatty acids, 4 % other acids and 2% unsaponifiable matter. Representative tall oil fatty acid structures are depicted in the appendix.

Tall oil fatty acids (TOFA) is the raw material from which all the other group members, except "fatty acids, tall oil, low boiling," are derived. TOFA was selected as representative of this category for testing purposes because all the substances in the tall oil fatty acids category are similar in chemical composition, being predominantly C18

unsaturated and saturated fatty acids, or their salts. Consequently, test results obtained on TOFA are most representative of the category.

In comments on the original test plane EPA requested further justification for the inclusion of fatty acids, C16-C18 and C18 unsaturated, branched and linear (CAS No. 68955-98-6; also called "monomer acid") and octadecanoic acid, branched and linear (CAS No. 68201-37-6; also called "hydrogenated monomer acid") because 50% of the composition of these two category members differed from the other four. EPA also requested confirmation that the branched and "probably cyclic" constituents cited in the test plan arise from the processing of tall oil fatty acid to other products. In its revised test plan, the sponsor provided additional data from testing conducted on monomer acid sodium or calcium salts. Although these chemicals are not HPV chemicals both of these salts of monomer acid readily dissociate into monomer acid in aqueous solution; thus, the test results for either of these monomer acid salts should be the functional equivalent of the non-salt (i.e., monomer acid). Likewise, the results should also be representative of octadecanoic acid due to similarity of composition and structure, octadecanoic acid being the hydrogenated form of monomer acid. Further, the sponsor confirmed that the cyclic structures in monomer acid are predominantly 1,2-di-substituted six-member rings that arise from the cyclization of the linoleic and linolenic acids present in TOFA. Based on this additional information, EPA agreed with the support for the category.

Hazard Characterization

Tall oil fatty acids and the other non-salts in this grouping category are liquids at room temperature; fatty acids tall oil sodium and potassium salts are solids. The members of this category have moderate to negligible vapor pressure and moderate solubility except for the salts which are dispersible in water. The members of this category have low mobility. They are expected to degrade at moderate rates by biodegradation and by atmospheric photooxidation, and negligible rates by hydrolysis. The persistence and bioaccumulation ranking for the members of this category are low (P1 and B1).

The evaluation of available toxicity data for fish and aquatic invertebrates and aquatic plants indicates the potential acute hazard to aquatic organisms is low based primarily on no effects observed at the water solubility limit (saturation) of category members.

The acute oral toxicity for the members of this category is low, based on testing of the category member, TOFA, and the supporting chemicals, monomer acid, sodium and calcium salts. Repeated exposures to TOFA via the oral route did not produce any signs of toxicity in animal studies. No reproductive or developmental toxicity was observed in rats exposed to TOFA in the diet for two-generations. Mutagenicity data with *in vitro* tests for the category member TOFA and the supporting chemical, monomer acid, sodium salt, showed no effects. Other *in vitro* tests with TOFA and the supporting chemical, monomer acid, calcium salt, did not induce effects on the chromosome.

No data gaps were identified under the HPV Challenge Program.

1. Physical-Chemical Properties and Environmental Fate

The physical-chemical properties of tall oil fatty acids and its related compounds are summarized in Table 1a, while the environmental fate properties are provided in Table 1b. Structures of all compounds are in the Appendix.

Physical-Chemical Properties Characterization

Tall oil fatty acids and the other non-salts in this grouping category are liquids at room temperature; fatty acids tall oil sodium and potassium salts are solids. The members of this category have moderate to negligible vapor pressure and moderate solubility except for the salts which have high solubility.

Table 1a. Physical Chemical Properties of Tall Oil, Fatty Acids, and Related Compounds [1]						
Endpoints	**Fatty acids, tall oil**	**Fatty acids, tall oil, sodium salts**	**Fatty acids, tall oil, potassium salts**	**Fatty acids, tall oil, low boiling**	**Fatty acids, C16-C18 & C18 unsaturated, branched and linear (Monomer acid)**	**Octadecanoic acid, branched and linear**
CAS No.	61790-12-3	61790-45-2	61790-44-1	65997-03-7	68955-98-6	68201-37-6
Molecular Weight[2]	No Data	No Data	No Data	No Data	No Data	No Data
Physical State	Liquid	Solid	Solid	Liquid	Liquid	Liquid
Melting point	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]
Boiling point	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]
Vapor pressure	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]
Water solubility	**12.6 mg/L (measured)**	Dispersible	Dispersible	**22.8 mg/L (measured)**	**15 mg/L (measured)**	**2.5 mg/L (measured)**
Henry's Law Constant	No Data	No Data	No Data	No Data	No Data	No Data
Log K_{ow}	**4.9-7.6 (pH 2) 3.6-7.4 (pH 7.5) (measured)**	**4.9-7.6 (pH 2) (measured)**	**4.9-7.6 (pH 2) (measured)**	**4.4-7.8 (pH 2) 4.6-8.0 (pH 7.5) (measured)**	**4.9 (pH 2) (measured)**	**5.6-6.1 (pH 2) (measured)**

[1] Pine Chemicals Association. 2004. Final Submission for Tall Oil Fatty Acids and Related Substances. http://www.epa.gov/chemrtk/pubs/summaries/tofars/c13055tc.htm
[2] These complex mixtures will not have a well-defined molecular weight, melting point, boiling point, vapor pressure or Henry's Law constant.

Environmental Fate Characterization

Tall oil fatty acids and its related substances possess low mobility. They are expected to degrade at moderate rates by biodegradation and by photolysis, and negligible rates by hydrolysis. The components of these mixtures are carboxylic acids that will exist primarily as anions in the environment; therefore, volatilization is negligible. Bioaccumulation is expected to be low based on estimated bioconcentration factors (BCF) of 10 for some representative components of these mixtures. The persistence and bioaccumulation rankings for this category are low (P1 B1).

