UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

DATE: November 29, 2005

ACTION MEMORANDUM

SUBJECT: Inert Reassessment–Rosins and Rosin Derivatives

FROM: Pauline Wagner, Chief Pauline Wagner 11/30/05
Inert Ingredient Assessment Branch
Registration Division (7505C)

TO: Lois A. Rossi, Director
Registration Division (7505C)

I. FQPA REASSESSMENT ACTION

Action: Reassessment of nine inert exemptions from the requirement of tolerance. The reassessment decision is to maintain each of the nine inert tolerance exemptions "as-is."

Chemicals, CAS Name and Numbers:

Chemical (as Listed in 40 CFR 180)	CAS Name and Number
Calcium salt of partially dimerized rosin, conforming to 21 CFR 172.210	Resin acids and rosin acids, dimers, calcium salts; 68648-50-0
Pentaerythritol ester of maleic anhydride modified wood rosin	not available
Rosin, dark wood (as defined in 21 CFR 178.3870(a)(1)(v))	not available
Rosin, gum	Rosin; 8050-09-7
Rosin, partially dimerized (as defined in 21 CFR 172.615)	not available
Rosin, partially hydrogenated (as defined in 21 CFR 172.615)	Resin acids and Rosin acids, hydrogenated, Me esters; 8050-15-5
Rosin, tall oil	Tall-oil rosin; 8052-10-6
Rosin, wood	Rosin; 8050-09-7
Sodium salt of the insoluble fraction of rosin	not available

CFR: 40 CFR part 180.910 and 40 CFR part 180.920

Use Summary: Commercially, rosins and rosin derivatives are used in paper sizing, printing inks, tackifiers, and adhesives. As inert ingredients in pesticide formulations, rosins and rosin derivatives are used in coating agents, plasticizers, surfactants, and related adjuvants of surfactants.

List Reclassification Determination: These nine rosins and derivatives can be listed under List 4B.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the nine exemptions from the requirement of a tolerance for the inert ingredients rosins and rosin derivatives (as listed in Section I of this memorandum) and with the List Classification determinations, as described above. I consider the nine exemptions established in 40 CFR part 180.910 and 40 CFR part 180.920 to be reassessed for purposes of FFDCA's section 408(q) as of the date of my signature, below. A *Federal Register* Notice regarding this tolerance exemption reassessment decision will be published in the near future.

Lois A. Rossi, Director
Registration Division

Date: 11/30/05

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

November 28, 2005

MEMORANDUM

SUBJECT: Reassessment of Nine Exemptions from the Requirement of a Tolerance for: (1) Calcium Salt of Partially Dimerized Rosin, Conforming to 21 CFR 172.210; (2) Pentaerythritol Ester of Maleic Anhydride Modified Wood Rosin; (3) Rosin, Dark Wood (as defined in 21 CFR 178.3870(a)(1)(v)); (4) Rosin, Gum; (5) Rosin, Partially Dimerized (as defined in 21 CFR 172.615); (6) Rosin, Partially Hydrogenated (as defined in 21 CFR 172.615); (7) Rosin, Tall Oil; (8) Rosin, Wood; and (9) Sodium Salt of the Insoluble Fraction of Rosin

FROM: Kathleen Martin, Chemist Kathleen Martin · 11/29/05
Inert Ingredient Assessment Branch
Registration Division (7505C)

TO: Pauline Wagner, Chief
Inert Ingredient Assessment Branch
Registration Division (7505C)

BACKGROUND

Attached is the science assessment for several rosins and rosin derivatives. This assessment is based on a structure activity relationship analysis conducted by the Office of Pollution Prevention and Toxics Structure Activity Team. The purpose of this document is to reassess nine existing exemptions from the requirement of a tolerance for residues of several rosins and rosin derivatives as required under the Food Quality Protection Act.

