

Final Report of the Amended Safety Assessment of Sodium Laureth Sulfate and Related Salts of Sulfated Ethoxylated Alcohols

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Abstract

Sodium laureth sulfate is a member of a group of salts of sulfated ethoxylated alcohols, the safety of which was evaluated by the Cosmetic Ingredient Review (CIR) Expert Panel for use in cosmetics. Sodium and ammonium laureth sulfate have not evoked adverse responses in any toxicological testing. Sodium laureth sulfate was demonstrated to be a dermal and ocular irritant but not a sensitizer. The Expert Panel recognized that there are data gaps regarding use and concentration of these ingredients. However, the overall information available on the types of products in which these ingredients are used and at what concentrations indicates a pattern of use. The potential to produce irritation exists with these salts of sulfated ethoxylated alcohols, but in practice they are not regularly seen to be irritating because of the formulations in which they are used. These ingredients should be used only when they can be formulated to be nonirritating.

Keywords

cosmetics, safety, sodium laureth sulfate, salts of sulfated ethoxylated alcohols

The Cosmetic Ingredient Review (CIR) Expert Panel previously evaluated the safety of sodium myreth sulfate, with the conclusion, based on data for sodium myreth sulfate and sodium laureth sulfate, that sodium myreth sulfate is safe as a cosmetic ingredient in the present practices of use and concentration.^{1, p157}

Sodium myreth sulfate is the sodium salt of sulfated, ethoxylated myristyl alcohol which is used as a surfactant and cleansing agent in cosmetics at concentrations ranging from >1.0%-5.0% to >50.0%. A formulation containing 7.0% sodium myreth sulfate was shown to be an ocular irritant in experimental animals and in some human test subjects. These irritant effects were similar to those previously reported for the chemically similar compound sodium laureth sulfate, which was shown to be safe for use in cosmetics. The report summarizes the safety test data on sodium laureth sulfate. Based upon the combined data cited in the report on both cosmetic ingredients, it is concluded that sodium myreth sulfate is safe as a cosmetic ingredient in the present practices of use and concentration.

The reference to data for sodium laureth sulfate acknowledges an earlier safety assessment completed for ammonium laureth sulfate and sodium laureth sulfate, in which the Expert Panel

acknowledged that although these ingredients can be eye and skin irritants, they can be used safely in the practices of use and concentration reported.^{2, p1}

Sodium laureth sulfate and ammonium laureth sulfate are used in cosmetic products as cleansing agents, emulsifiers, stabilizers, and solubilizers. The ingredients have been shown to produce eye and/or skin irritation in experimental animals and in some human test subjects; irritation may occur in some users of cosmetic formulations containing the ingredients under consideration. The irritant effects are similar to those produced by other detergents, and the severity of the irritation appears to increase directly with concentration. However, sodium and ammonium laureth sulfate have not evoked adverse responses in any other toxicological testing. On the basis of available

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information, the panel concludes that sodium laureth sulfate and ammonium laureth sulfate are safe as presently used in cosmetic products.

In 2002, the CIR Expert Panel considered all available new data on ammonium laureth sulfate and sodium laureth sulfate and reaffirmed that these ingredients are safe in the practices of use and concentration given.³

The CIR Expert Panel has further considered these related ingredients and determined that the data available for sodium myreth sulfate and for both ammonium laureth sulfate and sodium laureth sulfate support the safety of a larger group of chemically similar salts of sulfated ethoxylated alcohols.

Accordingly, the CIR Expert Panel is amending both original safety assessments to include other ingredients.^{1,2} This report addresses the safety of the following ingredients:

- Sodium myreth sulfate
- Ammonium capryleth sulfate
- Ammonium C12-15 pareth sulfate
- Ammonium laureth sulfate
- Ammonium myreth sulfate
- Magnesium coceth sulfate
- Magnesium laureth sulfate
- Magnesium myreth sulfate
- Magnesium oleth sulfate
- Sodium C10-15 pareth sulfate
- Sodium C12-13 pareth sulfate
- Sodium C12-15 pareth sulfate
- Sodium coceth sulfate
- Sodium deceth sulfate
- Sodium laneth sulfate
- Sodium laureth sulfate
- Sodium oleth sulfate
- Sodium trideceth sulfate
- Zinc coceth sulfate

