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Final Report on the Safety Assessment of Sodium Cetearyl Sulfate

Sodium Cetearyl Sulfate is the sodium salt of a mixture of cetyl and stearyl sulfate which is used as a surfactant and cleansing agent in cosmetics at concentrations ranging from ≤ 0.1 to 25.0%.

The LD_{50} was not achieved in two studies in which rats received a single oral dose of 5.0 ml/kg. In ocular irritation tests, 20.0% aqueous Sodium Cetearyl Sulfate was not irritating to the eyes of rabbits. Twenty percent Sodium Cetearyl Sulfate was not irritating to the skin of rabbits.

In a guinea pig sensitization study, Sodium Cetearyl Sulfate was not a sensitizer. Sodium Cetearyl Sulfate is less irritating to the skin than Sodium Lauryl Sulfate, whose safety test data are summarized in the report. Due to the chemical similarity of these two cosmetic ingredients, the safety test data on Sodium Lauryl Sulfate was considered to be applicable to the safety evaluation of this ingredient.

On the basis of the animal and clinical data on Sodium Cetearyl Sulfate and Sodium Lauryl Sulfate as presented in the report, it is concluded that Sodium Cetearyl Sulfate is safe as a cosmetic ingredient in the present practices of use and concentration.

INTRODUCTION

The toxicity of Sodium Cetearyl Sulfate is reviewed in this report. A summary of the toxicity data on a structurally similar cosmetic ingredient, Sodium Lauryl Sulfate, that has been reviewed by the CIR Expert Panel, is also included. With the exception that Sodium Cetearyl Sulfate contains 14 or 16 methene groups and Sodium Lauryl Sulfate contains 10 methene groups, the chemical formulas for both ingredients are identical. The available toxicity data on Sodium Lauryl Sulfate are considered to be supportive of the safety data on Sodium Cetearyl Sulfate.

CHEMISTRY

Chemical and Physical Properties

Sodium Cetearyl Sulfate (CAS No. 59186-41-3) is the sodium salt of a mixture of cetyl and stearyl sulfate that conforms generally to the formula:[1]

$$CH_3(CH_2)_nCH_2OSO_3Na$$

The values of *n* are 14 and 16. Sodium Cetostearyl Sulfate and Sodium Cetyl/Stearyl Sulfate are other names for this chemical. Sodium Cetearyl Sulfate is commercially available as a mixture of sodium salts of saturated fatty alcohol–sulfuric acid esters. Such a mixture consists of approximately equal parts of sodium cetyl sulfate and sodium stearyl sulfate. It is dispersible in most fatty substances and is also available as a 15% aqueous paste.[2] Properties of Sodium Cetearyl Sulfate are summarized in Table 1.

Methods of Production

Sodium Cetearyl Sulfate may be produced via the sulfation of cetearyl alcohol with either chlorosulfonic acid, sulfur trioxide, or sulfamic acid, followed by neutralization of the acid ester with sodium hydroxide.[3]

Analytical Methods

Sodium Cetearyl Sulfate has been identified via infrared spectroscopy.[2]

Impurities

The following impurities are present in Sodium Cetearyl Sulfate: inorganic chloride (2.2% maximum), unsulfated matter (4% maximum), and inorganic sulfate (5.5% maximum).[2]

COSMETIC USE

Sodium Cetearyl Sulfate is used as a surfactant and cleansing agent in cosmetics.[4]

The FDA cosmetic product formulation computer printout[5] is compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations.[6] Ingredients are listed in preset concentration ranges under specific product type categories. Since certain cosmetic ingredients are supplied by the

TABLE 1. PROPERTIES OF SODIUM CETEARYL SULFATE[2]

Color	White to faintly yellow powder
Solubility	Soluble in water
pH of 0.25% Aqueous Solution	6.5
Assay	90% minimum
Identification	Positive: Close match to a standard IR spectrum with no indication of foreign materials

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 two- to ten-fold error in the assumed ingredient concentration. Sodium Cetearyl Sulfate has been used in cosmetic products at concentrations ranging from ≤ 0.1 to 25.0% (Table 2).[5]