EXECUTIVE SUMMARY

This report provides a qualitative assessment for several rosins or rosin derivatives, which are pesticide inert ingredients with a total of nine tolerance exemptions under 40 CFR 180.910 and 40 CFR 180.920. Rosin is the residue left after distilling off the volatile oil from the oleoresin obtained from *Pinus palustris* (Longleaf pine) and other species of *Pinus* in the family *Pinaceae*. As such, rosin is not a single, unique chemical substance but rather of mixture of resin acids. Rosins (e.g., wood rosin, gum rosin) *per se* are the saps exuded from the tree. Rosin derivatives are those rosins that have been chemically altered by processes such as esterification, hydrogenation, polymerization, or saponification. Commercially, rosins and rosin derivatives are used in paper sizing, printing inks, tackifiers, and adhesives. As inert ingredients in pesticide formulations, rosins and rosin derivatives are used in coating agents, plasticizers, surfactants, and related adjuvants of surfactants.

Reliable toxicity data for the rosins and derivatives are limited. The Office of Pollution Prevention and Toxics Structure Activity Team conducted a structure-activity analysis and concluded that based on toxicological information available on similar chemical structures, there is low to moderate human health concerns due to potential dermal and respiratory sensitization; however, absorption is poor by all routes of exposure. Because the rosins are poorly absorbed, EPA expects exposure and risk via all routes (oral, dermal, and inhalation) to be low.

Taking into consideration all available information on the rosins and derivatives under consideration in this assessment, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure when considering exposure through food commodities and all other non-occupational sources for which there is reliable information. Therefore, it is recommended that the nine exemptions from the requirement of a tolerance established for residues of:

calcium salt of partially dimerized rosin, conforming to 21 CFR 172.210	(40 CFR 180.910)
pentaerythritol ester of maleic anhydride modified wood rosin	(40 CFR 180.910)
rosin, dark wood (as defined in 21 CFR 178.3870(a)(1)(v))	(40 CFR 180.920)
rosin, gum	(40 CFR 180.920)
rosin, partially dimerized (as defined in 21 CFR 172.615)	(40 CFR 180.910)
rosin, partially hydrogenated (as defined in 21 CFR 172.615)	(40 CFR 180.910)
rosin, tall oil	(40 CFR 180.920)
rosin, wood	(40 CFR 180.910)
sodium salt of the insoluble fraction of rosin	(40 CFR 180.920)

can be considered reassessed as safe under section 408(q) of the FFDCA.

I. Introduction

This report provides a qualitative assessment for several rosins or rosin derivatives, which are pesticide inert ingredients with a total of nine tolerance exemptions under 40 CFR 180.910 and 40 CFR 180.920. Data for the rosins are limited. However, based on structure activity relationships (SARs), the Office of Pollution Prevention and Toxics (OPPT) Structure Activity Team (SAT) determined that there is low to moderate health concern for dermal and respiratory sensitization but, absorption is poor by all routes of exposure. Thus, EPA does not anticipate exposure to be significant. Provided in the following paragraphs is a general description of the substances being assessed in this document.

"Rosin[1]" is the residue left after distilling off the volatile oil from the oleoresin obtained from *Pinus palustris* (Longleaf pine) and other species of *Pinus* in the family *Pinaceae*. As such, rosin is not a single, unique chemical substance but rather of mixture of resin acids (e.g., abietic and palustric acid).

Industrially, rosin is the most important natural resin because it is a renewable resource and as a result of its chemical constitution, can be modified in many different ways to give resins of widely varying compositions (Elvers et al 1989). In general, gum, wood, tall oil, and dark wood rosins are considered to be "native" rosins, which simply means that they are essentially cleaned-up forms of the material that comes out of the tree. Rosin derivatives are those rosins that have been chemically altered by processes such as esterification, hydrogenation, polymerization, or saponification. As described by the U.S. Food and Drug Administration (FDA) in 21 CFR 178.3870, rosins and rosin derivatives include:

- Native rosins—gum rosin, refined to color grade of K[2] or paler; wood rosin, refined to color grade of K or paler; tall oil rosin, refined to color grade of K or paler; and dark wood rosin, all or part of the residue after the volatile terpene oils are distilled from the oleoresin extracted from pine wood.

