Supporting Documents for Initial Risk-Based Prioritization of High Production Volume Chemicals

Rosin Adducts and Adduct Salts Category

Rosin, fumarated (CASRN 65997-04-8)

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

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

Rosin, maleated (CASRN 8050-28-0)

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

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

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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
Rosin Adducts and Adduct Salts

SPONSORED CHEMICALS

Rosin, fumarated	CAS No. 65997-04-8
Rosin, fumarated, sodium salt	CAS No. 68201-59-2
Rosin, fumarated, potassium salt	CAS No. 68649-83-2
Rosin, maleated	CAS No. 8050-28-0
Rosin, maleated, potassium salt	CAS No. 85409-27-4
Rosin, maleated/fumarated	CAS No. 68554-16-5

September 2008

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QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION FOR Rosin Adducts and Adduct Salts Category

1. Category Justification

The six members of the rosin adducts and adduct salts are derived from rosin. 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 and methods of derivation. Each category member is derived from rosin that has been chemically reacted with either fumaric acid or maleic anhydride. The sodium and potassium rosin adduct salts are simply the rosin adducts that have been reacted with either sodium hydroxide or potassium hydroxide. Therefore, all of the substances in this category are very similar in chemical composition being either fumarated or maleated adducts of rosin or rosin adduct salts. Rosin, fumarated (CAS# 65997-04-8) was selected as the representative substance in this category for ecotoxicity and mammalian toxicity testing. In addition, the fumarated rosin adduct is the most chemically and thermodynamically stable of the rosin adducts. Based on these data, EPA has concluded that the chemicals in this category can be grouped and evaluated together for the purposes of the HPV Challenge Program as they have similar structure, composition, physical-chemical and environmental fate properties and toxicity to aquatic and mammalian species. EPA further accepts this category for prioritization in the Chemical Assessment and Management Program (ChAMP).

2. Physical-Chemical Properties and Environmental Fate

The members of the rosin adducts and adduct salts category are complex mixtures (Class 2 substances). They are solids at room temperature and have a softening point but most decompose before melting. Water solubility is generally low to moderate, except for the adduct salts which are dispersible. Vapor pressures are negligible. The constituents of rosin adducts and adduct salts are expected to have low mobility in soil. Volatilization will be low since most of the constituents are ionic at environmental pH. Hydrolysis is expected to be negligible since the components of these mixtures do not possess hydrolysable functional groups, with the exception of the maleated substances. All members of the category are expected to have low bioaccumulation potential (B1). The salts in this category appear to have moderate persistence (P2) and while the non-salts appear to have higher persistence (P3).

3. Hazard Characterization

Aquatic Organism Toxicity. All aquatic toxicity studies submitted were conducted using Water Accommodated Fractions (WAFs). The evaluation of available acute toxicity data for fish, invertebrates and aquatic plants indicate the acute hazard to aquatic organisms is low based on no effects observed at the water solubility limit (saturation) of fumarated rosin. 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 raise uncertainty regarding the potential to have chronic effects.

Human Health Toxicity. Acute oral toxicity of members of the rosin adducts and adduct salts category is low. In a combined repeated-dose/reproductive/developmental toxicity study in rats, systemic, developmental and reproductive toxicity were low. The tested member of the category did not induce gene mutations or chromosomal aberrations *in vitro*.

4. Exposure Characterization

Four of the six rosin adducts and adduct salts category chemicals have aggregated production and/or import volumes in the ranges of 21 million to 110.5 million pounds. The aggregated production volumes exclude the two chemicals, rosin, fumarated maleated (CAS# 68554-16-5) and maleated rosin potassium salt (CAS# 85409-27-4) which do not have IUR submissions. Non-confidential IUR information for the rosin adducts and adduct salts category indicate that some of these chemicals are used as fixing agents in the manufacturing of other basic organic chemicals. Some other chemicals are used in the paper mill industry, or as intermediates in the manufacturing of soap and cleaning compound. All of the four chemicals that have IUR submissions also have commercial or consumer uses. Information submitted in the HPV Challenge Program indicates the rosin adducts are typically used as chemical intermediates to form derivatives that go into printing inks and a variety of surface coatings. The sodium and potassium rosin adduct salts (CAS# 68201-59-2, 68649-83-2 and 85409-27-4) are used in paper sizing to improve the final finish of the paper and to provide water resistance.

Potential Exposures to the General Population and the Environment: Based on the known uses, which include dispersive commercial and consumer use, releases to all media are likely. Therefore, based on the information considered, including the environmental fate, known uses, and the Agency's expert judgment, EPA identifies, for the purposes of risk-based prioritization, a medium potential that the general population and the environment might be exposed.