Chemistry

Definition and Structure

Table 1 presents synonyms, technical names, and trade names; chemical classes; definitions; and structures for each of the ingredients in this report as given in the *International Cosmetic Ingredient Dictionary and Handbook*.⁴

Use

Cosmetic

Table 2 presents the available product use information provided by manufacturers to the US Food and Drug Administration (FDA) under the Voluntary Cosmetic Reporting Program (VCRP) for sodium myreth sulfate, ammonium laureth sulfate, magnesium laureth sulfate, magnesium oleth sulfate, sodium coceth sulfate, sodium C12-15 pareth sulfate, sodium laureth sulfate, sodium oleth sulfate, and sodium trideceth sulfate.⁵

No uses were reported under the VCRP for ammonium capryleth sulfate, ammonium myreth sulfate, ammonium C12-15 pareth sulfate, magnesium coceth sulfate, magnesium myreth sulfate, sodium C10-15 pareth sulfate, sodium C12-13 pareth sulfate, sodium laneth sulfate, sodium deceth sulfate, or zinc coceth sulfate.

The reported use concentrations from a survey conducted by the Personal Care Products Council are shown in Table 2.⁶ No use concentrations were reported for ammonium myreth sulfate and magnesium myreth sulfate.

In some cases, ingredient uses were not reported to FDA in the VCRP; however, concentrations were provided to the Personal Care Products Council. It should be presumed that there is at least 1 use in a product category if a use concentration is reported in the industry survey. In other cases, the uses were reported but no concentration was provided. In that case, it may be presumed that the use concentrations are similar to other use concentrations of related ingredients in that product category.

As reported in the safety assessment of ammonium and sodium laureth sulfate, the laureth sulfate salts are used as shampoo, bath, and skin-cleansing ingredients, primarily because of both their high degree of foaming and detergency and their "softness" to the skin.² They also function as emulsifiers, stabilizers, and perfume solubilizers and are compatible with nonionics, amides, amphoteric, and other anionic systems. Their surface-active characteristics allow the laureth sulfates to be especially useful ingredients in products that require hard water tolerance and lime soap dispersing power. These last characteristics increase with the degree of ethoxylation.

Noncosmetic

The anionic surfactants included in this report are generally recognized for their thickening effect and ability to create lather; therefore, they have applications in industrial products including engine degreasers, floor cleaners, and car wash soaps.

New Safety Data

Ocular Irritation

Tests were performed on ammonium alcohol ethoxy sulfate (the length of alkyl chain and degree of ethoxylation was not specified) in 10% and 20% concentrations of a liquid formulation containing 9% active material. This substance was found to be nonirritating when instilled into the eyes of 20 human volunteers.⁷

Mucosal Irritation

When applied once daily for 2 weeks to male and female genitalia, a 25% solution of a product containing 9% ammonium alcohol ethoxy sulfate was found to be nonirritating.⁷

Table 1. Synonyms, Technical Names, and Trade Names, Chemical Classes, Definitions, and Structures⁴