- Modified rosins manufactured from rosins—partially hydrogenated rosin, catalytically hydrogenated to a maximum refractive index of 1.5012 at 100°C, and a color of WG or paler; and partially dimerized rosin, dimerized by sulfuric acid catalyst to a drop-softening point of 95°-105°C and a color of WG or paler.

- Rosin esters

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[1]"Rosin" is a solid form of "resin," which is obtained from pines and some other plants, mostly conifers, and is produced by heating fresh liquid resin to vaporize the volatile liquid terpene components (http://en.wikipedia.org/wiki/Rosin).

[2]The color shade is specified by letters. For example, in the United States the shades the lighter shades are denoted by X, WW, and WG (with X being the lightest) and the dark shades are N, M, and K (Elvers et al 1989).

Rosin salts and sizes—Calcium salt of partially dimerized rosin, conforming to 21 CFR 172.210.

Native rosins (i.e., gum, wood, tall oil, and dark wood), which are the purified and distilled rosins from the balsam of various species of pine (up to 80 different species), each have their own extraction method. For example, raw gum rosin is collected by wounding the tree and gathering the sap that flows out in some sort of container. The exudate is processed by melting it and allowing dirt and foreign material to settle out. Wood rosin on the other hand is gathered from the stumps of pine trees, which is the part richest in resin. Stumps that have remained in the soil for 10 years or more are dug out and cut up. The chips are extracted with naptha to obtain a relatively dark resin. The color can be removed by various processes. Tall-oil resin is also obtained from felled trees, through a process of wood digestion. (Elvers et al 1989)

Rosin derivatives are prepared by a wide variety of chemical processes, depending on the qualities desired and how the rosin will be used. For example, esterified rosins show a very good compatibility with elastomers (which are synthetic polymers with rubber-like characteristics. Partially esterified maleic rosins are important because of their high solubility in alcohol and water. Hydrogenated rosins are particularly oxidation-resistant. (Elvers et al 1989)

II. Use Information

Each native rosin and derivative has its own particular set of uses. The largest commercial use of rosin is in paper sizing to improve its water resistance (however, this use is being replaced by synthetic sizes). Modified rosins, metal resonates, and resin acid esters are used in the formulation of printing inks. Rosin esters are used extensively in pressure-sensitive adhesives as tackifiers. Rosins, modified rosins, and derivatives are used in hot-melt adhesives. Rosin ester resins are used as modifiers in the formulation of chewing gum. The soap of modified rosin has a long history as an emulsifier for the polymerization of styrene-butadiene rubber. (Kroschwitz 1996) Specific pesticidal and other uses are described below.

A. Pesticides

The tolerance exemptions for the rosins are provided in Table 1 below. Because a number of these tolerance expressions are described in terms of the FDA nomenclature (see 21 CFR 178.3870, rosins and rosin derivatives), the FDA name is also provided.