The persistence ratings for the salts are P2 and for the non-salts are P3. The bioaccumulation rating for both is B1. These ratings suggest that these chemicals are moderately to highly persistent in the environment; but are not bioaccumulative. Most compounds will be minimally mobile in soil and will adsorb strongly to solids and sediments in the aquatic environment. Members of this category are expected to biodegrade in the environment slowly; degradability for individual compounds will range from moderate to slow.

Potential Exposures to Workers: Based on the information considered, including IUR data and information submitted through the HPV Challenge Program, and in combination with the Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a high relative ranking for potential worker exposure. This relative ranking is based on the potential for dermal and inhalation exposure to solids and mist during industrial processing and use including commercial uses, substantially high production volume, and a relatively high number of potentially exposed workers (> 1,000 workers for three chemicals). These chemicals 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. All four of the chemicals for which there are IUR submissions reported commercial

and/or consumer uses. Non-confidential IUR information for many of these chemicals indicates that they are used in paper products.

Potential Exposures to Children: EPA identifies, for the purposes of risk-based prioritization, a medium potential that children might be exposed. All non-confidential IUR information reported no uses in products intended to be used by children; however, children may be exposed to these chemicals when contained in 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. Although these chemicals display moderate or high persistence, low acute hazard to fish, invertebrates and plants considered in combination with the low bioaccumulation suggests a low concern for potential risk of acute toxicity to aquatic organisms from environmental releases.

Potential Risk to the General Population from Environmental Releases (LOW CONCERN). EPA identifies a medium potential that the general population might be exposed from environmental releases. The potential human health hazard is expected to be low due to the lack of specific toxicity to animals following exposure to high doses. Although these chemicals display moderate or high persistence, the low hazard in combination with the low bioaccumulation suggest a low concern for potential risk to the general population from environmental releases.

Potential Risk to Workers (LOW CONCERN). EPA identifies a high relative ranking for the potential worker exposure. Overall, the potential health hazard of the category members is low. Therefore, taken together, the available information suggests a low overall concern for potential risks to workers.

Potential Risk to Consumers from Known Uses (LOW CONCERN). EPA identifies a high potential that consumers might be exposed to products containing these chemicals. The potential human health hazard is expected to be low due to the lack of specific toxicity to animals following exposure to high doses. Therefore, taken together, the available information suggests a low concern for potential risks to consumers.

Potential Risk to Children (LOW CONCERN). EPA identifies a medium potential that children might be exposed. The potential human health hazard is expected to be low due to the lack of specific toxicity to young animals following exposure to high doses. Therefore, 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
Rosin Adducts and Adduct Salts

SPONSORED CHEMICALS

Rosin, fumarated	CAS No. 65997-04-8
Rosin, fumarated, sodium salt	CAS No. 68201-59-2
Rosin, fumarated potassium salt	CAS No. 68649-83-2
Rosin, maleated	CAS No. 8050-28-0
Rosin, maleated, potassium salt	CAS No. 85409-27-4
Rosin, maleated/fumarated	CAS No. 68554-16-5

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SCREENING-LEVEL HAZARD CHARACTERIZATION OF HIGH PRODUCTION VOLUME CHEMICALS

Rosin Adducts and Adduct Salts Category

Introduction

The sponsor, Pine Chemicals Association, Inc., submitted a Test Plan and Robust Summaries to EPA for the Rosin Adducts and Adduct Salts Category on September 18, 2001. EPA posted the submission on the ChemRTK HPV Challenge website on October 12, 2001 (http://www.epa.gov/chemrtk/pubs/summaries/rosinadd/c13177tc.htm). EPA comments on the original submission were posted to the website on March 26, 2002. Public comments were also received and posted to the website. The sponsor submitted updated/revised documents on March 19, 2002, August 29, 2002, September 26, 2002, and November 18, 2004, which were posted to the ChemRTK website on April 2, 2002, September 5, 2002, October 17, 2002 and December 21, 2004, respectively. The Rosin Adducts and Adduct Salts Category consist of the following substances:

Rosin, fumarated	CAS No. 65997-04-8
Rosin, fumarated, sodium salt	CAS No. 68201-59-2
Rosin, fumarated potassium salt	CAS No. 68649-83-2
Rosin, maleated	CAS No. 8050-28-0
Rosin, maleated, potassium salt	CAS No. 85409-27-4
Rosin, maleated/fumarated	CAS No. 68554-16-5

