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Final Report on the Safety Assessment of Sodium Lauryl Sulfoacetate

Sodium Lauryl Sulfoacetate is a detergent used in cosmetic products. A 12% solution of the ingredient was slightly toxic to rats in an acute oral study. No treatment-related effects of significance were noted in rats in a subchronic study at a dose of 75 mg/kg/day. Some effects were observed at 250 and 750 mg/kg/day. Minimal to slight ocular irritation occurred in rabbits when tested with 3.0% Sodium Lauryl Sulfoacetate. A diluted product tested at 1% Sodium Lauryl Sulfate was nonirritating to the genital mucosa of rabbits. No skin irritation, sensitization, or phototoxicity was noted in guinea pigs exposed to a cosmetic product containing 2% Sodium Lauryl Sulfoacetate. Cosmetic products containing up to 16% Sodium Lauryl Sulfoacetate were nonmutagenic in the Ames *Salmonella*/microsome assay, both with and without activation. In clinical studies, Sodium Lauryl Sulfoacetate was a mild to strong skin irritant but not a sensitizer at concentrations up to 2.0%. The irritant effects are similar to those produced by other detergents, and the severity of the irritation appears to increase directly with concentration. It is concluded that Sodium Lauryl Sulfoacetate is safe for use in cosmetic products in the present practices of use and concentration.

INTRODUCTION

Sodium Lauryl Sulfoacetate is an organic salt with good emulsifying and dispersing characteristics. It is used as a foaming agent in bath products and in dentifrices and as an emulsifying agent in skin care preparations.

CHEMICAL AND PHYSICAL PROPERTIES

Definition and Structure

Sodium Lauryl Sulfoacetate is an organic detergent possessing wetting, scouring, emulsifying, and dispersing properties.[1] This organic salt (CAS No.

1847-58-1; $C_{14}H_{27}O_5S \cdot Na$) generally conforms to the formula:

$$CH_3(CH_2)_{10}CH_2O-\overset{\overset{O}{\|}}{C}CH_2SO_3Na$$

It has a molecular weight of 330. Sodium Lauryl Sulfoacetate is also known as Sodium Dodecyl Sulfoacetate.[2] For cosmetic use, Sodium Lauryl Sulfoacetate is normally supplied at the 70% active concentration[3] and assays at 68.0–72.0% with 53% maximum sulfonated ash and a maximum moisture content of 2%.[2] All concentration values quoted in this report are expressed as actual concentrations of the Sodium Lauryl Sulfoacetate in the test solution.

Physical Properties and Reactivity

Sodium Lauryl Sulfoacetate is a white solid in powder or flake form, with a sweet, pleasant odor.[2] One gram of Sodium Lauryl Sulfoacetate will dissolve in 100 ml water at 25°C. Sodium Lauryl Sulfoacetate is hygroscopic and has a specific gravity of 0.55.[1]

The pH of a 0.25% aqueous solution of Sodium Lauryl Sulfoacetate is between 6.9 and 7.1. It is stable in hard water and stable in weakly acidic and weakly alkaline solutions in a pH range of 5.0 to 8.5.[1]

No information was available on impurities found in Sodium Lauryl Sulfoacetate.

USE

Purpose in Cosmetics

Sodium Lauryl Sulfoacetate is used as a foaming or dispersing agent in dentifrice, in bubble bath, and other bath preparations. It is also used in other products as a wetting agent.[3]

Scope and Extent of Use in Cosmetics

Sodium Lauryl Sulfoacetate is an ingredient of 93 cosmetics according to the Food and Drug Administration's (FDA) list of cosmetic product formulations. The majority of these cosmetic products are bubble baths and bath additive products containing 1.0–50% Sodium Lauryl Sulfoacetate. However, it should be noted that these products are greatly diluted in use, and the actual concentration of Sodium Lauryl Sulfoacetate coming into contact with the skin is low. Sodium Lauryl Sulfoacetate is also an ingredient in dentifrices at concentrations of $\leq 5\%$.[4]

A list of cosmetic products containing Sodium Lauryl Sulfoacetate is presented in Table 1. The cosmetic product formulation information that is made available by the FDA is compiled through voluntary filing of such data

TABLE 1. Product Formulation Data—Sodium Lauryl Sulfoacetate[4]

Product category	*Total no. of formulations in category*	*Total no. containing ingredient*	*No. of product formulations within each concentration range (%)*[a]					
			> 50	*> 25–50*	*> 10–25*	*> 5–10*	*> 1–5*	*> 0.1–1*
Bath oils, tablets, and salts	237	1	—	—	—	—	1	—
Bubble baths	475	85	3	13	17	44	8	—
Dentifrices (aerosol, liquid, pastes, and powders)	42	3	—	—	—	—	1	2
Other personal cleanliness products	227	1	—	—	—	—	—	1
Skin cleansing preparations (cold creams, lotions, liquids, and pads)	680	2	—	—	1	—	1	—
Other skin care preparations	349	1	—	—	—	1	—	—
1981 TOTALS		93	3	13	18	45	11	3

[a]All concentration groups are expressed as concentrations of Sodium Lauryl Sulfoacetate as supplied (normally as a 70% dilution).

in accordance with Title 21 part 720.4 of the Code of Federal Regulations.[5] Ingredients are listed in prescribed 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. The fact that data are only submitted within the framework of preset concentration ranges also provides 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- to 10-fold error in the assumed ingredient concentration.

