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## **Safety Assessment of Sodium Lauryl Sulfoacetate as Used in Cosmetics**

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Status: Re-Review for Panel Consideration  
Release Date: September 1, 2022  
Panel Meeting Date: September 26-27, 2022

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Christina Burnett, Senior Scientific Analyst/ Writer, CIR.



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### **Memorandum**

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons  
From: Christina Burnett, Senior Scientific Analyst/Writer, CIR  
Date: September 1, 2022  
Subject: Re-Review of the Safety Assessment of Sodium Lauryl Sulfoacetate

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a review of the safety of Sodium Lauryl Sulfoacetate in 1987 with the conclusion that this ingredient is safe as a cosmetic ingredient in the present practices of use and concentration (report identified as *originalreport\_SodiumLaurylSulfoacetate\_092022* in the pdf). The Panel reaffirmed this conclusion in a re-review that was published in 2006 (*rereview2006\_SodiumLaurylSulfoacetate\_092022*).

Because it has been at least 15 years since the first re-review was published, in accord with CIR Procedures, the Panel should consider whether the safety assessment of Sodium Lauryl Sulfoacetate should be re-opened. An exhaustive search of the world's literature was performed for studies dated 2004 forward. No relevant published data were found. An historical overview, comparison of original and new use data, and the search strategy used are enclosed herein (*newdata\_SodiumLaurylSulfoacetate\_092022*). It should be noted that in the 2006 rereview summary a supplier of Sodium Lauryl Sulfoacetate had proposed conducting reproductive and developmental toxicity studies and making these available to the Panel upon completion. To the knowledge of CIR staff, these studies have not been submitted.

Also included for your review is a table of current and historical use data (*usetable\_SodiumLaurylSulfoacetate\_092022*). Since the initial re-review was considered, the frequency of use has increased slightly from 68 to 87 uses. In 2004, the maximum concentration of use for this to be 4% in leave-on products, 5% in rinse-off products, and 21% in products diluted for use. Concentration of use data for 2022 indicate that Sodium Lauryl Sulfoacetate is used at up to 2.5% in leave-on products (foot powders), up to 10.2% in rinse-off products (preshave lotions), and up to 8.4% in products diluted for use (bubble baths).

If, upon review of the new studies and updated use data, the Panel determines that a re-review is warranted, a draft amended report will be presented at an upcoming meeting.

**Re-Review - Sodium Lauryl Sulfoacetate - History and New Data**

(Christina Burnett – September 2022 meeting)

Ingredients (1)	Citation	Conclusion	Use - New Data	Use - Historical Data	Notes
<b>Sodium Lauryl Sulfoacetate</b> CAS No. 1847-58-1	JACT 6(3):261-277, 1987 – original report  IJT 25(S2):65-69, 2006 – re-review summary	safe as used  conclusion reaffirmed	frequency of use (2022): 87 uses conc of use (2021): 0.00028% - 10.2%	frequency of use (2002): 68 uses conc of use (2004): 0.6% - 21%	While number of uses have increased slightly, maximum concentration of use has decreased (from 4% to 2.5% in leave-ons, and from 21% to 8.4% in diluted products)

NR = Not Reported

NOTABLE NEW DATA			
Publication	Study Type	Results – Brief Overview	Different from Existing Data?
<i>no new published data</i>			

Search (from 2004 on)

PubMed

("Sodium Lauryl Sulfoacetate") OR (1847-58-1[EC/RN Number])– 2 hits; none useful

**Current and historical frequency and concentration of use according to duration and exposure for Sodium Lauryl Sulfoacetate**

	# of Uses		Max Conc of Use (%)	
	2022	2002	2022	2004
<b>Totals*</b>	<b>87</b>	<b>68</b>	<b>0.00028-10.2</b>	<b>0.6-21</b>
<b><i>Duration of Use</i></b>				
<i>Leave-On</i>	5	1	0.8-2.5	4
<i>Rinse-Off</i>	52	6	0.00028-10.2	5
<i>Diluted for (Bath) Use</i>	30	61	3-8.4	21
<b><i>Exposure Type</i></b>				
Eye Area	NR	NR	NR	NR
Incidental Ingestion	NR	1	0.74	0.7
Incidental Inhalation-Spray	1 <sup>a</sup>	1	1.5	2; 2 <sup>a</sup>
Incidental Inhalation-Powder	1 <sup>a</sup>	NR	2.5	1 <sup>b</sup> ; 2 <sup>a</sup>
Dermal Contact	53	64	0.00028-10.2	0.6-21
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	33	1	0.53-4.4	1-5
Hair-Coloring	1	2	3	NR
Nail	NR	NR	NR	4
Mucous Membrane	42	62	0.00028-10	0.6-21
Baby Products	1	NR	0.53	1

\*Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

<sup>a</sup> Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories

<sup>b</sup> It is possible these products are powders, but it is not specified whether the reported uses are powders.

