Final Report

On the Safety Assessment of Alkyl PEG Sulfosuccinates As Used in Cosmetics

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ABSTRACT: Alkyl PEG sulfosuccinates function mostly as surfactants/cleansing agents in cosmetic products. Dermal penetration of these ingredients would be unlikely because of their substantial polarity and molecular sizes. Negative oral carcinogenicity and reproductive and developmental toxicity data on chemically related laureths (PEG lauryl ethers) and negative repeated dose toxicity and skin sensitization data on disodium laureth sulfosuccinate supported the safety of these alkyl PEG sulfosuccinates in cosmetic products, but these ingredients do have the potential for causing ocular/skin irritation. The CIR Expert Panel concluded that the alkyl PEG sulfosuccinates are safe in the present practices of use and concentration when formulated to be non-irritating.

INTRODUCTION

The safety of the following ingredients in cosmetics is reviewed in this report:

- Disodium Laureth Sulfosuccinate
- Disodium Laureth-6 Sulfosuccinate
- Disodium Laureth-9 Sulfosuccinate
- Disodium Laureth-12 Sulfosuccinate
- Disodium Deceth-5 Sulfosuccinate
- Disodium Deceth-6 Sulfosuccinate
- Magnesium Laureth-3 Sulfosuccinate
- Disodium C12-14 Pareth-1 Sulfosuccinate
- Disodium C12-14 Pareth-2 Sulfosuccinate
- Disodium C12-15 Pareth Sulfosuccinate
- Disodium Coceth-3 Sulfosuccinate
- Disodium Laneth-5 Sulfosuccinate
- Disodium C12-14 Sec-Pareth-3 Sulfosuccinate
- Disodium C12-14 Sec-Pareth-5 Sulfosuccinate
- Disodium C12-14 Sec-Pareth-7 Sulfosuccinate
- Disodium C12-14 Sec-Pareth-9 Sulfosuccinate
- Disodium C12-14 Sec-Pareth-12 Sulfosuccinate
- Disodium Oleth-3 Sulfosuccinate

These ingredients function mostly as surfactants-cleansing agents in cosmetic products.

An amended CIR final safety assessment on alkyl PEG ethers, with a conclusion that these ingredients were safe in the present practices of use and concentration, was completed in 2011,[1] and data on laureths (PEG lauryl ethers) from that review were used to fill pertinent data gaps (i.e., carcinogenicity and reproductive and developmental toxicity) in the current safety assessment. These data have relevance because the first level metabolites of alkyl PEG sulfosuccinates would likely include the corresponding alkyl PEG ethers; e.g., magnesium laureth-3 sulfosuccinate may be metabolized to laureth-3 (PEG-3 lauryl ether) and sulfosuccinic acid.

An amended final safety assessment on sodium laureth sulfate and related salts of sulfated ethoxylated alcohols was published in 2010, with the conclusion that these cosmetic ingredients are safe in the present practices of use and concentration when formulated to be nonirritating.[2] Furthermore, a CIR amended final safety assessment on alkyl PEG ethers with a safe as used conclusion became publicly available this year,[1] and a CIR amended final safety assessment on dioctyl sodium sulfosuccinate (diethylhexyl sodium sulfosuccinate, current INCI name) with a similar conclusion was published in 1998.[3] Based on structural similarities, the applicability of data on alkyl PEG ethers (other than laureths), sodium laureth sulfate, and diethylhexyl sodium sulfosuccinate from the respective safety assessments has been considered in this safety assessment of alkyl PEG sulfosuccinates in cosmetic products.

CHEMISTRY

Definition and Structure

The definitions, structures, and functions of the anionic surfactants reviewed in this safety assessment are included in Table 1.[4] The ingredients in this review share a sulfo-substituted, succinic acid core. Accordingly, the salts of these materials are sulfosuccinates. The ingredients in this review are the salts of alkyl polyethylene glycol (PEG), mono-esters of

sulfosuccinic acid (even though none of the INCI names includes PEG, these ingredients are collectively referred to as alkyl PEG sulfosuccinates).[5] For example, disodium laureth sulfosuccinate consists of a twelve-carbon alkyl chain (lauryl), connected to the sulfosuccinate core via a PEG chain, wherein the average number of ethoxy repeat units (n) is between 1 and 4 (i.e., laureth-1 through laureth-4) (Figure 1).

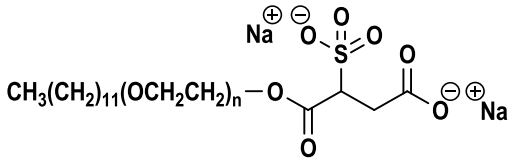


Figure 1. Disodium Laureth Sulfosuccinate

Chemical and Physical Properties

Sulfosuccinate monoesters contain a hydrophobic end that consists of a fatty alcohol chain.[5] The chain length and degree of saturation of the fatty acid may vary this hydrophobicity. The level of hydrophobicity imparted by the fatty alcohol is also affected by the different degrees of ethoxylation of the PEG chain. For instance, monoesters based on linear fatty alcohols are only partially soluble in water. Those based on fatty alcohol ethoxylates have greater water solubility. Water solubility is also increased when the structure contains branched chains. Solubility in less-polar solvents, such as isopropanol and 1,2-propylene glycol, is considered more difficult to achieve. Due to the ester linkage, these sulfosuccinate ingredients are sensitive to hydrolysis, especially under acidic conditions. Properties of sulfosuccinate ingredients (trade name materials included) are found in Table 2. Tables 3 and 4 contain specifications/actual composition data for disodium laureth sulfosuccinate trade name mixtures tested at various concentrations of disodium laureth sulfosuccinate in studies summarized later in the Toxicology section of this report.

Methods of Production

The synthesis of these ingredients occurs according to a 2-step procedure.[5] In the first step, maleic anhydride is reacted with an ethoxylated fatty alcohol. The second step involves sulfonation of the resulting maleic ester. In the production of disodium laureth sulfosuccinate, for example, a monoester is formed by reacting the ethoxylated alcohol (e.g., Laureth-2) with maleic anhydride.[6] The monoester is then reacted with sodium bisulfite to form the sulfosuccinate.[7,8]

Impurities

According to one report, disodium laureth sulfosuccinate contained the following impurities/by-products: residual sodium sulfite (< 0.1%), residual sodium sulfate (1 to 3%), residual laureth-2 (1 to 5%), and 1,4-dioxane by-product (< 10 ppm).[6] Another source indicates that a disodium laureth sulfosuccinate trade name material (active ingredient [40%]; anionic active matter [33%]) contains: < 1 ppm 1,4-dioxane and < 1 ppm ethylene oxide (if presence of either is technically unavoidable in good manufacturing practice); < 1 ppm residual monomers; and heavy metals, Pb (< 10 ppm), Ni (< 10 ppm), Cd (< 1 ppm), As (< 1 ppm), Sb (< 1 ppm), and Hg (< 0.2 ppm).[8] A third source indicates that disodium laureth sulfosuccinate contains formaldehyde at a maximum level of 0.056% and 1,4-dioxane at a maximum level of 0.001%.[9]

USE

Cosmetic

The ingredients reviewed in this safety assessment function mostly as surfactants-cleansing agents in cosmetic products. These and additional functions are included in Table 1.

According to information supplied to the Food and Drug Administration (FDA) by industry as part of the Voluntary Cosmetic Registration Program (VCRP), the following ingredients were being used in personal care products (mostly rinse-off products): disodium laureth sulfosuccinate, disodium laureth-6 sulfosuccinate, disodium deceth-6 sulfosuccinate, and disodium C12-14 pareth-2 sulfosuccinate.[10] These data are summarized in Table 5. Independent of these data, the results of a survey of ingredient use concentrations that was conducted by the Personal Care Products Council (Council) in 2011, also in Table 5, provided use concentrations for disodium laureth sulfosuccinate (0.06 to 10%).[11] The highest use concentration of this ingredient was in shampoos (noncoloring). Subsequent inclusion of magnesium laureth-3 sulfosuccinate in another Council survey yielded no use concentration data on this ingredient.[12] No uses of the remaining ingredients reviewed in this safety assessment were reported in the VCRP database or in the Council survey.