Contact Surfaces and Duration of Use

Sodium Lauryl Sulfoacetate may be applied to all areas of the skin, mucous membranes, oral mucosa, hair, and nails. Small amounts of Sodium Lauryl Sulfoacetate may remain in contact with the body for extended periods of time, considering the fact that bath additives are not usually rinsed off.

Noncosmetic Uses

For veterinary use, Sodium Lauryl Sulfoacetate is classified as a surfactant and is used in commercial enemas and antiseborrheics.[6]

METABOLISM

No information was available on the metabolism of Sodium Lauryl Sulfoacetate. However, the metabolism of lauryl alcohol has been reviewed in connection with the cosmetic safety assessment of sodium lauryl sulfate and ammonium lauryl sulfate.[7]

TOXICOLOGY

Percutaneous Toxicity

Sodium Lauryl Sulfoacetate can be absorbed through guinea pig skin. Two groups of 6 female weanling guinea pigs were immersed in either 0.2% aqueous Sodium Lauryl Sulfoacetate or distilled water for 4 h on 3 consecutive days. The solutions were maintained at 39°C during immersion. Seven blood samples from each animal were analyzed for Sodium Lauryl Sulfoacetate. Samples were taken before and after each immersion and 24 h after the final immersion. Each 0.5 ml blood sample was extracted with NaOH followed by pentane then HCl in order to hydrolyze the Sodium Lauryl Sulfoacetate. The dodecanol hydrolysis product was then extracted with trimethylamine and heptafluorobutyric anhydride in order to convert the dodecanol into

heptafluorobutyryl (HFB) derivatives. These HFB derivatives were analyzed in a gas chromatograph equipped with a ^{63}Ni electron-capture detector. The unknown amounts of Sodium Lauryl Sulfoacetate as reflected by HFB derivatives were quantitated by comparing the peak heights with data from known amounts of the HFB derivatives added into blood samples and prepared and analyzed by the same method. Skin thickness and overall condition of the animals were also observed. Skinfold thickness determinations were made before each immersion and 24 h after the final immersion. The blood concentrations of Sodium Lauryl Sulfoacetate reached a maximum at the end of each immersion, which increased with each subsequent immersion. The overall increase in skinfold thickness was 0.08 mm in control animals immersed in deionized water and 0.27 in guinea pigs immersed in 0.2% Sodium Lauryl Sulfoacetate. There were no toxic effects on treated animals after the first immersion in Sodium Lauryl Sulfoacetate. Some sluggishness and weakness were observed after the second immersion, and animals showed difficulty in breathing, inability to walk properly, sensitivity to touch and less of the righting reflex after the third and final immersion (Table 2).[8]

Acute Oral Toxicity

A bath additive containing 50% Sodium Lauryl Sulfoacetate was tested for oral toxicity using rats. Groups (10 per group) of fasted female Harlan Wistar rats weighing 115–135 g were given single oral doses of the bath additive as a 35% aqueous solution. Doses ranged from 5 to 14 g/kg of the bath additive (0.6–1.7 g/kg Sodium Lauryl Sulfoacetate). Leg weakness, obtunded righting reflex, ataxia, diuresis, and diarrhea were observed 1–5 h after treatment. Most deaths occurred 4–24 h after treatment. The bath product was slightly toxic, with an estimated LD_{50} of 5.75 g/kg (0.7 g/kg Sodium Lauryl Sulfoacetate; moderately toxic).[9]

TABLE 2. Skin Thickness and Blood Concentrations of Free Detergent in Guinea Pigs After Immersion Tests[8]

Sampling Interval	*Average Skin Thickness*[a] *(mm)*	*Average Blood Concentration*[a] *(ppm)*
Control	0.08[b]	0.06 ± 0.005[c]
Before 1st immersion	0.74 ± 0.05	0.1
After 1st immersion		0.70 ± 0.04
Before 2nd immersion	0.80 ± 0.05	0.22 ± 0.15
After 2nd immersion		1.73 ± 0.50
Before 3rd immersion	0.88 ± 0.04	0.23 ± 0.09
After 3rd immersion		12.7 ± 5.09
24 h after 3rd immersion	1.01 ± 0.03	0.33 ± 1.01

[a]Mean value from 6 animals.