NR – no reported use

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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

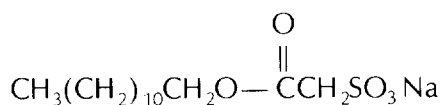
**S**odium Lauryl Sulfoacetate is an organic salt with good emulsifying and dispersing characteristics. It is used as a foaming agent in bath products and in dentifrices and as an emulsifying agent in skin care preparations.

## CHEMICAL AND PHYSICAL PROPERTIES

### Definition and Structure

Sodium Lauryl Sulfoacetate is an organic detergent possessing wetting, scouring, emulsifying, and dispersing properties.<sup>(1)</sup> This organic salt (CAS No.

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



It has a molecular weight of 330. Sodium Lauryl Sulfoacetate is also known as Sodium Dodecyl Sulfoacetate.<sup>(2)</sup> For cosmetic use, Sodium Lauryl Sulfoacetate is normally supplied at the 70% active concentration<sup>(3)</sup> and assays at 68.0–72.0% with 53% maximum sulfonated ash and a maximum moisture content of 2%.<sup>(2)</sup> 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.<sup>(2)</sup> 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.<sup>(1)</sup>

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.<sup>(1)</sup>

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.<sup>(3)</sup>

### 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  $\leq 5\%$ .<sup>(4)</sup>

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<sup>(4)</sup>

<i>Product category</i>	<i>Total no. of formulations in category</i>	<i>Total no. containing ingredient</i>	<i>No. of product formulations within each concentration range (%)<sup>a</sup></i>					
			<i>&gt; 50</i>	<i>&gt; 25–50</i>	<i>&gt; 10–25</i>	<i>&gt; 5–10</i>	<i>&gt; 1–5</i>	<i>&gt; 0.1–1</i>
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

<sup>a</sup>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.<sup>(5)</sup> 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.<sup>(6)</sup>

## **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.<sup>(7)</sup>

## **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



heptafluorobutyl (HFB) derivatives. These HFB derivatives were analyzed in a gas chromatograph equipped with a  $^{63}\text{Ni}$  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 loss of the righting reflex after the third and final immersion (Table 2).<sup>(8)</sup>

### 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  $\text{LD}_{50}$  of 5.75 g/kg (0.7 g/kg Sodium Lauryl Sulfoacetate; moderately toxic).<sup>(9)</sup>

**TABLE 2.** Skin Thickness and Blood Concentrations of Free Detergent in Guinea Pigs After Immersion Tests<sup>(8)</sup>

<i>Sampling Interval</i>	<i>Average Skin Thickness<sup>a</sup> (mm)</i>	<i>Average Blood Concentration<sup>a</sup> (ppm)</i>
Control	0.08 <sup>b</sup>	0.06 ± 0.005 <sup>c</sup>
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

<sup>a</sup>Mean value from 6 animals.

<sup>b</sup>Total difference in thickness in control animals only; final sample thickness – initial sample thickness. Other values are actual skin thickness in test animals.

<sup>c</sup>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.<sup>(10)</sup> 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.<sup>(10)</sup>

### 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.<sup>(9)</sup>

### 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.<sup>(9)</sup>

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.<sup>(11)</sup>

### 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 semioclusive 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.<sup>(12)</sup>

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.<sup>(9)</sup>

### 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.<sup>(13)</sup>

### 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

<i>Test type</i>	<i>No. and species of animals</i>	<i>Concentration of ingredient in product (%)</i>	<i>Product dose</i>	<i>Observation time</i>	<i>Comments</i>	<i>Reference</i>
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.<sup>(14)</sup>

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

An acne wash containing 0.7% Sodium Lauryl Sulfoacetate was tested for phototoxicity as above.<sup>(14)</sup> 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.<sup>(16)</sup>

