Tall Oil

Crop Production

Identification of Petitioned Substance

Chemical Name: Crude Tall Oil
Distilled Tall Oil

Other Names: Liquid Rosin, Tallol; Aceite de resina (Spanish); Talloel (German); Tallol (French), Liquid Resin

Trade Names: Crude Tall Oil, CTO (46 commercial manufacturers), Distilled Tall Oil

CAS Number: 8002-26-4

Other Codes: EINECS No. 232-304-6

Characterization of Petitioned Substance

Composition of the Substance:

Crude tall oil is an oily and viscous yellow-black liquid composed of a mixture of rosin acid (32.0% min), fatty acids (mainly oleic acid, palmatic acid and linoleic acid) and unsaponifiables (high-molecular alcohols, sterols and other alkyl hydrocarbon derivatives).

Composition of Typical Tall Oils (Pine Chemicals Association, Inc., 2008)

	Crude Tall Oil	**Distilled Tall Oil**
Acid Number	165	185
Fatty acids (%)	52	65
Resin acids (%)	40	30
Unsaponifiable matter (%)	8	5

Magee and Zinkel (1992) provide a complete chemical listing of the components in American distilled tall oils.

Properties of the Substance:

Ref. Weyerhaeuser, 2008 and Chemicalland21.com, 2009:

Physical State: Viscous Liquid
Color: Amber to dark brown
Odor: Odorless
Acid Value: 140 min (mg KOH/g)
pH Value: 2-4
Flash Point: 191° to 193°C (375° to 380°F)
Boiling Point (@780 mm Hg): 260°C (>500°F)
Solubility in Water: Negligible (0.5% max moisture)
Solubility in Solvents: Soluble in methanol, diethyl ether and acetone
Specific Gravity: 0.95- 1
Viscosity: Not Available
Vapor Density: Not Available
Auto Flammability: 315°C (599°F)
Molecular Weight: Variable

Specific Uses of the Substance: Crude tall oil (CTO) has been shown to be used to produce biodiesel fuel through supercritical methanol extraction (Green Car Congress, 2007). CTO has been used to produce plant sterols in treating human hypercholesterolemia disease. According to Conner et al. (1976), 20,000 tons of tall oil phytosterols are available to serve as a raw material for steroid drug production.

CTO is a major source of rosin. It is used as a binder in cement, as a component of drilling fluids for oil drills, and as an emulsifier for asphalt. Tall oil neutrals applied to plants serves as a natural insecticide and protect plants from insects and mites (U.S. Patent Office, 1989). Tall oil rosin and derivatives are used as a chewing gum base component, emulsifier and stabilizer/density adjustment agent for flavoring oils in beverages (FAO, 1996). It is found in Gatorade drink as an ingredient accessed at http://gatorade.elsstore.com/view/product/popup/?id=25071 and it is found in Pepsi carbonated soft drinks as an ingredient accessed at http://www.pepsiproductfacts.com/infobycategory.php?pc=p1062&t=1026&s=8&i=fingrdnt# . Tall oil rosin (TOR) is found in Wrigley's chewing gums as an ingredient accessed at http://nells.tripod.com/gum.html .

Approved Legal Uses of the Substance: Crude tall oil (CTO) breaks down by a high temperature (270° - 275°C), low pressure (800 – 1300 Pa) distillation process (Norlin, 2010) to tall oil fatty acid (TOFA), distilled tall oil (DTO), tall oil rosin (TOR) and tall oil pitch. According to the Forchem Tall Oil Life Cycle (Forchem Oy, 2009) distilled tall oil is used for paints, oil-based varnishes, and coatings, coating additives, surfactants, metalworking, oilfield chemicals, oil and fuel additives, pulp and paper chemicals. In addition, CTO is used for printing inks, adhesives (glues), rubber processing, mining chemicals, soaps and detergents, flotation agents, lubricants, biofuels, pesticide formulations, and road construction.

Action of the Substance: The major action of tall oil is a solvating, emulsifying, binding, coating, or drying agent.