Table 1b Environmental Fate Properties of Tall Oil, Fatty Acids, and Related Compounds [1]						
Endpoints	**Fatty acids, tall oil**	**Fatty acids, tall oil, sodium salt**	**Fatty acids, tall oil, potassium salt**	**Fatty acids, tall oil, low boiling**	**Fatty acids, C16-C18 & C18 unsaturated, branched and linear (Monomer acid)**	**Octadecanoic acid, branched and linear**
Photodegradation Half-life	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]
Hydrolysis Half-life	Stable	Stable	Stable	Stable	Stable	Stable
Biodegradation	**56-84% Readily biodegradable (measured)**	**98% Readily biodegradable (measured)**	**79% Inherently biodegradable (measured)**	**41% Readily biodegradable (measured)**	**67% Readily biodegradable (measured)**	**47% Readily biodegradable (measured)**
Bioconcentration (BCF)[3]	10 (oleic acid) 10 (linoleic acid) (estimated)	10 (oleic acid) 10 (linoleic acid) (estimated)	10 (oleic acid) 10 (linoleic acid) (estimated)	10 (oleic acid) 10 (linoleic acid) 10 (palmitic acid) (estimated)	10 (eladic acid) (estimated)	10 (stearic acid) (estimated)
Log K_{oc}	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]
Fugacity	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]
Persistence[4]	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)
Bioaccumulation[4]	B1 (low)	B1 (low)	B1 (low)	B1 (low)	B1 (low)	B1 (low)

[1] Pine Chemicals Association. 2004. Final Submission for Tall Oil Fatty Acids and Related Substances. http://www.epa.gov/chemrtk/pubs/summaries/tofars/c13055tc.htm
[2] These complex mixtures will not have well-defined photodegradation, K_{oc} and distribution in the environment (fugacity); therefore these endpoints were not estimated.
[3] US EPA. 2008. Estimation Programs Interface Suite™ for Microsoft® Windows, v 3.20. United States Environmental Protection Agency, Washington, DC, USA. http://www.epa.gov/opptintr/exposure/pubs/episuite.htm
[4] FR 1999, Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) Page 60194-60204.

Conclusion: Tall oil fatty acids and the other non-salts in this grouping category are liquids at room temperature; fatty acids tall oil sodium and potassium salts are solids. The members of this category have moderate to negligible vapor pressure and moderate solubility except for the salts which are dispersible in water. The members of this category have low mobility. They are expected to degrade at moderate rates by biodegradation and by atmospheric photooxidation, and negligible rates by hydrolysis. The persistence and bioaccumulation rankings for the members of this category are low (P1 and B1).

2. Environmental Effects – Aquatic Toxicity

A summary of aquatic toxicity data submitted for SIDS endpoints is provided in Table 2. The table also indicates where data for tested category members are read-across (RA) to untested members of the category.

Acute Toxicity to Fish

Fatty acids, tall oil (TOFA; CAS No. 61790-12-3)
Fathead minnows (*Pimephales promelas*) were exposed to the test substance as water accommodated fractions (WAFs) under static conditions for 96 hours. The loading rates were 0, 1, 10, 100 or 1000 mg/L and no analytical measurements were made on the WAFs. No effects were noted at any of the WAF loading rates. EPA does not consider the loading rate as the no effect concentration when the concentration exceeds the water solubility of the substance. Assuming exposure concentration in the WAF is the water solubility limit (saturation) for fatty acid, tall oil, the no effect concentration would be approximately 12.6 mg/L.
No effects at saturation

Fatty acids, C16-C18 and C18 unsaturated, branched and linear (monomer acid; CAS No. 68955-98-6)
Golden orfe *(Leuciscus idus)* were exposed to the test substance as water accommodated fractions (WAFs) under static conditions for 96 hours. The loading rate was 1000 mg/L and no analytical measurements were made on the WAFs. No effects were noted at the WAF loading rate. EPA does not consider the loading rate as the no effect concentration when the concentration exceeds the water solubility of the substance. Assuming exposure concentration in the WAF is the water solubility limit (saturation) for fatty acids, C16-C18 and C18 unsaturated, branched and linear, the no effect concentration would be approximately 15.0 mg/L.
No effects at saturation

Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt (monomer acid; calcium salt, CAS No. not assigned; supporting chemical)
Rainbow trout (Oncorhynchus mykiss) were exposed to the test substance as water accommodated fractions (WAFs) under static conditions for 96 hours. The loading rate was 100 mg/L and no analytical measurements were made on the WAFs. No effects were noted at the WAF loading rate.
No effects at saturation

Acute Toxicity to Aquatic Invertebrates

Fatty acids, tall oil (TOFA; CAS No. 61790-12-3)
Daphnia magna were exposed to the test substance as water accommodated fractions (WAFs) under static conditions for 48 hours. The loading rates were 0, 1, 10, 100 or 1000 mg/L and no analytical measurements were made on the WAFs. No effects were noted at any of the WAF loading rates. EPA does not consider the loading rate as the no effect concentration when the concentration exceeds the water solubility of the substance. Assuming exposure concentration in the WAF is the water solubility limit (saturation) for fatty acid, tall oil, the no effect concentration would be approximately 12.6 mg/L.
No effects at saturation

Fatty acids, C16-C18 and C18 unsaturated, branched and linear (monomer acid; CAS No. 68955-98-6)
Daphnia magna were exposed to the test substance as water accommodated fractions (WAFs) under static conditions for 48 hours. The loading rate was 1000 mg/L and no analytical measurements were made on the WAFs. No effects were noted at the WAF loading rate. EPA does not consider the loading rate as the no effect concentration when the concentration exceeds the water solubility of the substance. Assuming exposure concentration in the WAF is the water solubility limit (saturation) for fatty acids, C16-C18 and C18 unsaturated, branched and linear, the no effect concentration would be approximately 15.0 mg/L.
No effects at saturation

Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt (monomer acid; calcium salt; CAS No. not assigned; supporting chemical)

Daphnia magna were exposed to the test substance as water accommodated fractions (WAFs) under static conditions for 48 hours. The loading rate was 100 mg/L and no analytical measurements were made on the WAF. No effects were noted at the WAF loading rate.