Sodium Cetearyl Sulfate has been approved for use as a cosmetic ingredient in Japan.[7] It is not included in the list of substances that may not be used in cosmetic products marketed in countries of the European Economic Community.[8]

TOXICOLOGY

Acute Oral Toxicity

The acute oral toxicity of Sodium Cetearyl Sulfate, full strength, was evaluated according to the method of Hagan[9] using fasted, Wistar-derived albino rats (5 males, 5 females; weights = 200–250 g). Each animal received a dose of 5.0 ml/kg of the test substance via gavage. The animals were observed for a period of 14 days. Necropsy was performed at the end of the observation period. None of the animals died, and gross lesions were not observed at necropsy.[10] Similar results were obtained when Wistar albino rats (5 males, 5 females; weights 200–300 g) were tested with 10.0% aqueous Sodium Cetearyl Sulfate according to the same procedure.[11]

In another study, the acute oral toxicity of Sodium Cetearyl Sulfate (in olive oil) was evaluated using 10 male Wistar rats (average body weight-150 g). The test substance was administered via stomach tube at a dose of 10 g/kg, and the animals were observed for 8 days. The LD_{50} was not achieved at the administered dose.[12]

The acute oral toxicity of 20.0% aqueous Sodium Cetearyl Sulfate was evaluated using 10 rats (5 males, 5 females; weights 200–300 g). The animals were fed a dose of 5 ml/kg of test material and observed for 14 days. None of the animals died.[13]

Ocular Irritation

The ocular irritation potential of Sodium Cetearyl Sulfate undiluted was evaluated according to a modification of the procedure by Draize[14] using male and female albino New Zealand rabbits. The test substance (0.1 ml) was instilled into the right conjunctival sac of each animal; eyes were not rinsed. Untreated eyes served as controls. Reactions were scored on days 1, 2, 3, 4, and 7 post-instillation according to the Draize scale: 0 to 110. The mean ocular irritation scores were as follows: 14.0 (day 1), 13.0 (day 2), 16.3 (day 3), 20.1 (day 4), and 12.8 (day 7). Sodium Cetearyl Sulfate was classified as a moderate ocular irritant.[10]

In another study, the ocular irritation potential of 20.0% aqueous Sodium Cetearyl Sulfate was evaluated according to the method by Draize.[15] The test substance (0.1 ml) was instilled into the conjunctival sac of the right eye of each of three albino rabbits. Untreated eyes served as controls. Both treated and control eyes were scored every 24 h

TABLE 2. PRODUCT FORMULATION DATA FOR SODIUM CETEARYL SULFATE[5]

Product category	*Total no. of formulations in category*	*Total no. containing ingredient*	*No. of Product Formulations Within Each Concentration Range (%)*					
			Unreported concentration	*>10–25*	*>5–10*	*>1–5*	*>0.1–1*	*≤0.1*
Sachets	119	1	—	—	—	1	—	—
Cuticle softener	32	1	—	—	—	—	1	—
Bath soaps and detergents	148	1	—	1	—	—	—	—
Aftershave lotions	282	1	—	—	—	—	1	—
Skin cleansing preparations (cold creams, lotions, liquids, and pads)	680	5	2	—	—	—	3	—
Face, body and hand skin care preparations (excluding shaving preparations)	832	5	4	—	—	—	1	—
Moisturing skin care preparations	747	27	23	—	1	—	2	1
Night skin care preparations	219	1	—	—	—	—	1	—
Paste masks (mud packs)	171	2	—	—	—	2	—	—
Hair conditioning	478	2	2	—	—	—	—	—
Skin lighteners	44	1	1	—	—	—	—	—
Other skin care preparations	349	4	4	—	—	—	—	—
1984 TOTALS		51	36	1	1	3	9	1

for four days and on the seventh day according to the Draize scale: 0 to 110. Ocular irritation was not observed at any time during the study.[16]