Cosmetic products containing the ingredients reported as being used may be applied to the skin and hair, or, incidentally, may come in contact with the eyes and mucous membranes. Products containing these ingredients may be applied as frequently as several times per day and may come in contact with the skin or hair for variable periods following application. Daily or occasional use may extend over many years.

Disodium laureth sulfosuccinate is used in hair color sprays at a maximum reported concentration of 2%, and could be inhaled. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 μm.[13,14] Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable (i.e., able to enter the lungs) to any appreciable amount.[15,16]

Noncosmetic

Reportedly, sulfosuccinates are used to improve the wetting and spreading characteristics of water-soluble pesticide sprays and are found in liquid fertilizer, insecticides, fungicides, and herbicides.[5]

TOXICOKINETICS

Studies on the toxicokinetics of sulfosuccinate ingredients in this safety assessment, following oral, dermal, or inhalation exposure, were not found in the published literature.

TOXICOLOGICAL STUDIES

Acute Oral Toxicity

Disodium Laureth Sulfosuccinate

According to a material safety data sheet (MSDS) on disodium laureth sulfosuccinate (30 to 39.9% % by weight), the acute oral LD50 for this chemical is > 10,000 mg/kg (rats), based on data on components or similar materials. Additional details were not provided.[9]

In an acute oral toxicity test involving rats, the LD50 for a disodium laureth sulfosuccinate trade name material (active ingredient [40%]; anionic active matter [33%]) was > 3,000 mg/kg.[8] Additional study details were not provided.

Groups of 5 male and 5 female NMRI mice (~ 6 to 8 weeks old) were used to evaluate the genotoxicity of disodium laureth sulfosuccinate in a micronucleus test.[17] Test animals received a single oral dose of the test substance (dose = 2,000 mg/kg body weight) in distilled water and were monitored for signs of acute toxicity, up to 48 h post-dosing. None of the animals died and there was no evidence of clinical signs. Genotoxicty test results are summarized later in the report text.

The acute oral toxicity of disodium laureth sulfosuccinate (trade name material, 40% active matter) was evaluated using fasted, young adult male albino rats (number not stated).[18] After a single dose of the test substance (dose volume = 10 ml/kg) was administered by gavage, no adverse effects were observed. An LD50 of > 2,000 mg/kg was reported.

The acute oral toxicity of a trade name mixture containing 24% active material was evaluated using 10 Sprague-Dawley rats (5 males, 5 females; ages not stated).[19] Data on the composition of this material are included in Table 4. The total active material (disodium laureth sulfosuccinate plus sodium lauryl sulfoacetate) in this mixture was 24%. Of this 24%, 70% (16.8% of the total mixture) was disodium laureth sulfosuccinate and 30% (7.2% of the total mixture) was sodium lauryl sulfoacetate. Each rat received a 5,000 mg/kg oral dose (gavage) of the test substance, and the animals were observed for 15 days. Because the concentration of active material in the test material was 16.8%, each rat received an 840 mg/kg dose of disodium laureth sulfosuccinate (0.168 x 5,000 = 840 mg/kg). All of the female rats died within 24 h of dose administration, but all male rats survived to the end of the study. The following signs were observed in the male rats and in female rats: decreased activity, diarrhea, labored breathing, and an unsteady gait. Gross necropsy findings in the female rats included: distended/gas-filled stomach, red stomach mucosa and mucosal erosion of the stomach (with rugae absent), red intestinal mucosa, and red substance in the intestines. The trade name material containing 16.8% disodium laureth sulfosuccinate was classified as a toxic substance.

Disodium C12-14 Pareth-2 Sulfosuccinate

Similarly, information in an MSDS on Disodium C12-14 Pareth-2 Sulfosuccinate (~ 40% disodium mono-[polyoxyethylene alkyl) sulfosuccinate in trade name material) indicates that the acute oral LD50 of this chemical is 3,490 mg/kg (rats).[20] Additional details were not provided.

Acute Dermal Toxicity

Disodium Laureth Sulfosuccinate

According to an MSDS on disodium laureth sulfosuccinate (30 to 39.9% by weight), the acute dermal LD50 for this chemical is > 2,000 mg/kg (rabbits), based on data on components or similar materials. Additional details were not provided.[9]

Repeated Dose Oral Toxicity

Disodium Laureth Sulfosuccinate

The repeated dose oral toxicity of a disodium laureth sulfosuccinate trade name material (active ingredient [40%]; anionic active matter [33%]) was evaluated using groups of Sprague-Dawley Crl:CD (SD) BR rats.[21] The control (deionized water) and 1,000 mg/kg/day dose groups each contained 10 males and 10 females, and the 62.5 and 250 mg/kg dose groups each contained 5 males and 5 females. The test material was administered (dose volume = 10 ml/kg) 7 days per week for 4 consecutive weeks. At the end of the dosing period, some of the animals were observed during a 4-week recovery period and the remaining animals were killed for pathological investigations.

There were no treatment-related deaths or changes, based on ophthalmological examinations and evaluations for clinical signs, body weight changes, or food consumption. In the highest dose group (1,000 mg/kg/day), treatment-related increases in alkaline phosphatase (moderate) and in SGPT (slight) were observed in both sexes, and there was a trend toward increased protein in the urine in males of this group. These changes were not observed at the end of the recovery period. Mild reversible changes in the liver (increased weight and hypertrophy) were also observed in the highest dose group. The NOEL was considered to be 250 mg/kg/day.[21]

In another study, groups of Sprague-Dawley CD, SPF-quality rats (10 males, 10 females/group) received oral doses of disodium laureth sulfosuccinate (trade name material, composition not stated) daily for 28 days.[18] Three groups received doses of 100, 300, and 1,000 mg/kg body weight per day, and the fourth group served as the untreated control group. Additionally, a recovery group consisting of 5 males and 5 females was used to determine the reversibility of possible test substance-related findings. None of the animals died and, compared to the control group, there was no deviation in body weight development in any of the 3 dose groups.

The following test substance-related findings, all in the highest dose group, were reported: stimulation of propulsion (swallowing and peristalsis) and salivation, alterations in hematological parameters and in clinical chemistry (i.e., alterations in alanine aminotransferase [ALT] values), significantly increased liver weight, and ulceration and edema of the forestomach mucosa (local irritation effects) at macroscopic examination. Effects on the forestomach mucosa were not observed after a 34-day recovery period. Other findings included small cellular infiltrations (no further details) in 100 and 300 mg/kg dose groups. The systemic NOAEL was 300 mg/kg body weight in this study. Additionally, a no observed adverse effect concentration (NOAEC) of < 1% for local compatibility was deduced. It was stated that the labeling of this disodium laureth sulfosuccinate trade name material for possible toxic effects after chronic exposure is not necessary.[18]

Ocular Irritation

Disodium Laureth Sulfosuccinate

The ocular irritation potential of diluted disodium laureth sulfosuccinate (25% active matter in a trade name material) was evaluated according to OECD Guideline No. 405 using 4 rabbits of the Kleinrusse Chbb:HM strain.[18] The test substance (0.1 ml) was instilled once into the eye of each animal, and untreated eyes served as controls. Mean ocular irritation scores (24 h, 48 h, and 72 h) were as follows: 0.9 (cornea), 2.5 (conjunctival erythema), 1.1 (conjunctival edema), and 0 (iris). At the end of the observation period, slight conjunctival erythema (sore = 1) and slight corneal opacity (score = 1) persisted in one rabbit. It was concluded that the test material has to be classified and labeled to pose a risk of serious damage to the eyes.