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 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 the HPV submission, a search of the following databases was made from 2003 to June 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 rosin adducts and adduct salts are derived from rosin. 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 and methods of derivation. Each category member is derived from rosin that has been chemically reacted with either fumaric acid or maleic anhydride. The sodium and potassium rosin adduct salts are simply the rosin adducts that have been reacted with either sodium hydroxide or potassium hydroxide. Therefore, all of the substances in this category are very similar in chemical composition being either fumarated or maleated adducts of rosin or rosin adduct salts. Rosin, fumarated (CAS# 65997-04-8) was selected as the representative substance in this category for ecotoxicity and mammalian toxicity testing. In addition, the fumarated rosin adduct is the most chemically and thermodynamically stable of the rosin adducts.

Rosin is a naturally occurring substance found predominantly in pine trees and is obtained by chemical or distillation processes from the pulping of pine wood. There are three different types of rosins: gum, wood and tall oil rosin—the type depends on the way it is extracted from the pine tree. Gum rosin is derived by slashing the tree and collecting the gummy exudates, which are further distilled; wood rosin is obtained by solvent extraction of pine wood; and tall oil rosin is obtained by distillation of tall oil (the Tall Oil and Related Substance Category has also been sponsored and characterized under the HPV Challenge Program). Rosin is composed primarily of resin acids, a class of tricyclic carboxylic acids, and contains minor amounts of dimerized rosin and unsaponifiable matter (the Rosin and Salts Category has also been sponsored and characterized under the HPV Challenge Program).

Chemically, the three rosins are very similar, containing the same resin acids in slightly different ratios, and have the same CAS No. 8050-09-7.

In comments on the original test plan EPA questioned the justification of fumarated rosin as the representative compound for this category. The concern was that maleated rosin might be more biologically active than fumarated rosin. In the revised test plan, the sponsors explained that at the temperature where rosin/fumaric acid adduction occurs, isomerization and dehydration of a fraction of the fumaric acid to maleic anhydride invariably takes place. The result being that a portion (10-20%) of the adduct is the rosin/maleic anhydride reaction product and that any potential effects of the maleic anhydride adduct will be included in the testing of the fumaric acid adduct. The sponsors also stated that testing the fumaric acid adduct is equivalent to testing the maleic anhydride adduct because it is likely that the anhydride adduct will be readily hydrolyzed to the maleic acid adduct in an aqueous media and that since the maleic acid adduct and the fumaric acid adduct are cis-trans isomers, the hypothetical reactivity of the two adducts to proteins or other macromolecules should be equivalent. The sponsor also submitted additional data for maleated rosin (CAS # 68425-08-1) to demonstrate that the testing on fumarated rosin represents maleated rosin. EPA agrees that the rationale and additional test data support the assessment of the sponsored substances as a category.

Hazard Characterization

The members of the rosin adducts and adduct salts category are complex mixtures (Class 2 substances). They are solids at room temperature and have a softening point but most decompose before melting. Water solubility is generally low to moderate, except for the adduct salts which are dispersible. Vapor pressures are negligible. The constituents of rosin adducts and adduct salts are expected to have low mobility in soil. Volatilization will be low since most of the constituents are ionic at environmental pH. Hydrolysis is expected to be negligible since the components of these mixtures do not possess hydrolysable functional groups, with the exception of the maleated substances. All members of the category are expected to have low bioaccumulation potential (B1). The salts in this category appear to have moderate persistence (P2) while the non-salts appear to have higher persistence (P3).

The aquatic toxicity data submitted were generated using the Water Accommodated Fraction (WAF) method. The evaluation of available acute toxicity data for fish, invertebrates and aquatic plants indicate the acute hazard to aquatic organisms is low based on no effects observed at the water solubility limit (saturation) of fumarated rosin. 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 raise uncertainty regarding the potential to have chronic effects.

Acute oral toxicity of members of the rosin adducts and adduct salts category is low. In a combined repeated-dose/reproductive/developmental toxicity study in rats, systemic, developmental and reproductive toxicity were low. The tested member of the category did not induce gene mutations or chromosomal aberrations *in vitro*.

The chronic invertebrate toxicity test remains a data gap under the HPV Challenge Program.

1. Physical-Chemical Properties and Environmental Fate

The physical-chemical properties of members of the rosin adducts and adduct salts category are summarized in Table 1a, while their environmental fate properties are given in Table 1b. The structures of the compounds are provided in the Appendix.

Physical-Chemical Properties Characterization

The substances in rosin adducts and adduct salts category are solids at room temperature and have a softening point but decompose before they melt. Water solubility is generally low to moderate, except for the adduct salts which are dispersible. Vapor pressures are negligible.