Ingredient (CAS No.)	Synonyms/Technical Names/Trade Names	Definition	Formula/Structure
Ammonium capryleth sulfate (no CAS No.)	Ammonium polyethylene glycol (1-4) caprylyl ether sulfate Ammonium polyoxyethylene (1-4) myristyl ether sulfate Polyethylene glycol (1-4) caprylyl ether, ammonium salt Polyoxyethylene (1-4) myristyl ether sulfate, ammonium salt Ammonium pareth-25 sulfate	Ammonium salt of ethoxylated caprylyl sulfate that conforms generally to the formula where n has an average value between 1 and 4.	$\text{CH}_3(\text{CH}_2)_6\text{CH}_2(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{NH}_4$
Ammonium C12-15 pareth sulfate (no CAS No.)	Ammonium lauryl ether sulfate Ammonium polyoxyethylene alkyl ether sulfate (3E.O.) solution Ammonium polyoxyethylene lauryl ether sulfate solution PEG (1-4) lauryl ether sulfate, ammonium salt Polyethylene glycol (1-4) lauryl ether sulfate, ammonium salt Poly(oxy-1,2-ethanediyl), α -sulfo- ω -(dodecyloxy)-, ammonium salt Polyoxyethylene (1-4) lauryl ether sulfate ammonium salt	Ammonium salt of a sulfated polyethylene glycol ether of a mixture of synthetic C12-15 fatty alcohols. It conforms generally to the formula where R represents the C12-15 alcohols and n has a value between 1 and 4. Ammonium salt of ethoxylated lauryl sulfate that conforms generally to the formula (see structure) where n has a value between 1 and 4.	$\text{R}(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{NH}_4$ $\text{CH}_3(\text{CH}_2)_{10}\text{CH}_2(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{NH}_4$
Ammonium laureth sulfate (CAS Nos. 32612-48-9, generic; 67762-19-0, generic)	Ammonium myristyl ether sulfate Polyethylene oxide monotetradecyl ether sulfate ammonium salt ammonium (tetradecyloxy)-poly(oxy-1,2-ethanediyl) sulfate, ammonium salt Desulf AMES-603 Standapol EA-40 Sulfochem AM-60 Unipol EA-40 Zetesol MG/C	Ammonium salt of ethoxylated myristyl sulfate that conforms generally to the formula where n has a value between 1 and 4.	$\text{CH}_3(\text{CH}_2)_{12}\text{CH}_2(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{NH}_4$
Ammonium myreth sulfate (CAS No. 27731-61-9)			
Magnesium coceth sulfate (no CAS No.)		Magnesium salt of sulfated, ethoxylated coconut alcohol. It conforms generally to the formula (see structure) where R represents the alkyl groups derived from coconut oil and n has an average value of 3.	$[\text{R}(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3]_2\text{Mg}^{+2}$

(continued)

Table 1 (continued)

Ingredient (CAS No.)	Synonyms/Technical Names/Trade Names	Definition	Formula/Structure
Magnesium laureth sulfate (CAS No. 62755-21-9)	Magnesium lauryl ether sulfate AEC magnesium laureth sulphate Empicol EGB Empicol EGC Empicol EGC 70 Zoharpon MGES	Magnesium salt of ethoxylated lauryl sulfate that conforms generally to the formula where n has a value between 1 and 4.	$[\text{CH}_3(\text{CH}_2)_{11}(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3]_2 \text{Mg}^{+2}$
Magnesium myreth sulfate (no CAS No.)	Magnesium polyoxyethylene glycol (1-4) myristyl ether sulfate Magnesium polyoxyethylene (1-4) myristyl ether sulfate	Magnesium salt of the sulfated ethoxylated myristyl alcohol that conforms generally to the formula where n has an average value of 1 to 4.	$[\text{CH}_3(\text{CH}_2)_{13}(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3]_2 \text{Mg}^{+2}$
Magnesium oleth sulfate (CAS No. 87569-97-9)	Magnesium polyoxyethylene glycol (1-4) oleyl ether sulfate Magnesium polyoxyethylene (1-4) oleyl ether sulfate	Magnesium salt of sulfated, ethoxylated oleyl alcohol that conforms generally to the formula where n has an average value between 1 and 4.	
Sodium C10-15 pareth sulfate (no CAS No.)	None	Sodium salt of a sulfated polyethylene glycol ether of a mixture of synthetic C10-15 alcohols. It conforms generally to the formula where R represents the C10-15 alkyl group and n has an average value between 1 and 4.	$\text{R}(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{Na}$
Sodium C12-13 pareth sulfate (no CAS No.)	Sodium pareth-23 sulfate Sodium polyoxyethylene alkyl (12-13) ether sulfate (3E.O.) Aliscoap DA-35 Aliscoap DA-330S Empimin KESH 70 Empimin KSL 68 Empimin KSN27/LA Empimin KSN70/LA Genapol 23-2S	Sodium salt of a sulfated polyethylene glycol ether of a mixture of synthetic C12-13 fatty alcohols. It conforms generally to the formula where R represents the C12-13 alkyl group and n has an average value between 1 and 4.	$\text{R}(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{Na}$
Sodium C12-15 pareth sulfate (CAS No. 91648-56-5)	Sodium pareth-25 sulfate Sodium polyoxyethylene alkyl (12-15) ether sulfate (3E.O.) Sulfuric acid, mono[2-[2-[2-(C12-15 alkyloxy)ethoxy]ethoxy]ethyl] esters, sodium salts Empicol ESB 3/X; ESB70/X Empimin KSN70/L Nikkol NES-203-27 Rhodasurf L-790, Rhodasurf LA Series Zetesol AO 328 Zoharpon ETA 270, ETA 603, ETA 700	Sodium salt of a sulfated polyethylene glycol ether of a mixture of synthetic C12-15 fatty alcohols. It conforms generally to the formula where R represents the C12-15 alkyl group and n has an average value between 1 and 4.	$\text{R}(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{Na}$