According to an MSDS on disodium laureth sulfosuccinate (30 to 39.9% by weight), this chemical substance is considered a moderate to strong eye irritant, based on data on components or similar materials.[9] Additional details were not provided.

The ocular irritation potential of a trade name mixture containing 10% active material was evaluated using 6 New Zealand white, young adult rabbits (ages not stated).[22] Data on the composition of this material are included in Table 4. The total active material (disodium laureth sulfosuccinate plus sodium lauryl sulfoacetate) in this mixture is 24%. Of this 24%, 70% (16.8% of the total mixture) is disodium laureth sulfosuccinate and 30% (7.2% of the total mixture) is sodium lauryl sulfoacetate. Because the trade mixture evaluated contained 10% active material, the concentration of disodium laureth sulfosuccinate tested was 1.68% (0.10 x 0.168 = 1.68%). The undiluted test substance (0.1 ml) was instilled into the right eye of each rabbit. Contralateral eyes served as controls. Ocular irritation reactions were scored according to the method of Draize at 24 h, 48 h, and 72 h post-instillation. A positive ocular response was observed in all rabbits tested, and the trade name mixture was classified as a primary ocular irritant.

Disodium C12-14 Pareth-1 Sulfosuccinate

According to an MSDS on disodium C12-14 pareth-1 sulfosuccinate (~ 30% disodium mono-[polyoxyethylene alkyl) sulfosuccinate in trade name material), a 3% solution in physiological saline of a similar chemical is a minimal ocular irritant (unrinsed eyes) and a non-irritant (rinsed eyes) in guinea pigs.[23] Additional details were not provided.

Disodium C12-14 Pareth-2 Sulfosuccinate

Similarly, information in an MSDS on disodium C12-14 pareth-2 sulfosuccinate (~ 40% disodium mono-[polyoxyethylene alkyl) sulfosuccinate in trade name material) indicates that a 3% solution of this material in physiological saline is a minimal ocular irritant (unrinsed eyes) and that a 3% solution in physiological saline of a similar chemical is a non-irritant (rinsed eyes) in guinea pigs.[20] Additional details were not provided.

Irritation and Sensitization

Disodium Laureth Sulfosuccinate

Non-Human Studies

A disodium laureth sulfosuccinate trade name material (active ingredient [40%]; anionic active matter [33%]) was evaluated in skin irritation tests involving rabbits.[8] At a concentration of 3% active matter (effective concentration = 1.2% active ingredient; procedure not stated), the test substance was non-irritating. In the Duhring chamber test, the test substance was non-irritating at a concentration of 2% active matter (effective concentration = 0.40 x 0.02 = 0.8% active ingredient). Details relating to either test procedure were not provided. [18] The same test material did not induce mucous membrane irritation in rabbits when tested at a concentration of 3% active matter (effective concentration = 0.40 x 0.03 = 1.2% active ingredient).[8] Details relating to the test procedure were not provided.

The skin sensitization potential of the same disodium laureth sulfosuccinate trade name material (active ingredient [40%]; anionic active matter [33%]) was evaluated in the maximization test using 2 groups of 20 guinea pigs of the Pirbright White strain.[8] One of the groups served as the control group. Test concentrations administered during induction included 10% disodium laureth sulfosuccinate (4% active matter; effective concentration = 1.6% active ingredient) in physiological saline (intradermal induction) and 5% (2% active matter; effective concentration = 0.8% active ingredient) in physiological saline (dermal induction). The challenge concentration was 2% active matter (effective concentration = 0.8% active ingredient), and reactions were scored at 24 h and 48 h post-exposure. None of the animals had signs of primary skin irritation or sensitization, and the test substance was considered non-sensitizing.

The skin irritation potential of a disodium laureth sulfosuccinate trade name material (25% active matter) was evaluated using 5 albino rabbits according to OECD guideline No. 404.[18] The test substance was applied to one flank (shave dorsal skin) of each animal. An untreated area served as the control. The contact time under occlusive conditions was 4 h. Skin reactions were described as weak, with scores of 0.2 for erythema and 0 for edema at 24 h, 48 h, and 72 h.

A skin sensitization study on the same disodium laureth sulfosuccinate trade name material (25% active matter), performed according to the Magnusson-Kligman method, involved guinea pigs of the Pirbright Hoe: DHPK strain.[18] The number of animals tested was not stated. Based on the results of a preliminary study on a 10% dilution of the test substance in deionized water, a 5% dilution of the test substance (effective concentration = 1.6% active matter) was applied during induction (intracutaneous and epicutaneous; 48 h occlusive conditions) and during the challenge (epicutaneous) phase. Following both induction procedures, the animals were challenged with the test substance under occlusive conditions for 24 h. Challenge application did not result in any signs of adverse dermal reactions.

Ten guinea pigs per sex were initially injected with 10% disodium laureth sulfosuccinate in water (0.05 ml), followed by injection with 10% disodium laureth sulfosuccinate in Freund's Complete Adjuvant (FCA, 0.05 ml), and, then, FCA (0.05 ml).[24] After a 7-day non-treatment period, the animals were challenged dermally with 5% disodium laureth sulfosuccinate in water and then re-challenged with 5% disodium laureth sulfosuccinate in water. Control animals were treated with water only. Skin sensitization was not observed in any of the animals tested with disodium laureth sulfosuccinate or water.

According to an MSDS on disodium laureth sulfosuccinate (30 to 39.9% by weight), this chemical substance is considered a severe skin irritant, based on data on components or similar materials. Additional details were not provided.[9]

Disodium C12-14 Pareth-1 Sulfosuccinate

According to an MSDS on a disodium C12-14 pareth-1 sulfosuccinate trade name material (~ 30% disodium mono-[polyoxyethylene alkyl] sulfosuccinate), a 10% aqueous solution of a similar chemical is neither a primary nor cumulative skin irritant in guinea pigs.[23] Additional details were not provided.

Disodium C12-14 Pareth-2 Sulfosuccinate

Information in an MSDS on a disodium C12-14 pareth-2 sulfosuccinate trade name material (~ 40% disodium mono-[polyoxyethylene alkyl] sulfosuccinate) indicates that a 10% aqueous solution of this chemical is neither a primary nor cumulative skin irritant in guinea pigs.[20] Additional details were not provided.

Human Studies

The skin irritation potential of disodium laureth sulfosuccinate was evaluated using 12 healthy subjects (between ages of 22 and 64 years).[25] The test substance was diluted in a citrate buffer (final pH = 6 ± 0.5). Finn chambers (12 mm) containing 10% disodium laureth sulfosuccinate (50 µl) were applied to the left volar forearm and removed after 48 h. Citrate buffer (10 mM) served as the control. Sites were examined 1 h after patch removal on day 1 and after 24 h on day 2. Transepidermal water loss, cutaneous blood flow, and skin capacitance were also measured. Erythema (mild irritation) was observed on day 1. Application of the citrate buffer control also resulted in erythema. Compared to the control, transepidermal water loss was significantly elevated on day 2 after test substance application. The test substance did not induce a significant increase in cutaneous blood flow, but caused a decrease in skin capacitance.

Patch tests were performed to evaluate the role of pre-existing dermatitis in the response to irritants.[26] The study involved 40 healthy subjects and 480 patients with the following types of skin disease: active atopic dermatitis (n =40), psoriasis (n = 57), eczema (n = 124), urticaria (n = 79), and pruritus (n = 40). The 6 groups (males and females; mean age range: 18 to 55) were patch tested with 5% and 10% aqueous solutions of disodium laureth sulfosuccinate (volume = 17 µl). Patch tests were applied on both sides of the upper back for 48 h using Al-test on Fixomul. Reactions were scored 1 h after removal of the strips. For urticaria patients, 2 additional strips were applied to both sides of the back and then removed 30 minutes later. There were no positive reactions to either test concentration of disodium laureth sulfosuccinate in healthy subjects or patients with pre-existing dermatitis.