Table 1a. Physical-Chemical Properties of Rosin Adducts and Adducts Salts[1]						
	Rosin fumarated	**Rosin fumarated, sodium salt**	**Rosin fumarated, potassium salt**	**Rosin maleated**	**Rosin maleated, potassium salt**	**Rosin maleated/ fumarated**
CAS No.	65997-04-8	68201-59-2	68649-83-2	8050-28-0	85409-27-4	68554-16-5
Physical State	Solid	Solid	Solid	Solid	Solid	Solid
Melting Point	No data[2]	No data[2]	No data[2]	No data[2]	No data[2]	No data[2]
Boiling Point	Decomposes before boiling[2]	Decomposes before boiling[2]	Decomposes before boiling[2]	Decomposes before boiling[2]	Decomposes before boiling[2]	Decomposes before boiling[2]
Vapor Pressure	Negligible[2]	Negligible[2]	Negligible[2]	Negligible[2]	Negligible[2]	Negligible[2]
Water Solubility	**9.0 mg/L at 20°C (measured)**	Dispersible	Dispersible	**1.38 mg/L at 20°C (measured)**	Dispersible	**0.58 mg/L at 20°C (measured)**
Log K_{ow}	**4.4–7.0 (measured)**	**1.5–6.6 (measured)**	**3.2–6.6 (measured)**	**1.5–7.6 (measured)**	**1.4–7.9 (measured)**	**1.5–6.6 (measured)**

[1]Pine Chemicals Association, Inc. 2004. Revised Robust Summaries for Rosin Adducts and Adduct Salts, http://www.epa.gov/chemrtk/pubs/summaries/rosinadd/c13177tc.htm, Accessed March 19, 2008.
[2]These complex mixtures will not have a well defined melting point, boiling point or vapor pressure.

Environmental Fate Characterization

The constituents of rosin adducts and adduct salts are expected to have low mobility in soil. Based on the results of ready biodegradation screening studies for these complex mixtures, the components of rosin adducts and adduct salts are expected to biodegrade slowly in the environment. Rosin adducts and adduct salts will be minimally volatile from soil and water surfaces since most of the constituents are ionic at environmental pH. Hydrolysis is expected to be negligible since the components of these mixtures do not possess hydrolysable functional groups, with the exception of the maleated substances. The potential for bioconcentration in aquatic organisms for the components of these mixtures is expected to be low (B1). The salts in this category appear to have moderate persistence (P2) while the non salts appear to have higher persistence (P3).

Table 1b. Environmental Fate Properties of Rosin Adducts and Adducts Salts[1]						
Property	**Rosin fumarated**	**Rosin maleated**	**Rosin maleated/ fumarated**	**Rosin fumarated, sodium salt**	**Rosin fumarated, potassium salt**	**Rosin maleated, potassium salt**
CAS No.	65997-04-8	8050-28-0	68554-16-5	68201-59-2	68649-83-2	85409-27-4
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	**15% after 28 days (measured) Not readily biodegradable**	**0.34% after 28 days (measured) Not readily biodegradable**	**19% after 28 days (measured) Not readily biodegradable**	**48% after 28 days (measured) Not inherently biodegradable**	**50.5% after 28 days (measured) Not inherently biodegradable**	**59.2% after 28 days (measured) Not inherently biodegradable**
Bioconcentration[3]	BCF = 10–56	BCF = 3–10	BCF = 3–10	BCF = 10–56	BCF = 10–56	BCF = 3–10
Log K_{oc}	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]
Fugacity (Level III Model)	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]	No Data[2]
Persistence[4]	P3 (high)	P3 (high)	P3 (high)	P2 (moderate)	P2 (moderate)	P2 (moderate)
Bioaccumulation[4]	B1 (low)	B1 (low)	B1 (low)	B1 (low)	B1 (low)	B1 (low)

[1]Pine Chemicals Association, Inc. 2004. Revised Robust Summaries for Rosin Adducts and Adduct Salts, http://www.epa.gov/chemrtk/pubs/summaries/rosinadd/c13177tc.htm, Accessed March 19, 2008.
[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. Estimations performed using a representative structure as shown in the appendix.
[4]Federal Register. 1999. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) pp. 60194–60204.