The ocular irritation potential of 10.0% aqueous Sodium Cetearyl Sulfate was evaluated using six young adult albino rabbits. The test substance (0.1 ml) was instilled into the conjunctival sac of one eye of each animal, after which the eyelids were held together for one second and then released. The untreated eye served as the control. Ocular reactions were scored at one, two, three, and seven days post-instillation according to the Draize scale: 0 to 110. The identification of positive reactions was based on the following: ulceration of the cornea, other than a fine stippling; opacity of the cornea, other than a slight dulling of the normal luster; inflammation of the iris, other than a slight deepening of the folds or a slight circumcorneal injection of the blood vessels; and obvious conjunctival swelling with partial eversion of the lids or a diffuse crimson-red conjunctiva with individual vessels not easily discernible. Iridial and corneal effects were observed in 4 and 6 animals, respectively, having cleared during the seven-day observation period. Sodium Cetearyl Sulfate (10.0% aqueous) is a moderate, transient irritant to the rabbit eye when instillation is not followed by ocular rinsing.[11]

Skin Irritation

The skin irritation potential of Sodium Cetearyl Sulfate, undiluted strength, was evaluated according to the method of Draize et al.[14] using six albino New Zealand rabbits (3 males, 3 females; 1.8–2.4 kg). Single applications of the test substance (0.5 ml) were made to abraded and intact skin sites that had been clipped free of hair. Sites were covered with occlusive patches secured with adhesive tape, and the trunk of each animal was wrapped with an impermeable occlusive wrapping. Reactions were scored at 24 and 72 h post-application according to the scales: 1 (very slight erythema) to 4 (severe erythema to slight eschar formation) and 1 (very slight edema) to 4 (severe edema). The mean scores at 24 and 72 h were averaged in order to calculate the primary irritation index. The primary irritation index was 0.8, interpreted as slight irritation.[10]

In another study, the skin irritation potential of 20.0% aqueous Sodium Cetearyl Sulfate was evaluated using six albino rabbits. The animals were immobilized and the test substance (0.5 ml) was applied to intact and abraded skin sites (2 × 2 cm) that had been clipped free of hair. Each site was covered with a patch that was sealed in place with surgical tape. At the end of the 24 h contact period and 48 h later, sites were scored according to the method of Draize:[15] 0 (no erythema) to 4 (severe erythema to slight eschar formation) and 0 (no edema) to 4 (severe edema). Skin irritation was not observed at any time during the study.[17]

The skin irritation potential of 10.0% aqueous Sodium Cetearyl Sulfate was evaluated using six adult albino rabbits. The test substance (0.5 ml or 0.5 g) was applied, under a patch made of surgical gauze, to shaved intact and abraded skin sites on the back of each animal. The sites were scored at 24 and 72 h post-application and primary irritation indices were interpreted according to Draize scoring criteria: primary irritation index (PII) < 2.0 (mild irritant), PII $= 2.0$ to 5.0 (moderate irritant), and PII > 5.0 (severe irritant). Erythema was observed on abraded and intact skin of all animals. In only one animal, erythema had cleared by 72 h post-application. Edema was observed in two animals, abraded skin only, at 24 and 72 h and in an additional two animals, abraded and intact skin, at 24 and 72 h. The PII was 1.88, classifying the test substance as a mild irritant.[11]

Skin Sensitization

The skin sensitization potential of Sodium Cetearyl Sulfate was evaluated using 20 white female guinea pigs of the Pirbright breed (average body weight 463 g). The control group consisted of 10 guinea pigs with an average body weight of 458 g. According to the method of Landsteiner,[18] small quantities of a 25.0% aqueous solution of the test substance were rubbed into the shaved skin of the hindquarters at 24 h intervals for a total of ten applications. After a 14-day nontreatment period, two applications (24 h interval) of 1.0% aqueous Sodium Cetearyl Sulfate were made. Reactions were not observed in experimental or control groups at any time during the study.[19]

SUMMARY OF DATA ON SODIUM LAURYL SULFATE

Absorption and Excretion

The percutaneous absorption of [^{14}C]Sodium Lauryl Sulfate was evaluated using guinea pigs. The test substance (in distilled water) was rubbed into the skin of the flank for 10 min. Sites were rinsed with water and covered with non-occlusive patches for 24 h. Radioactivity was not detected in the feces, kidney, or carcass, and 0.1% of the applied dose was deteted in exhaled CO_2 and in the urine. Most of the radioactivity was either detected at the application site, rinsed from the test site, or retained by the patch. After rats were injected intraperitoneally or subcutaneously with [^{14}C]Sodium Lauryl Sulfate, the main route of excretion was via the urine.

