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Final Report on the Safety Assessment of TEA Stearate[1]

Abstract: TEA Stearate is the triethanolamine salt of stearic acid used as a surfactant-cleansing agent and a surfactant-emulsifying agent in a wide variety of cosmetic formulations. Published data on TEA Stearate as an individual ingredient were not available, but data on its two components, TEA and stearic acid, were previously reviewed and considered adequate to evaluate the safety of TEA Stearate. Information from the earlier reports was summarized in this report and updated with more recent data on TEA. These data were consistent with the conclusion that TEA is safe for use in rinse-off cosmetic formulations, that its concentration should not exceed 5% in leave-on formulations, and that in no case should it be used in products containing *N*-nitrosating agents. Stearic Acid was found safe as used. Because the TEA salt of stearic acid is not expected to exhibit any toxic effects not seen with the separate moities, these conclusions, including the concentration limit for TEA, are considered applicable to TEA Stearate, once adjusted for the appropriate molecular weights. Therefore, it is concluded that TEA Stearate is safe as used in cosmetic formulations designed for discontinuous, brief use followed by thorough rinsing; that it is safe in concentrations not to exceed 15% in formulations intended for prolonged contact with the skin; and that it should not be used in products under conditions resulting in *N*-nitrosation reactions. **Key Words:** TEA Stearate—Stearic acid—TEA—Triethanolamine.

TEA Stearate is the triethanolamine salt of stearic acid and is used as a surfactant-cleansing agent and surfactant-emulsifying agent (Nikitakis, 1988). Published metabolism, toxicological, mutagenic, carcinogenic, and clinical data are not available for TEA Stearate as an individual ingredient; however, TEA Stearate is often indicated in cosmetic formulations by listing its two components, triethanolamine (TEA) and stearic acid, separately. As final reports on the safety assessments of Triethanolamine (Elder, 1983) and Stearic Acid (Elder, 1987) have been published by the Cosmetic Ingredient Review (CIR) Expert Panel, the relevant data contained in the two reports, as well as additional published data on TEA, were extracted and are summarized in this review as a basis for the assessment of safety of TEA Stearate.

CHEMISTRY

Definition and Structure

TEA Stearate (CAS No. 4568-28-9) is the triethanolamine salt of stearic acid and conforms to the following formula (Estrin et al., 1982):

[1] Reviewed by the Cosmetic Ingredient Review Expert Panel.

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$$CH_3(CH_2)_{16}COOH \cdot N(CH_2CH_2OH)_3$$

TEA Stearate is also known as Triethanolamine Stearate (Estrin et al., 1982; Hawley, 1971); Octadecanoic Acid compound with 2,2',2''-Nitrilotris[Ethanol] (1:1) (Estrin et al., 1982); and Trihydroxyethylamine Stearate (Greenberg and Lester, 1954).

Properties

TEA Stearate is a cream-colored wax-like solid (Hawley, 1971; Greenberg and Lester, 1954) that has a faint fatty odor (Hawley, 1971). The physical and chemical properties of TEA Stearate are summarized in Table 1.

Analytical Methods

To 1 g of TEA Stearate, add 10 ml of warm water, dissolve, and add a sufficient amount of dilute hydrochloric acid until the liquid turns acidic; an oil layer separates (Yakuji Nippo Ltd., 1986).

Impurities

The TEA for TEA Stearate is available in two grades. The technical grade contains 85% TEA, thus containing more diethanolamine (DEA) as an impurity than the higher grade (99% TEA). Upon *N*-nitrosation, DEA gives rise to the animal carcinogen *N*-nitrosodiethanolamine (NDELA) (International Agency for Research on Cancer [IARC], 1978). In the presence of stearic acid and in a nonaqueous solution, the technical-grade TEA yielded more NDELA upon nitrosation with nitrite than the 99% TEA (Powell, 1987).

A lotion of TEA Stearate was spread over a 1-cm^2 surface and exposed to air

TABLE 1. *Physical and chemical properties of TEA Stearate*

Property	Description	References
Color	Cream	Hawley (1971); Greenberg and Lester (1954)
Appearance	Wax-like solid	Hawley (1971); Greenberg and Lester (1954)
Odor	Faint fatty	Hawley (1971)
Empirical formula	$C_{18}H_{36}O_2 \cdot C_6H_{15}NO_3$	Estrin et al. (1982)
Melting point	42–44°C	Hawley (1971)
Specific gravity	0.968	Hawley (1971); Greenberg and Lester (1954)
pH value (at 25°C) (5% aqueous dispersion)	8.8–9.2	Hawley (1971)
Solubility	Soluble in methyl and ethyl alcohol, mineral spirits, mineral oil, and vegetable oil; dispersible in hot water soluble in alcohol	Hawley (1971); Greenberg and Lester (1954)
Reactivity	Combustible	Hawley (1971)
Loss on drying	<11.2%	Yakuji Nippo Ltd. (1986)

containing 100 to 600 ppb of nitrogen dioxide at 20 to 37°C for 24 h (Powell, 1987). The technical-grade TEA formed at least threefold greater amounts of NDELA than the 99% TEA.