The skin irritation potential of a trade name mixture containing 24% active material was evaluated in a 14-day cumulative irritation test using 28 subjects (ages not stated).[27] Disodium laureth sulfosuccinate comprised 70% of the active material; thus, the effective concentration of disodium laureth sulfosuccinate in the trade name mixture was 16.8%. Sodium lauryl sulfoacetate was also included in the mixture. The effective concentration was diluted (1% dilution) to a test concentration of 0.168% disodium laureth sulfosuccinate in the trade mixture. The test concentration (100 µl) was applied repeatedly to estimate the mean number of days of continuous exposure that would produce a clinical irritation grade of 2. The positive control (1% SLS) was similarly applied. The mean number of days of continuous exposure to the 0.168% disodium laureth sulfosuccinate trade mixture that produced a clinical irritation grade of 2 was 9.86 days (3.93 days for positive control). A cumulative irritation score of 163 (based on N = 10) was reported for this trade mixture (score of 346 for positive control), classifying it as possibly a mild irritant during normal use. The positive control was classified as an experimental irritant.

The skin irritation and sensitization potential of a trade name mixture containing 10% active material was evaluated in a repeated insult patch test using 51 subjects (males and females; 19 to 65 years old).[28] Data on the composition of this material are included in Table 3. The total active material (disodium laureth sulfosuccinate plus sodium lauryl sulfoacetate) in this mixture) is 24%. Of this 24%, 70% (16.8% of the total mixture) is disodium laureth sulfosuccinate and 30% (7.2% of the total mixture) is sodium lauryl sulfoacetate. Because the trade mixture evaluated contained 10% active material, the concentration of disodium laureth sulfosuccinate tested was 1.68% (0.1 x 16.8% = 1.68%). During induction, an occlusive patch containing the test material (0.2 ml) was applied (24 h) repeatedly to the back of each subject for a total of 9 applications. After a 10- to 21-day non-treatment period, a challenge patch was applied to a new test site and reactions were scored at 24 h and 48 h post-application. Barely perceptible erythema (1 subject) and barely perceptible to moderate cumulative irritant reactions (3 subjects) were observed during induction. Reactions were not observed during the challenge phase. It was concluded that the trade name mixture containing 1.68% disodium laureth sulfosuccinate did not induce clinically significant irritation or any evidence of allergic contact dermatitis.

Disodium Pareths Sulfosuccinates

The following skin irritation study is included because the CAS Number 68115-56-5 for the chemical tested [poly(oxy-1,2-ethanediyl), alpha-(3-carboxy-1-oxosulfopropyl)-omega- hydroxy-, C10-C16 alkyl ethers, disodium salts] is generic for any disodium C10-16 alkyl laureth sulfosuccinate. It contains disodium sulfosuccinate and other components (e.g., sodium lauryl sulfoacetate) that differ from disodium laureth sulfosuccinate only by modest variations in chain length. The test article is also identified as 15% Alconate L-3. In this study, 6 New Zealand white rabbits each received a single dermal application of 15% Alconate-L3 (0.5 ml) at two 2 cm^2 sites, abraded and intact, on opposite sides. Each site was covered with an occlusive patch (2 cm^2) for 24 h, and reactions were scored at 24 and 72 h. The test substance was not classified as a dermal irritant under the conditions of this test (primary irritation index = 3.15).[29]

Comedogenicity

The comedogenicity of a trade name mixture containing 24% active material was evaluated using 3 young adult New Zealand white rabbits (1 male, 2 females; ages not stated).[30] Data on the composition of this material are included in Table 3. The total active material (disodium laureth sulfosuccinate plus sodium lauryl sulfoacetate) in this mixture) is 24%. Of this 24%, 70% (16.8% of the total mixture) is disodium laureth sulfosuccinate and 30% (7.2% of the total mixture) is sodium lauryl sulfoacetate. The test substance (undiluted; volume not stated) was applied to the left ear of each rabbit for 3 consecutive weeks (5 consecutive days/week). Untreated right ears served as controls. At the end of the dosing period, control and treated ears were excised and subjected to microscopic examination for comedone formation. Neither follicular hyperkeratosis nor comedone formation was observed during week 1. However, hyperkeratosis and dry, flaky skin were observed on all treated ears from week 2 to the end of the study. Reactions were not observed on untreated ears throughout the study. Acanthotic thickening (hyperplasia) of the epithelium, mild hyperkeratosis, and mild acute inflammatory infiltrates in the dermal layers were observed at microscopic examination of treated ears. However, there was no evidence of comedone formation. Based on microscopic findings, the trade name mixture containing 16.8% disodium laureth sulfosuccinate received a comedogenic score of 1, defined as an increase in visible hyperkeratosis without comedone formation.

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

The following reproductive toxicity study summaries are included in the amended CIR final safety assessment on alkyl PEG ethers.[1]

Laureths

The reproductive and teratogenic toxicity of compounds analogous to laureth-9 was evaluated.[31] Groups of 25 gravid female rabbits were dosed orally with 0, 50, 100, or 200 mg/kg bw $C_{12}AE_6$ (alcohol ethoxylate[AE] with 12 carbon atoms in alkyl chain; average number of ethylene oxide units = 6) on days 2-16 of gestation, and the animals were killed and necropsied on day 28 of gestation. In the 100 and 200 mg/kg groups, ataxia and a slight decrease in body weights was evidence of maternal toxicity. No effects on reproductive parameters were noted. Nine control animals and 1 test animal died during the study. Based on maternal toxicity, the NOAEL was >50 mg/kg bw/day.

Groups of 25 male and 25 female CD rats were used to evaluate the reproductive toxicity of $C_{14-15}AE_7$ in a two-generation study. The animals were fed a diet containing 0, 0.05, 0.1, and 0.5% of the test article (equivalent to approximately 0, 25, 50, and 250 mg/kg bw/day). In three test groups, males and females were given treated feed throughout the study; in another three groups, females only were dosed, and dosing was performed on days 6-15 of gestation. Additional details regarding study and dosing regimen were not provided. No compound-related differences in fertility, gestation, or viability indices were observed, and the NOAEL for reproduction with dietary administration of $C_{14-15}AE_7$ was >0.5% (equivalent to 250 mg/kg bw/day).

In addition, effects on the F_C generation, i.e. offspring from the third mating of the F_0 and F_1 parental generation, were examined. Gravid female rats were necropsied and examined on either day 13 or day 21 of gestation. Differences in maternal and fetal indices were observed in the test groups compared to the controls, but these effects were not considered test-compound related. Parental female rats and pups of the high-dose group had reduced body weight gains. In the 0.5% continuous feeding test group, increased mean liver weights of males and females of the P_1

generation and an increase in relative liver to body weights of males of the 0.5% continuous feeding group of the P_2 generation at 60 days were considered compound-related. The NOAEL for maternal and developmental toxicity was 50 mg/kg bw/day.