(continued)

Table 1 (continued)

Ingredient (CAS No.)	Synonyms/Technical Names/Trade Names	Definition	Formula/Structure
Sodium coceth sulfate (no CAS No.)	Sodium polyethylene glycol (1-4) coconut ether sulfate Sodium polyoxyethylene (1-4) coconut ether sulfate Zetanol 270/C, LES 2/C	Sodium salt of the sulfate ester of the polyethylene glycol ether of coconut alcohol that conforms generally to the formula where R represents the alkyl groups derived from coconut oil and n has an average value of 1 to 4.	$R(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{Na}$
Sodium deceth sulfate (no CAS No.)	Sodium decyl ether sulfate	Sodium salt of sulfated ethoxylated decyl alcohol that conforms generally to the formula where n has an average value between 1 and 4.	$\text{CH}_3(\text{CH}_2)_9(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{Na}$
Sodium laneth sulfate (CAS No. 68919-23-3, generic)	Sodium polyoxyethylene lanolin ether sulfate	Sodium salt of sulfated ethoxylated lanolin alcohol that conforms generally to the formula where R represents the lanolin alcohol radical and n has a value between 1 and 4.	$R(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{Na}$
Sodium laureth sulfate (CAS Nos. 1335-72-4; 3088-31-1; 9004-82-4, generic; 68585-34-2, generic; 68891-38-3, generic; 91648-56-5)	Dodecyl sodium sulfate PEG-(1-4) lauryl ether sulfate, sodium salt Polyethylene glycol (1-4) lauryl ether sulfate, sodium salt Poly(oxy-1,2-ethanediyl), α -sulfo- ω -(dodecyl-oxy)-, sodium salt Polyoxyethylene (1-4) lauryl ether sulfate, sodium salt Sodium PEG lauryl ether sulfate Sodium polyoxyethylene lauryl ether sulfate Sodium polyoxyethylene lauryl sulfate Sodium laureth sulfate is offered under 120 trade names and is included in I I I trade name mixtures.	Sodium laureth sulfate is the sodium salt of sulfated ethoxylated lauryl alcohol that conforms generally to the formula (see structure) where n averages between 1 and 4.	$\text{CH}_3(\text{CH}_2)_{11}(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{Na}$
Sodium myreth sulfate (CAS No. 25446-80-4)	PEG-(1-4) myristyl ether sulfate, sodium salt Polyethylene glycol (1-4) myristyl ether sulfate, sodium salt Sodium myristyl ether sulfate Sodium polyoxyethylene myristyl ether sulfate (3E.O.) Sodium polyoxyethylene myristyl ether sulfate solution DeSulf SMES-603 Standapol ES-40 Sulfochem ME-60 Texapon K 14 S, Texapon K 14 S Spez 70% Unipol ES-40 Zetanol 470	Sodium salt of sulfated ethoxylated myristyl alcohol that conforms generally to the formula where n has a value between 1 and 4.	$\text{CH}_3(\text{CH}_2)_{13}(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{Na}$

(continued)

Table I (continued)

Ingredient (CAS No.)	Synonyms/Technical Names/Trade Names	Definition	Formula/Structure
Sodium oleth sulfate (CAS No. 27233-34-7)	Sodium polyethylene glycol (1-4) oleyl ether sulfate Sodium polyoxyethylene (1-4) oleyl ether sulfate	Sodium salt of the sulfate ester of the polyethylene glycol ether of oleyl alcohol that conforms generally to the formula where n has an average value between 1 and 4.	
Sodium trideceth sulfate (CAS No. 25446-78-0)	Sodium polyoxyethylene tridecyl sulfate Sodium tridecyl ether sulfate Cedepal TD-407; TD-484; TD-403 DeSulf STDES-30 Genapol XRO Rhodapex EST-30 Sulfochem TD-3 Zetesol ZN	Sodium salt of sulfated ethoxylated tridecyl alcohol (qv) that conforms generally to the formula where n has a value between 1 and 4.	$\text{CH}_3(\text{CH}_2)_{12}(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3\text{Na}$
Zinc coceth sulfate (no CAS No.)		Zinc salt of sulfated, ethoxylated coconut alcohol that conforms generally to the formula where R represents the alkyl groups derived from coconut alcohol and n has an average value of 3.	$[\text{R}(\text{OCH}_2\text{CH}_2)_n\text{OSO}_3]_2\text{Zn}^{+2}$