USE

Cosmetic

TEA Stearate is used in cosmetic formulations as a surfactant-cleansing agent or a surfactant-emulsifying agent (Nikitakis, 1988). The product formulation data submitted to the Food and Drug Administration (FDA) in 1993 for TEA Stearate indicated that it was contained in 60 cosmetic product formulations where it is called TEA Stearate (Table 2). However, TEA Stearate is often indicated in formulations by listing stearic acid and triethanolamine separately. Both ingredients are added to the formulation, where they combine to form TEA Stearate. Data submitted by the FDA indicated that there were 1,355 cosmetic formulations that contained both stearic acid and triethanolamine (FDA, 1993) (Table 3). Therefore, TEA Stearate was reported to be used in a total of 1,415 cosmetic formulations in 1993.

TEA Stearate was used in a variety of baby, bath, eye makeup, fragrance, hair, makeup, nail, personal cleanliness, shaving, skin, and suntan preparations (FDA, 1993).

The cosmetic industry no longer reports concentration of use values to the FDA (Federal Register, 1992); however, product formulation data submitted to the FDA in 1984 indicated that TEA Stearate was used at concentrations of 1% or lower in shaving creams; 10% or lower in skin-cleansing products, moisturizing

TABLE 2. *Product formulation data for TEA Stearate (FDA, 1993)*

Product category	Total no. of formulations in category	Total no. containing ingredient
Eyeliner	579	1
Other eye makeup preparations	120	1
Foundations	299	6
Makeup bases	148	1
Nail creams and lotions	18	2
Shaving creams	138	4
Cleansing preparations	702	4
Face and neck preparations (excluding shaving preparations)	182	1
Body and hand preparations (excluding shaving preparations)	957	15
Foot powders and sprays	31	1
Moisturizing preparations	806	13
Paste masks (mud packs)	257	3
Other skin care preparations	745	6
Suntan gels, creams, and liquids	212	2
1993 Totals		60

TABLE 3. *Product formulation data for Stearic Acid and Triethanolamine (FDA, 1993)*

Product category	Total no. of formulations in category	Total no. containing ingredient
Baby lotions, oils, powders, and creams	47	3
Other baby products	27	2
Other bath preparations	111	1
Eyebrow pencil	95	1
Eyeliner	579	19
Eye shadow	569	3
Eye makeup remover	86	2
Mascara	178	63
Other eye makeup preparations	120	16
Perfumes	248	1
Powders	271	1
Sachets	28	3
Other fragrance preparations	127	18
Hair conditioners	597	3
Shampoos (noncoloring)	845	2
Other hair preparations	356	1
Hair rinses (coloring)	59	1
Other hair coloring preparations	54	8
Blushers (all types)	255	2
Face powders	266	2
Foundations	299	93
Lipstick	850	3
Makeup bases	148	53
Rouges	31	3
Makeup fixatives	11	3
Other makeup preparations	129	16
Cuticle softeners	25	5
Nail creams and lotions	18	4
Nail polish and enamel removers	33	1
Other manicuring preparations	70	1
Bath soaps and detergents	335	14
Deodorants (underarm)	255	1
Other personal cleanliness products	296	5
Aftershave lotions	211	4
Shaving creams (aerosol, brushless, and lather)	138	84
Other shaving preparation products	46	5
Cleansing preparations	702	99
Depilatories	48	2
Face and neck preparations (excluding shaving preparations)	182	32
Body and hand preparations (excluding shaving preparations)	957	281
Foot powders and sprays	31	3
Moisturizing preparations	806	269
Night preparations	210	56
Paste masks (mud packs)	257	31
Skin fresheners	220	3
Other skin-care preparations	745	76
Suntan gels, creams, and liquids	212	42
Indoor tanning preparations	49	2
Other suntan preparations	57	12
1993 Totals		1,355

products, and other skin care preparations; 25% or lower in face, body, and hand preparations; and 5% or lower in suntan products (FDA, 1984).