No effects at saturation

Toxicity to Aquatic Plants

Fatty acids, tall oil (TOFA; CAS No. 61790-12-3)

Green algae *(Pseudokirchneriella subcapitata)* were exposed to the test substance as water accommodated fractions (WAFs) under static conditions for 72 hours. The loading rates were 0, 125, 250, 500 and 1000 mg/L and no analytical measurements were made on the WAFs. At 72 hours, some inhibition of growth rate (< 50%) was observed at the loading rate of 1000 mg/L. EPA does not consider the loading rate as the no effect concentration when the concentration exceeds the water solubility of the substance. Assuming exposure concentration in the WAF is the water solubility limit (saturation) for fatty acids, tall oil, the EC_{50} would be > 12.6 mg/L, indicating low acute toxicity.

EC_{50} > Water solubility limit (12.6 mg/L)

Fatty acids, C16-C18 and C18 unsaturated, branched and linear (monomer acid; CAS No. 68955-98-6)

Green algae *(Scenedesmus subspicatus)* were exposed to the test substance as water accommodated fractions (WAFs) under static conditions for 72 hours. The loading rate was 1000 mg/L and no analytical measurements were made on the WAF. No effects were noted at the WAF loading rate. EPA does not consider the loading rate as the no effect concentration when the concentration exceeds the water solubility of the substance. Assuming exposure concentration in the WAF is the water solubility limit (saturation) for fatty acids, C16-C18 and C18 unsaturated, branched and linear (monomer acid), the no effect concentration would be approximately 15.0 mg/L.

No effects at saturation

Conclusion: The evaluation of available aquatic toxicity data for fish and aquatic invertebrates indicates the potential acute hazard to aquatic organisms is low based primarily on no effects observed at the water solubility limit (saturation) of category members.

In comments on the original test plan, EPA recommended that the sponsor conduct chronic toxicity testing on invertebrates (i.e. the daphnid 21-day reproduction test) instead of the proposed acute toxicity tests. The sponsor proceeded to conduct the acute toxicity tests and results showed no effects at saturation. While the acute testing did not show toxicity in aquatic organisms, the physical-chemical properties of the substances in this category indicate they are soluble or dispersible in water at concentrations that could cause chronic effects. However, based on the environmental fate data none of the category members are expected to be persistent or bioaccumulative in the environment, therefore mitigating chronic toxicity concerns.

Table 2. Summary of Environmental Effects – Aquatic Toxicity Data							
Endpoints	**Fatty acids, tall oil (61790-12-3)**	**Fatty acids, tall oil, sodium salts (61790-45-2)**	**Fatty acids, tall oil, potassium salts (61790-44-1)**	**Fatty acids, tall oil, low boiling (65997-03-7)**	**Fatty acids, C16-C18 & C18 unsaturated, branched and linear (Monomer acid) (68955-98-6)**	**Monomer acid, calcium salt, (supporting chemical) (No CAS#)**	**Octadecanoic acid, branched and linear (68201-37-6)**
Fish 96-h LC_{50} (mg/L)	**NES [1]**	No Data NES[1] (RA)	No Data NES[1] (RA)	No Data NES[1] (RA)	**NES [1]**	**NES [1]**	No Data NES[1] (RA)
Aquatic Invertebrates 48-h EC_{50} (mg/L)	**NES [1]**	No Data NES[1] (RA)	No Data NES[1] (RA)	No Data NES[1] (RA)	**NES [1]**	**NES [1]**	No Data NES[1] (RA)
Aquatic Plants 72-h EC_{50} (mg/L)	**>12.6**	No Data >12.6 (RA)	No Data >12.6 (RA)	No Data >12.6 (RA)	**NES [1]**	Data not expected for supporting chemical	No Data NES[1] (RA)

[1]NES = No effects at saturation (water solubility limit); (RA) = Read Across.

3. Human Health Effects

A summary of health effects data submitted for SIDS endpoints is provided in Table 3. The table also indicates where data for tested category members are read-across (RA) to untested members of the category.

Acute Oral Toxicity

Fatty acids, tall oil (TOFA; CAS No. 61790-12-3)
Sprague-Dawley rats (5/sex/dose) were administered TOFA via oral gavage at 10,000 mg/kg-bw and observed for 14 days. None of the animals died. Gross necropsy revealed no treatment-related effects.
LD_{50} > 10,000 mg/kg-bw

Fatty acids, C16-C18 and C18 unsaturated, branched and linear, sodium salt (monomer acid, sodium salt; CAS No. not assigned, supporting chemical)
Sprague-Dawley rats (3/sex/dose) were administered monomer acid, sodium salt via oral gavage at 2000 mg/kg-bw and observed for 14 days. None of the animals died. Gross necropsy revealed no treatment-related effects.
LD_{50} > 2000 mg/kg-bw

Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt (monomer acid, calcium salt; CAS No. not assigned, supporting chemical)
Sprague-Dawley rats (3/sex/dose) were administered monomer acid, calcium salt via oral gavage at 2000 mg/kg-bw and observed for 14 days. None of the animals died. Gross necropsy revealed no treatment-related effects.
LD_{50} > 2000 mg/kg-bw

Repeated-Dose Toxicity

Fatty acids, tall oil (TOFA; CAS No. 61790-12-3)
Charles River rats (10/sex/dose) were administered TOFA at 0, 5, 10 and 25% (approximately corresponding to 0, 2500, 5000 and 12,500 mg/kg-bw/day) in the diet for 90 days. No adverse effects on body weight, clinical laboratory parameters, organ weights or gross or microscopic findings were observed. There was a slight decrease in food consumption in the 10 and 25% (approximately 5000 and 12,500 mg/kg-bw/day) groups.
NOAEL > 12,500 mg/kg-bw/day