Status

U.S. Environmental Protection Agency: This product does not contain any chemical components with known CAS numbers that exceed the de minimis reporting levels established by SARA Title III, Section 313 and U.S. EPA Title 40 Code of Federal Regulation (CFR) Part 372. This product has been reviewed according to the EPA Hazard Categories promulgated under SARA, Title III, Sections 311 and 312 and is considered under applicable definition to meet all hazard categories, except is an immediate (acute) health hazard. Tall oil is considered exempt from the requirement of a tolerance under U.S. EPA 40 CFR 180.910 for use in pesticide formulation applied to growing crops and crops after harvest (pre- and post harvest uses). Residues of the substance are considered exempted from an EPA tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or raw agricultural commodities after harvest (40 CFR 180.910). Tall oil is exempt from the requirement of a tolerance under U.S. EPA 40 CFR 180.389 for use as surfactants or related adjuvants of surfactants (40 CFR section 180.1001) to be accessed at http://www.setonresourcecenter.com/cfr/40CFR/P180_389.HTM .

U.S. Food and Drug Administration: Tall oil (rosin) is listed as a food additive (indirect and direct) in the FDA's regulations in Title 21 Code of Federal Regulation (CFR). The petitioned substance and its derivatives may safely be used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food (21 CFR section 178.3870). It is considered as a food additive for direct addition to food for human consumption to adjust the density of citrus oils used in the preparation of beverages at a maximum 100 parts per million level, and to provide for the use of steam distillation or steam stripping as a method of purification for producing glycerol ester of wood rosin, gum rosin, or tall oil rosin (21 CFR section 172.735). The petitioned substance is approved as a softener for chewing gum (21 CFR section

172.615). Tall oil (rosin) can be used as a flavoring in alcoholic beverages (21 CFR section 172.510). The substance can also be used as a coating on fresh citrus fruit (21 CFR section 172.210).

Association of American Feed Control Officials, Inc (AAFCO), Atlanta, GA.: Modified Tall Oil (MTO) in feeds according to O'Quinn et al. (2000) when fed to pigs does not appear to affect growth performance as formerly suggested by the AAFCO (1985) but improves carcass lean content and may additionally improve color and some other aspects of meat quality in growing finishing pigs.

International: Crude Tall is on the Canadian Domestic Substance List (DSL). According to the Pine Chemicals Association (2007) the reports on the toxicity and environmental testing of crude tall oil (CTO) were reviewed and approved by the International Maritime Organization for CTO shipment in bulk tankers at http://www.pinechemicals.org/ . Crude tall oil can be used as an insecticide repellent and is approved by the European Food Safety Authorization (EFSA) and is included in EU registration directive, EEC 91/414 Annex I for biopesticides (27 and 28 October 2008) to be accessed at http://www.pesticides.gov.uk/approvals.asp?id=2594

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: Is the petitioned substance formulated or manufactured by a chemical process? (From 7 U.S.C. § 6502 (21).

The manufacture of tall oil occurs by a series of chemical processes. First, the pine or coniferous tree wood is chemically digested in the named Kraft pulping process where the wood chips are digested under alkaline conditions (pH 14) for 18 hours at 50°C to free the wood fibers (Cantrill, 2008). The extractives dissolve in the pulping of pine trees solution (black liquor pulping soap). The black liquor substances are concentrated, are allowed to settle, and then the soapy material is separated from the cellulose pulp (Cantrill, 2008) by a surface skimming process. The skimmed off material is called tall oil soap and is the sodium salt of tall oil (U.S. EPA, 2009). Tall oil soap is then acidulated with sulfuric acid to pH 4.0 to yield crude tall oil. The tall oil soap is reacted with the sulfuric acid (H_2SO_4) at 102°C (Agnello and Barnes, 1960) to form crude tall oil using the following reaction (Wansbrough, 1987):

$$R\text{-}COONa + H_3O^+ \longrightarrow R\text{-}COOH + H_2O + Na^+$$

The acids formed from the reaction, along with other compounds of similar volatility in small amounts make up the crude tall oil.

$2C_{18}H_{32}COONa + H_2SO_4 \rightarrow 2C_{18}H_{32}COOH + Na_2SO_4$ (Louis Agnello and Ellis Barnes, 1960)

$2C_{19}H_{29}COONa + H_2SO_4 \rightarrow 2C_{19}H_{29}COOH + Na_2SO_4$ (Louis Agnello and Ellis Barnes, 1960)