[b]Total difference in thickness in control animals only; final sample thickness – initial sample thickness. Other values are actual skin thickness in test animals.

[c]Mean and standard error from quadruplicate samples from a single, untreated animal with no Sodium Lauryl Sulfoacetate added to sample.

Parenteral Toxicity

The acute intraperitoneal lethal dose of Sodium Lauryl Sulfoacetate was estimated in rats as 0.25 g/kg by Epstein et al.[10] Groups of rats received either 0.15 g/kg or 0.5 g/kg intraperitoneal injections resulting in 0/10 deaths at the low dose and 10/11 deaths at the higher dose.

Subcutaneous Toxicity

The irritation potential of Sodium Lauryl Sulfoacetate was evaluated by subcutaneous injection. Groups of 2 rats were given a single, 1 ml subcutaneous injection of 0.274%, 0.63%, 1.25%, 2.5%, or 5% (1 rat only) Sodium Lauryl Sulfoacetate and observed for 1 week for evidence of lesions at the site of injection. The subcutaneous irritation increased as the dose of Sodium Lauryl Sulfoacetate increased: no reactions were observed in the rats of the 0.27% and 0.63% groups, 1 rat given 1.25% had sloughing of the skin, both rats given 2.5% had sloughing of the skin, and 1 rat had a lump at the injection site. One rat given 5% Sodium Lauryl Sulfoacetate had both sloughing of the skin and a lump at the injection site. Sodium Lauryl Sulfoacetate was an irritant when administered by subcutaneous injection.[10]

Mucous Membrane Irritation

The genital mucosae of 6 albino rabbits, 3 males and 3 females, were each treated with a single 0.1 ml application of a 1% aqueous solution of a bath additive containing 50% Sodium Lauryl Sulfoacetate (equivalent to 0.0005 ml of 35% Sodium Lauryl Sulfoacetate). No signs of irritation were noted during the 7-day observation period.[9]

Ocular Irritation

Six albino rabbits were treated in 1 eye with 0.1 ml of a 1% (w/v) solution of a bath additive containing 35% Sodium Lauryl Sulfoacetate. The animals were observed for 4 to 7 days. Slight conjunctival redness was observed 1 h after treatment and had dissipated by 48 h. The cornea and iris appeared normal.[9]

The ocular irritation potential of a milk bath containing 30% Sodium Lauryl Sulfoacetate was evaluated using 3 female New Zealand rabbits. A single application of 0.1 ml of a 10% aqueous solution of the milk bath (resulting in a 3.0% solution of Sodium Lauryl Sulfoacetate) was instilled into the conjunctival sac of the left eye of rabbits. The right eye was untreated and served as the control. Eyes were examined for irritation 1 h after application, then daily until the irritation had disappeared. All rabbits had minimal conjunctival irritation at 1 and 24 h and no irritation at 48 h. Irritation scores were 4, 6, and 4 (max. 110) at 1 h, and 2, 4, and 4 at 24 h.[11]

Skin Irritation

Undiluted Sodium Lauryl Sulfoacetate moistened with 0.9% saline was applied to the shaved backs of 6 New Zealand rabbits. The 4 test sites per animal were covered by semiocclusive patches, and the 0.5 g application of test material remained in contact with the test site for 24 h. Test sites were scored for erythema and edema 30 min and 24 h after patch removal. The mean primary irritation score (PII) for the group was 2.7 (max. 8.0), and 1 animal had areas of possible necrosis within the test site at 24 h. Undiluted Sodium Lauryl Sulfoacetate was a moderate skin irritant.[12]

The skin irritation potential of a bath product containing 35% Sodium Lauryl Sulfoacetate was studied using rabbits. The backs of 3 albino rabbits were shaved and divided into 2 test sites per rabbit. Daily topical applications of 500 mg (150 mg Sodium Lauryl Sulfoacetate) of undiluted bath additive in powdered form was administered to 1 site per animal; the contralateral site received daily applications of a 1% solution of the bath additive (0.35% Sodium Lauryl Sulfoacetate). The animals were treated for 4 days. No irritation was observed at the sites treated with the powdered bath product. All sites treated with the 1% solution had slight erythema on day 2 but were normal at day 7.[9]

Skin Sensitization

A cream shampoo containing 2.1% Sodium Lauryl Sulfoacetate was tested for sensitization in guinea pigs by a modification of the method of Buehler and Griffith. A 10% aqueous dilution of the cream shampoo was topically administered under occlusive patches in 0.5 ml doses to the shaved backs of 10 healthy female Hartley guinea pigs. Three inductive patches were applied at weekly intervals, and challenge patches were applied 2 and 3 weeks after the last inductive patch. Twenty-four hours after each application, the sites were scored on a scale of 0 (no erythema) to 4 (severe erythema—beet red—to eschar formation). No erythema was observed after any inductive or challenge patches. It was concluded that this product did not cause sensitization under these test conditions.[13]