Table 2. Reported Uses and Use Concentrations as a Function of Product Category in Cosmetics

Product Category	2007 Uses ⁵	2008 Use Concentrations ⁶
Sodium myreth sulfate		
Makeup		
Eye shadow (1061)	— ^a	0.008%
Noncoloring hair preparations		
Shampoos (1022)	14	0.6%-20.0%
Hair tonics, dressings, etc (623)	—	0.01%
Hair coloring products		
Hair dyes and colors (1600)	1	
Shaving preparations		
Shaving cream (135)	1	
Bath preparations		
Bath soaps and detergents (594)	1	7%
Bath oils, tablets, and salts (207)	1	
Bubble baths (256)	5	
Other bath preparations (276)	2	
Personal hygiene products		
Douches (8)	—	10%
Skin care preparations		
Cleansers (1009)	1	20%
Total uses/ranges for sodium myreth sulfate	26	0.008%-20%
Ammonium laureth sulfate		
Baby products		
Shampoos (38)	1	—
Other baby products (64)	1	—
Bath preparations		
Oils, tablets, and salts (207)	1	10%
Bubble baths (256)	45	—
Other bath preparations (276)	3	—
Fragrance preparations		
Other fragrance preparations (187)	1	—
Noncoloring hair preparations		
Conditioners (715)	1	—
Permanent waves (169)	1	—
Rinses (46)	3	—
Shampoos (1022)	149	7%-36%
Hair tonics, dressings, etc (623)	2	—
Other noncoloring hair preparations (464)	1	—
Hair coloring products		
Hair dyes and colors (1600)	—	5%
Makeup		
Makeup bases (273)	2	—
Personal hygiene products		
Bath soaps and detergents (594)	21	1%-20%
Other personal hygiene products (390)	5	—
Skin care preparations		
Cleansers (1009)	14	1%-30%
Face and neck creams, lotions, etc (546)	1	—
Body and hand creams, lotions, etc (992)	2	8%
Paste masks (312)	1	—
Total uses/ranges for ammonium laureth sulfate	255	1%-36%
Magnesium laureth sulfate		
Baby products		
Shampoos (38)	3	0.4%
Baby lotions, oils, powders, and creams (67)	—	0.2%
Other baby products (64)	1	0.4% ^b
Eye makeup products		
Eye makeup remover (114)	10	0.02%-0.04%

(continued)

Table 2 (continued)

Product Category	2007 Uses ⁵	2008 Use Concentrations ⁶
Noncoloring hair preparations		
Shampoos (1022)	23	0.05%-4%
Bath preparations		
Bath soaps and detergents (594)	3	0.05%-3%
Personal cleanliness products		
Other personal cleanliness products (390)	—	7% ^c
Skin care preparations		
Cleansers (1009)	11	0.7%
Paste masks (mud packs) (312)	—	2%
Other skin care preparations (915)	1	—
Total uses/ranges for magnesium laureth sulfate	52	0.02%-7%
Magnesium oleth sulfate		
Baby products		
Shampoos (38)	2	0.1%
Baby lotions, oils, powders, and creams (67)	—	0.04%
Other baby products (64)	1	0.1%
Eye makeup products		
Eye makeup remover (114)	12	0.01%-0.02%
Noncoloring hair preparations		
Shampoos (1022)	20	0.2%
Other noncoloring hair preparations (464)	1	—
Personal cleanliness products		
Bath soaps and detergents (594)	3	0.2%
Other personal cleanliness products (390)	1	0.1% ^d
Skin care preparations		
Cleansers (1009)	8	0.2%
Paste masks (mud packs) (312)	—	—
Other skin care preparations (915)	1	—
Total uses/ranges for magnesium oleth sulfate	49	0.01%-0.2%
Sodium coceth sulfate		
Bath preparations		
Bubble baths (256)	1	—
Other bath preparations (276)	1	—
Eye makeup preparations		
Eye makeup remover (114)	1	—
Fragrance preparations		
Other fragrance preparations (187)	1	—
Noncoloring hair preparations		
Shampoos (noncoloring) (1022)	—	0.8%
Body and hand creams, lotions, and powders (992)	—	0.2%
Personal cleanliness products		
Bath soaps and detergents (594)	2	—
Other personal cleanliness products (390)	2	—
Sodium coceth sulfate		
Skin care preparations		
Cleansers (1009)	5	—
Total uses/ranges for sodium coceth sulfate	13	0.2%-0.8%
Sodium C12-15 pareth sulfate		
Personal hygiene products		
Douches (8)	—	0.2%
Skin care preparations		
Cleansing (1009)	1	—
Total uses/ranges for sodium C12-15 pareth sulfate	1	0.2%
Sodium laureth sulfate		
Baby products		
Shampoos (38)	15	10%
Other baby products (64)	22	5%-25%