Commercially, crude tall oil is fractionally distilled to manufacture tall oil fatty acids and tall oil rosin (U.S. EPA, 2009). A fraction from the distillation process is distilled tall oil, which has the same CAS registry number as crude tall oil. The petitioned substance is distilled tall oil (CAS No. 8002-26-4) that is formulated with the biofungicide (Australian tea tree leaf oil or CAS No. 85085-48-9) in the product named "Timorex Gold" (Biomor Israel Ltd.). The natural distilled tall oil serves as an emulsifier and solvating agent in the product formulation. The Timorex product contains 66% natural tea oil as the active fungicide ingredient in the formulation. Tea oil is steam distilled from the leaf of the Australian plant *Melaleuca alternifolia*.. Tea tree oil contains over 100 components, mostly monoterpenes, sesquiterpenes and their alcohols (Reuveni et al., 2009). Even though tall oil can serve as an organic pesticide it is not considered an active ingredient in the formulated product because of U.S. EPA's definition of active ingredient as follows:

Active ingredient (A.I.): The chemical or substance component of a pesticide product that can kill, repel, attract, mitigate or control a pest or that acts as a plant growth regulator, desiccant, or nitrogen stabilizer.

The remainder of a formulated pesticide product consists of one or more “inert ingredients” (such as water, solvents, emulsifiers, surfactants, clay and propellants), which are there for reasons other than pesticidal activity.

This definition found in the U.S. EPA pesticide glossary can be accessed at: http://www.epa.gov/pesticides/glossary/index.html

Evaluation Question #2: Is the petitioned substance formulated or manufactured by a process that chemically changes the substance extracted from naturally occurring plant, animal, or mineral sources? (From 7 U.S.C. § 6502 (21).

Crude tall oil is obtained as a chemical byproduct of the Kraft (sulfate) paper process in the alkaline treatment by sodium hydroxide or sodium bicarbonate under pressure with sodium sulfide of natural wood pulp from trees, especially pinewood from pine trees. The volatized gases are condensed to yield sulfate turpentine. The black liquor is concentrated and left to settle. The top insoluble layer known as “tall oil soap” is skimmed off from the surface (Weyerhaeuser, 2008). The tall oil soap is then reacted with sulfuric acid to form crude tall oil. An alternative acid to use is boric acid, but it is not used because it is expensive and interferes with the paper making process. The crude tall oil is fractionally distilled by high temperature, low pressure into distilled tall oil (having the rosin acid content of 10 - 35%) and further refinery gives rise to tall oil fatty acid (TOFA) with CAS No. 61790-12-3 (the rosin acid content of 1 - 10%), according to reference Chemicalland21.com (2009).

Evaluation Question #3: Is the petitioned substance created by naturally occurring biological processes? (From 7 U.S.C. § 6502 (21).

Tall oil products are materials extracted from wood pulp, especially pine tree wood, which is a renewable natural resource. During the process of pulping coniferous trees to make paper, sodium salts of chemicals (tall oil soap) occurring naturally in the trees are produced as a co-product (U.S. EPA, 2009). When acidulated, this soap becomes Crude Tall Oil (U.S. EPA, 2009).

Evaluation Question #4: Is there environmental contamination during the petitioned substance’s manufacture, use, misuse, or disposal? (From 7 U.S.C. § 6518 (m) (3).

During the manufacture of tall oil, the precursors or extractives dissolve in the pulping solution (black liquor), are concentrated, and then skimmed. The skimmed material is called tall oil soap and is the sodium salt of tall oil (U.S. EPA, 2009). Tall oil soap is then acidulated with sulfuric acid to pH 4.0 to yield crude tall oil. A by-product of this acidulation is "wastewater, tall oil soap acidulation," which is essentially a 12% solution of sodium sulfate containing dilute amounts (1 to 2%) of tall oil (U.S. EPA, 2009). Since the petitioned tall oil is not soluble in water it is not a dangerous substance to contaminate groundwater sources. After the tall oil is skimmed off the “black liquor”, the liquor is recycled for further use in the paper making process. The final waste stream (the aqueous layer formed by acidulation of tall oil soap with H_2SO_4) after the tall oil is extracted ends up and is discharged into a pulp mill’s wastewater treatment system. It is either recycled to the pulping process or diverted to wastewater treatment (U.S. EPA, 2008, pg. 2). However, U.S. EPA lists effluent limits and pollution guidelines to wastewater streams from manufacture for tall oil rosin (TOR) are in 40 CFR, part 454, §454.42 to be assessed at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=1c0c4500aa79ec12d283ff15fdad2f34&rgn=div8&view=text&node=40:29.0.1.1.25.4.5.3&idno=40

According to this U.S. EPA section 454.22 of title 40 reference, the biochemical oxygen demand (BOD_5) in effluent for TOR is 0.995 milligram per liter (mg/L) for the maximum discharge in any one day and 0.529 mg/L for the maximum average daily value for 30 consecutive days. The total suspended solids (TSS) non-filterable in effluent for TOR are 0.705 mg/L and 0.243 mg/L for the maximum average daily value for 30 consecutive days. The acceptable pH range is 6.0 to 9.0. EPA (2008a) states a low concern for potential worker exposure risk to tall oil and its related substances.