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.<sup>(17)</sup>

### 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.<sup>(18)</sup>

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.<sup>(19)</sup>

### 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  $\mu\text{g}$  to 1000  $\mu\text{g}$  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.<sup>(20)</sup>

Two other cosmetic products containing either 2.1% or 13.3% Sodium Lauryl Sulfoacetate, respectively, were tested for mutagenicity as described above.<sup>(20)</sup> 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.<sup>(21,22)</sup>

### 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.<sup>(23)</sup>

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.<sup>(24)</sup>



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<sup>(25)</sup> and Jordan and King.<sup>(26)</sup> 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.<sup>(27)</sup>

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.<sup>(28)</sup> Clinical studies are summarized in Table 4.

**TABLE 4.** Clinical Assessment of Safety

<i>Test type</i>	<i>No. of subjects</i>	<i>Vehicle or product type</i>	<i>Concentration of Sodium Lauryl Sulfoacetate</i>	<i>Dose</i>	<i>Comments</i>	<i>Reference</i>
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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## SODIUM DEHYDROACETATE AND DEHYDROACETIC ACID

A safety assessment of Sodium Dehydroacetate and Dehydroacetic Acid was published in 1985 with the conclusion that these ingredients are safe as cosmetic ingredients in the present practices of use and concentration (Elder 1985). Studies available since that safety assessment was completed, along with updated information regarding uses and use concentrations were considered by the CIR Expert Panel. The Panel determined to not reopen this safety assessment.

**Sodium Dehydroacetate** was used in 260 products in 1981, based on voluntary reports provided to FDA by industry; use concentrations ranged from less than 0.1% to 1% (Elder 1985). In 2002 there were 325 uses (FDA 2002) and according to an industry survey the current range of use concentrations is 0.00003% to 0.5% (CTFA 2002).

**Dehydroacetic Acid** was used in 139 products in 1981, based on voluntary reports provided to FDA by industry; use concentrations ranged from less than 0.1% to 1% (Elder 1985). In 2002 there were 88 uses (FDA 2002) and according to an industry survey the current range of use concentrations is 0.007% to 0.7% (CTFA 2002).

Table 22 presents the available use and concentration information. The most recent information now constitutes the present practices of use.

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## SODIUM LAURYL SULFOACETATE

A safety assessment on Sodium Lauryl Sulfoacetate was published in 1987 with the 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 concentration” (Elder 1987). Studies available since that safety assessment was completed, along with updated information regarding uses and use concentrations, were considered by the CIR Expert Panel. After reviewing the available data, the Panel determined to not reopen this safety assessment.

Sodium Lauryl Sulfoacetate was used in 93 products in 1981, based on voluntary reports provided to FDA by industry; use concentrations ranged from >0.1% to >50% (Elder 1985). In 2002 there were 68 uses (FDA 2002) and according to an industry survey in 2004 the current range of use concentrations is 0.6% to 21% (CTFA 2004).

Table 23 presents the available use and concentration information. The most recent information now constitutes the present practices of use.

The CIR Expert Panel did note that Stepan Company had submitted robust summaries and test plans on Sodium Lauryl Sulfoacetate as part of EPA’s high production volume chemical testing program. This submission argued that the only missing data were reproductive and developmental toxicity data. The company proposed conducting such a study. Though the Panel noted that there are no data in the published literature,

<sup>23</sup> Available for review: Director, Cosmetic Ingredient Review, 1101 17th Street, NW, Suite 412, Washington, DC 20036-4702, USA.

**TABLE 22**  
Historical and current uses and use concentrations for Sodium Dehydroacetate and Dehydroacetic Acid (*Continued*)

Product category	1981 uses (Elder 1985)	2002 uses (FDA 2002)	1981 concentrations (Elder 1985) %	2003 concentrations (CTFA 2003) %
<b>Skin care</b>				
Cleansing creams, lotions, etc.	15	8	≤0.1–1	0.007–0.02
Face and neck skin care	16*	11	≤0.1–1*	0.01–0.08
Body and hand skin care		9		0.03–0.05
Moisturizers	10	10	≤0.1–1	—
Night skin care	5	2	≤0.1–1	0.03
Paste masks/mud packs	3	6	≤0.1–1	—
Skin fresheners	2	—	≤0.1	—
Other skin care	9	16	≤0.1–1	0.03
Wrinkle smoothers**	2	—**	≤0.1	—**
<b>Suntan</b>				
Suntan gels, creams, and liquids	3	—	>0.1–1	0.2
Indoor tanning preparation	—	5	—	—
Other suntan preparations	1	—	>0.1–1	—
<b>Total Uses/Ranges for Dehydroacetic Acid Totals</b>	<b>139</b>	<b>88</b>	<b>≤0.1–1</b>	<b>0.007–0.7</b>

\*These categories were combined in 1981 but are now separate.