International

TEA Stearate is listed in the *Comprehensive Licensing Standards of Cosmetics* by category, Part I (Nikko Chemical Co., Ltd., 1992). It is also listed in the *Japanese Cosmetic Ingredient Dictionary*, Volume IV, as approved for use in cosmetic products marketed in Japan (Cosmetic, Toiletry, and Fragrance Association [CFTA], 1983).

Noncosmetic

TEA Stearate is used as an emulsifying agent in the pharmaceutical industry. It is also used in emulsifying benzyl benzoate solutions (Rossoff, 1974).

GENERAL BIOLOGY

Absorption, Distribution, Metabolism, Excretion

Published absorption, distribution, metabolism, and excretion data for TEA Stearate were not available. Metabolism data for TEA were not given in the TEA report, but a study was found in the published literature and is included below. Metabolism data from the Stearic Acid report (Elder, 1987) were extracted and are summarized in this section.

A gas chromatography assay to determine TEA in biological fluids was developed, and the metabolism of TEA was studied using male and female rats (Kohri et al., 1982). Oral administration of TEA resulted in rapid absorption in the gastrointestinal tract and excretion of primarily unchanged TEA in the urine.

Stearic acid is absorbed and digested in animals and humans; it is primarily transported via the lymphatic system. Of several common fatty acids studied, stearic acid was the most poorly absorbed. Radioactivity from labelled fatty acids administered orally, intravenously, intraperitoneally, and intraduodenally has been found in blood, lymph, and various tissues.

ANIMAL TOXICOLOGY

Published animal toxicology data for TEA Stearate were not available. Toxicology data from the TEA report (Elder, 1983) and Stearic Acid report (Elder, 1987) were extracted and are summarized in this section.

The oral median lethal dose (LD_{50}) of TEA for rats ranged from 4.19 g/kg to 11.26 g/kg; TEA was practically nontoxic to slightly toxic according to the terminology of Hodge and Sterner (1949). The i.p. LD_{50} of TEA for mice was 1.450 g/kg. Acute and subchronic dermal irritation studies using rabbits reported little potential for irritation. The results of chronic oral ingestion studies in which TEA was administered to rats and guinea pigs were limited primarily to hepatic and renal lesions. Chronic cutaneous TEA administration using rats, rabbits, and guinea pigs also produced evidence of hepatic and renal damage. TEA was not a

sensitizer, and a lotion containing 1% TEA was not phototoxic to guinea pigs. With long contact time, 100% TEA was an ocular irritant to rabbits. A spermicidal preparation containing 1.92% TEA was not irritating to rat vaginal mucosa. Topical application of TEA to pregnant rats did not produce teratogenic effects.

Acute oral administration of stearic acid to rats produced little toxicity. Acute dermal administration of 100 m*M* or less of stearic acid to guinea pigs and rabbits resulted in mild erythema and induration. In subchronic toxicity studies of stearic acid using rats, findings included thrombosis, aortic atherosclerosis, anorexia, and mortality. No toxicity was observed in a subchronic toxicity study in which chicks were fed diets containing 50% stearic acid. Short-term dermal application of a formulation containing 2.0% stearic acid produced slight edema and desquamation in rabbits. In rats, subchronic dermal studies of a formulation containing concentrations of 5% or less stearic acid resulted in moderate skin irritation. Single-insult occlusive patch tests (SIOPT) of stearic acid, 35 to 65% in vehicle and 1 to 13% in formulation, produced no or transient defined erythema and slight, if any, edema in rabbits. A formulation containing 1% stearic acid was a weak sensitizer, and formulations containing 2.8% stearic acid were not photosensitizers in guinea pigs. Draize tests of stearic acid, alone and at 1 to 13% in formulation, produced no or minimal ocular irritation in rabbits.

MUTAGENICITY

Published mutagenicity data for TEA Stearate were not available. Mutagenicity data from the TEA report (Elder, 1983) and Stearic Acid report (Elder, 1987) were extracted and are summarized in this section.

TEA was not mutagenic in the Ames test, nor was it mutagenic in cultures of *Bacillus subtilus*. In an unscheduled DNA synthesis assay, TEA did not cause DNA-damage-inducible repair.

Stearic acid was not mutagenic in the Ames test or in a spot test. It was inactive in inducing aneuploidy and did not increase the occurrence of mitotic crossing over in the D_6 strain of *Saccharomyces cerevisiae*.

CARCINOGENICITY

Published carcinogenicity data for TEA Stearate were not available. Carcinogenicity data from the TEA report (Elder, 1983) and the Stearic Acid report (Elder, 1987) were extracted and are summarized in this section.