Evaluation Question #5: Is the petitioned substance harmful to the environment? (From 7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i).)

Available data indicate that the potential acute hazard of the tall oil to fish, aquatic invertebrates and aquatic plants is low (U.S. EPA, 2008a). The environmental effects of tall oil (MorningStar Consulting, 2008) were reported to EPA. Available environmental effects data and acute toxicity to fish, *Daphnia magna* or aquatic invertebrates, and green algae or aquatic plants were provided using the following terms:
LC50 or Lethal concentration 50 in milligrams per liter (mg/L) represents the concentration causing death to 50% of the exposed test organisms in a given time period.
LL50 or Lethal level 50 in mg/L represents the level of any environmental factor (pH, temperature, etc.) that causes death to 50% of the exposed group of organisms in a given time period.
EC50 or Effect concentration 50 in mg/L represents the concentration causing measurable effects to 50% of the exposed test organisms in a given time period.
EL50 or Effect level 50 in mg/L represents the level of any environmental factor causing measurable effects to 50% of the exposed test organisms in a given time period.

The acute toxicity data of tall oil (MorningStar Consulting, 2008) in an aquatic environment reported to EPA are given as follows:
The LC50 and LL50 for fish are 10 mg/L and greater than 1000 mg/L respectively at 96 hours.
The EC50 and LL50 for aquatic invertebrates are 55.7 mg/L and greater than 1000 mg/L respectively at 48 hours.
The EC50 and EL50 for algae are 0.79 to 9 mg/L and 854 mg/L respectively at 72 hours.

U.S. EPA (2001) state volatilization from water may be significant since many of the individual mixture components from tall oil and tall oil acidulation wastewater have low water solubilities and moderate Henry's Law constants in atm^3m^3/mol. If these substances enter the atmosphere in this manner they will be degraded rapidly by reaction with photochemically generated hydroxyl radicals and by reaction with ozone and nitrate radicals (EPA, 2001). Based on their environmental fate characterization (generally not persistent or bio-accumulative) the hazard of the substance to aquatic organisms under chronic exposure conditions is expected to be low because it is virtually insoluble in water (U.S. EPA, 2008a) at a determined 9 mg/L water solubility (Pine Chemicals Association, 2003) . U.S. EPA (2008a) state that the low bioaccumulation potential and low environmental persistence characteristics along with low acute toxicity to fish, aquatic invertebrates, and aquatic plants, suggest a low concern for potential risk to aquatic organisms from environment releases.

Evaluation Question #6: Is there potential for the petitioned substance to cause detrimental chemical interaction with other substances used in organic crop or livestock production? (From 7 U.S.C. § 6518 (m) (1).)

Study data by the U.S. Environmental Protection Agency (2008a) indicate no potential for the distilled tall oil to cause detrimental chemical interaction with other substances used in crop or animal livestock production. Repeated oral exposures of high doses of tall oil in animal studies showed minimal mammalian toxicity (U.S. EPA, 2008a, pg. 1 and pg. 3). In EPA (2008b) studies male and female Sprague-Dawley rats were administered tall oil concentrations up to 20,000 parts per million (ppm) in their diets. At 20,000 ppm (1600 mg/kg/kg-body weight/day) decreased food consumption, decreases in body and adrenal gland weights and increases in bilirubin and alkaline phosphatase levels were observed in both sexes. There were increases in liver weight, spleen weight and cholesterol levels in males and decreases in white blood cell count and ovary weight in females (U.S. EPA, 2008b, p. 16). The petitioned substance was administered to Charles River rats in their diet for up to 90 days and the test data showed the No Observed Effect Level (NOEL) was 5% at 2500 mg/kg/day (Pine Chemicals Association, 2004). Due to its low water solubility (9 mg/L) and lack of any measurable vapor pressure (effectively zero) at ambient temperature, stable hydrolysis (U.S. EPA, 2008b), and high biodegradability (60 to 73 percent biodegradation by microbes after 28 days, U.S. EPA, 2008b), there is no opportunity for tall oil and related substances to enter the atmosphere (Pine Chemicals Association, 2003). The addition of tall oil in swine diets improved belly firmness and reduced backfat of growing-finishing pigs without affecting the palatability of pork loin (longissimus muscle) chops (Waylan et al., 2002).