Reproductive/Developmental Toxicity

Fatty acids, tall oil (TOFA; CAS No. 61790-12-3)
Sprague-Dawley rats (30 female and 15 male/dose) were administered TOFA via the diet at 0, 5 and 10 % (~ 0, 2500 and 5000 mg/kg-bw/day) starting at 20 days pre-mating (parental generation) and continuing through weaning of the F1 generation. After weaning, 20 F1 males and 20 F1 females per group were maintained on the parental diet. At 100 days of age, these rats were mated and were allowed to deliver pups (F2). The F2 generation was followed until weaning. Parameters evaluated included F1 reproductive parameters, F1 fertility, viability, lactation, and gestation indices, hematology, serum chemistry, urinalysis, organ weights, gross pathology of F1 and F2 animals, and microscopic pathology of the F2 pups. There were no treatment-related effects on reproductive performance, the number of liveborn or stillborn F1 litters and pups, or weaning weight of the F1 pups. No treatment-related changes in fertility, viability, lactation, or gestation indices were found. No changes in hematology, clinical chemistry and urinalysis parameters, organ weights were noted and gross and microscopic pathology revealed no treatment-related effects.
NOAEL (systemic toxicity) ~5000 mg/kg-bw/day
NOAEL (developmental/reproductive toxicity) ~5000 mg/kg-bw/day

Genetic Toxicity – Gene Mutation

In vitro
Fatty acids, tall oil (TOFA; CAS No. 61790-12-3)
Ames assays were performed using five strains of *Salmonella typhimurium* (TA98, TA100, TA1535, TA1537 and TA1538) in the presence and absence of metabolic activation and up to 10,000 µg/plate of test substance. No increases in mutation frequency were reported at any concentration tested with or without metabolic activation. Solvent/vehicle control and response of the positive controls were not provided in the robust summary.
Fatty acids, tall oil was not mutagenic in this assay.

Fatty acids, C16-C18 and C18 unsaturated, branched and linear, sodium salt (monomer acid, sodium salt; CAS No. not assigned, supporting chemical)
Ames assays were performed using five strains of *Salmonella typhimurium* (TA98, TA100, TA1535, TA1537 and TA1538) in the presence and absence of metabolic activation and up to 5,000 µg/plate of test substance. No increases in mutation frequency were reported at any concentration tested with or without metabolic activation. Solvent/vehicle control and response of the positive controls were not provided in the robust summary.
Fatty acids, C16-C18 and C18 unsaturated, branched and linear, sodium salt was not mutagenic in this assay.

Genetic Toxicity – Chromosomal Aberrations

In vitro
Fatty acids, tall oil (TOFA; CAS No. 61790-12-3)
Chinese hamster ovary cells were treated with concentrations of TOFA ranging from 5 – 156 µg/mL, with and without metabolic activation. Solvent/vehicle control and response of the positive controls were not provided in the robust summary. Chromosome aberrations were induced only at cytotoxic concentrations. No chromosomal aberrations were observed at concentrations that were not cytotoxic: 10 µg/mL (with metabolic activation) and 78 µg/mL (without metabolic activation).
Fatty acids, tall oil did not induce chromosome aberrations in this assay.

Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt (monomer acid calcium salt; CAS No. not assigned, supporting chemical)
Human lymphocytes were treated with concentrations of monomer acid calcium salt ranging from 0 – 500 µg/mL, with and without metabolic activation. Solvent/vehicle control and response of the positive controls were not provided in the robust summary. Chromosome aberrations were induced only at cytotoxic concentrations. No chromosomal aberrations were observed at concentrations that were not cytotoxic (150 µg/mL), with and without metabolic activation.
Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt did not induce chromosome aberrations in this assay.

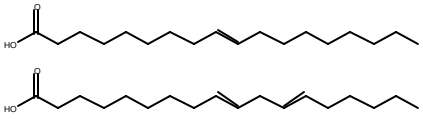
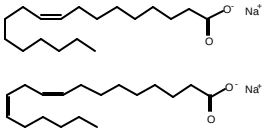
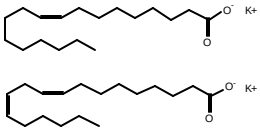
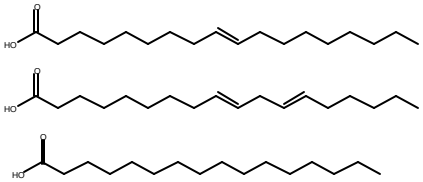
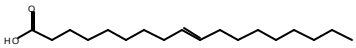
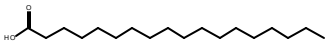
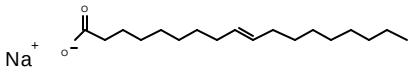
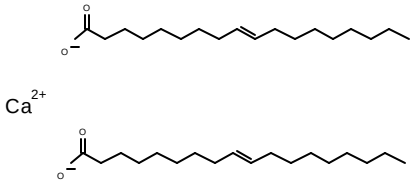
Conclusion: The acute oral toxicity for the members of this category is low, based on testing of the category member, TOFA, and the supporting chemicals, monomer acid, sodium and calcium salts. Repeated exposures to TOFA via the oral route did not produce any signs of toxicity in animal studies. No reproductive or developmental toxicity was observed in rats exposed to TOFA in the diet for two-generations. Mutagenicity data with *in vitro* tests for the category member TOFA and the supporting chemical, monomer acid, sodium salt, showed no effects. Other *in vitro* tests with TOFA and the supporting chemical, monomer acid, calcium salt, did not induce effects on the chromosome.