The reproductive toxicity of $C_{12}AE_6$ was evaluated in a similar study, and the groups of 50 rats were fed 0, 25, 50, or 250 mg/kg bw/day of the test article in the diet. No treatment-related effects on behavior, appearance, survival, or fertility were observed in any of the test groups. Parental and offspring weight gain was reduced in the 250 m/kg group. In the 250 mg/kg group, statistically significant increases in embryo lethality and soft tissue anomalies were observed, and in the 50 mg/kg group, a statistically significant decrease in mean fetal liver weights was observed. None of these effects were considered test article-related. The NOAEL for reproduction was >250 mg/kg bw/day, and the NOAELs for maternal and developmental toxicity were 50 mg/kg bw/day $C_{12}AE_6$ in the diet.[31]

GENOTOXICITY

Disodium Laureth Sulfosuccinate

A disodium laureth sulfosuccinate trade name material (active ingredient [40%]; anionic active matter [33%]) was not mutagenic in the Ames test.[8] Details relating to the test procedure were not included. The mutagenicity of another disodium laureth sulfosuccinate trade name material (32% active matter) was evaluated using the following *Salmonella typhimurium* strains with and without metabolic activation:[18] TA 100, TA 1535, TA 1537, TA 1538, and TA 98. The test substance was evaluated at concentrations ranging from 0.32 µl to 200 µl/plate. A bacteriotoxic effect was observed at a dose of 200 µl/plate. The test material was not mutagenic, with or without metabolic activation, over the range of concentrations tested.

The genotoxicity of a trade name material identified as disodium laureth sulfosuccinate was evaluated in the micronucleus test using groups of 5 male and 5 female NMRI mice (~ 6 to 8 weeks old).[17] Test animals received a single oral dose of the test substance (dose = 2,000 mg/kg body weight) in distilled water. Results relating to acute oral toxicity are included in that section of the safety assessment. Cyclophosphamide (CPA) and distilled water served as positive and negative controls, respectively. Two thousand polychromatic erythrocytes (PCE's) per mouse were analyzed for the presence of micronuclei in bone marrow smears. For an investigation of bone marrow toxicity, the proportion of PCE's among total erythrocytes was evaluated on the basis of ~ 200 erythrocytes. The frequency of micronucleated PCE's in the vehicle control group was within the physiological range, whereas, the positive control was genotoxic. Disodium laureth sulfosuccinate did not induce an increase in the number of micronucleated PCE's in any of the test groups. There was also no statistically significant difference in the proportion of PCE's among total erythrocytes when compared to the vehicle control. Disodium laureth sulfosuccinate was not genotoxic.

CARCINOGENICITY

The following carcinogenicity study summaries are included in the amended CIR final safety assessment on alkyl PEG ethers.[1]

Laureths

The carcinogenic potential of compounds analogous to laureth-9 was evaluated.[31] *Groups of 65 rats/gender were fed a diet containing 0, 0.1, 0.5, and 1% $C_{14-15}AE_7$ for 2 yrs. At 1 yr, 14-15 animals per gender were killed and necropsied. No compound-related changes were seen in behavior or appearance at any time. Survival rate was comparable between test and control animals. Body weight gains were significantly decreased in females of the 0.5 and 1.0% groups and males of the 1% group. At necropsy, no differences in relative or absolute organ weights were observed between test and control animals. There was no evidence of a carcinogenic effect.*

$C_{12-13}AE_{6.5}$ was fed to 100 Sprague-Dawley rats at concentrations up to 1% in feed for 2 yrs. Feed consumption, and correspondingly, body weight gain, was decreased for females fed 0.5 or 1% and for males fed diets containing 1% of the test compound. No microscopic effects were seen, and $C_{12-13}AE_{6.5}$ was not carcinogenic.[31]

SUMMARY

The safety of the following ingredients in cosmetics is reviewed in this safety assessment: disodium laureth sulfosuccinate, disodium laureth-6 sulfosuccinate, disodium laureth-9 sulfosuccinate, disodium laureth-12 sulfosuccinate, disodium deceth-5 sulfosuccinate, disodium deceth-6 sulfosuccinate, magnesium laureth-3 sulfosuccinate, disodium C12-14 pareth-1 sulfosuccinate, disodium C12-14 pareth-2 sulfosuccinate, disodium C12-15 pareth sulfosuccinate, disodium coceth-3 sulfosuccinate, disodium laneth-5 sulfosuccinate, disodium C12-14 sec-pareth-3 sulfosuccinate, disodium C12-14 sec-pareth-5 sulfosuccinate, disodium C12-14 sec-pareth-7 sulfosuccinate, disodium C12-14 sec-pareth-9 sulfosuccinate, disodium C12-14 sec-pareth-12 sulfosuccinate, and disodium oleth-3 sulfosuccinate.

Together, data reported to the Food and Drug Administration's Voluntary Cosmetic Registration Program in 2011 and the results of a 2011 Personal Care Products Council (Council) survey indicated use of the following ingredients in cosmetics, mostly in rinse-off products: disodium laureth sulfosuccinate (0.06% [eyeliner] to 10% [noncoloring shampoos]), disodium laureth-6 sulfosuccinate, disodium deceth-6 sulfosuccinate, and disodium C12-14 pareth-2 sulfosuccinate. Subsequent inclusion of magnesium laureth-3 sufosuccinate in a 2011 Council Survey yielded no use concentration data on this ingredient. Therefore, of the 18 ingredients included in the survey, only use concentration data on disodium laureth sulfosuccinate were reported.

A method for the production of disodium laureth sulfosuccinate involves ethoxylation of a fatty alcohol, esterification with maleic acid anhydride, addition of sodium sulfite, and neutralization with sodium hydroxide. Impurities present in disodium laureth sulfosuccinate include 1,4-dioxane, ethylene oxide, and formaldehyde. According to an MSDS on disodium laureth sulfosuccinate, this chemical contains formaldehyde at a maximum level of 0.056% and 1,4-dioxane at a maximum level of 0.001%.

Studies on the toxicokinetics of sulfosuccinates, following oral, dermal, or inhalation exposure, reviewed in this safety assessment were not found in the published literature. However, certain predictions may be made based on their chemical and physical properties. Due to the ester linkage, these sulfosuccinate ingredients are sensitive to hydrolysis, especially under acidic conditions. Accordingly, if these ingredients have the ability to penetrate the skin, then first level metabolites would likely include the corresponding alkyl PEG ethers (e.g., magnesium laureth-3 sulfosuccinate may be metabolized to Laureth-3 and sulfosuccinic acid).

In 2 acute oral toxicity studies on disodium laureth sulfosuccinate trade name materials involving rats, LD50's of >10,000 mg/kg and > 2,000 mg/kg were reported. However, all of the female rats that received a single 840 mg/kg oral dose of a trade name material containing 16.8% disodium laureth sulfosuccinate died within 24 h of dosing, whereas, all male rats survived to the end of the study. An acute oral LD50 of 3,490 mg/kg (rats) was reported for disodium C12-14 pareth-2 sulfosuccinate. Reportedly, the acute dermal LD50 for one disodium laureth sulfosuccinate trade name material is > 2,000 mg/kg (rabbits), based on data on components or similar materials. In two 28-day oral toxicity studies (rats) on disodium laureth sulfosuccinate trade name materials, an NOEL of 250 mg/kg/day and a systemic NOAEL of 300 mg/kg/day were reported. Increased liver weight was observed in both studies.

A disodium laureth sulfosuccinate trade name material (25% active matter) was classified as posing a risk of serious ocular damage in rabbits. Furthermore, a trade name mixture containing 1.68% active disodium laureth sulfosuccinate was classified as a primary ocular irritant in rabbits. Disodium C12-14 pareth-2 sulfosuccinate (~ 40% disodium mono-[polyoxyethylene alkyl) sulfosuccinate in trade name material) was minimally irritating to the eyes of guinea pigs when tested as a 3% solution in physiological saline.