According to Hochman (2010) a layer of wax containing tall oil (rosin) can be applied as a coat to organic lemons, limes, grapefruits, oranges, tangerines as a protective barrier against moisture loss and dehydration. Karen Hochman (2010) provides the point that the wax coating is on the outer peel portion of the citrus fruits so it would not cause detrimental chemical effect. Also, the U.S. FDA allows the use of the petitioned substance as a coating on fresh citrus fruit (21 CFR section 172.210).

<u>Evaluation Question #7:</u> Are there adverse biological or chemical interactions in the agro-ecosystem by using the petitioned substance? (From 7 U.S.C. § 6518 (m) (5).)

There is some information available to indicate that distilled tall oil has virtually no harmful biological or chemical interactions in the agro-ecosystem. The ecological toxicity assessment of this petitioned substance indicates it has virtually no toxic effects or apparent harm to fish, plants, and animals (U.S. EPA, 2008a, pg. 1 and pg. 3). Based on mammalian toxicity data presented by Pine Chemicals Association (2004) presented to U.S. EPA tall oil is non-toxic. Pine Chemicals Association (2004) data is summarized as follows:

Tall oil has no acute oral toxicity (i.e., LD_{50} = > 10,000 mg/kg) and repeat dose toxicity data demonstrate no observed effect level (NOEL) of 2500 mg/kg/day. No evidence of reproductive or developmental toxicity was observed in a two generation study. Genotoxicity test results show no evidence of mutagenicity in *Salmonella* (i.e., Ames test) for tall oil. Chromosomal aberrations in Chinese hamster ovary cells were evident only at concentrations of tall oil that were overtly toxic to the cells.

U.S. EPA (2007) provided their acute toxicity study data of tall oil on animals as follows:

Sprague-Dawley rats (5/sex) were administered crude tall oil via oral route at 6000 mg/kg-body weight and observed for 14 days. One death was noted. Tall oil has no acute oral toxicity (i.e., LD_{50} = > 6,000 mg/kg-body weight). Repeat dose toxicity data on the rates demonstrate at 20,000 ppm or 16,000 mg/kg-body weight/day (the highest dose tested) there is decreased food consumption, decreases in body and adrenal gland weights and increases in bilrubin and alkaline phosphatase levels in both sexes. There was also a decrease in implantation sites at 20,000 ppm or 16,000 mg/kg-body weight/day (the highest dose tested).
Mutagenicity potential of tall oil was evaluated *in vitro* in Ames assays using five strains of *Salmonella typhimurium* in the presence and absence of metabolic activation and up to 5,000 µg/plate of test substance and no increases in mutation frequency were observed at any concentration tested.
In vitro chromosomal aberration assays (CAS No. 8002-26-4) were conducted using Chinese hamster ovary cells with and without metabolic activation, using tall oil at concentration ranging from 10 to 78 µg/mL. Chromosomal aberrations were observed with tall oil with metabolic activation, but only at cytotoxic concentration (30 µg/mL). No aberrations were observed at concentrations that were not cytotoxic with or without metabolic activation.

For potential ecototoxicological effects, tall oil or related substances are non-toxic to aquatic organisms. The acute toxicity data of tall oil (Pine Chemicals Association, 2003 and 2004) in an aquatic environment reported to EPA are given as follows:

The acute no observed effect loading rate ($NOEL_r$) for fish is 1000 mg/L at 96 hours.
The acute no observed effect loading rate ($NOEL_r$) for aquatic invertebrates (Daphnia) is 1000 mg/L at 48 hours.
The acute no observed effect loading rate ($NOEL_r$) for algae is 854 mg/L at 72 hours.

U.S. EPA (2007) provided their acute toxicity study data of tall oil on aquatic organisms as follows:

The acute no observed effect loading rate ($NOEL_r$) for Fathead minnows (*Pimephales promelas*) is 1000 mg/L at 96 hours.