Dermal application of TEA to mice for 18 months produced neither carcinogenic nor cocarcinogenic activity. There was a greater incidence of malignant lymphoid tumors in female mice fed diets containing TEA for their entire life span than in control mice or male mice fed the same diet.

Low incidences of carcinomas, sarcomas, and lymphomas were observed in mice given single and/or repeated s.c. injections of 82 mg or less of stearic acid. Stearic acid, at 50 g/kg/day or less of stearic acid in feed, was not carcinogenic to mice.

CLINICAL ASSESSMENT OF SAFETY

Published clinical data for TEA Stearate were not available. Clinical data from the TEA report (Elder, 1983) and Stearic Acid report (Elder, 1987) were extracted and are summarized in this section.

TEA and cosmetic products containing TEA produced mild dermal irritation at concentrations greater than 5%; there was little sensitization. Products containing TEA concentrations of 20.04% or greater were neither phototoxic nor photosensitizing.

In an SIOPT, 40% stearic acid in mineral oil was nonirritating. SIOPT and 21-day cumulative irritation studies using formulations containing 2.6 to 13% stearic acid produced no or moderate irritation. The resulting erythema was generally not related to the fatty acid concentration in the formulations. In open, occlusive, and semiocclusive repeated-insult patch tests, a maximization test, and prophetic patch tests of formulations containing less than 1 to 13% stearic acid, minimal to moderate irritation was observed in a few subjects; no sensitization was reported. The intensity of observed reactions to the formulations was not directly related to fatty acid concentration. Formulations containing 1 to 13% stearic acid were not photosensitizers in human subjects; slight reactions were observed with a few induction patches.

SUMMARY

TEA Stearate is used as a surfactant-cleansing and a surfactant-emulsifying agent in 60 cosmetic product formulations according to information submitted to the FDA.

Little data on TEA Stearate metabolism, toxicology, mutagenicity, or carcinogenicity were available; there were no clinical data. Therefore, this report primarily presents data on TEA and Stearic Acid separately, with the view that these data are applicable to TEA Stearate.

No TEA Stearate absorption/metabolism data were available. Orally administered TEA was noted to be excreted, unchanged, in the urine of rats. Data on stearic acid show that it is absorbed and digested in animals, with metabolites appearing in blood, lymph, and various tissues.

No data were available on TEA Stearate animal toxicology; summaries of toxicology studies on TEA and Stearic Acid that report no adverse effects are presented.

Because no TEA Stearate mutagenicity data were available, the uniformly negative mutagenicity data for TEA and Stearic Acid are included. The identical situation existed for carcinogenicity, and those data are also included.

No clinical data were available on TEA Stearate; the report summarized the data showing TEA to be mildly irritating but not phototoxic nor photosensitizing. The data showing Stearic Acid not to be irritating or only mildly irritating are included, along with that on the lack of photosensitization.

DISCUSSION

The CIR Expert Panel, upon reviewing the data summarized in this report from previous CIR reports on TEA and Stearic Acid, determined that the salt of TEA

and Stearic Acid (TEA Stearate) would be no more toxic, and may be less toxic, than its individual components. Therefore, the data listed in a previously released "Insufficient Data Announcement" for TEA Stearate were no longer required for a conclusion of safety. TEA Stearate was determined to be safe for use in cosmetic formulations in accordance with the restrictions placed on the individual components of the ingredient.

The Expert Panel had previously concluded that TEA (approximate molecular weight of 149) is safe for use in cosmetic formulations designed for discontinuous, brief use followed by a thorough rinsing from the skin; should not exceed 5% in formulation for products intended for prolonged contact with the skin; and should not be used in products containing *N*-nitrosating agents. The Panel had also concluded previously that Stearic Acid (approximate molecular weight of 284) is safe as used in cosmetic formulations.

Comparison of the molecular weights of the two component ingredients showed that TEA Stearate comprises approximately one-third TEA and two-thirds Stearic Acid. Based on this information, it was determined that TEA Stearate should not exceed 15% in the formulation of cosmetic products designed for prolonged contact with the skin so that the TEA concentration does not exceed 5% in formulation and that TEA Stearate should not be used in products under conditions resulting in *N*-nitrosation reactions.

CONCLUSION

On the basis of the available data presented in this report, the CIR Expert Panel concludes that TEA Stearate is safe as used in cosmetic formulations designed for discontinuous, brief use followed by thorough rinsing. In products intended for prolonged contact with the skin, the concentration of TEA Stearate should not exceed 15% in formulation. TEA Stearate should not be used in products under conditions resulting in *N*-nitrosation reactions.

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