Table 3. Summary of Human Health Data

Endpoints	**Fatty acids, tall oil (61790-12-3)**	**Fatty acids, tall oil, sodium salts (61790-45-2)**	**Fatty acids, tall oil, potassium salts (61790-44-1)**	**Fatty acids, tall oil, low boiling (65997-03-7)**	**Fatty acids, C16-C18 and C18 unsaturated, branched and linear (Monomer acid) (68955-98-6)**	**Monomer acid, sodium salt, (supporting chemical) (not assigned)**	**Monomer acid, calcium salt, (supporting chemical) (not assigned)**	**Octadecanoic acid, branched and linear (68201-37-6)**
Acute Oral Toxicity LD_{50} (mg/kg-bw)	**> 10,000**	No Data > 10,000 (RA)	No Data > 10,000 (RA)	No Data > 10,000 (RA)	No Data > 2000 (RA)	**> 2000**	**> 2000**	No Data > 2000 (RA)
Repeated-Dose Toxicity (mg/kg-bw/day)	**NOAEL > 12,500**	No Data NOAEL> 12,500 (RA)	No Data NOAEL> 12,500 (RA)	No Data NOAEL> 12,500 (RA)	No Data NOAEL> 12,500 (RA)	Data not expected for supporting chemical	Data not expected for supporting chemical	No Data NOAEL> 12,500 (RA)
Reproductive/ Developmental Toxicity (mg/kg-bw/day) Systemic/Developmental / Reproductive Toxicity	**NOAEL> ~5000**	No Data NOAEL > ~5000 (RA)	No Data NOAEL > ~5000 (RA)	No Data NOAEL > ~5000 (RA)	No Data NOAEL > ~5000 (RA)	Data not expected for supporting chemical	Data not expected for supporting chemical	No Data NOAEL > ~5000 (RA)
Genetic Toxicity – Gene Mutation ***In vitro***	**Negative**	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	**Negative**	Data not expected for supporting chemical	No Data Negative (RA)
Genetic Toxicity – Chromosomal Aberrations ***In vitro***	**Negative**	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	Data not expected for supporting chemical	**Negative**	No Data Negative (RA)

Measured data in bold text; (RA) = Read Across.

APPENDIX

Tall Oil, Fatty Acids, and Related Compounds		
CAS No.	**Chemical Name**	**Representative structures [1]**
SPONSORED CHEMICALS		
61790-12-3	Tall oil, fatty acids[2]	
61790-45-2	Fatty acids, tall oil, sodium salt[3]	
61790-44-1	Fatty acids, tall oil, potassium salt[4]	
65997-03-7	Fatty acids, tall oil, low boiling[5]	
68955-98-6	Fatty acids, C16-C18, branched and linear (Monomer acid)[6]	
68201-37-6	Octadecanoic acid, branched and linear[7]	
SUPPORTING CHEMICALS		
No CAS No. assigned	Fatty acids, C16-C18, branched and linear, sodium salt (sodium salt of Monomer acid)	
No CAS No. assigned	Fatty acids, C16-C18, branched and linear, calcium salt (calcium salt of Monomer acid)	

[1]Principle constituents that is typical for each member of this class.
[2]The principle constituents are 48% oleic acid and 35% linoleic acid. Other constituents are palmitic acid (1%), stearic acid (2%), conjugated linoleic acid (7%), and other fatty acids.
[3]Produced from distilled tall-oil by neutralization with sodium hydroxide. The composition is complex but probably consists largely of the sodium salts of oleic and linoleic acid.
[4]Produced from distilled tall-oil by neutralization with potassium hydroxide. The composition is complex but probably consists largely of the potassium salts of oleic and linoleic acid.
[5]The principle constituents are 36% palmitic acid, 32% oleic acid, and 23% linoleic acid.
[6]The chemical composition is primarily elaidic acid and other C18 acids.
[7]Similar in composition to fatty acids, C16-C18, branched and linear, except that all constituents are saturated acids.

Screening Level Exposure Characterization for HPV Challenge Chemical

Tall Oil Fatty Acids and Related Substances Category

CAS #(s):
61790-12-3; 61790-44-1; 61790-45-2;
65997-03-7; 68201-37-6; 68955-98-6

September 2008

Prepared by

Exposure Assessment Branch
Chemical Engineering Branch
Economics, Exposure and Technology Division
Office of Pollution Prevention and Toxics
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Washington, DC 20460-0001

Screening Level Exposure Characterization
Tall Oil Fatty Acids and Related Substances Category

Non-CBI Executive Summary

The six chemicals in the tall oil fatty acids (TOFA) and related substances category (CAS # 61790-12-3; 61790-45-2; 61790-44-1; 65997-03-7; 68955-98-6; 68201-37-6) have aggregated production and/or import volumes in the United States of 650 million to 1.7 billion pounds.[12] These aggregated volumes exclude octadecanoic acid, branched and linear (CAS # 68201-37-6), which does not have Inventory Update Reporting (IUR) submissions.

Non-confidential information in the IUR indicates that these chemicals were manufactured and/or imported at numerous companies and sites. Most companies and sites use the fractionated product(s) as a reactant or component in formulated products. More detailed information can be found in the non-confidential IUR Data Summary Section at the end of the document. Non-confidential IUR information indicates a variety of uses for the tall oil fatty acids category, including uses as intermediates, lubricants, surfactants, flotation agents, viscosity adjustors, fuels, and adhesives.

Information submitted as part of the High Production Volume (HPV) Challenge Program provides information on manufacturing, processing, and use.[13] TOFA is a distillation fraction of crude tall oil (see Risk Characterization/Exposure Characterization for Tall Oil and Related Substances Category). Crude tall oil is fractionally distilled to yield several fractions, two of which are included in this category: TOFA (CAS # 61790-12-3) and fatty acids, tall oil, low boiling (CAS # 65997-03-7). The remaining members of this group are all derived from TOFA.