Table 1. Tolerance Exemptions Being Reassessed in this Document

CITATION AS IT APPEARS IN 40 CFR				CAS REGISTRY NUMBER and NAME	FDA NAME[c]
40 CFR 180	Tolerance Exemption Expression	Limits	Uses		
.910[a]	Calcium salt of partially dimerized rosin, conforming to 21 CFR 172.210	none	Coating agent	Resin acids and rosin acids, dimers, calcium salts; 68648-50-0	rosin salts, including calcium salts of rosins manufactured by the partial or complete saponification of any one of the rosins or modified rosins (21 CFR 178.3870 (a)(4))
.910[a]	Pentaerythritol ester of maleic anhydride modified wood rosin	none	Plasticizer	not available	Pentaerythritol ester of maleic anhydride-modified wood rosin…
.920[b]	Rosin, dark wood (as defined in 21 CFR 178.3870(a)(1)(v))	none	Surfactants, related adjuvants of surfactants	not available	dark wood rosin, all or part of the residue after the volatile terpene oils are distilled from the oleoresin extracted from pine (21 CFR 178.3870 (a)(1)(iv))
.920[b]	Rosin, gum	none	Surfactants, related adjuvants of surfactants	Rosin; 8050-09-7	gum rosin, refined to color grade of K or paler (21 CFR 178.3870 (a)(1)(i))
.910[a]	Rosin, partially dimerized (as defined in 21 CFR 172.615)	none	Surfactants, related adjuvants of surfactants	not available	partially dimerized rosin, dimerized by sulfuric acid catalyst to a drop-softening point of 95°-105°C and a color of WG or paler (21 CFR 178.3870 (a)(2)(iii))
.910[a]	Rosin, partially hydrogenated (as defined in 21 CFR 172.615)	none	Surfactants, related adjuvants of surfactants	Resin acids and Rosin acids, hydrogenated, Me esters; 8050-15-5	partially hydrogenated rosin, catalytically hydrogenated to a maximum refractive index of 1.5012 at 100°C (21 CFR 178.3870 (a)(2)(i))
.920[b]	Rosin, tall oil	none	Surfactants, related adjuvants of surfactants	Tall-oil rosin; 8052-10-6	Tall oil rosin, refined to color grade of K or paler
.910[a]	Rosin, wood	none	Surfactants, related adjuvants of surfactants	Rosin; 8050-09-7	Wood rosin, refined to color grade of K or paler
.920[b]	Sodium salt of the insoluble fraction of rosin	none	Surfactants, related adjuvants of surfactants	not available	not applicable

[a]Residues listed in 40 CFR 180.910 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities (RACs) after harvest.

[b]Residues listed in 40 CFR 180.920 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only.

[c]See 21 CFR 178.3870 (rosins and rosin derivatives).

B. FDA Food Additive Uses

Provided in Table 2 are the FDA food uses for the rosins, which may include the native rosins and rosin derivatives.

Table 2. FDA Food Uses for Rosins

Name	21 CFR
COLOR ADDITIVES EXEMPT FROM CERTIFICATION	
Diluents in color additive mixtures for food use exempt from certification	73.1
FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION	
Coatings on fresh citrus fruit	172.210
Natural flavoring substances and natural substances used in conjunction with flavors	172.510
Synthetic flavoring substances and adjuvants	172.515
Chewing gum base	172.615
Glycerol ester of wood rosin	172.735
Oleic acid derived from tall oil fatty acids	172.862
INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS	
Adhesives	175.105
Pressure-sensitive adhesives	175.125
Resinous and polymeric coatings	175.300
Resinous and polymeric coatings for polyolefin film	175.320
INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS	
Components of paper and paperboard in contact with aqueous and fatty foods	176.170
Components of paper and paperboard in contact with dry food	176.180
Defoaming agents used in coatings	176.200
Defoaming agents used in the manufacture of paper and paperboard	176.210
INDIRECT FOOD ADDITIVES: POLYMERS	
Cellophane	177.1200
Closures with sealing gaskets for food containers	177.1210
Rubber articles intended for repeated use	177.2600
INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS	
Antioxidants and/or stabilizers for polymers	178.2010
Animal glue	178.3120
Preservatives for wood	178.3800
Reinforced wax	178.3850
Rosins and rosin derivatives	178.3870
IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD	
Packaging materials for use during the irradiation of prepackaged foods	179.45

III. Physical and Chemical Properties

Rosin consists predominantly of rosin acids belonging to the terpene group[3]. The rosin acids have the molecular formula $C_{20}H_{30}O_2$ (molecular weight 302.45) and thus belong to the diterpenes. A large number of these isomeric rosin acids exist, they differ only in the position of the two double bonds. Provided in Figure 1 are two rosin acid isomers—abietic and pimaric acid. (Elvers et al 1989) The specific composition for each rosin depends on the country where the tree is located, its species, and the conditions under which the specific rosin was processed. Specific acid components of three native rosins are listed in Table 3 (Pine Chemicals Association 2004).

