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Amended Safety Assessment of Tall Oil Acid, Sodium Tallate, Potassium Tallate, and Ammonium Tallate

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Abstract

Tall oil acid is a mixture of oleic and linoleic acids (fatty acids) and rosin acids derived from tall oil, a by-product of pulp from resinous woods, used in cosmetic products as a surfactant at concentrations up to 8%. Ammonium, potassium, and sodium salts also are listed as cosmetic ingredients. In addition to the studies summarized in this report, extensive toxicity, genotoxicity, and carcinogenicity studies in animals are available for oleic, lauric, palmitic, myristic, and stearic fatty acids as published earlier by the Cosmetic Ingredient Review (CIR). These data may be extrapolated to tall oil acid and its salts. There are no reports of current uses or use concentration data for ammonium tallate, nor are use concentration data available for the other salts. The CIR Expert Panel found tall oil acid, ammonium tallate, potassium tallate, and sodium tallate to be safe cosmetic ingredients in the given practices of use and concentration.

Keywords

safety, cosmetics, Tall Oil Acid, tallates

The Cosmetic Ingredient Review (CIR) Expert Panel previously evaluated the safety of tall oil acid in cosmetics, finding it to be safe for use in cosmetic products.[1] The Expert Panel considered that the available data in that safety assessment were sufficient to also support the safety of the salts of tall oil acid that are used in cosmetics. This report, therefore, is an amended safety assessment of tall oil acid that includes sodium tallate, potassium tallate, and ammonium tallate as used in cosmetics. This safety assessment includes new data on tall oil acid, along with all available data addressing the safety of the sodium, potassium, and ammonium salts.

Because tall oil contains fatty acids, the CIR Expert Panel also considered relevant its earlier safety assessment of oleic, palmitic, myristic, and stearic acids and the finding that these fatty acids were safe for use in cosmetics.[2] In 2006, the Expert Panel considered all newly available data on these fatty acids and reaffirmed that conclusion.[3]

Chemistry

Tall Oil Acid

According to the *International Cosmetic Ingredient Dictionary and Handbook*, tall oil acid (CAS No. 61790-12-3) is the mixture of rosin acids and fatty acids recovered from the hydrolysis of tall oil (Table 1).[4]

Some technical and other names and trade names for tall oil acid given in the *International Cosmetic Ingredient Dictionary and Handbook* include the following[4]:

Technical and other names

- Acids, tall oil
- Fatty acids, tall oil

Trade names

- Actinol EPG
- Actinol FA-1
- Actinol FA-2
- Pamak 4

Sodium Tallate

According to the *International Cosmetic Ingredient Dictionary and Handbook*, sodium tallate (CAS No. 61790-45-2) is the sodium salt of tall oil acid (qv).[4]

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Table 1. Definitions and Functions of Tall Oil Acid and Its Salts as Given in the *International Cosmetic Ingredient Dictionary and Handbook*[4]

Ingredient	Definition	Function(s)
Tall oil acid	Mixture of rosin acids recovered from the hydrolysis of tall oil	Surfactants, cleansing agents Surfactants, emulsifying agents
Ammonium tallate	The ammonium salt of tall oil acid	Surfactants, cleansing agent
Potassium tallate	The potassium salt of tall oil acid	Surfactants, cleansing agents Surfactants, emulsifying agents
Sodium tallate	The sodium salt of tall oil acid	Surfactants, cleansing agents Surfactants, emulsifying agents

Potassium Tallate

According to the *International Cosmetic Ingredient Dictionary and Handbook*, potassium tallate (CAS No. 61790-44-1) is the potassium salt of tall oil acid (qv).[4] A synonym for potassium tallate is tall oil acid, potassium salt. A trade name mixture is Akypogene ZA 97 SP.