The HPV submission indicates that TOFA and the other substances in this category are consumed almost entirely as industrial intermediates where they are reacted or further distilled to produce other chemicals. Of the various TOFA distillation and reaction products, it is estimated that greater than 75% are marketed and consumed in non-dispersive commercial applications in the production of dimer acids, polyamide adhesive resins, alkyd resins for paint, polyester lubricants, plasticizers, and metal working fluids. The main use of TOFA is as a raw material for the production of a wide variety of other chemicals. The largest single use of TOFA is for the production of dimer acids that are then converted into coatings, adhesives, and printing inks. Another important end use for TOFA is in the production of alkyd resins that go into paints and printing inks. The tall oil fatty acid sodium or potassium salts are used as surfactants in liquid soaps for both industrial and household cleaning and disinfectant products. They also find uses in metal working fluids and in lubricants. Octadecanoic acid, branched and linear (hydrogenated monomer) is an intermediate in the production of isostearic acid from monomer acid and does not have any other specific commercial use.

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[12] USEPA, 2006. Partial Updating of TSCA Chemical Inventory.
[13] Pine Chemicals Association, 2001. HPV Test Plan for Tall Oil Fatty Acids and Related Substances. April 2001. Accessed 6/20/08 at http://www.epa.gov/chemrtk/pubs/summaries/tofars/c13055tp.pdf.

Potential Exposures to the General Population and the Environment: Based on use information, there may be potential for environmental releases, although the quantity of releases to various media including water is unknown. These chemicals are not expected to be persistent in the environment (P1) and their bioaccumulation potential (B1) is low.[14] Based on the information considered, including environmental fate, known uses, and the Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a medium potential that the general population and the environment might be exposed.

Potential Exposures to Workers: Based on the information considered and in combination with Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, 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 relatively high number of potentially exposed workers. Tall oil fatty acids do not have OSHA Permissible Exposure Limits (PELs).[15]

Potential Exposures to Consumers: EPA identifies, for the purposes of risk-based prioritization, a high potential that consumers might be exposed based on the use of products containing these chemicals. Though the substances in this category are reported to be consumed mostly as industrial intermediates, where they are reacted or further distilled to produce other chemicals, five of the six TOFAs, have IUR submissions that indicate commercial/consumer uses. Public information from the National Institutes of Health Household Products Database indicates that fatty acids, tall oil (CAS # 61790-12-3) is used in several consumer products, including car wax, hand cleaner, metal polish, and heavy-duty disinfectant cleaner, and that fatty acids, tall oil, sodium salts (CAS # 61790-45-2) is used in hand cleaners.[16]

Potential Exposures to Children: EPA identifies, for the purposes of risk-based prioritization, a high potential that children might be exposed. Specifically, non-confidential IUR information for tall oil fatty acid potassium salts (CAS # 61790-44-1) reported uses in products intended to be used by children. Though IUR submissions for the remainder of the tall oil fatty acids category reported no uses in products intended to be used by children, exposures to children, may be expected to occur through the household use of some consumer products.

Below are summaries of non-confidential information in the IUR for five of the six chemicals in the tall oil fatty acids category.

This exposure characterization was completed using both public, non-confidential sources, and one or more IUR submissions that were available as of this writing.

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[14] USEPA, 2008. Screening-Level Hazard Characterization for High Production Volume Chemicals. Chemical Category Name: Tall Oil Fatty Acids and Related Substances.

[15] NIOSH, 1988. OSHA PEL Project Documentation. Accessed, 6/20/08. http://www.cdc.gov/niosh/pel88/npelcas.html.

[16] NIH, 2008. National Institutes of Health. Household Products Database. Accessed, 7/21/08. http://householdproducts.nlm.nih.gov/index.htm.

Non Confidential IUR Data Summary: **Fatty acids, tall-oil (CAS # 61790-12-3)**

Manufacturing/Import Information

Production (including import volume):	100 million to 500 million pounds
List of non-CBI companies/sites*:	Corsicana Technologies Inc./Corsicana, TX Eastman Chemical Company/Courtland, VA Georgia-Pacific Corporation/Crossett, AR Hercules Incorporated/Wilmington, DE Kemira Chemicals, Inc./Kennesaw, GA MeadWestvaco Corporation/confidential site(s) Rhodia Inc./Cranbury, NJ
Maximum number of exposed workers**:	greater than 1,000 (including those of manufacturing, industrial processing and use)
Highest non-CBI maximum concentration*:	greater than 90%
Non-CBI physical forms*:	liquid

* Note: There may be other companies/sites, concentrations, and physical forms that are claimed CBI.
** There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a “Not Readily Obtainable” (NRO) response among the submissions.

Table 1 Industrial Processing and Use Information Reported in 2006 IUR		
Processing Activity	**Industrial Sector**	**Function in Industrial Sector**
Processing as a reactant	All Other Chemical Product and Preparation Manufacturing	Intermediates
Processing as a reactant	Other Basic Organic Chemical Manufacturing	Intermediates
Processing as a reactant	Other Basic Organic Chemical Manufacturing	Not Readily Obtainable
Processing as a reactant	Resin and Synthetic Rubber Manufacturing	Intermediates
Processing as a reactant	Soap and Cleaning Compound Manufacturing	Intermediates
Processing as a reactant	Tire Manufacturing	Intermediates
Processing - incorporation into formulation, mixture, or reaction product	All Other Chemical Product and Preparation Manufacturing	Lubricants
Processing - incorporation into formulation, mixture, or reaction product	All Other Chemical Product and Preparation Manufacturing	Surface active agents
Processing - incorporation into formulation, mixture, or reaction product	Other Basic Organic Chemical Manufacturing	Flotation agents
Processing - incorporation into formulation, mixture, or reaction product	Other Basic Organic Chemical Manufacturing	Intermediates
Processing - incorporation into formulation, mixture, or reaction product	Other Nonmetallic Mineral Mining and Quarrying	Surface active agents
Processing - incorporation into formulation, mixture, or reaction product	Other Petroleum and Coal Products Manufacturing	Corrosion inhibitors and anti-scaling agents
Processing - incorporation into formulation, mixture, or reaction product	Other Petroleum and Coal Products Manufacturing	Lubricants
Processing - incorporation into formulation, mixture, or reaction product	Pesticide and Other Agricultural Chemical Manufacturing	Agricultural chemicals (nonpesticidal)
Processing - incorporation into formulation, mixture, or reaction product	Resin and Synthetic Rubber Manufacturing	Flotation agents
Processing - incorporation into formulation, mixture, or reaction product	Soap and Cleaning Compound Manufacturing	Other
Processing - incorporation into formulation, mixture, or reaction product	Textile and Fabric Finishing Mills	Surface active agents
Processing--repackaging	Other Basic Organic Chemical Manufacturing	Not Readily Obtainable
Additional line item(s) may be claimed as CBI		