Acute Inhalation Toxicity

The exposure (2–5 min) of mice and rabbits to aerosolized 15.0 and 25.0% aqueous Sodium Lauryl Sulfate resulted in irritation of the respiratory tract.

Acute Oral Toxicity

In acute oral toxicity studies involving rats, the following LD_{50} values were reported: 0.8 to 1.10 g/kg (10.0% Sodium Lauryl Sulfate), 6.3 ml/kg (28.2% Sodium Lauryl Sulfate), 1290 mg/kg (86.0% Sodium Lauryl Sulfate), 2.7 mg/kg (purified 100.0% Sodium Lauryl Sulfate), and 1.0 mg/kg (unpurified 100.0% Sodium Lauryl Sulfate). Products containing 21.0% Sodium Lauryl Sulfate caused depression and death of all animals (rats) when administered in doses of 5.0 g/kg.

Acute Dermal Toxicity

In a study involving rabbits, the dermal LD_{50} of Sodium Lauryl Sulfate was greater than 10 g/kg. In another study, a 10 ml/kg dose of a formulation containing 26.0% Sodium Lauryl Sulfate caused depression, labored respiration, nasal discharge, and severe dermal irritation in albino rabbits.

Subchronic Oral Toxicity

In a 13-week subchronic oral toxicity study, rats were fed 40, 200, 1000, or 5000 ppm Sodium Lauryl Sulfate in the diet. The only abnormal finding was an increase in

absolute organ weight (5000 ppm dose). Increased hepatic triglyceride, decreased serum triglyceride, and bronchopneumonia were observed in rats that were given 0.25% Sodium Lauryl Sulfate in their drinking water for 5 months. In another study, significant growth retardation was observed in albino rats that were fed 2.0% Sodium Lauryl Sulfate (in diet) for 4 months; 8.0% in the diet caused death within 2 weeks.

Chronic Oral Toxicity

No abnormalities were reported in a chronic oral toxicity study in which rats were fed concentrations of 0.25, 0.5, or 1.0% Sodium Lauryl Sulfate (in diet) for 2 years. In another chronic study, beagle pups were fed diets containing 0.67, 1.0, or 2.0% Sodium Lauryl Sulfate for one year. Decreased weight gain was reported only for rats in the 2.0% group.

Ocular Irritation

The results of Draize ocular irritation tests (with and without rinsing) on 1.0 to 100.0% Sodium Lauryl Sulfate indicated that ocular irritation increased with increasing concentrations and decreased when eyes were rinsed. In other Draize tests, a product containing 5.1% Sodium Lauryl Sulfate induced mild ocular irritation and products containing 21.0% Sodium Lauryl Sulfate were severely irritating (no ocular rinsing) and mildly irritating (ocular rinsing). A shampoo containing 26.0% Sodium Lauryl Sulfate also induced mild ocular irritation in rinsed eyes.

Skin Irritation

In Draize skin irritation tests, single 24 h applications (under occlusion) of 2.0, 10.0, and 20.0% Sodium Lauryl Sulfate caused primary skin irritation in rats. Results from other Draize tests (rabbits, single exposure) are as follows: 0.65% Sodium Lauryl Sulfate induced mild skin irritation; 10.0% (under occlusive patches) induced mild skin irritation in one study and severe skin irritation (abraded and intact skin) in another; 28.2% was a moderate primary irritant (abraded and intact skin); 30.0% was a severe irritant; and 100.0% Sodium Lauryl Sulfate was a moderate irritant. Slight erythema was observed in mice 30 min after the application of 10.0% Sodium Lauryl Sulfate (single exposure) to the skin of mice.

Repeated applications of 1.0% Sodium Lauryl Sulfate twice daily for 3 days induced erythema and edema in rats; 5.0 to 10.0% concentrations caused thickening of the epidermis and scaling and cracking of the stratum corneum. In mice, 1.0% Sodium Lauryl Sulfate induced erythema after eight to nine applications and 2.5% Sodium Lauryl Sulfate induced widespread edema and capillary enlargement in the dermis after five applications. The following observations were made after Sodium Lauryl Sulfate was applied repeatedly to rabbits over a 14 day period: very slight to slight erythema (1.0% Sodium Lauryl Sulfate), moderate chemical burns (5.0%), and severe chemical burns (25.0%).