The Environmental Protection Agency reported the following synonyms for this chemical[5]:

- Fatty acids, tall-oil, potassium salts
- Tall oil, potassium salt
- Potassium soap of tall oil fatty acids (C18)
- Tall oil acids, potassium salt
- Tall oil fatty acid potassium soap

Ammonium Tallate

According to the *International Cosmetic Ingredient Dictionary and Handbook*, ammonium tallate (CAS No. 68132-50-3) is the ammonium salt of tall oil acid (qv).[4] Some technical and other names for ammonium tallate include fatty acids, tall oil, ammonium salts and tall oil fatty acids, and ammonium salts.

Physical and Chemical Properties and Composition

Tall oil acid, as used in cosmetic products, is a clear, pale-yellow liquid with a characteristic fatty odor and consists mainly of oleic acid (40%), linoleic acid (38%), other fatty acids (13%), and rosin acids (0.6%). Tall oil acid is soluble in most polar and nonpolar organic solvents, but it is insoluble in water.[6]

The chemical and physical properties of tall oil acid, sodium tallate, potassium tallate, and ammonium tallate are presented in Table 2.

Dybdahl[7] reported that the octanol/water partition coefficient (log P_{ow}) for fatty acids in tall oil acid ranged from 4.4 to 8.3 at pH 2 and from 3.6 to 7.4 at pH 7.5. A mixture of 7 materials with known log P_{ow} values was used for reference.[7]

According to Whitman,[8] tall oil acid is composed mainly of palmitic acid, stearic acid, oleic acid, and linoleic acid, which are all natural products derived from the pulping of pine trees. All of these fatty acids are labeled "generally recognized as safe" (GRAS) food additives by the Food and Drug Administration (FDA).[9]

Table 2. Physical and Chemical Properties and Chemical Class of Tall Oil Acid, Sodium Tallate, Potassium Tallate, and Ammonium Tallate

Ingredient and Properties	Value/Description
Tall oil acid	
Chemical class[4]	Fatty acids[4]
Description	Pale color, oily liquid[22]
Iodine value (Wijs)[31]	130
Saponification value[31]	200
Rosin acids (%)[31]	0.5
Unsaponifiables (%)[31]	0.5
Color (Gardner)[31]	1
Flash point, Cleveland Open Cup test[31]	400 °F
Specific gravity at 25°C	0.897
Viscosity (cps, at 25°C)[31]	20
Sodium tallate	
Chemical class[4]	Soaps[4]
Potassium tallate	
Chemical class[4]	Soaps[4]
Ammonium tallate	
Chemical class[4]	Soaps[4]

Taylor and King[10] reported that tall oil is a dark, odorous liquid.[10] Fatty acids, rosin acids, sterols, and other compounds mainly make up this resinous material. The chemical composition of tall oil varies with the age, species, and geographical location of the source coniferous trees. The resin acids are diterpene carboxylic acids based on an alkyl-substituted perhydrophenanthrene ring structure, and the fatty acids are predominantly 18-carbon, straight-chain mono-unsaturated or di-unsaturated fatty acids.

The Pine Chemicals Association[11] reported that the following chemicals are collectively known as tall oil fatty acids and tall oil fatty acid salts:

- CAS No. 61790-12-3, fatty acids, tall-oil (tall oil acid)
- CAS No. 65997-03-7, fatty acids, tall oil, low boiling
- CAS No. 68955-98-6, fatty acids, C16-C18 and C18 unsaturated, branched and linear
- CAS No. 68201-37-6, octadecanoic acid, branched and linear
- CAS No. 61790-44-1, fatty acids, tall oil, potassium salts (potassium tallate)

Table 3. Composition of Typical Tall Oil Fatty Acid[11]

Common Name	Chemical Structure	Percentage of Composition
Palmitic acid	$CH_3(CH_2)_{14}COOH$	1
Stearic acid	$CH_3(CH_2)_{16}COOH$	2
Oleic acid	$CH_3(CH_2)_7CH{=}CH(CH_2)_7COOH$	48
Linoleic acid	$CH_3(CH_2)_4CH{=}CHCH_2CH{=}CH(CH_2)_7COOH$	35
Conjugated linoleic acid[a]	$CH_3(CH_2)_xCH{=}CHCH{=}CH{-}(CH_2)_yCOOH$	7
Other acids[b]	—	4
Unsaponifiable matter	—	2