Table 2 Commercial/Consumer Uses Reported in 2006 IUR		
Commercial/Consumer Product Category Description	**Highest Maximum Concentration Range**	**Use in Children's Products**
Agricultural products	1% - 30%	No
Fabrics, textiles and apparel	1% - 30%	No
Glass and ceramic products	1% - 30%	No
Lubricants, greases and fuel additives	1% - 30%	No
Paints and coatings	1% - 30%	No
Paper products	1% - 30%	No
Rubber and plastic products	1% - 30%	No
Soaps and detergents	1% - 30%	No
Other	1% - 30%	No
Additional line item(s) may be claimed as CBI		

Non Confidential IUR Data Summary: **Fatty acids, tall-oil, sodium salts (CAS # 61790-45-2)**

Manufacturing/Import Information

Production (including import volume): 500 million to 1 billion pounds

List of non-CBI companies/sites*:

The Clorox Company/Caguas, PR
The Clorox Company/Pearl, MS
Cobitco, Inc./Denver, CO
DuPont Performance Elastomers LLC/ Louisville, KY
E.A. Mariani Asphalt Co./Tampa, FL
Ecolab, Inc./Joliet, IL
Ecolab, Inc./McDonough, GA
Georgia-Pacific Corporation/ Cedar Springs, GA
Georgia-Pacific Corporation/ Monticello, MS
Georgia-Pacific Corporation/Palatka, FL
GP Cellulose, LLC/Brunswick, GA
GP Cellulose, LLC/New Augusta, MS
Green Bay Packaging/Morrilton, AR
NK Asphalt Partners (dba Holly Asphalt Company)/confidential site(s)
Oxy Vinyls, LP/La Porte, TX
Paramount Petroleum Corporation/ Portland, OR
Piedmont Chemical Industries Inc./ High Point, NC
SemMaterials L.P./confidential site(s)
Shepherd Chemical/Norwood, OH
W.R. Grace, Performance Chemicals/ North Bergen, NJ
W.R. Grace, Performance Chemicals/ Cambridge, MA
W.R. Grace, Performance Chemicals/ Chicago, IL
W.R. Grace, Performance Chemicals/ Lithonia, GA
W.R. Grace, Performance Chemicals/ Los Angeles, CA

Maximum number of exposed workers**: greater than 1,000
Highest non-CBI maximum concentration*: greater than 90%
Non-CBI physical forms*: water or solvent wet solid; liquid

* Note: There may be other companies/sites, concentrations, and physical forms that are claimed CBI.
** There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

Table 1
Industrial Processing and Use Information
Reported in 2006 IUR

Processing Activity	Industrial Sector	Function in Industrial Sector
Processing as a reactant	Other Basic Organic Chemical Manufacturing	Intermediates
Processing as a reactant	Other Basic Organic Chemical Manufacturing	Other
Processing as a reactant	Other Nonmetallic Mineral Mining and Quarrying	Intermediates
Processing as a reactant	Paperboard Mills	Intermediates
Processing as a reactant	Printing Ink Manufacturing	Intermediates
Processing as a reactant	Pulp Mills	Other
Processing as a reactant	Ready-Mix Concrete Manufacturing-	Processing aid, not otherwise listed
Processing - incorporation into formulation, mixture, or reaction product	All Other Chemical Product and Preparation Manufacturing	Functional fluids
Processing - incorporation into formulation, mixture, or reaction product	All Other Chemical Product and Preparation Manufacturing	Lubricants
Processing - incorporation into formulation, mixture, or reaction product	Other Basic Organic Chemical Manufacturing	Intermediates
Processing - incorporation into formulation, mixture, or reaction product	Other Basic Organic Chemical Manufacturing	Viscosity adjustors
Processing - incorporation into formulation, mixture, or reaction product	Soap and Cleaning Compound Manufacturing	Surface active agents
Use--nonincorporative activities	Other Basic Organic Chemical Manufacturing	Intermediates
Additional line item(s) may be claimed as CBI		

Table 2 Commercial/Consumer Uses Reported in 2006 IUR		
Commercial/Consumer Product Category Description	**Highest Maximum Concentration Range**	**Use in Children's Products**
Lubricants, greases and fuel additives	Less than 1%	No
Polishes and sanitation goods	1% - 30%	No
Other	Greater than 90%	No
Additional line item(s) may be claimed as CBI		

Non Confidential IUR Data Summary: **Fatty acids, tall-oil, potassium salts (CAS # 61790-44-1)**

Manufacturing/Import Information

Production (including import volume):	1 million to 10 million pounds
List of non-CBI companies/sites*:	ArrMaz Custom Chemicals/Mulberry, FL Corsicana Technologies Inc./Corsicana, TX Eastman Chemical Company/Courtland, VA Ecolab, Inc./City of Industry, CA Ecolab, Inc./Garland, TX Ecolab, Inc./Hebron, OH Ecolab, Inc./Joliet, IL Ecolab, Inc./Martinsburg, WV Ecolab, Inc./McDonough, GA Ecolab, Inc./San Jose, CA Georgia-Pacific Corporation/ Bedford Park, IL Hercules Incorporated/Wilmington, DE Houghton International Inc./Allentown, PA Kemira Chemicals, Inc./Kennesaw, GA Lockhart Chemical Company/Flint, MI Memphis Solutions/Memphis, TN W.R. Grace, Performance Chemicals/ Chicago, IL W.R. Grace, Performance Chemicals/ Milwaukee, WI Rhodia Inc./Cranbury, NJ RichardsApex Inc/Philadelphia, PA The Valspar Corporation/Orangeburg, SC
Maximum number of exposed workers**:	greater than 1,000
Highest non-CBI maximum concentration*:	greater than 90%
Non-CBI physical forms*:	water or solvent wet solid; liquid

* Note: There may be other companies/sites, concentrations, and physical forms that are claimed CBI.
** There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a “Not Readily Obtainable” (NRO) response among the submissions.