The acute no observed effect loading rate ($NOEL_r$) for aquatic invertebrates (*Daphnia magnia*) is 1000 mg/L at 48 hours.
The acute no observed effect loading rate ($NOEL_r$) for Green algae (*Pseudokirchneriella subcapitata*) is 1000 mg/L at 72 hours.

In greenhouse and field trials on chrysanthemum and cabbage, Xie and Isman (1995) did not observe any plant toxicity following once a week applications of tall oil at a concentration of 1%. The 1% tall oil was observed to cause 50% mortality and 55% deterrency of aphids, especially at the second-instar stage and it provided pest control for other soft-bodied insects. Xie and Isman (1995) suggested mortality was a consequence of both deterrent (starvation) and toxic actions of the tall oil. In separate studies of Xie et al. (1993) results showed that resin acids are responsible for antifeedant and growth inhibitory action of crude tall oil (containing 27% total resin acids) against the variegated cutworm (caterpillars of night-flying moths). Bioassays with commercial pure resin acids (abietic, dehydroabietic, and isopimaric acids) did verify the importance of individual resin acids to the bioactivity of crude tall oil (Xie et al., 1993). Each of the test chemicals inhibited cutworm larvae in a dose-dependent manner and no synergistic action was involved (Xie et al., 1993).

<u>Evaluation Question #8</u>*:* Are there detrimental physiological effects on soil, organisms, crops, or livestock by using the petitioned substance? (From 7 U.S.C. § 6518 (m) (5).)

According to the Pine Chemicals Association (2003), the five physicochemical variables required to be measured and evaluated in the Screening Information Data Sets (SIDS) battery for U.S. EPA's screening studies and hazard characterization of a high production volume (HPV) chemical like tall oil include melting point, boiling point, vapor pressure, octanol-water partition coefficient (K_{ow}), and water solubility. According to the U.S. EPA (2007) the measured physicochemical properties are listed as given for tall oil (CAS No. 8002-26-4) and are evaluated as follows:

Melting point (°C) and boiling point (°C) temperatures were not determined because tall oil is a complex mixture and will either not give a sharp melting point when heated or will decompose on heating at a high temperature before it melts or boils. The vapor pressure (hPa at 25°C or ambient conditions) is negligible or fundamentally zero so measurement is not obtainable. The measured water solubility for tall oil is 9 mg/L at 20°C. This is an analytical measurement issue also because tall oil is basically insoluble in water at 25°C or ambient temperature conditions. The log of the partition coefficient (K_{ow}) for tall oil equals a range of values (4.9-7.7) measured (EPA, October 2007, p. 6, Table 1) rather than a single value representative of the complex mixture.

There is no consistency of partition coefficient (K_{ow}) results between tests when tall oil is measured as a complex mixture because when the analyst uses standardized methods to determine the K_{ow} range of values for crude tall oil, the petitioned chemical substance will readily fractionate into its various components before the analysis is even complete. Hence, in the same U.S. EPA (October 2007) document above on page 4 the log K_{ow} values for tall oil are provided as follows:

Log K_{ow} = 4.9 to 8.2 (measured at pH 2)

In order to have an accurate and reliable measurement for partition coefficient (K_{ow}) values for tall oil, the partition coefficients of individual fatty acid constituents or individual substance components are determined separately in the complex mixture by standard analytical methods. EPA (2007) provided the log K_{ow} values for tall oil (page 4) as follows:

Log K_{ow} = 3.5 to 5.4 (measured at pH 7.5) for five components

The K_{ow} values provide a significant measurement for EPA of the environmental fate of crude tall oil chemical and its related components. According to the U.S. EPA (1999, 64 FR 60194), solubility in octanol solvent (as a substitute for fat) is not a good predictor of bioaccumulation in fish. K_{ow} is correlated with the potential for a chemical to bioaccumulate in organisms; the bioconcentration factor (BCF) can be predicted from log K_{ow} (EPA, 1999). For example, a log K_{ow} of 4 versus a log K_{ow} of 5 is equivalent to a BCF of approximately 1,000 versus 5,000, respectively (EPA, 1999). The bioaccumulation for tall oil is expected to be low based on estimated bioconcentration factor (BCF) of 10 (EPA, 2008b) for some representative components (oleic acid and linoleic acid) of the mixture and based on the accumulation of the substance in aquatic organisms living in contaminated environments.