[a] $x + y = 12$; x usually 4 or 5; y usually 7 or 8.
[b] Other acids include 5,9,12-octadecatrienoic acid; linoleic acid; 5,11,14-eicosatrenoic acid; cis,cis-5,9-octadecadienoic acid; eicosadienoic acid; elaidic acid; cis-11 octadecanoic acid; C-20, C-22, C-24 saturated fatty acids.

- CAS No. 61790-45-2, fatty acids, tall oil, sodium salts (sodium tallate)

Tall oil fatty acids and their derivatives are composed of a complex mixture and are often difficult to characterize. Their composition is variable. The melting point cannot be measured because these substances either will not give a sharp melting point when heated or will decompose before they melt. Tall oil fatty acid and all other nonsalts in this category are liquids at room temperature. Boiling points cannot be determined because these substances will decompose before they boil. Under ambient conditions, the vapor pressure of these chemicals is essentially zero, and experimental measurement is not possible. The partition coefficients can yield a range of values representing the various components rather than a single value representing the mixture.

The composition of a given tall oil fatty acid depends on the origin of the tall oil and the fractionation conditions used for its production. The composition of a typical tall oil fatty acid provided by Pine Chemicals Association[11] is shown in Table 3.

According to Waylan et al,[12] modified tall oil (from which tall oil acid is derived) has a high content of conjugated linoleic acid (67.4%) from further processing the fatty acid portion of tall oil.

Use

Cosmetics

Balsam and Sagarin described tall oil acid as a substitute for oleic acid or other fatty acids in formulating cosmetics.[13] According to these authors, tall oil acid is converted to a soap by reaction with bases and then used primarily as a conditioner or emulsifier in hair dyes and bleaches.

The Pine Chemicals Association stated that tall oil fatty acid salts are widely used as surfactants in liquid soaps.[11]

As given in the *International Cosmetic Ingredient Dictionary and Handbook*, tall oil acid functions as a surfactant (cleansing agent and emulsifying agent) in cosmetics.[4] The tall oil acid salts also function as surfactants (cleansing agents and emulsifying agents) in cosmetics.

Manufacturers report current uses of cosmetic ingredients, as a function of product type, to the US FDA under the Voluntary Cosmetic Registration Program (VCRP). Use concentration data are obtained from a survey of the industry done by the industry trade association, formerly the Cosmetic, Toiletry, and Fragrance Association (CTFA) and now the Personal Care Products Council.

Table 4 presents the current product uses reported under the VCRP for tall oil acid, sodium tallate, and potassium tallate in cosmetics along with the total number of products in each category.[14] For example, of a total of 135 shaving cream products, only 1 use of tall oil acid was reported. Clearly, most shaving cream products do not contain tall oil acid. The industry survey done by CTFA reported use concentrations for tall oil acid from 0.6% to 8.0%.[15] No use concentration data were reported for the tall oil acid salts, and no product uses for ammonium tallate were reported under the VCRP.[14-16]

Noncosmetic

As included in the Code of Federal Regulations (CFR), the FDA has approved tall oil acid for use as an indirect food additive and defoaming agent used in the manufacture of paper and paperboard products and coatings of articles intended for use in packaging, transporting, or holding food (21CFR parts 176.200, 176.210, and 720.4).

The use of tall oil acid in preparations of edible oils and edible fat compositions has been patented.[17,18] Tall oil acid is used as a raw material for protective coatings, particularly in alkyd resins, soaps, detergents, and disinfectants.[19]

Pearl[20] stated that large quantities of tall oil acid are used as intermediate chemicals; they are further processed or modified chemically before being incorporated into a product or used in production.