(continued)

Table 2 (continued)

Product Category	2007 Uses ⁵	2008 Use Concentrations ⁶
Bath products		
Bath oils, tablets, salts (207)	7	14%
Bubble baths (256)	117	6%-24%
Bath capsules (5)	1	—
Other bath products (276)	114	6%-19%
Eye makeup products		
Eyeliners (639)	1	—
Lotion (32)	1	—
Eye makeup remover (114)	16	0.1%
Mascara (308)	18	0.1%-0.3%
Fragrance preparations		
Other fragrance preparations (187)	6	18%
Noncoloring hair preparations		
Conditioners (715)	2	0.7%
Permanent waves (169)	—	0.6%
Rinses (46)	1	—
Shampoos (1022)	745	11%-50%
Tonics, dressings, etc (623)	8	—
Other noncoloring hair preparations (464)	13	—
Hair coloring products		
Hair dyes and colors (1600)	134	3%-10%
Coloring shampoos (27)	26	—
Bleaches (103)	1	—
Other hair coloring products (73)	4	14%
Makeup		
Foundations (530)	4	—
Bases (273)	1	—
Other makeup (304)	1	15%
Oral hygiene products		
Dentifrices (8)	1	—
Personal hygiene products		
Bath soaps and detergents (594)	512	2%-47%
Douches (8)	3	—
Feminine deodorants (7)	2	7%
Other personal hygiene products (390)	106	13%-16%
Shaving preparations		
Aftershaves (260)	2	—
Shaving cream (135)	11	1%-5%
Shaving soap (2)	2	—
Other shaving preparations (64)	4	—
Skin care products		
Cleansers (1009)	206	0.6%-25%
Face and neck creams, lotions, etc (546)	19	—
Body and hand creams, lotions, etc (992)	19	11%-17%
Foot powders and sprays (43)	1	11%
Moisturizers (1200)	6	0.5%
Paste masks (312)	6	—
Other skin care products (915)	20	—
Suntan products		
Suntan gels, creams, lotions (138)	1	—
Other suntan products (41)	1	—
Total uses/ranges for sodium laureth sulfate	2180	0.1%-50%
Sodium oleth sulfate		
Baby products		
Shampoos (38)	2	0.4%
Baby lotions, oils, powders, and creams (67)	—	0.1%
Other baby products (64)	1	0.4%

(continued)

Table 2 (continued)

