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Final Report on the Safety Assessment of Tall Oil Acid

Tall Oil Acid is a mixture of oleic, linoleic, and rosin acids derived from the hydrolysis of tall oil, a byproduct of wood pulp. Cosmetics formulated with Tall Oil Acid include hair dyes and bleaches, shampoos, skin cleansing preparations, and a shaving cream. Tall Oil Acid is approved for use as an indirect food additive.

When fed to rats as 15% of the total caloric intake, Tall Oil Acid was nontoxic; however, it had a growth-retarding effect. No treatment-related effects were observed in rats fed diets containing 5% and 10% Tall Oil Acid over two generations.

Liquid soap formulations containing up to 12% Tall Oil Acid did not cause dermal irritation, sensitization, or photosensitization in human subjects.

On the basis of data included in the report on Tall Oil Acid, and the available data on Oleic Acid, it is concluded that Tall Oil Acid is safe for use in cosmetic products.

INTRODUCTION

Tall Oil Acid is the CTFA name and synonym for the highly purified form of Tall Oil Fatty Acids (CAS No. 61790-12-3). The data included in this report are from studies on Tall Oil Fatty Acids as a specific ingredient. These data are augmented in the Discussion section of this report by the data from CIR safety evaluations on the individual constituents of Tall Oil Acid.

CHEMICAL AND PHYSICAL PROPERTIES

Definition and Physical Properties

Tall Oil Fatty Acid (CAS No. 61790-12-3) is defined in the *Cosmetic Ingredient Dictionary* as the mixture of fatty acids and rosin acids recovered from the hydrolysis and fractional distillation of Tall Oil. It is a byproduct of wood pulp.[1] 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%).[2] Tall

TABLE 1. Chemical and Physical Properties of Tall Oil Acid as Recommended for Use in Cosmetic Products[2]

Property	*Value*
Acid value	198
Iodine value (Wijs)	130
Saponification value	200
Rosin acids (%)	0.5
Unsaponifiables (%)	0.5
Color (Gardner)	1
Flash point, C.O.C.	400°F
Specific gravity (25°/25°C)	0.897
Viscosity (cps, 25°C)	20

Oil Acid is soluble in most polar and nonpolar organic solvents but it is insoluble in water.[2] A synonym for Tall Oil Acid is Tall Oil Fatty Acid. Chemical and physical properties of Tall Oil Fatty Acid are listed in Table 1.

Analytical Methods

Quantitative and qualitative determinations of Tall Oil Fatty Acid include infrared spectroscopy,[2] gas chromatography,[3] and gel permeation chromatography.[4]

Method of Manufacture

Tall Oil is produced from the byproducts of the Kraft pulping of rosinous woods, mainly pine. The rosins and fatty acids in the wood are both dissolved in and saponified by the alkaline cooking medium and occur in the black liquor as sodium soaps. When concentrated and cooled, these soaps separate as skimmings, which are then removed and acidified to yield Tall Oil.[5] The fatty acid fraction resulting from saponification is refined by fractional distillation at low temperatures and pressure to become Tall Oil Acid.[6]

USE

Cosmetic

Tall Oil Acid is used as a substitute for oleic acid or other fatty acids in formulating cosmetics. It is converted to a soap by reaction with bases and then used primarily as a conditioner or emulsifier in hair dyes and bleaches.[7]

Tall Oil Acid was reported as used in 139 cosmetic formulations by the voluntary reporting program of the Food and Drug Administration (FDA). Of these, 134 formulations containing Tall Oil Acid were hair dyes and bleaches. Tall Oil Acid was also used in two shampoos, two skin cleansing preparations, and one shaving cream. The majority of the hair dyes and bleaches contained Tall Oil Acid in the > 10–25% range. The shampoos, skin cleansing prepara-

TABLE 2. Product Formulation Data[8]

Product category	Total no. of formulations in category	Total no. containing ingredient	No. of product formulations within each concentration range (percentage)	
			> 10–25	≤ 10
Hair shampoos (noncoloring)	798	2	—	2
Hair dyes and bleaches	1012	134	104	30
Shaving cream (aerosol, brushless, and lather)	124	1	—	1
Skin cleansing preparations (cold creams, lotions, liquids, and pads)	707	2	—	2
1987 TOTALS		139	104	35

tions, shaving cream, and the rest of the hair dyes and bleaches contained ≤ 10% Tall Oil Acid[8] (Table 2).