\*\*No longer considered as cosmetic product categories.

which suggest that the reproductive and developmental toxicity potential of Sodium Lauryl Sulfoacetate is an issue, it was agreed that the results of the proposed reproductive and developmental toxicity study would be considered when available.

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<sup>24</sup> Available for review: Director, Cosmetic Ingredient Review, 1101 17th Street, NW, Suite 412, Washington, DC 20036-4702, USA.

## SODIUM SESQUICARBONATE, SODIUM BICARBONATE, AND SODIUM CARBONATE

A safety assessment of Sodium Sesquicarbonate, Sodium Bicarbonate, and Sodium Carbonate was published in 1987 with the conclusion that these ingredients are safe as presently used in cosmetic products (Elder 1987). Studies available since that safety assessment was completed, along with updated information regarding uses and use concentrations, were considered by the CIR Expert Panel. After reviewing the available data, the Panel determined to not reopen this safety assessment.

**Sodium Sesquicarbonate** was used in 111 products in 1981, based on voluntary reports provided to FDA by industry; use concentrations ranged from >1% to 50% (Elder 1985). In 2002 there were 24 uses (FDA 2002) and according to an industry survey in 2004 the current range of use concentrations is 2.0% to 90% (CTFA 2004).

**Sodium Bicarbonate** was used in 45 products in 1981, based on voluntary reports provided to FDA by industry; use concentrations ranged from less than 0.1% to 50% (Elder 1985). In 2002 there were 70 uses (FDA 2002) and according to an industry survey in 2004 the current range of use concentrations is 0.006% to 95% (CTFA 2004).

**Sodium Carbonate** was used in 25 products in 1981, based on voluntary reports provided to FDA by industry; use concentrations ranged from less than 0.1% to 25% (Elder 1985). In 2002 there were 21 uses (FDA 2002) and according to an industry survey in 2004 the current range of use concentrations is 0.000002% to 51% (CTFA 2004).

Table 24 presents the available use and concentration information. The most recent information now constitutes the present practices of use.

**TABLE 23**  
Historical and current cosmetic product uses and concentrations for Sodium Lauryl Sulfoacetate

Product category	1981 uses (Elder 1987)	2002 uses (FDA 2002)	1981 concentrations (Elder 1987) %	2004 concentrations (CTFA 2004) %
<b>Baby care</b>				
Lotions, oils, powders, and creams	—	—	—	1
<b>Bath</b>				
Oils, tablets and salts	1	13	>1–5	5–21
Soaps and detergents	—	—	—	0.6–4
Bubble baths	85	21	>1–>50	6–10
Other bath	—	27	—	6–10
<b>Fragrances</b>				
Other fragrances	—	1	—	2
<b>Noncoloring hair care</b>				
Shampoos	—	1	—	1–5
<b>Hair coloring</b>				
Bleaches	—	2	—	—
<b>Nail care</b>				
Other nail care	—	—	—	4
<b>Oral hygiene</b>				
Dentifrices	3	1	>0.1–5	—
Other oral hygiene	—	—	—	0.7*
<b>Personal hygiene</b>				
Douches	—	—	—	2
Other personal hygiene	1	—	>0.1–1	2
<b>Shaving</b>				
Shaving cream	—	—	—	2
<b>Skin care products</b>				
Cleansing creams, lotions, etc.	2	2	>1–25	4
Body and hand skin care	—	—	—	2
Foot powders and sprays	—	—	—	3
Other skin care	1	—	>5–10	—
<b>Total uses/ranges for Sodium Lauryl Sulfoacetate</b>	<b>93</b>	<b>68</b>	<b>&gt;0.1–&gt;50</b>	<b>0.6–21</b>

\*A denture cleanser.

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