Conclusion: The members of the rosin adducts and adduct salts category are complex mixtures (Class 2 substances). They are solids at room temperature and have a softening point but most decompose before melting. Water solubility is generally low to moderate, except for the adduct salts which are dispersible. Vapor pressures are negligible. The constituents of rosin adducts and adduct salts are expected to have low mobility in soil. Volatilization will be low since most of the constituents are ionic at environmental pH. Hydrolysis is expected to be negligible since the components of these mixtures do not possess hydrolysable functional groups, with the exception of the maleated substances. All members of the category are expected to have low bioaccumulation potential (B1). The salts in this category appear to have moderate persistence (P2) while the non-salts appear to have higher persistence (P3).

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

Rosin, fumarated (CAS No. 65997-04-8)
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 rosin, the no effect concentration would be approximately 9.0 mg/L.
No effects at saturation

Acute Toxicity to Aquatic Invertebrates

Rosin, fumarated (CAS No. 65997-04-8)
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 rosin, the no effect concentration would be approximately 9.0 mg/L.
No effects at saturation

Toxicity to Aquatic Plants

Rosin, fumarated (CAS No. 65997-04-8)
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, 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 rosin, the no effect concentration would be approximately 9.0 mg/L.
No effects at saturation

Conclusion: The available aquatic toxicity data submitted were generated using the Water Accommodated Fraction method. The evaluation of available aquatic toxicity data for fish, aquatic invertebrates and algae indicates no acute effects were observed at the water solubility limit (saturation) of fumarated rosin.

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). 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 raise uncertainty regarding the potential to have chronic effects. Therefore, the chronic invertebrate toxicity test remains a data gap under the HPV Challenge Program.

Table 2. Summary of Environmental Effects – Aquatic Toxicity Data

Endpoints	Rosin, fumarated 68997-04-8)	Rosin, fumarated, sodium salt 68201-59-2)	Rosin, fumarated, potassium salt (68649-83-2)	Rosin, maleated (8050-28-0)	Rosin, maleated, potassium salt (85409-27-4)	Rosin, maleated/ fumarated 68554-16-5)
Fish 96-h LC_{50} (mg/L)	**NES** [1]	No Data NES[1] (RA)	No Data NES[1] (RA)	No Data NES[1] (RA)	No Data NES[1] (RA)	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)	No Data NES[1] (RA)	No Data NES[1] (RA)
Aquatic Plants 72-h EC_{50} (mg/L)	**NES** [1]	No Data NES[1] (RA)	No Data NES[1] (RA)	No Data NES[1] (RA)	No Data NES[1] (RA)	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

Rosin, fumarated (CAS No. 65997-04-8)
Female Sprague-Dawley rats were administered a single oral dose of rosin, fumarated via gavage at 2000 mg/kg-bw and observed for 14 days. No mortality or signs of toxicity reported.
LD_{50} (females) > 2000 mg/kg-bw

Rosin, maleated (CAS No. 8050-28-0)
Female Sprague-Dawley rats administered a single oral dose of rosin, maleated via gavage at 2000 mg/kg-bw and observed for 14 days. No mortality or signs of toxicity reported.
LD_{50} (females) > 2000 mg/kg-bw

Repeated-Dose Toxicity

Rosin, fumarated (CAS No. 65997-04-8)
In a combined repeated-dose/reproductive/developmental toxicity screening test, Sprague-Dawley rats (10/sex/dose) were administered rosin, fumarated, via the diet at 0, 1000, 3000 or 10,000 ppm (approximately 91, 260 or 500 mg/kg-bw/day, respectively) daily for 4 weeks. Males were dosed for 4 weeks, starting from 2-weeks prior to mating. Females were dosed 2 weeks prior to mating and until day 6 of lactation. At 3000 and 10,000 ppm, there was a decrease in mean body weight gain and food consumption in both sexes. In females at 10,000 ppm, results of histopathology revealed significant decrease in adrenal weights and thymic atrophy. Clinical observations associated with treatment were abnormal colored urine at all treatment levels and soft fecal output at 3000 and 10,000 ppm.
LOAEL ~ 260 mg/kg-bw/day (based on decreased body weight gain)
NOAEL ~ 91 mg/kg-bw/day

Reproductive Toxicity

Rosin, fumarated (CAS No. 65997-04-8)
In the combined repeated-dose/reproductive/developmental toxicity screening test described previously, there were slight increases in time to mating and in the duration of gestation and slight decreases in the mean number of implants per pregnancy noted at the 10,000 ppm dose.
LOAEL (reproductive toxicity) ~ 500 mg/kg-bw/day (based on increased time to successful mating and decreased mean number of implants)
NOAEL (reproductive toxicity) ~ 260 mg/kg-bw/day