Phototoxicity

An acne wash containing 0.7% Sodium Lauryl Sulfoacetate was evaluated for phototoxicity using guinea pigs. The backs of 2 female guinea pigs were shaved and divided by tape into 4 treatment areas. One-tenth milliliter of a 20% aqueous dilution of the test material was applied to 2 test sites per animal, and the other 2 test sites received Oxsoralen, a phototoxic agent, as a positive control. Fifteen to twenty minutes after application, 1 side of the animals' backs was exposed to UVA light (320–400 nm, No. F40BL, 40W Westinghouse Blacklights) for 60 min. Residual material was then removed by washing, and the test sites were scored for erythema 24 h later on a scale of 0 (no erythema) to 4 (severe erythema). Exposed and unexposed treatment sites

TABLE 3. Animal Skin Irritation, Skin Sensitization, and Phototoxicity

Test type	*No. and species of animals*	*Concentration of ingredient in product (%)*	*Product dose*	*Observation time*	*Comments*	*Reference*
Skin irritation	6 rabbits	70	0.5 g in 24-h semioccluded patch	24 h	Group PII = 2.7 (max. 8.0). Moderate skin irritant	12
Skin irritation	3 rabbits	35	500 mg powdered product or 50 ml of a 1% (0.5% ingredient) solution of product; daily for 4 days	7 days	No irritation at sites treated with undiluted product. Slight erythema at sites treated with 1% solution	9
Skin sensitization (modification of Buehler and Griffith method)	10 F Hartley guinea pigs	2.1	0.5 ml of a 10% aqueous solution of product (2.1% ingredient). Three inductive patches at 1-week intervals. Two challenge patches 2 and 3 weeks after induction	6 weeks	No reactions; not a sensitizer	13
Phototoxicity	2 F guinea pigs	0.7	0.1 ml of a 20% product solution (0.2% ingredient) followed by 1 h UVA exposure	24 h	Exposed and unexposed treatment sites had very slight erythema. Not phototoxic	14
Phototoxicity	3 F guinea pigs	2.1	0.1 ml of 25% product solution (0.75% ingredient) followed by 1 h UVA exposure	24 h	No reactions. Not phototoxic	15
Phototoxicity	3 F guinea pigs	0.7	0.1 ml of product followed by 1 h UVA exposure	24 h	No reactions. Not phototoxic	16

had a score of 1. Positive control sites scored 4, and unexposed controls had scores of 0. It was concluded that a 20% aqueous dilution (0.14% Sodium Lauryl Sulfoacetate) of the formulation was not phototoxic to guinea pigs.[14]

A 25% dilution of a cream shampoo containing 3% Sodium Lauryl Sulfoacetate (0.5% Sodium Lauryl Sulfoacetate) was tested for phototoxicity as described above.[14] Three female guinea pigs had no reactions at exposed and unexposed sites, and the product was nonphototoxic in guinea pigs.[15]

An acne wash containing 0.7% Sodium Lauryl Sulfoacetate was tested for phototoxicity as above.[14] The acne wash was tested undiluted in 3 female guinea pigs. No reactions were observed, and the acne wash was not phototoxic under the conditions of the test.[16]

Animal skin irritation, skin sensitization, and phototoxicity studies and results are presented in Table 3.

Short-Term Dermal Toxicity

The subchronic dermal toxicity of an acne wash containing 0.7% Sodium Lauryl Sulfoacetate was evaluated in purebred Yorkshire pigs. Three groups of 6 animals each (3 male and 3 female pigs) received 1.0 ml/kg of 0.9% saline (control), 0.5 ml/kg product, or 1.0 ml/kg product on the close-clipped skin of the back twice daily for 30 days. The skin of half of the animals in each group was abraded. The treated sites had slight reddening and/or focal scabs. The investigators attributed these effects to mechanical trauma, since there were no lesions or local irritation. Daily clinical observations, weekly body weight values, serum chemistry evaluations, gross observations at necropsy, and microscopic evaluations of tissues were negative for indications of systemic toxicity. The pigs receiving 1.0 ml/kg had slightly decreased mean hemoglobin values at the end of the study, but these values were within reported reference ranges and were not considered significant. This treatment group had significantly smaller (by weight) adrenal glands on an absolute basis. However, there was no difference when compared on a relative weight basis.[17]