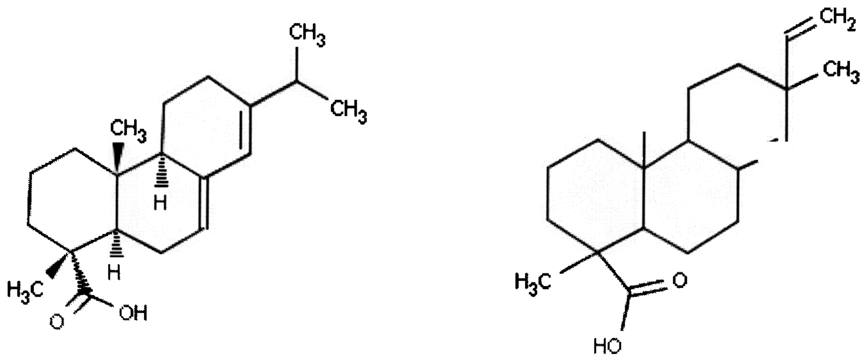

Figure 1. Abietic Acid (left) and Pimaric Acid (right)

Table 3. Typical Isomeric Components of Three Native Rosins

Component		Gum Rosin	Wood Rosin	Tall Oil Rosin
Rosin Acids	Abietic	20%	45%	35%
	Isopimaric	18%	11%	7%
	Palustric	18%	10%	10%
	Pimaric	2%	3%	3%
	Dehydroabietic	4%	8%	20%
	Neoabietic	18%	7%	4%
Other (e.g., other rosin acids, high boiling fatty acids)		38%	23%	25%

The double bonds in abietic acid can be polymerized in the presence of catalysts such as sulfur, p-toluenesulfonic acid, or sulfuric acid. The common polymerized rosins contain between 40 to 80 percent dimeric acid. The melting point of the series increases from 70°C (native rosin) to 140°C (80 percent dimeric acid). All polymerized rosins have a low tendency to crystallize, and a high oxidation stability. The double bonds of abietic acid, which are prone to oxidation, can be removed by hydrogenation.

[3] A terpene is a ten-carbon, unsaturated aliphatic cyclic hydrocarbon that is derived from plants. A 20-carbon atom, which is what the rosin acids consist of, is called a diterpene.

Partial hydrogenation occurs much more readily and rapidly than complete hydrogenation. (Elvers et al 1989)

Rosin has a melting point of about 70°C and is brownish to bright yellow. Gum rosin has a slightly sweet and aromatic odor. The tendency of rosin to crystallize largely depends on its purity—the fewer isomers of $C_{20}H_{30}O_2$ the greater the tendency to crystallize. A large number of gum resins tend to crystallize while the polymerized and hydrogenated types of rosin do not crystallize at all.

Melting points of several rosins are: gum rosin (65-85°C); wood rosin (about 73° C); polymeric rosin (80 to 140°C); and hydrogenated rosin (about 68°C).

IV. Hazard Assessment

A. Hazard Profile

Limited reliable toxicity data are available for the rosins. The OPPT SAT conducted an SAR analysis and concluded that based on toxicological information available on similar chemical structures, there is low to moderate human health concerns due to potential dermal and respiratory sensitization; however, absorption is poor by all routes of exposure. (U.S. EPA 2005a) In 2004 the Pine Chemical Association's High Production Volume Chemical Task Force submitted a Test Plan ("Rosins and Rosin Salts;" The Pine Chemicals Association 2004) under EPA's High Production Volume (HPV) Challenge Program.[4] In summary, they found that the rosins are "non-toxic." In reviewing the food safety of some glycerol esters of rosins, the WHO/FAO Expert Committee on Food Additives (JEFCA)[5] reported some acute, subchronic, and chronic toxicity data for the rosins (IPCS 1975 and 1996); they are discussed below in the section "Toxicological Data." In summary, they found that via the oral route: the rosins are not acutely toxic; some effects are seen (decreased body weight) at >600 mg/kg bw/day in a 90-day study; and effects are seen (i.e., decreased body and organ weight) at >400 mg/kg bw/day in a 24-month study. EPA expects that toxicity for the rosin derivatives would be less than that for the rosins as the molecules are larger.