Developmental Toxicity

Rosin, fumarated (CAS No. 65997-04-8)
In the combined repeated-dose/reproductive/developmental toxicity screening test described previously, dams showed decreased body weight gain and food consumption at 3000 and 10,000 ppm. Slight decreases in the mean number of implants per pregnancy were followed by reduction in litter size and litter weight evident at 10,000 ppm.
LOAEL (maternal toxicity) ~ 260 mg/kg-bw/day (based on decreased body weight gain)
NOAEL (maternal toxicity) ~ 91 mg/kg-bw/day
LOAEL (developmental toxicity) ~ 500 mg/kg-bw/day (based on reduced litter size and weight)
NOAEL (developmental toxicity) ~ 260 mg/kg-bw/day

Genetic Toxicity – Gene Mutation

In vitro
Rosin, fumarated (CAS No. 65997-04-8)
In a reverse mutation test, *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and *Escherichia coli* WP2uvrA were exposed to rosin, fumarated at concentrations of 17, 50, 167, 600, 1667 and 5000 µg/plate in the presence and absence of metabolic activation. Positive controls were employed (responses were not reported). No increases in mutation frequency were reported at any concentration of fumarated rosin with or without metabolic activation.
Rosin, fumarated was not mutagenic in this assay.

Genetic Toxicity – Chromosomal Aberrations

In vitro
Rosin, fumarated (CAS No. 65997-04-8)
In a cytogenetic test, Chinese hamster ovary cells were exposed to rosin, fumarated at concentrations of 20 – 200 µg/mL without metabolic activation and 5 – 80 µg/mL with S9 mix. No increase in the number of aberrations in exposed cells was measured in either the presence or absence of metabolic activation. Positive controls were employed (responses were not reported).
Rosin, fumarated did not increase chromosomal aberrations in this assay.

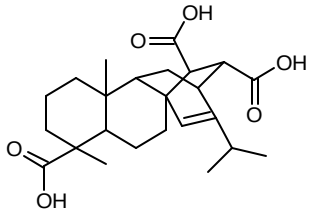
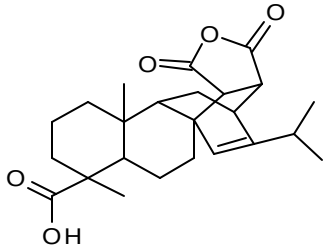
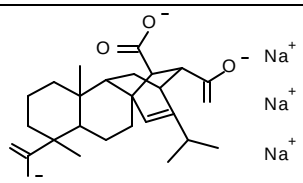
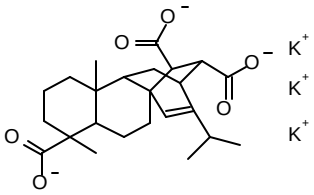
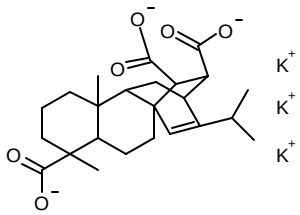
Conclusion: Acute oral toxicity of members of the rosin adducts and adduct salts category is low. In a combined repeated-dose/reproductive/developmental toxicity study in rats, systemic, developmental and reproductive toxicity were low. The tested member of the category did not induce gene mutations or chromosomal aberrations *in vitro*.

Table 3. Summary of Health Effects Data

Endpoints	Rosin, fumarated (68997-04-8)	Rosin, fumarated, sodium salt (68201-59-2)	Rosin, fumarated, potassium salt (68649-83-2)	Rosin, maleated (8050-28-0)	Rosin, maleated potassium salt (85409-27-4)	Rosin, maleated/ fumarated (68554-16-5)
Acute Oral Toxicity LD_{50} (mg/kg-bw)	**> 2000**	No Data > 2000 (RA)	No Data > 2000 (RA)	**> 2000**	No Data > 2000 (RA)	No Data > 2000 (RA)
Repeated-Dose Toxicity Oral (mg/kg-bw/day)	**NOAEL ~ 91 LOAEL ~ 260**	No Data NOAEL ~ 91 LOAEL ~ 260 (RA)	No Data NOAEL ~ 91 LOAEL ~ 260 (RA)	No Data NOAEL ~ 91 LOAEL ~ 260 (RA)	No Data NOAEL ~ 91 LOAEL ~ 260 (RA)	No Data NOAEL ~ 91 LOAEL ~ 260 (RA)
Reproductive / Developmental Toxicity (mg/kg-bw/day)						
Systemic and Maternal Toxicity	**NOAEL ~ 91 LOAEL ~ 260**	No Data NOAEL ~ 91 LOAEL ~ 260	No Data NOAEL ~ 91 LOAEL ~ 260	No Data NOAEL ~ 91 LOAEL ~ 260	No Data NOAEL ~ 91 LOAEL ~ 260	No Data NOAEL ~ 91 LOAEL ~ 260
Reproductive and Developmental Toxicity	**NOAEL ~ 260 LOAEL ~ 500**	NOAEL ~ 260 LOAEL ~500 (RA)	NOAEL ~ 260 LOAEL ~500 (RA)	NOAEL ~ 260 LOAEL ~500 (RA)	NOAEL ~ 260 LOAEL ~500 (RA)	NOAEL ~ 260 LOAEL ~500 (RA)
Genetic Toxicity – Gene Mutation ***In vitro***	**Negative**	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	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)	No Data Negative (RA)