Tall oil acid and its derivatives are used in the manufacturing of rubber, paper, soaps and detergents, printing inks, metalworking fluids, corrosion inhibitors, and plasticizers.[11,21,22]

General Biology

Absorption, Distribution, Metabolism, Excretion

No data are available on absorption, distribution, metabolism, and excretion.

Table 4. Current Uses and Concentrations of Tall Oil Acid, Sodium Tallate, and Potassium Tallate in Cosmetics

Product Category	Ingredient Uses (Total No. of Products in Category)[14]	Use Concentrations, %[15]
Tall oil acid		
Hair coloring preparations		
Hair dyes	NR (1600)[a]	0.6 (0.3 after dilution)
Personal hygiene products		
Other personal hygiene products	3 (390)	NR[a]
Shaving preparations		
Shaving cream	1(135)	NR[a]
Skin care preparations		
Skin cleansing creams, lotions, liquids, and pads	2 (1009)	8
Total uses/ranges for tall oil acid	6	8
Sodium tallate		
Personal hygiene products		
Other personal hygiene products	6 (390)	NR[a]
Total uses/ranges for sodium tallate	6	NR
Potassium tallate		
Personal hygiene products		
Other personal hygiene products	9 (390)	NR[a]
Total uses/ranges for potassium tallate	9	NR

NR, data not reported.

[a] In some cases, ingredient uses were not reported to FDA in the voluntary industry product survey program, but concentrations were provided. In other cases, the uses were reported, but no concentration was provided.

Animal Toxicology

Acute Oral Toxicity

Mallory[23] reported on an acute oral toxicity study in Sprague-Dawley rats (10 males, 10 females). Each animal received a single oral gavage dose of 10 000 mg/kg tall oil acid and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. None of the animals died. One hour after dosing, piloerection was observed in 1 male, and abnormal stance was observed in 1 male and 1 female. By 4 hours, these effects had resolved. No body weight effects were observed. Gross necropsy revealed no treatment-related effects. The acute oral median lethal dose of tall oil acid was greater than 10 000 mg/kg.

Short-Term Oral Toxicity

An experiment was conducted to study the effect of tall oil acid distillate on the growth of rats. The distillate used in this study was described by the authors as containing 1.8% to 2.2% rosin and 2.8% to 3.2% unsaponifiable matter. It was composed of 42.8% linoleic acid, 38.8% oleic acid, and 17.4% other fatty acids. Male weanling Sprague-Dawley rats, 10 per group and weighing 40 to 60 g, were fed diets containing 15%, 30%, and 60% of the total calories as tall oil acid distillate for 4 weeks. Control groups received diets containing the same percentages of soybean oil. Feed consumption and body weight were measured at least every other day. The growth rate of animals fed a diet with 15% tall oil acid distillate did not differ significantly from that of the control group. Animals in the group receiving 30% of their calories from tall oil acid distillate had a significantly lower growth rate than did the controls, and their feed consumption was slightly more than half that of the control group. One animal in the 15% group died during the experiment. All 10 of the animals in the 60% group died in the first 4 days of the start of the experiment. The author concluded that there was "a growth-retarding or possibly a toxic factor in the tall oil fatty acid distillate."[24]

Subchronic Oral Toxicity Study

Fancher[25] reported on a 90-day subchronic oral toxicity of tall oil fatty acid in albino rats. Tall oil fatty acid was administered to Charles River rats (10 males, 10 females) in the diet at concentrations of 0%, 5%, 10%, or 25% for 90 days. The approximate doses were 0, 2500, 5000, or 12 500 mg/kg/d. Two control rats died during blood sampling. No other deaths occurred and no clinical signs were observed. Body weight and body weight gain were not affected by treatment, but food consumption was slightly decreased at 10% and 25%. No changes in hematology, clinical chemistry, or urinalysis parameters occurred at any dose. At gross pathology, no treatment-related effects were noted at any dose. No consistent organ weight changes and no histopathological effects were reported. Based on these data, the no observed effect level (NOEL) was 5% (approximately 2500 mg/kg/d).