ORAL TOXICITY

Sodium Lauryl Sulfoacetate was evaluated for oral toxicity in a 28-day range-finding study with CD strain rats. The surfactant was dissolved in distilled water and administered by gavage at doses of either 50, 200, or 800 mg/kg/day for 28 consecutive days to 3 groups of rats (5 males and 5 females per group). The aqueous test solution containing Sodium Lauryl Sulfoacetate was given at a constant volume of 10 ml/kg/day. A fourth group of 5 male and 5 female rats served as controls and received distilled water alone (10 ml/kg/day). Feed consumption and body weights were measured weekly, and body weight group means were calculated twice weekly. At termination of the 28-day treatment, blood samples were obtained from all rats, and all animals were subjected to necropsy. At necropsy, macroscopic examinations

of the brain, kidney, and liver were made, and the weights of those organs were recorded. No histopathological examinations were performed. No deaths occurred throughout the treatment period. Poor coat condition was noted in all animals dosed with 800 mg/kg/day and in females dosed with 200 mg/kg/day. Postdose salivation was observed in all animals of the 800 mg/kg/day group from day 18 to day 28. Body weight gain of females from the 200 mg/kg/day group was similar to controls after 2 weeks of treatment but was reduced by 8% after 3 weeks and by 9% after 4 weeks of treatment. Females of the 800 mg/kg/day group had a reduction in body weight gain of 10–12% throughout the treatment period when compared with controls. The 50 mg/kg/day group had body weight gains similar to those of control animals. Females of the high-dose group (800 mg/kg/day) had an overall decrease of 7% in feed consumption when compared to controls. Feed consumption was reduced by 5% during week 1 and by 9% by week 4. Females of the 200 mg/kg/day group had an overall decrease of 6% in feed consumption. The decrease was 4% for week 1 and 9% by week 4. Feed consumption in the 50 mg/kg/day group remained similar to that of controls throughout the treatment period. Feed conversion ratios did not indicate any clear pattern of change. No changes of toxicological significance were observed in hematology or blood biochemistry. Hematology parameters measured included hematocrit, hemoglobin, erythrocyte count, mean cell volume, mean cell hemoglobin concentration, and total leukocyte count. Blood chemistry parameters measured included blood urea nitrogen, glucose, alkaline phosphatase, glutamate pyruvate transaminase, glutamate oxaloacetate transaminase, and total protein. Body weight-related brain and kidney weights were significantly increased in females of the 800 mg/kg/day group. Absolute and body weight-related liver weights also were increased in males from the high-dose group, but these increases were not statistically significant. At necropsy, black foci on the nonglandular mucosa of the stomach were found in 1 male from the 800 mg/kg/day group.[18]

Sodium Lauryl Sulfoacetate was evaluated for subchronic oral toxicity in a 13-week study with CD (SD) BR strain rats. The surfactant was dissolved in distilled water and administered by gavage at doses of either 75, 250, or 750 mg/kg/day for 91 consecutive days to 3 groups of rats (20 males and 20 females per group). The aqueous test solution containing Sodium Lauryl Sulfoacetate was given at a constant volume of 10 ml/kg/day. A fourth group of 20 males and 20 females served as controls and received distilled water (10 ml/kg/day). Animals were observed daily, and feed consumption and body weight group means were taken weekly. Ophthalmoscopic examinations were made on all animals before the study and on rats of the high-dose and control groups after 4 and 12 weeks of treatment. Urinalysis, hematology, and blood chemistry determinations were made before the study and after 4 and 12 weeks of treatment in 10 males and 10 females of each group. After 13 weeks of treatment, all rats were subjected to necropsy, during which the weights of selected organs of 10 males and 10 females were recorded. Selected tissues of the high-dose and control groups also were examined microscopically. No treatment-related deaths occurred. In the group of animals given 750 mg/kg/day, body weight gain was reduced by 7% in males and was increased by 7%