Bold = measured data; (RA) = Read Across

APPENDIX

Sponsored Chemicals		
Chemical Name	**CAS No.**	**Representative Structure[1]**
Rosin fumarated[2]	65997-04-8	
Rosin maleated[3]	8050-28-0	
Rosin maleated/fumarated[4]	68554-16-5	See above
Rosin fumarated, sodium salt[5]	68201-59-2	
Rosin fumarated, potassium salt[6]	68649-83-2	
Rosin maleated, potassium salt[7]	85409-27-4	

[1]Principle constituents that are typical for each member of this class. Rosin adducts and adduct salts are derived from pine trees. The quantity and type of components varies according to the type of pine tree, climate and terrain, and distillation conditions.
[2]The chemical structure is the principal constituent in tall-oil rosin reacted with fumaric acid.
[3]The chemical structure is the principal constituent in tall-oil rosin reacted with maleic anhydride.
[4]The chemical structure is a mixture of the principal constituent in tall-oil rosin reacted with fumaric acid and maleic anhydride.
[5]The chemical structure is the principal constituent in tall-oil rosin reacted with fumaric acid followed by neutralization of the carboxylic acid functionality with sodium hydroxide.
[6]The chemical structure is the principal constituent in tall-oil rosin reacted with fumaric acid followed by neutralization of the carboxylic acid functionality with potassium hydroxide.
[7]The chemical structure is the principal constituent in tall-oil rosin reacted with maleic anhydride followed by neutralization of the carboxylic acid functionality with potassium hydroxide.

Screening Level Exposure Characterization for HPV Challenge Chemicals

Rosin Adducts and Adduct Salts Category

CAS #(s): 65997-04-8; 68201-59-2; 68649-83-2; 8050-28-0; 85409-27-4; 68554-16-5

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Screening Level Exposure Characterization
Rosin Adducts and Adduct Salts Category

Non-CBI Executive Summary

The 6 rosin adducts and adduct salts category chemicals have aggregated production and/or import volumes in the ranges of 21 million to 110.5 million pounds[12]. The aggregated production volumes exclude the two chemicals, rosin, fumarated maleated (CAS# 68554-16-5) and maleated rosin potassium salt (CAS# 85409-27-4), which do not have Inventory Update Reporting (IUR) submissions. Non-confidential IUR information indicates that these chemicals were manufactured and/or imported by the following companies:

CAS# 65997-04-8:

- Akzo Nobel Coatings Inc.
- DIC Imaging Products USA, LLC
- Georgia-Pacific Corporation
- Hercules Incorporated
- Hercules Incorporated
- Hercules Incorporated
-

CAS# 68201-59-2:

- Hercules Incorporated

CAS# 68649-83-2:

- Confidential

CAS# 8050-28-0:

- Georgia-Pacific Corporation

There may be other company names that are claimed confidential. Non-confidential IUR information for the rosin adducts and adduct salts category indicate that some of these chemicals are used as fixing agents in the manufacturing of other basic organic chemicals. Some other chemicals are used in the paper mill industry, or as intermediates in the manufacturing of soap and cleaning compounds. All of the four chemicals that have IUR submissions also have commercial or consumer uses. Information submitted in the High Production Volume (HPV) Challenge Program indicates the rosin adducts are typically used as chemical intermediates to form derivatives that go into printing inks and a variety of surface coatings[13]. The sodium and

[12] USEPA, 2006. Inventory Update Reporting Database.
[13] Pine Chemicals Association, 2004. Final Submission for Rosin Adducts and Adduct Salts. http://www.epa.gov/HPV/pubs/summaries/rosinadd/c13177rt2.pdf. Accessed, 7/3/08.

potassium rosin adduct salts (CAS# 68201-59-2, 68649-83-2 and 85409-27-4) are used in paper sizing to improve the final finish of the paper and to provide water resistance.