Chronic Toxicity and Irritation

Data on chronic toxicity, ocular irritation, mucosal irritation, and dermal irritation were not available.

Reproductive and Developmental Toxicity

Tall oil acid had no effects when tested for reproductive and developmental toxicity in Sprague-Dawley rats in a full 2-generation study.[26] The test material was administered in the diet at concentrations of 0%, 5%, or 10% to 30 females per group and 15 males per group. The approximate doses were 0, 2500, and 5000 mg/kg/d. Males and females (F0) began treatment at 80 days of age and were mated at 100 days of age. Treatment of the F0 animals continued through the weaning of the first generation (F1). After weaning, the F1 males and females were maintained on the treatment diet. At 100 days of age, they were mated and allowed to deliver pups (F2).

There were no treatment-related effects on reproductive performance or on any parameter measured in either the F1 or F2 pups. No treatment-related changes in fertility, viability, lactation, or gestation indices were observed. Hematology, clinical chemistry, and urinalysis parameters were similarly unchanged, and there were no developmental effects in any F1 or F2 offspring. Tall oil acid did not alter or otherwise affect the reproduction or development of rats in this study at doses as high as 10% (approximately 5000 mg/kg/d).[26]

A 2-generation reproduction study was conducted in which tall oil acid was fed to Charles River CD Sprague-Dawley rats. The rats were classified into 5 groups each consisting of 15 males and 30 females. The experimental groups included negative control, 5% tall oil acid, 10% tall oil acid, 5% oleic acid, and 10% oleic acid. Tall oil acid used in this study was only described as a clear amber-colored liquid with a heavy odor similar to a vegetable oil. The rats (the F0 generation) were fed the test diets for approximately 3 weeks and were then put in mating cages with 1 male and 2 females per cage. The F1 litter was weaned onto the test chemical diets, and 20 female and 20 male rats were carried on to sexual maturity, having been fed the test diet for approximately 180 days, for each of the 5 test groups. These rats were then arranged in mating groups, and the following parameters were measured for the parents and offspring: mating behavior, number of pregnant dams, total number of pups (live born, stillborn, number discarded on day 4, and number alive on day 21), average number of pups per litter (born, day 4, and weaned), and the average weaning weight of the pups. The fertility, viability, lactation, and gestation indices were computed. Clinical chemistry determinations were made for 5 male and 5 female rats from each test group of the F1 generation. Rats from each test group of the F1 generation, 10 males and 10 females, were examined for any abnormalities occurring in hematologic and urinalysis values and organ weights. All rats, whether they died or were killed, were necropsied. No treatment-related effects were found. Several animals had lesions of chronic respiratory and renal diseases, which are endemic in this strain of rat.[27]

Genotoxicity

Godek[28] reported that tall oil fatty acid was not mutagenic in the Ames assay. It was tested for mutagenicity in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538 at concentrations of 100, 1000, and 10 000 μg per plate, with and without metabolic activation. Information regarding the controls was not provided. No increases in mutation frequency were reported at any concentration, with or without metabolic activation. Tall oil acid was not mutagenic in this assay, and there are no in vivo genotoxicity data using mammalian cells.

Carcinogenicity

No carcinogenicity studies using these cosmetic ingredients were available.

Clinical Assessment of Safety

Dermal Irritation

CTFA[29] reported that tall oil acid in a liquid soap was tested for dermal irritancy potential. The soap contained 12% tall oil acid and was tested at a concentration of 25% in water for a total tested concentration of 3% tall oil acid. The controlled use study was performed according to the CTFA testing guidelines.[30] This type of study is expected to detect adverse reactions under the conditions of expected normal use. The hands and fingers of 54 subjects were examined every week during the 4 weeks of in-use study. No positive reactions occurred during the test, and the soap was nonirritating.