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[4]The goal of the HPV program (http://www.epa.gov/chemrtk/volchall.htm) is to collect and make publicly available a complete set of baseline health and environmental effects data on those chemicals that are manufactured in, or imported into, the United States in amounts equal to or exceeding one million pounds per year. Industry sponsors volunteer to evaluate the adequacy of existing data and to conduct tests where needed to fill the gaps in the data, and EPA (and the public) has an opportunity to review and comment on the sponsors' robust summary report.

[5]JEFCA conducts toxicological evaluations of food additives and contaminants in food. The resulting monographs are used by the Codex Alimentarius Commission and national governments to set international food standards and safe levels for protection of the consumer.

B. Toxicological Data

Acute Toxicity

Provided in Table 4 are the available acute toxicity data for the rosins. The oral toxicity data are from a JEFCA report (IPCS 1975) which cites unpublished industry data. The sensitization information rely on an International Chemical Safety Card (NIOSH 2004) which indicates that "repeated or prolonged contact may cause skin sensitization" and that "repeated or prolonged inhalation exposure may cause asthma." Note that the OPPT SAT also pointed out the potential for dermal and inhalation sensitization from exposure to the rosins.

Table 4. Summary of Acute Toxicity Data for the Rosins (IPCS 1975)

Parameter		Rosin	Toxicity Value (mg/kg bw)	Reference
Oral LD_{50}	mouse	pale gum	4,600	IPCS 1975
		pale wood	4,100	IPCS 1975
		pale tall oil	4,600	IPCS 1975
	rat	pale gum	7,600	IPCS 1975
		pale wood	8,400	IPCS 1975
		pale tall oil	7,600	IPCS 1975
	guinea pig	pale gum	4,100	IPCS 1975
		pale wood	4,100	IPCS 1975
		pale tall oil	4,600	IPCS 1975
Dermal Sensitization		gum rosin	potential	NIOSH 2004
Respiratory Sensitization		gum rosin	potential	NIOSH 2004

Subchronic Toxicity (IPCS 1996)

In a 90-day oral toxicity study, rats were fed a diet containing 0; 0.01; 0.05; 0.2; or 1.0% (0; 6.4; 36; 119; or 674 mg/kg bw/day) wood rosin. Feeding at a 5.0% level was attempted; however all the animals died within the first eight days therefore this dose level was discontinued. No mortalities were noted and no significant effects were seen in the clinical chemistry parameters. Body weights were significantly reduced throughout the study for male and female rats fed 1.0% wood rosin. Organ weights revealed statistically significant increases in both liver to body-weight and brain to body-weight ratios for male and female rats at the 1.0% wood rosin level when compared to control groups. No pathological lesions, either macroscopic or microscopic, related to wood rosin treatment were observed in any of the organs of treated animals.

Chronic Toxicity (IPCS 1996)

In a 24-month oral toxicity study, rats were fed a diet containing 0; 0.05; 0.2; or 1% (to 0; 24; 88; or 434 mg/kg bw/day) wood rosin. At 12 months some of the animals were sacrificed for gross and microscopic pathology studies. All surviving animals were killed at 24 months and organ weights were recorded and pathological examinations were conducted. At both 12 and 24 months, body weights were significantly lower than controls in both males and females at the 1% diet level. No significant effects were noted in mortality, hematology, urinalysis, and gross or microscopic pathology. Elevated liver to body-weight ratios were noted in high-dose females, with some sporadic significant differences were noted between treated groups and one or other of the control groups with respect to organ to body-weight ratios for the kidneys, spleen and gonads.

In a 24-month oral toxicity study, dogs were fed a diet containing 0.05% or 1.0% (14 or 260 mg/kg bw/day) wood rosin. No effects were seen in mortality, hematology, urinalysis, liver and kidney function tests, gross and microscopic pathological examinations, and behavioral changes. At the 1% dose, some increase in liver and kidney size was noted (although no pathology was present).