Table 1 Industrial Processing and Use Information Reported in 2006 IUR		
Processing Activity	**Industrial Sector**	**Function in Industrial Sector**
Processing - incorporation into formulation, mixture, or reaction product	All Other Chemical Product and Preparation Manufacturing	Lubricants
Processing - incorporation into formulation, mixture, or reaction product	Household and Institutional Furniture Manufacturing	Processing aid, not otherwise listed
Additional line item(s) may be claimed as CBI		

Table 2 Commercial/Consumer Uses Reported in 2006 IUR		
Commercial/Consumer Product Category Description	**Highest Maximum Concentration Range**	**Use in Children's Products**
Lubricants, greases and fuel additives	1% - 30%	No
Metal products	Less than 1%	Yes
Soaps and detergents	N/A	No
Wood and wood furniture	Less than 1%	No
Additional line item(s) may be claimed as CBI		

Non Confidential IUR Data Summary: **Fatty acids, tall-oil, low boiling (CAS # 65997-03-7)**

Manufacturing/Import Information

Production (including import volume):	50 to 100 million pounds
List of non-CBI companies/sites*:	Eastman Chemical Company/Courtland, VA Georgia-Pacific Corporation/Crossett, AR
Maximum number of exposed workers**:	greater than 1,000
Highest non-CBI maximum concentration*:	greater than 90%
Non-CBI physical forms*:	liquid

* Note: There may be other companies/sites, concentrations, and physical forms that are claimed CBI.
** There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

Table 1
Industrial Processing and Use Information
Reported in 2006 IUR

Processing Activity	Industrial Sector	Function in Industrial Sector
Processing--incorporation into article	Resin and Synthetic Rubber Manufacturing	Fuels
Processing as a reactant	All Other Chemical Product and Preparation Manufacturing	Intermediates
Processing as a reactant	Other Basic Organic Chemical Manufacturing	Processing aid, not otherwise listed
Processing as a reactant	Resin and Synthetic Rubber Manufacturing	Intermediates
Processing as a reactant	Soap and Cleaning Compound Manufacturing	Intermediates
Processing - incorporation into formulation, mixture, or reaction product	All Other Chemical Product and Preparation Manufacturing	Surface active agents
Processing - incorporation into formulation, mixture, or reaction product	Other Basic Organic Chemical Manufacturing	Intermediates
Processing - incorporation into formulation, mixture, or reaction product	Other Petroleum and Coal Products Manufacturing	Fuels
Processing - incorporation into formulation, mixture, or reaction product	Resin and Synthetic Rubber Manufacturing	Flotation agents
Additional line item(s) may be claimed as CBI		

Table 2 Commercial/Consumer Uses Reported in 2006 IUR		
Commercial/Consumer Product Category Description	**Highest Maximum Concentration Range**	**Use in Children's Products**
Lubricants, greases and fuel additives	N/A	No
Other	1% - 30%	No
Additional line item(s) may be claimed as CBI		

Non Confidential IUR Data Summary: **Fatty acids, C16-18 and C18-unsatd., branched and linear (CAS # 68955-98-6)**

Manufacturing/Import Information

Production (including import volume):	1 million to 50 million pounds
List of non-CBI companies/sites*:	Cognis Corporation/Kankakee, IL Croda Inc./Chicago, IL
Maximum number of exposed workers**:	100 to 999
Highest non-CBI maximum concentration*:	greater than 90%
Non-CBI physical forms*:	liquid

* Note: There may be other companies/sites, concentrations, and physical forms that are claimed CBI.
** There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a “Not Readily Obtainable” (NRO) response among the submissions.

Table 1 Industrial Processing and Use Information Reported in 2006 IUR		
Processing Activity	**Industrial Sector**	**Function in Industrial Sector**
Processing--incorporation into article	Stationery Product Manufacturing	Intermediates
Processing as a reactant	All Other Chemical Product and Preparation Manufacturing	Intermediates
Processing as a reactant	Other Basic Organic Chemical Manufacturing	Intermediates
Processing as a reactant	Resin and Synthetic Rubber Manufacturing	Intermediates
Processing as a reactant	Soap and Cleaning Compound Manufacturing	Intermediates
Processing as a reactant	Toilet Preparation Manufacturing	Intermediates
Processing - incorporation into formulation, mixture, or reaction product	Adhesive Manufacturing	Adhesives and binding agents
Processing - incorporation into formulation, mixture, or reaction product	All Other Chemical Product and Preparation Manufacturing	Lubricants
Processing - incorporation into formulation, mixture, or reaction product	All Other Chemical Product and Preparation Manufacturing	Surface active agents
Processing - incorporation into formulation, mixture, or reaction product	Other Nonmetallic Mineral Mining and Quarrying	Surface active agents
Processing - incorporation into formulation, mixture, or reaction product	Other Petroleum and Coal Products Manufacturing	Fuels
Processing - incorporation into formulation, mixture, or reaction product	Textile and Fabric Finishing Mills	Intermediates
Use--nonincorporative activities	Other Basic Organic Chemical Manufacturing	Fuels
Additional line item(s) may be claimed as CBI		

Table 2 Commercial/Consumer Uses Reported in 2006 IUR		
Commercial/Consumer Product Category Description	**Highest Maximum Concentration Range**	**Use in Children's Products**
Adhesives and sealants	1% - 30%	No
Fabrics, textiles and apparel	Less than 1%	No
Lubricants, greases and fuel additives	N/A	No
Other	1% - 30%	No
Additional line item(s) may be claimed as CBI		