in females. Males in the 250 mg/kg/day group had a 7% decrease in body weight. Body weight gain in the animals of the 75 mg/kg/day group was similar to that of controls. Over 13 weeks, males dosed with 750 mg/kg/day had a 5% reduction in feed intake, whereas females given the same dose had a 5% increase in feed intake. Increased salivation was noted in both the high and intermediate dose groups beginning at weeks 3 and 8, respectively. Decreased hemoglobin concentration was observed in all treated males after 4 weeks; however, this change was not apparent after 12 weeks. Leukocyte count was reduced in males of the 750 mg/kg/day group after weeks 4 and 12. At weeks 4 and 12, blood urea nitrogen was increased in females in all treatment groups, and glutamate pyruvate transaminase activity was reduced in males of all exposed groups. Of the hematological and blood biochemical changes that were observed, all were within historical control values for the particular laboratory and were not considered related to administration of Sodium Lauryl Sulfoacetate. No other hematological or blood chemistry changes were noted. Urine volume was increased in females in the 750 mg/kg/day group at weeks 4 and 12; specific gravity of the urine was reduced at week 12. Males in the high-dose group had marginal changes in urine volume and specific gravity. No other treatment-related urinary changes were noted at urinalysis. Increased liver weights and liver/body weight ratios were observed in females in the high-dose group. No other treatment-related effects were found in organ weights. The eyes of all rats of the 750 mg/kg/day group were comparable to those of control animals. No lesions were found at necropsy that could be attributed to Sodium Lauryl Sulfoacetate. However, at macroscopic examination, a dose-related hyperplasia was found in the gastric nonglandular squamous epithelium in all three treatment groups, including 32/40 rats (15 males and 17 females) in the 750 mg/kg/day group, 8/40 rats (5 males and 3 females) in the 250 mg/kg/day group, and 1/40 (1 male) rats in the 75 mg/kg/day group. One female in the control group also had gastric hyperplasia. This gastric hyperplasia was characterized by acanthosis, hyperkeratosis, and an increase in the number of mitoses. In many rats of the high and intermediate dose groups, focal erosion in the nonglandular squamous epithelium and varying degrees of gastritis were seen in association with the epithelial hyperplasia. According to the investigators, these lesions were toxicologically significant and were indicative of either "irritation to the nonglandular epithelium by the direct action of the gavage-administered test compound on the epithelial surface," or "stress-related gastritis and epithelial erosion with reparative epithelial hyperplasia." In rats of the low-dose group, no associated epithelial erosion or gastritis was observed, and the low incidence of epithelial hyperplasia was not considered significant. No other treatment-related effects were observed in other organs or tissues. Changes noted in the stomachs of a few animals, but not considered toxicologically significant, included distention of gastric glands, single mucosal cysts, and a keratin inclusion cyst. All blood chemistry parameters examined in this chronic study were within the normal expected range. There was no significant difference between the test and control group for hematological parameters, urinalysis, and organ weights. Organs and tissues of the high-dose and control groups examined microscopically included adrenal glands, aortic arch, brain,

cecum, cervical and mesenteric lymph nodes, colon, duodenum, epididymides, eyes, heart, ileum, jejunum, kidneys, liver, lungs, mammary glands, optic nerve, ovaries, pancreas, pituitary gland, prostate, spleen, stomach, testes, thymus, thyroid glands, urinary bladder, aorta, bone, esophagus, salivary glands, sciatic nerve, skeletal muscle, spinal cord, tongue, trachea, and bone marrow. No significant difference was observed.[19]

Mutagenicity

A cleansing bar containing 16.1% Sodium Lauryl Sulfoacetate was assayed for mutagenicity in the Ames *Salmonella*/microsome plate test. The dose range was 1.0 μg to 1000 μg per plate. Six strains of *Salmonella* and *Saccharomyces* were used in the tests. The cleansing bar was not genotoxic in any of the assays, either with or without addition of liver microsomal enzyme preparations from Aroclor 1254-induced rats. The product was not mutagenic under these test conditions.[20]

Two other cosmetic products containing either 2.1% or 13.3% Sodium Lauryl Sulfoacetate, respectively, were tested for mutagenicity as described above.[20] Neither product was genotoxic with or without addition of a rat liver microsomal enzyme preparation; it was concluded that neither product was mutagenic in the test system.[21,22]

CLINICAL ASSESSMENT OF SAFETY

The primary irritation potential of a milk bath containing 30% Sodium Lauryl Sulfoacetate was evaluated in a single insult patch test using 100 subjects. The product was administered as a 10% aqueous solution (3.0% ingredient) in a 48-h occlusive patch to the subject's back. The dose per patch was 0.1 ml. The test sites were scored for erythema and edema 15 min and 24 h after patch removal. No erythema or edema was observed, and the milk bath was not a primary irritant.[23]

The skin irritation potential of an aqueous solution containing 0.7% w/v Sodium Lauryl Sulfoacetate was evaluated in 16 subjects. The test solution was applied for 48 h under an occlusive patch to the scapular region of the back. Following examination of the treated skin, the test material was reapplied to the same site for a second 48-h period (total Sodium Lauryl Sulfoacetate exposure, 96 h). Skin responses were graded on a scale of 0 (no visible reaction) to 4+ (intense erythema, edema, and vesicular erosion). In those individuals who had skin reactions of $>1+$, no further applications were made. Test sites were evaluated for skin erythema and edema at 48 and 96 h after the initial exposure. At the 48-h evaluation, 4 subjects had no skin reaction (score, 0), 9 had mild erythema (score, 1+), and 3 had intense erythema (score, 2+). At 96 h, 3 subjects had no skin reaction, 9 had mild skin erythema, 1 had intense skin erythema, and 3 subjects had no score because they were not treated with a second patch.[24]