Disodium laureth sulfosuccinate (10% in citrate buffer) was classified as a mild skin irritant in healthy subjects. In dermatitis patients and healthy subjects in another study, disodium laureth sulfosuccinate (5% and 10% aqueous solutions) did not induce skin irritation. The results of a human cumulative skin irritation study on a trade name mixture containing 0.168% disodium laureth sulfosuccinate predicted that this material would be a mild skin irritant during normal use. A trade name mixture containing 1.68% disodium laureth sulfosuccinate did not induce clinically significant irritation or any evidence of allergic contact dermatitis in normal human subjects. A disodium C10-16 alkyl laureth sulfosuccinate, similar to

disodium laureth sulfosuccinate, and a disodium laureth sulfosuccinate trade name material (effective test concentrations = 0.8% and 1.2% active ingredient) did not induce skin irritation in rabbits. Skin sensitization was not observed at an effective challenge concentration of 0.8% active ingredient in a separate study (guinea pigs) involving the same tradename material. At a higher concentration (25% active matter), a different disodium laureth sulfosuccinate tradename material also did not induce skin irritation, and sensitization was not observed in guinea pigs when the material was diluted to an effective concentration of 1.6% active matter. A 10% aqueous solution of a disodium C12-14 pareth-2 sulfosuccinate tradename material (~ 40% disodium mono-[polyoxyethylene alkyl] sulfosuccinate) induced neither primary nor cumulative irritation in guinea pigs.

A trade name mixture containing 16.8% disodium laureth sulfosuccinate induced an increase in visible hyperkeratosis, without comedone formation, in rabbits.

In two-generation oral reproductive studies with dietary administration of compounds analogous to laureth-9, the NOAEL for reproductive toxicity was >250 mg/kg bw/day, and the NOAELs for maternal and developmental toxicity was 50 mg/kg bw/day.

Ames test and micronucleus test results for disodium laureth sulfosuccinate trade name materials were negative. Compounds that are analogous to laureth-9 were not carcinogenic in feeding studies in which rats were given up to 1% in the diet for 2 years.

DISCUSSION

The CIR Expert Panel noted that negative mammalian genotoxicity data on disodium laureth sulfosuccinate were received in response to a previous request for data, but dermal absorption and inhalation toxicity data were not received. In the absence of inhalation and dermal absorption data, the Panel reasoned that skin penetration of these alkyl PEG sulfosuccinates would be unlikely because of their substantial polarity and molecular sizes. In addition, the high acute LD50s reported in oral animal studies suggested that the absorption of these substances through the skin at relevant doses has little potential to cause systemic effects.

The Panel did acknowledge that statistically significant increases in liver weights in animals that received repeated oral doses of disodium laureth sulfosuccinate were reported, but given the absence of any other findings indicative of liver toxicity, such findings were not considered to be relevant. The Panel noted that sulfosuccinates have the potential for causing ocular/skin irritation, but not sensitization. Therefore, products containing these ingredients should be formulated to be non-irritating.

Because disodium laureth sulfosuccinate can be used at maximum reported concentration of 2% in cosmetics that may be sprayed (hair color sprays), the Panel discussed the issue of incidental inhalation exposure. In the absence of sufficient inhalation data, the Panel considered data characterizing the potential for alkyl PEG sulfosuccinates to cause systemic toxicity, genotoxicity, ocular or dermal irritation, or sensitization, and the potential for laureths to cause reproductive and developmental toxicity or carcinogenicity. The Panel noted that 95 – 99% of the droplets/particles produced in cosmetic aerosols would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable to any appreciable amount. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, this information suggested that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic toxic effects.

The Panel also addressed the potential for ethylene oxide and 1,4-dioxane impurities in alkyl PEG sulfosuccinates. Due to the volatility of ethylene oxide, it would be unexpected to find any appreciable quantity of the chemical residing as an impurity in these ingredients. The available data bear out that current methods of manufacture do not result in significant levels of ethylene oxide. The available data have demonstrated contaminant levels of 1,4-dioxane to be less than 10 ppm in these ingredients, again supporting that current methods of manufacture do not result in significant levels of 1,4-dioxane. Because of the toxicity of ethylene oxide and 1,4-dioxane, the Panel stressed that the cosmetics industry should continue to

use the necessary procedures to remove these impurities from the alkyl PEG sulfosuccinates before blending them into cosmetic formulations.

According to an MSDS on disodium laureth sulfosuccinate, this chemical may contain formaldehyde at a maximum level of 0.056%. The Panel noted that this level is less than the 0.076% formaldehyde limit established by the Panel in its final safety assessment on this ingredient, and is well below the threshold for any toxicological concerns relating to this chemical. Furthermore, the effective formaldehyde concentration yielded by disodium laureth sulfosuccinate in formulation would be even lower, considering that this ingredient is being used at concentrations up to 10% in rinse-off products and at concentrations up to 2% in leave-on products. At the maximum use concentration of 10%, the formaldehyde concentration would be no more than 0.006%.

CONCLUSION

The CIR Expert Panel concluded that the following cosmetic ingredients are safe in the present practices of use and concentration described in this safety assessment when formulated to be non-irritating:

- Disodium Laureth Sulfosuccinate
- Disodium Laureth-6 Sulfosuccinate
- Disodium Laureth-9 Sulfosuccinate*
- Disodium Laureth-12 Sulfosuccinate*
- Disodium Deceth-5 Sulfosuccinate*
- Disodium Deceth-6 Sulfosuccinate
- Magnesium Laureth-3 Sulfosuccinate*
- Disodium C12-14 Pareth-1 Sulfosuccinate*
- Disodium C12-14 Pareth-2 Sulfosuccinate
- Disodium C12-15 Pareth Sulfosuccinate*
- Disodium Coceth-3 Sulfosuccinate*
- Disodium Laneth-5 Sulfosuccinate*
- Disodium C12-14 Sec-Pareth-3 Sulfosuccinate*
- Disodium C12-14 Sec-Pareth-5 Sulfosuccinate*
- Disodium C12-14 Sec-Pareth-7 Sulfosuccinate*
- Disodium C12-14 Sec-Pareth-9 Sulfosuccinate*
- Disodium C12-14 Sec-Pareth-12 Sulfosuccinate*
- Disodium Oleth-3 Sulfosuccinate*

Were ingredients in this group not in current use to be in the future (indicated by *), the expectation is that they would be used in product categories and at concentrations comparable to others in the group.

Table 1. Definitions, Functions, and Structures of the Sulfosuccinate Ingredients[4]