Product Category	2007 Uses ⁵	2008 Use Concentrations ⁶
Eye makeup preparations		
Eye makeup remover (114)	11	0.01%-0.02%
Noncoloring hair preparations		
Shampoos (1022)	19	0.5%
Other noncoloring hair preparations (464)	1	
Personal cleanliness products		
Bath soaps and detergents (594)	3	0.4%-2%
Other personal cleanliness products (390)	1	0.4% ^a
Skin care preparations		
Cleansing (1009)	8	0.2%
Other skin care preparations (915)	1	—
Total uses/ranges for sodium oleth sulfate	47	0.01%-2%
Sodium trideceth sulfate		
Baby products		
Shampoos (38)	25	3%
Baby lotions, oils, powders, and creams (67)	—	3%
Other baby products (64)	20	2%-3%
Bath preparations		
Other bath preparations (276)	1	—
Eye makeup		
Eye makeup removers (114)	7	—
Noncoloring hair preparations		
Shampoos (1022)	13	2%-17%
Hair coloring products		
Coloring shampoos (27)	1	—
Personal hygiene products		
Bath soaps and detergents (594)	29	2%-10%
Other personal cleanliness products (390)	1	3%-19%
Feminine hygiene deodorants (7)	—	3%
Skin care preparations		
Cleansing (1009)	35	0.6%-18%
Total uses/ranges for sodium trideceth sulfate	132	0.6%-19%

^a Dash indicates not reported. In some cases, ingredient uses were not reported to FDA in the voluntary industry product survey program; however, concentrations were provided. In other cases, the uses were reported but no concentration was provided.

^b 0.4% in a baby wash.

^c 7% in a shower gel.

^d 0.1% in a shower gel.

^e 0.4% in a shower gel.

Summary

An earlier safety assessment by the Cosmetic Ingredient Review Expert Panel considered sodium laureth sulfate and ammonium laureth sulfate and another had considered sodium myreth sulfate. This amended safety assessment combined and extended the previous assessments to include all salts of sulfated ethoxylated alcohols. Sodium laureth sulfate was the most studied of this group of cosmetic ingredients, all of which are salts of sulfated, ethoxylated alcohols, used primarily as surfactant emulsifiers and cleansing agents in soaps and shampoos, over a wide range of concentrations from 0.008% to 50.0%.

Data on additional ingredients were limited and did not raise any safety concerns.

Discussion

The CIR Expert Panel recognized that most of the acute oral toxicity, dermal irritation and sensitization, subchronic and chronic oral toxicity, reproductive and developmental toxicity, carcinogenicity, and photosensitization studies have been conducted on ammonium laureth sulfate and sodium laureth sulfate. There are limited safety test data on most of the other ingredients included in this safety assessment. Sodium and ammonium laureth sulfate have not evoked adverse responses in any toxicological testing, including acute oral toxicity, subchronic and chronic oral toxicity, reproductive and developmental toxicity, carcinogenicity, and photosensitization studies. These data, however, are considered a sufficient basis

for concluding that the other ingredients are safe in the practices of use and concentration described in the safety assessment because of the fundamental chemical similarities between them and because they all are chemically similar salts (salts are expected to be dissociated in any product formulation independent of whether the salt is sodium, ammonium, magnesium, or zinc) of sulfated ethoxylated alcohols, and they all function as surfactants in cosmetic formulations. Based on these considerations, safety test data on 1 ingredient may be extrapolated to all of them.

The CIR Expert Panel also recognized that there are data gaps regarding use and concentration of these ingredients. However, the overall information available on the types of products in which these ingredients are used and at what concentrations indicates a pattern of use that was considered by the Expert Panel in assessing safety. (Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable with others in the group.)

The panel noted that sodium laureth sulfate and ammonium laureth sulfate can produce eye and/or skin irritation in experimental animals and in some human test subjects; irritation may occur in some users of cosmetic formulations containing these ingredients. The irritant effects, however, are similar to those produced by other detergents, and the severity of the irritation appears to increase directly with concentration.

Conclusion

The CIR Expert Panel concludes that sodium myreth sulfate, ammonium capryleth sulfate, ammonium myreth sulfate, ammonium laureth sulfate, ammonium C12-15 pareth sulfate, magnesium coceth sulfate, magnesium laureth sulfate, magnesium myreth sulfate, magnesium oleth sulfate, sodium coceth sulfate, sodium C10-15 pareth sulfate, sodium C12-13 pareth sulfate, sodium C12-15 pareth sulfate, sodium laneth sulfate, sodium laureth sulfate, sodium oleth sulfate, sodium deceth sulfate,

sodium trideceth sulfate, and zinc coceth sulfate are safe as cosmetic ingredients in the present practices of use and concentration when formulated to be nonirritating.¹

Authors' Note

Unpublished sources cited in this report are available from the Director, Cosmetic Ingredient Review, 1101 17th Street, Suite 412, Washington, DC 20036, USA.

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