EPA (1999) states that K_{ow} is a coefficient which serves as a substitute for the partitioning of chemicals between water and fat, and cannot be accurately estimated via separate determinations of solubility in pure octanol and water (i.e., by calculating the ratio of the pure solvent solubilities). Dybdah (1993) conducted a physiochemical property evaluation of distilled tall oil using a Partition Coefficient (n-Octanol/Water) or Pow [Kow] determination using a High Performance Liquid Chromatograph (HPLC) Method. The Octanol/Water Partition Coefficient (Pow or commonly indicated as K_{ow}) is correlated to water solubility, soil/sediment sorption coefficient, and bioconcentration of the distilled tall oil. At pH 2, the log Pow [Kow] values of eight components in tall oil were 6.1, 6.5, 7.0, 7.4, 7.6, 7.8, 8.1, and 8.2. At pH 7.5, the log Kow values of five components in tall oil were 3.5, 4.2, 4.5, 4.7, and 5.4 (Dybdah, 1993, pg. 21). Due to the distribution coefficient, n-octanol/water data, an accumulation of tall oil in organisms is not expected.

Study data by the U.S. Environmental Protection Agency (2008a) indicate no potential for the distilled tall oil to cause detrimental chemical interaction with other substances used in crop or animal livestock production. Movement of distilled tall oil in the environment would be very limited.

The release or transport and distribution tendency of tall oil from a particular environmental compartment or partition (e.g., air, water, soil and sediment) and the photodegradation tendency were provided to EPA by MorningStar Consulting (2008) as follows:

Less than 0.1 nanograms (ng) of tall oil escaped from 1 cubic meter (m^3) of air
7 to 8 grams (g) of tall oil escaped from 1 liter (L) of water
28 to 29 milligrams (mg) of tall oil escaped from 1 kilogram (kg) of soil
63 to 64 milligrams (mg) of tall oil escaped from 1 kilogram (kg) of sediment

Half (50%) of tall oil undergoes photodegradation in 2 hours or less.

<u>Evaluation Question #9:</u> Is there a toxic or other adverse action of the petitioned substance or its breakdown products? (From 7 U.S.C. § 6518 (m) (2).)

According to the Pine Chemicals Association, Inc. HPV Task Force (2003) no adverse health consequences would be associated with any exposures to tall oil or related substances. For potential ecotoxicological effects, the data on tall oil or its breakdown products demonstrate they are non-toxic to aquatic organisms including fish, daphnia and algae with the no observed effect loading rate or NOELr for each test at greater 1000 mg/L (Pine Chemicals Association, Inc., 2003, pg. 23). Volatilization to air and hence inhalation exposure would be minimal due to the essential lack of a vapor pressure for this petitioned substance. Exposure is generally limited to dermal contact during manufacture of the products derived from tall oil. P. A. Botham et al., 2008 states that tall oil rosin (a by-product of pulping) when tested in guinea pigs in its non-oxidized form was found to be not a skin sensitizer. However, a guinea pig maximization test (GPMT) showed that tall oil rosin (TOR) in its readily oxidized form can be considered a skin sensitizer and should follow labeling and regulatory requirements of the European Union. A human patch testing study in 1785 patients investigated dermal contact sensitivity to TOR (Johnson and Bonner, 2009). A total of 50 patients (2.8%) tested positive for TOR 48 or 72 hours after application. Males experienced a 1.8% incidence

(11/613) and females exhibited a 3.3% incidence (39/1172). Patients at age 50 years or older had a higher incidence (4.4%) of sensitivity to TOR in the study.

Evaluation Question #10: Is there undesirable persistence or concentration of the petitioned substance or its breakdown products in the environment? (From 7 U.S.C. § 6518 (m) (2).)

Available data indicate tall oil has low persistence and low bioaccumulation potential (U.S. EPA, 2008a, pg. 2). According to Madsen (1993) distilled tall oil (CAS No. 8002-26-4) degrades 43% after 7 days and 60% after 28 days.

The release or transport and distribution tendency of tall oil from a particular environmental compartment or partition (e.g., air, water, soil and sediment) and the photodegradation tendency were provided to EPA by MorningStar Consulting (2008) as follows:

Less than 0.1 nanograms (ng) of tall oil escaped from 1 cubic meter (m^3) of air
7 to 8 grams (g) of tall oil escaped from 1 liter (L) of water
28 to 29 milligrams (mg) of tall oil escaped from 1 kilogram (kg) of soil
63 to 64 milligrams (mg) of tall oil escaped from 1 kilogram (kg) of sediment

Half (50%) of tall oil undergoes photodegradation in 2 hours or less.