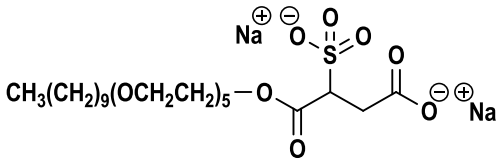
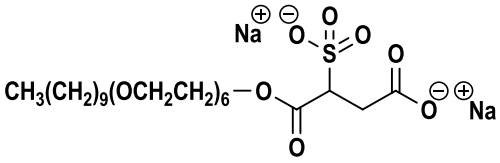
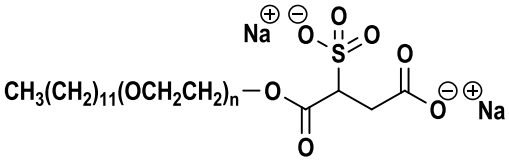
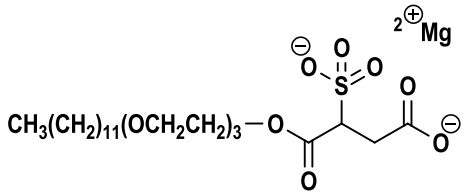
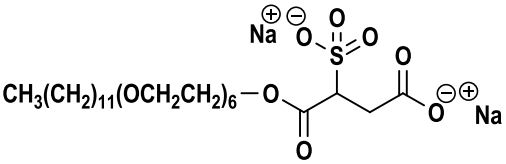
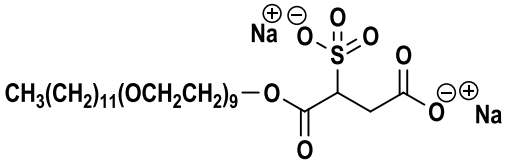
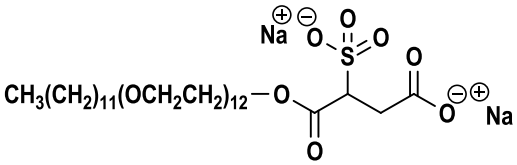
Ingredient CAS No.	Definition	Function(s)	Formula/structure
Disodium Deceth-5 Sulfosuccinate 68311-03-5 (CAS No. is generic for any disodium deceth sulfosuccinate)	Disodium Deceth-5 Sulfosuccinate is a disodium salt of the half ester of an ethoxylated decyl alcohol and sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant – Hydrotrope	
Disodium Deceth-6 Sulfosuccinate 68311-03-5 (CAS No. is generic for any disodium deceth sulfosuccinate)	Disodium Deceth-6 Sulfosuccinate is a disodium salt of the half ester of an ethoxylated decyl alcohol and sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	
Disodium Laureth Sulfosuccinate 39354-45-5 58450-52-5 (CAS Nos. are generic for any disodium laureth sulfosuccinate) 40754-59-4 42015-08-0 (CAS Nos. are specific to triethoxylated (i.e. laureth-3))	Disodium Laureth Sulfosuccinate is the disodium salt of an ethoxylated lauryl alcohol half ester of sulfosuccinic acid. 68815-56-5 (CAS No. is generic for any disodium C10-16 alkyl laureth sulfosuccinate)	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant – Hydrotrope	 wherein n averages between 1 and 4 (i.e. Laureth-1 through Laureth-4)
Magnesium Laureth-3 Sulfosuccinate	Magnesium Laureth-3 Sulfosuccinate is the magnesium salt of the half ester of an ethoxylated lauryl alcohol and sulfosuccinic acid.	Surfactant - Cleansing Agent	
Disodium Laureth-6 Sulfosuccinate 39354-45-5 (CAS No. is generic for any disodium laureth sulfosuccinate)	Disodium Laureth-6 Sulfosuccinate is the disodium salt of an ethoxylated lauryl alcohol half ester of sulfosuccinic acid. 40754-59-4[sic; specific to disodium laureth-3 sulfosuccinate]	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	
Disodium Laureth-9 Sulfosuccinate 39354-45-5 (CAS No. is generic for any disodium laureth sulfosuccinate)	Disodium Laureth-9 Sulfosuccinate is the disodium salt of an ethoxylated lauryl alcohol half ester of sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	
Disodium Laureth-12 Sulfosuccinate 39354-45-5 (CAS No. is generic for any disodium laureth sulfosuccinate)	Disodium Laureth-12 Sulfosuccinate is the disodium salt of an ethoxylated lauryl alcohol half ester of sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	

Table 1. Definitions, Functions, and Structures of the Sulfosuccinate Ingredients[4]

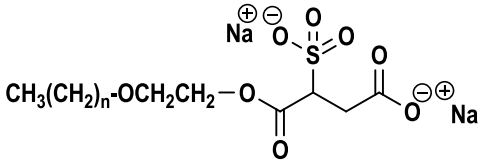
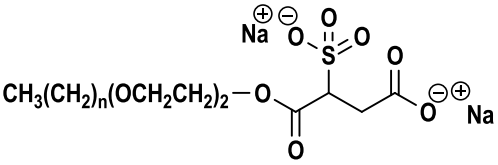
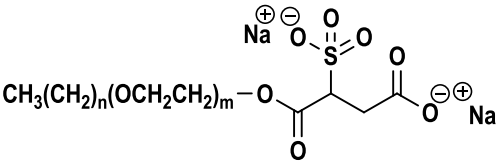
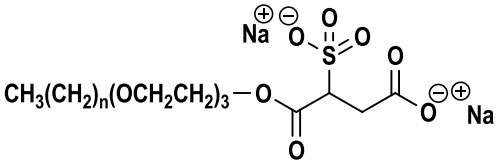
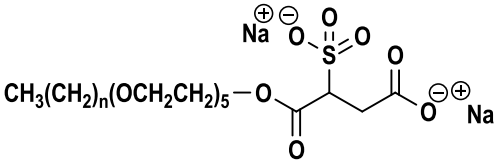
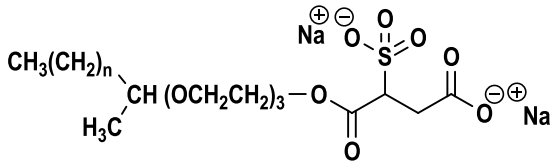
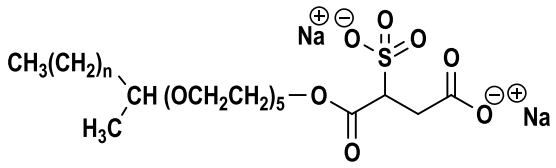
Ingredient CAS No.	Definition	Function(s)	Formula/structure
Disodium C12-14 Pareth-1 Sulfosuccinate	Disodium C12-14 Pareth-1 Sulfosuccinate is the disodium salt of an ethoxylated, partially esterified sulfosuccinic acid.	Surfactant - Cleansing Agent	 wherein n averages between 11 and 13 (i.e. Laureth-1 through Myreth-1)
Disodium C12-14 Pareth-2 Sulfosuccinate	Disodium C12-14 Pareth-2 Sulfosuccinate is the disodium salt of an ethoxylated, partially esterified sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	 wherein n averages between 11 and 13 (i.e. Laureth-2 through Myreth-2)
Disodium C12-15 Pareth Sulfosuccinate	Disodium C12-15 Pareth Sulfosuccinate is the disodium salt of an ethoxylated, partially esterified sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	 wherein n averages between 11 and 14, and m averages between 1 and 4 (i.e. Laureth-2 through Pentadeceth-4)
Disodium Coceth-3 Sulfosuccinate	Disodium Coceth-3 Sulfosuccinate is the disodium salt of the half ester of Coceth-3 and sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Emulsifying Agent	 wherein n represents the alkyl groups derived from coconut alcohol
Disodium Laneth-5 Sulfosuccinate 68890-92-6 (CAS No. is generic for any disodium laneth sulfosuccinate)	Disodium Laneth-5 Sulfosuccinate is a disodium salt of the half ester of Laneth-5 and sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	 wherein n represents the alkyl groups derived from lanolin alcohol.
Branched			
Disodium C12-14 Sec-Pareth-3 Sulfosuccinate	Disodium C12-14 Sec-Pareth-3 Sulfosuccinate is a disodium salt of the half ester of a mixture of ethoxylated, secondary C12-14 alcohols and sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	 wherein n averages between 9 and 11 (i.e. *sec*-Laureth-3 through *sec*-Myreth-3)
Disodium C12-14 Sec-Pareth-5 Sulfosuccinate	Disodium C12-14 Sec-Pareth-5 Sulfosuccinate is a disodium salt of the half ester of a mixture of ethoxylated, secondary C12-14 alcohols and sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	 wherein n averages between 9 and 11 (i.e. *sec*-Laureth-5 through *sec*-Myreth-5)

Table 1. Definitions, Functions, and Structures of the Sulfosuccinate Ingredients[4]