In skin irritation studies involving human subjects, Sodium Lauryl Sulfate was tested at concentrations of 0.1 to 10.0%. In all cases, reactions observed in open patch tests were less severe than those in closed patch tests, and skin irritation increased with increasing test substance concentrations.

Comedogenicity

Repeated applications of 1.0 and 5.0% Sodium Lauryl Sulfate to the ears of albino rabbits resulted in comedone formation. However, comedones were not observed after repeated applications of 10.0% Sodium Lauryl Sulfate to the trunks of mice.

Skin Irritation and Sensitization

Neither skin irritation nor sensitization reactions were observed in 599 human subjects patch tested (prophetic patch test, occlusive patches) with a makeup foundation containing 2.5% Sodium Lauryl Sulfate. In a repeated insult patch test (occlusive patches), a shampoo (diluted to 0.21% Sodium Lauryl Sulfate) induced skin irritation. Allergic reactions to the shampoo (diluted to 0.105% Sodium Lauryl Sulfate) were not observed during the challenge phase. In another repeated insult patch test (occlusive patches), 57 human subjects were tested with a shaving cream containing 1.26% Sodium Lauryl Sulfate. Slight to severe erythema was observed during induction and slight to moderate erythema during the challenge phase.

In a Draize cumulative irritation test, a shampoo (diluted to 1.45% Sodium Lauryl Sulfate) was applied under occlusive patches to 102 human subjects. Patterns of skin irritation, but not sensitization, were observed. Repeated applications (open patches) of a foundation formulation containing 2.5% Sodium Lauryl Sulfate were made to 249 human subjects. Mild, nonvesicular reactions were observed during induction, and no sensitization reactions were observed during the challenge phase.

Photosensitization

A makeup foundation product containing 2.5% Sodium Lauryl Sulfate did not induce photosensitization in any of the 599 human subjects tested. Challenge sites were irradiated with ultraviolet (UV) light for 1 h. In a repeated insult patch test involving 249 human subjects, test sites were irradiated with UV light after the first, fourth, seventh, and tenth inductions and after removal of the challenge patch. The distribution of reactions was as follows: 1 mild reaction (1st induction), 2 mild reactions (4th induction), three mild reactions (7th induction), no reactions (10th induction), and four mild reactions (challenge).

Mutagenicity

The incidence of chromosomal aberrations in the bone marrow of rats fed 1.13 and 0.56% Sodium Lauryl Sulfate in the diet for 90 days was not significantly different from that of the control group. Additionally, no clastogenic effects were noted.

Carcinogenicity

In a one-year chronic study, beagle dogs were fed Sodium Lauryl Sulfate at concentrations of up to 2.0% in the diet. No tumorigenic effects were noted.

Teratogenicity

The teratogenic potential of Sodium Lauryl Sulfate was evaluated using pregnant JCL/ACR mice. Daily applications (dose 1.5 ml/kg) of 0.4, 4.0, and 6.0% aqueous

solutions were made to the backs of three groups of mice, respectively, on days 6 to 13 of gestation. Brain hernia, cleft palate, open eyelids, polydactylia, and clubfoot were observed in offspring of the 0.4% treatment group. Cleft palate and open eyelids were also observed in 4.0 and 6.0% treatment groups. Digital anomalies and bent tail were observed in 4.0 and 6.0% treatment groups, respectively. Additionally, a significant delay in bone ossification was noted with increasing concentrations of Sodium Lauryl Sulfate. Abnormalities in the offspring of untreated mice included open eyelids, polydactylia, bent tail, and clubfoot. Only abdominal hernia and open eyelids were observed in the offspring of water-treated controls. Open eyes and cleft palate are thought to be growing phenomena in JCL/ACR mice. Therefore, the occurrene of these anomalies in experimental and control mice may or may not be significant.

SUMMARY

Sodium Cetearyl Sulfate (CAS No. 59186-41-3) is the sodium salt of a mixture of cetyl and stearyl sulfate. It is produced via the sulfation of cetearyl alcohol with either chlorosulfonic acid, sulfur trioxide, or sulfamic acid, followed by neutralization of the ester with sodium hydroxide.