The FDA cosmetic product formulation computer printout[8] is compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations.[9] Ingredients are listed in preset concentration ranges under specific product type categories. Since certain cosmetic ingredients are supplied by the manufacturer at less than 100% concentration, the value reported by the cosmetic formulator may not necessarily reflect the actual concentration found in the finished product; the actual concentration would be a fraction of that reported to the FDA. Data submitted within the framework of preset concentration ranges provide the opportunity for overestimation of the actual concentration of an ingredient in a particular product. An entry at the lowest end of a concentration range is considered the same as one entered at the highest end of that range, thus introducing the possibility of a 2–10-fold error in the assumed ingredient concentration.

Tall Oil Acid, as used in cosmetic formulations, may contact the hair, scalp, skin, face, nails, and eyes as well as occasional contact with the rest of the body including the mouth and nose. Individuals using these products may use them at a variety of frequencies ranging from once a day, for the shaving cream, shampoos and skin cleansing preparations, to once every few weeks for the hair dyes, colors, and bleaches.

Noncosmetic

Tall Oil Acid is approved for use as a defoaming agent used in the manufacture of paper and paperboard products and coatings of articles intended for use in packaging, transporting, or holding food.[9] The use of Tall Oil Acid in preparations of edible oils and edible fat compositions has been patented.[10,11] Tall Oil Acid is used as a raw material for protective coatings, particularly in alkyd resins, soaps, detergents, and disinfectants.[12] Large quantities of Tall Oil Acid are also used as intermediate chemicals; they are further processed or modified chemically before being incorporated into a product or used in production. Some examples of their use as intermediate chemicals include: conversion to Tall Oil Fatty Acid amines, polymerization to form

dimers for use in adhesives and printing inks, conversion to epoxidized esters for the stabilization and plasticization of polyvinyl chloride resins, condensation with ethylene oxide to form detergents and general purpose surfactants, and esterification for use as lubricants and textile processing aids.[5]

ANIMAL TOXICOLOGY

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 defined by the authors as containing 1.8–2.2% rosin and 2.8–3.2% 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/group and weighing 40–60 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. Food 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 the control group. Animals in the group receiving 30% of their calories from Tall Oil Acid distillate had a significantly lower growth rate than that of the controls and their feed consumption was slightly more than half 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."[6]

Hase and Stowell,[13] conducted a study to determine the effects of different fractions of Tall Oil Acid on the diet of growing rats. The feeding experiment lasted approximately 40 days. Groups of 6 young male rats of a mixed strain were fed diets containing 6.0% of the various fats tested, which corresponds to 15% of the total energy of the diet. The animals were weighed, and feed consumption was monitored daily. Tall Oil Acid distillate containing approximately 2% rosin and 2% neutral material and having an acid value of 193.4 was used in the feeding experiments. Concentrates of cyclized and aromatized fatty acid methyl esters weighing 194 g were obtained from the Tall Oil Acid distillate. These concentrates were diluted in corn oil to their approximate concentrations in Tall Oil Acid: approximately 0.5–2% for the cyclized acids and 0.2–1.1% for the aromatized acids. The "neutral" material from the Tall Oil Acid was also prepared and diluted in corn oil to a concentration of 3.0%. Rosin was prepared and diluted to concentrations of 3.0 and 12.0% in corn oil. Oleic acid served as a control substance. All of the test solutions, with the exception of the "neutral" material, had a strong suppressive action on the growth of the rats. The "neutral" material had no effect on the growth of the rats. None of the fractions of the Tall Oil Acid tested had as strong an effect as the whole Tall Oil Acid did in decreasing the rate of growth compared with controls. The authors reported that the growth-suppressive factor in Tall Oil Acid was probably due to several different compounds.

Reproduction Studies

A two-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. A detailed chemical description of the Tall Oil Acid used in this study was not included with the report, although it was described as a clear amber-colored liquid with a heavy odor similar to a vegetable oil. The rats (the F_0 generation) were fed the test diets for approximately 3 weeks and were then put in mating cages with one male and two females per cage. The F_1 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 (liveborn, 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 also computed. Clinical chemistry determinations were made for five male and five female rats from each test group of the F_1 generation. Rats from each test group of the F_1 generation, 10 male and 10 female, were also 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 did have lesions of chronic respiratory and renal diseases, which are endemic in this strain of rat.[14]

CLINICAL ASSESSMENT OF SAFETY: DERMAL IRRITATION AND SENSITIZATION

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.[15] 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.[16]

A prophetic patch test was conducted, according to the method of Schwartz and Peck,[17] with a liquid soap containing 12% Tall Oil Acid. The formulation was tested undiluted. The 100 subjects received two patches 10–14 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.[18]

A liquid soap containing 12% Tall Oil Acid was also tested in a repeat insult patch test in accordance with the method of Shelanski and Shelanski.[19]

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 also exposed to ultraviolet (UV) 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.[18]

SUMMARY

Tall Oil Acid is a mixture of oleic and linoleic fatty acids and rosin acids derived from the hydrolysis of Tall Oil, a byproduct of pulp from resinous woods (mainly pine). Tall Oil Acid is produced from the fractional distillation of Tall Oil.