According to U.S. EPA (2008b) tall oil (CAS No. 8002-26-4) remains in a liquid state as a complex mixture at room temperature. The substance is measured to be readily 60 to 73% biodegradable and undergoes photolysis at 28 days, hydrolysis is at a negligible rate, persistence is ranked P1 (low), and bioaccumulation is ranked B1 (low). The bioaccumulation for tall oil is expected to be low based on estimated bioconcentration factor (BCF) of 10 (EPA, 2008b) for some representative components (oleic acid and linoleic acid) of the mixture and based on the accumulation of the substance in aquatic organisms living in contaminated environments.

Evaluation Question #11: Is there any harmful effect on human health by using the petitioned substance? (From 7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i) and), 7 U.S.C. § 6518 (m) (4).)

There is sufficient data on acute mammalian toxicity for tall oil demonstrating that this compound is non-toxic to humans (Pine Chemicals Association, Inc. HPV Task Force, 2003, pg. 23). In fact recent research has successfully demonstrated a use for tall oil phytosterols in treating human patients with hypercholesterolemia (O'Quinn et al., 2000). Repeated oral exposures of tall oil in animal studies show it has low toxicity to human health (U.S. EPA, 2008a). There was no developmental toxicity and low reproductive toxicity observed in a combined repeated dose/reproductive/ developmental toxicity screening test with tall oil (U.S. EPA, 2008a). Table 3 in U.S. EPA (2007) document provides a summary of human health data for tall oil (CAS 8002-26-4) as follows:

Acute oral toxicity data shows LD_{50} is greater than 6000 mg/kg-body weight (human bw).
Repeated dose toxicity data shows NOEL is 80 mg/kg-bw/day and LOAEL is 414 mg/kg-bw/day.
Reproductive (Maternal) toxicity data shows NOEL is 80 mg/kg-bw/day and LOAEL is 414 mg/kg-bw/day.
Developmental toxicity data shows NOEL is 414 mg/kg-bw/day and LOAEL is 1600 mg/kg-bw/day.
Genetic toxicity data shows gene mutation *in vitro* is negative and shows chromosomal aberrations *in vitro* is negative.

LD_{50} equals lethal level 50.
NOEL equals no observable effects level.
LOAEL equals lowest observable adverse effects level.

Evaluation Question #12: Is there a wholly natural product that could be substituted for the petitioned substance? (From 7 U.S.C. § 6517 (c) (1) (A) (ii).)

A substitute is animal tallow, which is obtained wholly naturally as a rendered form of beef or mutton fat. Tallow fatty acids (21 CFR 172.660) like plant derived tall oil fatty acids can be used for the production of soaps and lubricants. About 35% of the United States fatty acid production and more than 50% of the unsaturated fatty acid part comes from tall oil (Goldstein, 1993). Tall oil is a major source of fatty acids (Sheely and Potts, 1958). Another natural substitute for the petitioned substance includes terpene extracts from soft woods (Gershenzon and Dudareva, 2007).

Evaluation Question #13: Are there other already allowed substances that could be substituted for the petitioned substance? (From 7 U.S.C. § 6517 (m) (6).)

Neem oil could be substituted for the petitioned substance or distilled tall oil. Organic neem oil of vegetable origin shares several of the uses of distilled tall oil including being allowed as a bio-pesticide for powdery mildew (Green Earth Products, 2009, ref. 1 and Wikipedia, 2009, pg. 2). However, neem oil is not a good source of rosin acids like tall oil. However, neem oil is a good source of fatty acids as tall oil. Other approved substitutes for the petitioned substance include vegetable oils (ICIS, 2003), and white mineral oil (Arizona Chemical, 2009).

Evaluation Question #14: Are there alternative practices that would make the use of the petitioned substance unnecessary? (From 7 U.S.C. § 6517 (m) (6).)

Farmers could use various alternative methods as crop rotation and usage of beneficial insects (Green Earth Products, 2009, ref. 2) which would make the use of the petitioned substance (distilled tall oil) in an organic formulated pesticide product unnecessary. The application of plant sterols as food and beverage ingredients would make the petitioned substance unnecessary (FSANZ, 2009; Cantrill, 2008). The daily intake (ADI) for plant sterols or phytosterols has already been established by FSANZ (2009) to be 40 mg/kg body weight (human).

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