Other Toxicological Parameters

No reliable data have been identified for mutagenicity, carcinogenicity, neurotoxicity, or developmental and reproductive toxicity.

C. Special Considerations for Infants and Children

Based on the SAT's assessment that the rosins are poorly absorbed by all routes of exposure, there is no concern, at this time, for increased sensitivity to infants and children to the rosins and derivatives under consideration in this assessment (see Table 1) when used as inert ingredients in pesticide formulations. For the same reason, a safety factor analysis has not been used to assess risk and, therefore, the additional tenfold safety factor for the protection of infants and children is also unnecessary.

V. Environmental Fate Characterization and Drinking Water Considerations (U.S. EPA 2005b)

The rosins and rosin derivatives are mostly composed of rosin acids with very little known about their actual composition. A search of the readily available literature did not result in the identification of known physical-chemical properties or environmental fate and transport information. Given their origin, it is likely that basic quantified physical-chemical properties such as vapor pressure or solubility would be expressed as a range of values because they are likely to be as variable as the composition of rosin acids and other compounds that make us the substances. Structurally, these substances are not likely to be readily degradable given that their component compounds are themselves unlikely to be readily biodegradable. However, due to the uncertainly associated with this group of substances, OPPT's HPV Challenge Program has requested the sponsoring organization conduct a Ready Biodegradability study according to Organization for Economic Cooperation and Development (OECD) protocols. When available, these results would serve to reduce the environmental uncertainty. In the interim, it is reasonable to assume they will not be readily degradable. As such, environmental half-lives in soil and water would conservatively exceed weeks for primary degradation.

These compounds are likely to be poorly soluble, not very mobile in soils, non-volatile and unlikely to bioconcentrate or bioaccumulate. Once in water they will partition to sediments and suspended materials. During drinking water treatment, the rosins are likely to be readily removed during coagulation, flocculation and sedimentation. In addition, oxidation in the presence of ozone or chlorination is likely. Although there is a great deal of uncertainty as to the likely concentrations in drinking water, concentration exceeding a part per billion do not appear likely given the postulated properties, behavior in drinking water treatment plants and the anticipated use pattern.

VI. Exposure Assessment

According to the OPPT SAT analysis, the rosins are poorly absorbed by all routes of exposure. Therefore, no further exposure assessment is necessary.

VII. Aggregate Exposures

In examining aggregate exposure, the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other nonoccupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

For the rosins and derivatives under consideration in this document (see Table 1), a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the lack of human health concerns associated with exposure to these rosins as inert ingredients in pesticide formulations.

VIII. Cumulative Exposure

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to the rosins and derivatives under consideration in this document, and any other substances and, this material does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that the rosins and derivatives under consideration in this document (see Table 1) have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

IX. Human Health Risk Characterization

The OPPT SAT conducted an SAR analysis for the rosins. Based on toxicological information available on similar chemical structures, the SAT concluded that rosins are predicted to be poorly absorbed by all routes of exposure. Because the rosins are poorly absorbed, EPA expects exposure and risk via all routes (oral, dermal, and inhalation) to be low. This finding is consistent with Ullman's Encyclopedia of Industrial Chemistry (Elvers et al 1989) where it is reported that native rosin "can be regarded as harmless and nontoxic. This also applies to many of its derivatives and modified rosins." The encyclopedia reports that the health of about one hundred workers, who were in daily contact with a large number of modified rosins, was followed for more than 25 years. No damaging effects on health could be established.

Taking into consideration all available information on the rosins and derivatives under consideration in this document (see Table 1), it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to these substances when considering exposure through food commodities and all other non-occupational sources for which there is reliable information. Therefore, it is recommended that the nine exemptions from the requirement of a tolerance established for residues of:

calcium salt of partially dimerized rosin, conforming to 21 CFR 172.210	(40 CFR 180.910)
pentaerythritol ester of maleic anhydride modified wood rosin	(40 CFR 180.910)
rosin, dark wood (as defined in 21 CFR 178.3870(a)(1)(v))	(40 CFR 180.920)
rosin, gum	(40 CFR 180.920)
rosin, partially dimerized (as defined in 21 CFR 172.615)	(40 CFR 180.910)
rosin, partially hydrogenated (as defined in 21 CFR 172.615)	(40 CFR 180.910)
rosin, tall oil	(40 CFR 180.920)
rosin, wood	(40 CFR 180.910)
sodium salt of the insoluble fraction of rosin	(40 CFR 180.920)

can be considered reassessed as safe under section 408(q) of the FFDCA.