Tall Oil acid was reported to be used in a total of 139 cosmetic formulations. Cosmetics formulated with Tall Oil Acid include hair dyes and bleaches, shampoos, skin cleansing preparations, and a shaving cream. Tall Oil Acid is approved for use as an indirect food additive.

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.

No treatment-related effects were observed in rats used in a two-generation feeding study. The rats were fed diets containing 5% and 10% Tall Oil Acid.

Liquid soap formulations containing up to 12% Tall Oil Acid did not cause dermal irritation, sensitization, or photosensitization in human subjects.

DISCUSSION

The fatty acids in Tall Oil Acid have been previously reviewed by the Cosmetic Ingredient Review Expert Panel. Oleic acid was assessed as safe for use in cosmetics. Cosmetic-grade oleic acid occurs as a mixture of fatty acids containing a minimum of 70% oleic acid and a range of 2–12% linoleic acid. A brief review of the data included in the Oleic Acid safety evaluation that support the data on Tall Oil Acid included in this report follows.

Fatty acids are absorbed, digested, and transported in animals and humans. When administered orally, intravenously, intraperitoneally, and intraduodenally, radioactive fatty acids were found in various solid tissues, and in blood and lymph. Serial oxidation and reduction reactions yielding actyl CoA are involved in the β-oxidation of fatty acids.[20]

Dermal applications of oleic acid, from concentrations of 50–75%, to the skin of mice, rabbits, and guinea pigs resulted in a range of reactions from none to signs of erythema, hyperkeratosis, and hyperplasia. Local inflammation and necrosis resulted from intradermal injections of oleic acid. Increased

comedone formation in the skin of the treated ears of two species of rabbits was associated with oleic acid and its UVA-induced peroxides.[26]

Oleic acid induced mitotic aneuploidy in in vitro mutagenicity tests, although it was an inhibitor of mutagenicity produced by positive controls in other tests. The number of mitotic crossing-over events was not increased by oleic acid, nor did oleic acid increase the number of sister chromatid exchange over background. No carcinogenic data were available on Tall Oil Acid; however, no malignant neoplasms were induced by repeated subcutaneous injections of 1–16.5 mg of oleic acid in two strains of mice. Intestinal and gastric neoplasms were found in mice receiving daily dietary concentrations of oleic acid of up to 200 mg/mouse.[20]

Oleic acid, in concentrations of 100% or 40–50% in mineral oil, was nonirritating in clinical primary and cumulative irritation studies. Single insult occlusive patch tests, soap chamber tests, and 21-day cumulative irritation studies of oleic acid in cosmetic formulations at 2–93% produced mild to intense erythema, but the results were generally not related to the fatty acid concentrations. No primary or cumulative irritation or sensitization was reported in clinical repeated insult patch tests, maximization tests, and prophetic patch tests with cosmetic product formulations containing a range of concentrations of < 1–14% oleic acid. Cosmetic formulations containing 1–13% oleic acid produced no photosensitization in the subjects tested. Mascara formulations containing 2% and 3% oleic acid produced no treatment-related ocular irritation in female subjects involved in 3-week exaggerated-use studies.[20]

The Expert Panel includes in this evaluation the safety test data summarized above on metabolism, dermal irritation and sensitization, clinical safety, and mutagenicity on oleic acid in lieu of data on whole Tall Oil Acid, containing less than 0.6% rosin acids. Other cosmetic ingredients, such as avocado oil and coconut oil, contain lesser amounts of oleic acid and linoleic acid and have also been reviewed and judged by the Expert Panel to be safe for use as cosmetic ingredients.[21,22]

CONCLUSION

On the basis of the data included for Tall Oil Acid in this report, and the data summarized from the CIR Final Report on Oleic Acid, the Expert Panel concludes that Tall Oil Acid is safe for use in cosmetic products.

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