An aqueous solution containing 0.18% w/v Sodium Lauryl Sulfoacetate was evaluated for skin irritation and sensitization in 152 panelists using the repeated insult patch test described by Jordan[25] and Jordan and King.[26] Excluded from the test panel were those with known skin conditions. For the induction phase, the test solution was applied under an occlusive patch to the scapular region of the back every Monday, Wednesday, and Friday for 3 consecutive weeks for a total of 9 applications. The induction patches remained in place for 48 h and were applied to the same skin site. In instances where people had significant skin reactions, the test solution was applied to an adjacent skin site. Following a 14-day nontreatment period, 2 consecutive challenge applications were made for 48 h to a site adjacent to the induction site. Skin reactions were scored on a scale of 0 (no reaction) to 4 (bullae or extensive erosions involving at least 50% of the test area). Skin irritation was noted at one or more evaluations during the induction period in 145 of the 152 panelists. Scores for the majority of these irritation reactions ranged from 1 + (macular, faint erythema involving at least 25% of the test area) to 2 + (moderately intense erythema, with and without infiltration, and involving at least 25% of the test area). Two of the 145 reactors had 3 + induction reactions (strong, infiltrated erythema and accompanying vesicles or superficial erosions involving at least 25% of the test area). The irritation in 19 panelists was significant enough to warrant changing the induction site. During the challenge phase, a total of 79 of 152 subjects developed 1 + or 2 + skin reactions to one or both applications. Fifty panelists reacted to the first challenge patch, and 58 panelists reacted to the second challenge patch. However, it was the investigators' conclusion that these challenge reactions were irritant responses and not allergic in nature.[27]

A Modified Schwartz/Peck Procedure and an in-use test of a bath preparation containing 35% Sodium Lauryl Sulfoacetate were conducted with 47 subjects. Occlusive patches containing 0.1 ml of 1% or 2% (w/w) solution of the bath preparation were administered to the upper back or inner arm of women between the ages of 18 and 65. At the end of 48 h, the patches were removed and scored on a scale of 0 (negative) to 4 + (erythema, edema/induration, with or without ulceration). Twenty-four hours later, the test sites were scored again. Subjects were then sent home and instructed to use the product at least once a day for 4 weeks. Half of the subjects were instructed to use 3 scoopfuls in a full bathtub of water, and the other subjects were instructed to use 1-1/2 capfuls under full force running water. At the end of the 4 weeks, challenge patches were administered and scored as above, except that only a 1% concentration was used. Forty-eight and 72 h after the initial patch was applied, 7/47 and 15/47 panelists, respectively, had a 1 + reaction (erythema only). No subjective or objective reactions were reported during the in-use portion of the test. Forty-eight hours after the challenge patch was applied, 17/47 subjects had a 1 + reaction and 1 subject had a 2 + (erythema and edema or induration) reaction. Seventy-two hours after the challenge patch application, 11/47 subjects had a 1 + reaction, and one subject had a 2 + reaction. The investigators did not consider any of the reactions clinically significant. The product was neither a strong irritant nor an allergic sensitizer.[28] Clinical studies are summarized in Table 4.

TABLE 4. Clinical Assessment of Safety

Test type	*No. of subjects*	*Vehicle or product type*	*Concentration of Sodium Lauryl Sulfoacetate*	*Dose*	*Comments*	*Reference*
Skin irritation, single patch	100	Milk bath	3.0% (10% aqueous solution of milk bath that contains 30% ingredient)	0.1 ml	No erythema or edema. Not a skin irritant	23
Skin irritation, 2 consecutive patches	16	Water	0.7%		Intense erythema in 3 subjects. A primary irritant	24
Repeated Insult Patch Test	152	Water	0.18%		145/152 panelists had irritant reactions to at least 1 induction patch. 50/152 panelists reacted to 1st challenge patch; 58/152 reacted to 2nd challenge patch. Reactions considered irritant responses and not allergic in nature	27
Schwartz/Peck and in-use test	47	Bath product	35% (1–2% aqueous solution of product used for induction and challenge patches)	Patches—0.1 ml; in-use—1 1/2 or 3 scoopfuls in a full bath daily for 4 weeks	Induction patch—7/47 had erythema at 48 h; 15/47 had erythema at 72 h. No objective or subjective reactions during in-use portion of study. Challenge patch—17/47 had erythema and 1/47 had erythema and edema at 48 h; 11/47 had erythema and 1/47 had erythema and edema at 72 h. Reactions not considered clinically significant. Not a strong irritant, not a sensitizer	28

SUMMARY

Sodium Lauryl Sulfoacetate is a white, solid organic salt with a sweet, pleasant odor. It is a detergent used for its wetting, scouring, emulsifying, and dispersing properties and is stable in hard water and in slightly basic or acidic (pH 5–8.5) solutions.

In cosmetics, Sodium Lauryl Sulfoacetate is an ingredient primarily of bath preparations, where it acts as a foaming agent. It constitutes 5–50% of these preparations, but the actual concentration coming into contact with the skin is much less due to product dilution in bath water.