A prophetic patch test also was conducted with a liquid soap containing 12% tall oil acid. The formulation was tested undiluted. The 100 subjects received 2 patches 10 to 14 days apart; both open and closed patches were used. None of the subjects had positive reactions at any of the patch sites. The soap formulation was nonirritating.[29]

Dermal Sensitization and Photosensitization

A liquid soap containing 12% tall oil acid was tested in a repeat-insult patch test. The soap formulation was tested undiluted. A total of 11 patches were applied to the skin of 50 panelists. It was not stated how long the patches stayed in contact with the skin or at what interval the patches were applied. The subjects were exposed to ultraviolet light, of an unspecified wavelength, at patch numbers 1, 4, 7, 10, and 11. No positive reactions were observed at open or closed patch sites. The soap formulation was determined to be nonsensitizing and nonphotosensitizing.[29]

Summary

Tall oil acid is a mixture of oleic and linoleic fatty acids and rosin acids derived from the hydrolysis of tall oil, a by-product of pulp from resinous woods (mainly pine). Safety assessments of the oleic and linoleic acids previously were reported. The salts of tall oil acid also were included in this

safety assessment, including sodium tallate, potassium tallate, and ammonium tallate.

Tall oil acid was reported in 2006 to be used in a small number of formulations at concentrations ranging from 0.6% to 8%. Similar numbers of uses were reported for sodium and potassium tallate, although no use concentration data were available. Ammonium tallate was not reported to be used.

When fed to rats as 15% of total caloric intake, tall oil acid was nontoxic. At 30% and 60% of total caloric intake, tall oil acid had a growth-retarding or toxic effect. Growth was reduced in rats fed tall oil acid at 6% of their diet by mass, equal to 15% of the total calories. The subchronic oral NOEL was 5%.

No treatment-related effects were observed in rats used in a 2-generation feeding study. The rats were fed diets containing 5% and 10% tall oil acid.

Tall oil acid was determined to be nonmutagenic in the Ames assay when tested at concentrations of 100, 1000, and 10 000 μg/plate.

Liquid soap formulations containing up to 12% tall oil acid did not cause dermal irritation, sensitization, or photosensitization in human subjects in a repeat insult patch test.

Discussion

The CIR Expert Panel recognized that there are limited animal and human toxicity data and dermal irritation/sensitization studies for tall oil acid. Tall oil acid is, however, known to be composed of fatty acids for which safety test data were available.

When considered with the subchronic and chronic oral toxicity, reproductive and developmental toxicity, genotoxicity, carcinogenicity, and photosensitization studies available for oleic acid, lauric acid, palmitic acid, myristic acid, and stearic acid, the available data for tall oil acid itself are a sufficient basis for reaching a conclusion regarding tall oil acid. It is the experience of the panel in its review of fatty acids of varying carbon chain lengths that there is little difference in toxicity.

The panel also considered that there is little difference between members of this family of salts of tall oil acid. The salts are expected to be dissociated in any product formulation independent of whether the salt is sodium, potassium, or ammonium. Accordingly, the available data for tall oil acid are considered supportive of the safety of the entire group as used in cosmetics.

The CIR Expert Panel recognizes that there are data gaps regarding use and concentration of these ingredients. However, the overall information available on the types of products in which these ingredients are used and at what concentrations indicates a pattern of use, which was considered by the Expert Panel in assessing safety.

Conclusion

The CIR Expert Panel concluded that tall oil acid, sodium tallate, potassium tallate, and ammonium tallate are safe as cosmetic ingredients in the practices of use and concentration as described in this safety assessment. In the case that ingredients in this group not in current use are used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group.

Authors' Note

Unpublished sources cited in this report are available from the Director, Cosmetic Ingredient Review, 1101 17th Street, Suite 412, Washington, DC 20036, USA.

Declaration of Conflicting Interests

No potential conflict of interest relevant to this article was reported. F. Alan Andersen and Valerie Robinson are employed by the Cosmetic Ingredient Review.

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