X. Ecotoxicity and Ecological Risk Characterization

As with the environmental fate of these compounds, there is a lack data available on the rosin and rosin derivatives. The HPV program has reviewed available surrogate information and commented on a proposed testing plan for these compounds. Once recommended test data are available, these data should provide insights on the effects uncertainty based on the substances' rosin acid components.

Several studies were available in the open literature for the isomeric rosin acids, which make up these compounds. Table 5 provides a summary of the data from the Agency's Ecotox Database (http://www.epa.gov/ecotox. Acute toxicity was on the order of the low parts per million (ppm) for most species for four of the rosin acids on which data were available (i.e., pimaric, abietic, palustric, and dehydroabietic acid). Several rosin acids were toxic in the mid- to high parts per billion (ppb) range to several species such as Coho salmon (pimaric, abietic, and dehydroabietic acids), Rainbow trout (palustric and dehydroabietic acids) and Northern pike (dehydroabietic acid). Although there is considerable uncertainty with the toxicity of the rosins and rosin derivatives, they are unlikely to be more toxic than the rosin acids compounds and very unlikely to be as low as the compounds in the "terpene" family; the rosin acids are member of the "diterpene" family. Several of the terpene compounds exhibit acute effects in the low parts per billion, in the range of two to three orders of magnitude more toxic then diterpenes. It is also important to note that available toxicity studies for the rosin acids may well exceed the water solubility of these compounds, further reducing potential risks to aquatic organisms. Rosin acids have predicted solubility's below a part per million.

Literature information on the potential for rosin acids to bioconcentrate (plasma and whole body) was also available in the Agency's Ecotox Database. Bioconcentration factors (BCF) were below 500 for dehydroabietic acid using Rainbow trout in laboratory studies (four-day exposure) and below 100 in field studies (two- to 10-day exposure). Rainbow trout BCFs were around 100 for pimaric and abietic acid in the laboratory (four- to 30-day exposures) and much less than 100 for abietic acid in field studies (two- to 10-day exposures). Laboratory Rainbow trout BCF studies were reported a less than

25 (range of exposure from five to 30 days). Length of exposure did not appear to have an affect on the BCF.

Using the toxicity information below as a surrogate for the rosins and assuming a half-life of 100 days (representing primary degradation of between weeks to months; not readily biodegradable) and an adsorption coefficient of 1000 (Log K_{oc} for several of the rosin acids exceed 4; rosins are likely to have higher log K_{oc}s), application rates exceeding 2 pounds per acre may approach the listed species level of concern for the Coho salmon.

Table 5. Summary of Effects Data on Select Rosin Acids

Species	Rosin Acid (μg/L or ppb)			
	Pimaric	Abietic	Palustric	Dehydroabietic
Harpacticoid copepod (96h [a]LC_{50})		6200		
Daphnia magna (48h LC_{50})				2470 – 38300
Coho salmon (96h LC_{50})	320	410		750 – 1750
Fathead minnow (96h LC_{50})		2380		1500–45500
Rainbow trout (96h LC_{50})			550	770 –1850
Bluegill sunfish (96h LC_{50})				3800–6400
Northern pike (96h LC_{50})				700
Bleak (*Alburnus alburnus*) (96h LC_{50})				1850
Crucian carp (96h LC_{50})				1690
Whitefish (96h LC_{50})				1010
Sockeye salmon (96h LC_{50})				1380–2230
Lake trout (48h LC_{50})				1200

[a]LC_{50} refers to the lethal concentration where 50 percent of the test species died.

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