Potential Exposures to the General Population and the Environment: Based on the known uses, which include dispersive commercial and consumer use, releases to all media are likely. Therefore, based on the information considered, including the environmental fate, known uses, and the Agency's expert judgment, EPA identifies, for the purposes of risk-based prioritization, a medium potential that the general population and the environment might be exposed.

The persistence ratings for the salts are P2 and for the non-salts are P3. The bioaccumulation rating for both is B1. These ratings suggest that these chemicals are moderately to highly persistent in the environment; but are not bioaccumulative. Most compounds will be minimally mobile in soil and will adsorb strongly to solids and sediments in the aquatic environment. Members of this category are expected to biodegrade in the environment slowly; degradability for individual compounds will range from moderate to slow.

Potential Exposures to Workers: Based on the information considered, including IUR data and information submitted through the HPV Challenge Program, and in combination with the Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a high relative ranking for potential worker exposure. This relative ranking is based on the potential for dermal and inhalation exposure to solids and mist during industrial processing and use including commercial uses, substantially high production volume, and a relatively high number of potentially exposed workers (> 1,000 workers for three chemicals). These chemicals do not have OSHA Permissible Exposure Limits (PELs)[14].

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. All four of the chemicals for which there are IUR submissions reported commercial and/or consumer uses. Non-confidential IUR information for many of these chemicals indicates that they are used in paper products.

Potential Exposures to Children: EPA identifies, for the purposes of risk-based prioritization, a medium potential that children might be exposed. All non-confidential IUR information reported no uses in products intended to be used by children; however, children may be exposed to these chemicals when contained in consumer products.

Below are summaries of non-confidential information in the IUR for each of the individual chemicals in this 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.

[14] NIOSH, 1988. OSHA PEL Project Documentation. http://www.cdc.gov/niosh. Accessed, 7/3/08.

Non Confidential IUR Data Summary: CAS# 65997-04-8

Manufacturing/Import Information

Production and import volume:	10 million to 50 million pounds
List of non-CBI companies*:	Akzo Nobel Coatings Inc. DIC Imaging Products USA, LLC Georgia-Pacific Corporation Hercules Incorporated Hercules Incorporated Hercules Incorporated
Maximum number of exposed workers**:	1,000 or greater (including those of manufacturing, processing and use)
Highest non-CBI maximum concentration:	greater than 90% by weight
Non-CBI physical forms*:	dry powder; solid; liquid

* There may be other companies and physical forms that are claimed confidential.
** 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	Other Basic Organic Chemical Manufacturing	Fixing 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
Paper products	Not readily obtainable	No
Additional line item(s) may be claimed as CBI		

Non Confidential IUR Data Summary: CAS# 68201-59-2

Manufacturing/Import Information

Production and import volume:	<500,000 pounds
List of non-CBI companies*:	Hercules Incorporated
Maximum number of exposed workers**:	less than 100 (including those of manufacturing, processing and use)
Highest non-CBI maximum concentration:	greater than 90%
Non-CBI physical forms:	confidential

* There may be other companies that are claimed confidential.
** 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
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
Claimed as CBI		

Non Confidential IUR Data Summary: CAS#68649-83-2

Manufacturing/Import Information

Production and import volume:	10 million to 50 million pounds
List of non-CBI companies:	confidential
Maximum number of exposed workers**:	1,000 or greater (including those of manufacturing, processing and use)
Highest non-CBI maximum concentration:	greater than 90%
Non-CBI physical forms*:	liquid

* There may be other physical forms that are claimed confidential.
** 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	Paper Mills	Other
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
Paper products	Less than 1%	No
Additional line item(s) may be claimed as CBI		

Non Confidential IUR Data Summary: CAS# 8050-28-0

Manufacturing/Import Information

Production and import volume:	1 million to 10 million pounds
List of non-CBI companies*:	Georgia-Pacific Corporation
Maximum number of exposed workers**:	1,000 or greater (including those of manufacturing, processing and use)
Highest non-CBI maximum concentration:	greater than 90%
Non-CBI physical forms*:	dry powder; liquid

* There may be other companies and physical forms that are claimed confidential.
** 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	Soap and Cleaning Compound Manufacturing	Intermediates
Processing--incorporation into formulation, mixture, or reaction product	Other Basic Organic Chemical Manufacturing	Fixing 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
Paper products	Not readily obtainable	No
Other	Greater than 90%	No
Additional line item(s) may be claimed as CBI		