Toxicity studies were conducted with cosmetic products or aqueous dilutions of cosmetic products containing Sodium Lauryl Sulfoacetate. A bath product containing 35% Sodium Lauryl Sulfoacetate and diluted to 35% in aqueous solution (12.2% Sodium Lauryl Sulfoacetate) was slightly toxic to rats in an acute oral study. A bath product containing 35% Sodium Lauryl Sulfoacetate and diluted to 1% in water was nonirritating to the genital mucosa of rabbits. Minimal to slight ocular irritation was observed in rabbits tested with cosmetic products containing 35% and 30% Sodium Lauryl Sulfoacetate and diluted and tested at 0.35% and 3.0% Sodium Lauryl Sulfoacetate. In a skin irritation study with rabbits, a powdered bath product containing 35% Sodium Lauryl Sulfoacetate produced no irritation; however, when the product was diluted to 1% in water, slight skin irritation was observed. No skin irritation or sensitization was noted in guinea pigs exposed to a cream shampoo containing 2.1% Sodium Lauryl Sulfoacetate and diluted to 10% in water. No phototoxicity was observed in guinea pigs treated with UV light and cosmetic products or aqueous dilutions of cosmetic products containing 0.14%, 0.53%, or 0.7% Sodium Lauryl Sulfoacetate. No toxicity was noted in pigs exposed in a dermal study to an acne wash containing 1.0% Sodium Lauryl Sulfoacetate.

Toxicity studies were also conducted with the ingredient itself. In a guinea pig immersion study, Sodium Lauryl Sulfoacetate was absorbed through the skin, as evidenced by increased blood concentration of the surfactant. The acute intraperitoneal lethal dose of Sodium Lauryl Sulfoacetate in rats was estimated to be 0.25 g/kg and was an irritant when administered by subcutaneous injection at concentrations of 1.25, 2.5, and 5%. In studies with rabbits, Sodium Lauryl Sulfoacetate moistened with saline solution was a moderate skin irritant. In a 28-day study with rats, the surfactant was administered by gavage at doses of 50, 200, or 800 mg/kg/day. Observed dose-related effects included reduced feed consumption, decreased body weight gain, poor coat conditions, and salivation. Black foci of the nonglandular mucosa of the stomach were noted in one animal of the high-dose group. In a 91-day study with rats, Sodium Lauryl Sulfoacetate was administered by gavage at doses of 75, 250, or 750 mg/kg/day. No treatment-related effects of significance were noted in rats of the low-dose group. However, observed effects in the mid-dose and high-dose groups included postdose salivation, changes in body weight gain, feed consumption, absolute and body weight-related liver weights, and urinalysis determinations. Hyperplasia of the nonglandular squamous epithelium was noted in the mid-dose and high-dose rats. This hyper-

plasia was characterized by acanthosis, hyperkeratosis, and an increase in the number of mitoses. Associated with the epithelial hyperplasia was a focal erosion of the nonglandular epithelium and varying degrees of gastritis.

Cosmetic products containing 16%, 13.3%, and 2.1% Sodium Lauryl Sulfoacetate were nonmutagenic in the Ames *Salmonella*/microsome assay, both with and without activation using Aroclor-induced rat liver fractions.

In clinical studies, Sodium Lauryl Sulfoacetate was a mild to strong skin irritant at concentrations in aqueous solution of 0.18 and 0.7%. In one repeated insult patch test with 152 panelists, 79 subjects developed skin reactions at challenge to 0.18% Sodium Lauryl Sulfoacetate in aqueous solution; however, these reactions were considered nonallergic in nature. A bath product formulated with 30% Sodium Lauryl Sulfoacetate and diluted to 10% in aqueous solution was nonirritating to human skin, whereas another bath product formulated with 35% Sodium Lauryl Sulfoacetate and tested as-is in an in-use study or diluted to 1 or 2% in aqueous solution was irritating but nonsensitizing to human skin.

DISCUSSION

Sodium Lauryl Sulfoacetate is a mild ocular irritant and a skin irritant in experimental animals and produces irritation in humans patch tested at concentrations of 0.18 and 0.7%. In some cosmetic formulations, however, the irritant property is attenuated. The irritant effects are similar to those produced by other detergents, and the severity of the irritation appears to increase directly with concentration. The longer this ingredient stays in contact with the skin, the greater is the likelihood of irritation, which may or may not be evident to the user. Conversely, Sodium Lauryl Sulfoacetate appears to pose less potential hazard when in products designed for brief, discontinuous use, following which they are thoroughly rinsed from the surface of the skin.

CONCLUSION

On the basis of the available data presented in this report, the Expert Panel concludes that Sodium Lauryl Sulfoacetate is safe as a cosmetic ingredient in the present practices of use and concentrations.

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