Sodium Cetearyl Sulfate is used as a surfactant and cleansing agent in cosmetics at concentrations ranging from $\leq$ 0.1 to 25.0%.

The LD_{50} was not achieved in two studies in which rats received a single oral dose (5.0 ml/kg) of Sodium Cetearyl Sulfate (full strength) and 10.0% aqueous Sodium Cetearyl Sulfate, respectively. In other acute oral toxicity studies of Sodium Cetearyl Sulfate (in olive oil) and 20.0% aqueous Sodium Cetearyl Sulfate, the LD_{50} was not achieved at doses of 10 g/kg of body weight and 5 ml/kg of test material, respectively.

In Draize ocular irritation tests, 20.0% aqueous Sodium Cetearyl Sulfate was not irritating to the eyes of rabbits. In Draize skin irritation tests, 20.0% aqueous Sodium Cetearyl Sulfate was not irritating to the skin of rabbits.

In a skin sensitization study involving guinea pigs, Sodium Cetearyl Sulfate was tested at concentrations of 25.0 and 1.0% during induction and challenge phases, respectively. Reactions were not observed at any time during the study.

DISCUSSION

Sufficient data on Sodium Cetearyl Sulfate are not available for the Expert Panel's complete review of this ingredient. The Expert Panel has determined that a chemically similar cosmetic ingredient, Sodium Lauryl Sulfate [CH_3-$(CH_2)_{10}CH_2$-SO_3Na], is safe for use in cosmetic formulations designed for discontinuous, brief use, followed by thorough rinsing from the surface of the skin, and established a concentration limit of 1.0% for this ingredient in products intended for prolonged contact with the skin.[20] With the exception that Sodium Cetearyl Sulfate contains 14 or 16 methene groups and Sodium Lauryl Sulfate contains 10 methene groups, the chemical formulas for these sodium salts of saturated, fatty alcohol-sulfuric acid esters are identical. Additionally, Sodium Cetearyl Sulfate and Sodium Lauryl Sulfate are produced via the sulfation of cetearyl alcohol (C-16–C-18) and lauryl alcohol (C-12), respectively, with either chlorosulfonic acid or sulfur trioxide, followed by neutralization of the acid ester with

sodium hydroxide. Data on Sodium Lauryl Sulfate are being used by the Expert Panel in its safety assessment of Sodium Cetearyl Sulfate.

Results from studies involving animals suggest that Sodium Cetearyl Sulfate is less irritating to the skin than Sodium Lauryl Sulfate. Particularly, single 24 h applications of 20.0% aqueous Sodium Cetearyl Sulfate and 20.0% Sodium Lauryl Sulfate resulted in no skin irritation and primary skin irritation, respectively. Also, neither skin irritation nor sensitization was observed in a repeated insult patch test in which 25.0 and 1.0% aqueous Sodium Cetearyl Sulfate were applied during induction and challenge phases, respectively.

Human repeated insult patch test data were available on Sodium Lauryl Sulfate but not on Sodium Cetearyl Sulfate. When subjects were tested with a formulation containing 1.26% Sodium Lauryl Sulfate, reactions were observed during the induction and the challenge phase.

In that repeated applications of 25.0% aqueous Sodium Cetearyl Sulfate, followed by a challenge with 1.0% aqueous Sodium Cetearyl Sulfate, did not cause any reactions in animals, and whereas, induction and challenge reactions to a 1.26% Sodium Lauryl Sulfate formulation were observed in humans, it is reasonable to suggest that the skin irritation and sensitization potentials of Sodium Cetearyl Sulfate in humans would be less than those of Sodium Lauryl Sulfate. Based on this interpretation of the data, the Expert Panel did not believe it was necessary to request human sensitization test data for Sodium Cetearyl Sulfate.

CONCLUSION

On the basis of the animal and clinical data on Sodium Cetearyl Sulfate and Sodium Lauryl Sulfate presented in this report, the CIR Expert Panel concludes that Sodium Cetearyl Sulfate is safe as a cosmetic ingredient in the present practices of use and concentration.

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