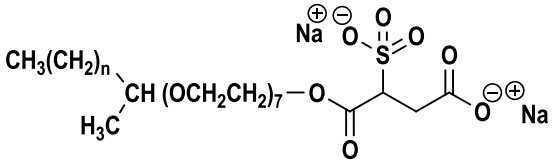
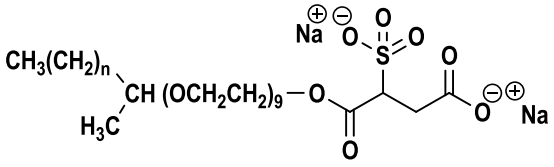
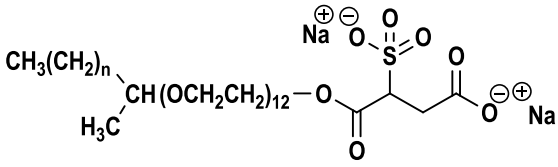
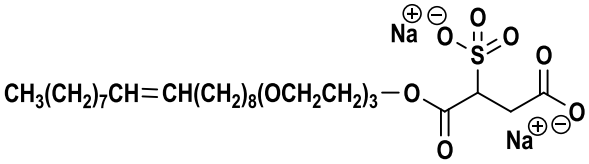
Ingredient CAS No.	Definition	Function(s)	Formula/structure
Disodium C12-14 Sec-Pareth-7 Sulfosuccinate	Disodium C12-14 Sec-Pareth-7 Sulfosuccinate is a disodium salt of the half ester of a mixture of ethoxylated, secondary C12-14 alcohols and sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	 wherein n averages between 9 and 11 (i.e. *sec*-Laureth-7 through *sec*-Myreth-7)
Disodium C12-14 Sec-Pareth-9 Sulfosuccinate	Disodium C12-14 Sec-Pareth-9 Sulfosuccinate is a disodium salt of the half ester of a mixture of ethoxylated, secondary C12-14 alcohols and sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	 wherein n averages between 9 and 11 (i.e. *sec*-Laureth-9 through *sec*-Myreth-9)
Disodium C12-14 Sec-Pareth-12 Sulfosuccinate	Disodium C12-14 Sec-Pareth-12 Sulfosuccinate is a disodium salt of the half ester of a mixture of ethoxylated, secondary C12-14 alcohols and sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	 wherein n averages between 9 and 11 (i.e. *sec*-Laureth-12 through *sec*-Myreth-12)
Unsaturated			
Disodium Oleth-3 Sulfosuccinate	Disodium Oleth-3 Sulfosuccinate is the disodium salt of an Oleth-3 (Ω-9 unsaturated) half ester of sulfosuccinic acid.	Surfactant - Cleansing Agent; Surfactant - Foam Booster; Surfactant - Hydrotrope	

Table 2. Properties of Sulfosuccinate Ingredients

Properties	Disodium Laureth Sulfosuccinate (and as trade name materials)	Disodium C12-14 Pareth-1 Sulfosuccinate (Beaulight ESS-10P)	Disodium C12-14 Pareth-2 Sulfosuccinate (Beaulight ESS)
Form	~32% active solution in water (clear liquid).[6] water white liquid, as CHEMCCINATE™ DSLS SURFACTANT [CAS No. 68815-56-5]).[9] Clear, colorless to slightly yellowish liquid surfactant raw material (as TEXAPON® SB 3 KC [CAS No. 68815-56-5], average of 3 moles of ethylene oxide).[7] Colorless liquid (as SETACIN 103 SPEZIAL [CAS No. 39354-45-5]).[32]	Cololorless or pale yellow liquid at 20^{0}C.[23]	Colorless or pale yellow liquid at 20^{0}C.[20]
% Composition	CHEMCCINATE™ DSLS SURFACTANT: 30 to 39.9% by weight disodium laureth sulfosuccinate.[9] TEXAPON® SB 3 KC: dry residue (38 to 42%); anionic surfactant, m.w. 550 (31.5 to 34.5%); sulfate content (max. 1%); 0.5% citric acid and 0.4% potassium sorbate as preservatives.[7] SETACIN 103 SPEZIAL: active ingredient (40%), anionic active matter (33%), and water content (60%).[32]	~ 30% disodium mono-(polyoxyethylene alkyl) sulfosuccinate (CAS No. 68911-93-3); ~ 70% water.[23]	~ 40% disodium mono-(polyoxyethylene alkyl) sulfosuccinate (CAS No. 68911-93-3); ~ 60% water.[20]
Odor	Alcohol (as CHEMCCINATE™ DSLS SURFACTANT).[9]	Slightly specific.[23]	Slightly specific.[20]
Molecular weight	~ 548;[6] 550 (as SETACIN 103 SPEZIAL).[32]		
Specific Gravity	1.11;[6] also 1.11 (at 20^{0}C) as CHEMCCINATE™ DSLS SURFACTANT and as SETACIN 103 SPEZIAL.[9,32,33]	1.10 (at 25^{0}C).[23]	1.15 (at 30^{0}C).[20]
pH	6.6 to 7 (at 10% in water) as CHEMCCINATE™ DSLS SURFACTANT;[9] 4.5 to 5.5 (TEXAPON® SB 3 KC 10% solution);[7] 6.3 (SETACIN 103 SPEZIAL 10% solution).[32]	~ 6.8 (10% aqueous solution).[23]	~ 7 (2% aqueous solution).[20]
Solubility	Water soluble, as CHEMCCINATE™ DSLS SURFACTANT and as SETACIN 103 SPEZIAL.[9,32]	Water soluble.[23]	Water soluble.[20]
Freezing point	Not determined (as CHEMCCINATE™ DSLS SURFACTANT).[9]	~ 0^{0}C.[23]	below 0^{0}C.[20]
Boiling point	100^{0}C (as CHEMCCINATE™ DSLS SURFACTANT).[9]	~ 100^{0}C.[23]	~ 100^{0}C.[20]

Table 3. Specifications for a Disodium Laureth Sulfosuccinate (16.8% active)/Sodium Lauryl Sulfoacetate (7.2% active) Trade Name Mixture[34]

Composition	Limits
% Active (molecular weight 491)	23-27
% Solids	30-35
pH (10% aqueous)	5.5-6.5
% Sodium Sulfate	3% max
% Sodium Chloride	2% max
Residual peroxide	Nil
Viscosity (CPS) @ 25°C	10,000 max
Formaldehyde	Positive

Table 4. Composition Data on a Disodium Laureth Sulfosuccinate (16.8% active)/Sodium Lauryl Sulfoacetate (7.2% active) Trade Name Mixture[35]

Composition	Value
% Active (molecular weight 491)	24
% Solids	32
pH (10% aqueous)	6.3
% Sulfate	2.2
% Sulfite	Nil
% Chloride	1.4
Bleach (% H_2O_2)	Nil
Viscosity (CPS) @ 25°C	236
Sodium Citrate	0.14
Formalin	Positive

Table 5. Current Frequency and Concentration of Use According to Duration and Type of Exposure[10,11,12]

	Disodium Laureth Sulfosuccinate		Disodium Laureth-6 Sulfosuccinate		Disodium Deceth-6 Sulfosuccinate	
	# of Uses	Conc. (%)	# of Uses		# of Uses	
Exposure Type						
Eye Area	2	0.06	NR		6	
Incidental Ingestion	NR	NR	NR		NR	
Incidental Inhalation-sprays	2	2	NR		NR	
Incidental Inhalation-powders	NR	NR	NR		NR	
Dermal Contact	480	0.06 to 9	NR		NR	
Deodorant (underarm)	NR	NR	NR		NR	
Hair - Non-Coloring	125	2 to 10	3		NR	
Hair-Coloring	1	2	NR		NR	
Nail	NR	NR	NR		NR	
Mucous Membrane	417	0.8 to 8	NR		NR	
Baby Products	5	NR	3		NR	
Duration of Use						
Leave-On	15	0.06 to 2	NR	NR	6	NR
Rinse-Off	592	0.4 to 10	3	NR	NR	NR
Diluted for (bath) use	59	1 to 4	NR	NR	NR	NR
Totals/Conc. Range	607	0.06 to 10	3	NR	6	NR
	Disodium C12-14 Pareth-2 Sulfosuccinate					
	# of Uses					
Exposure Type						
Eye Area	NR					
Incidental Ingestion	NR					
Incidental Inhalation-sprays	NR					
Incidental Inhalation-powders	NR					
Inhalation	NR					
Dermal Contact	NR					
Deodorant (underarm)	NR					
Hair - Non-Coloring	4					
Hair-Coloring	NR					
Nail	NR					
Mucous Membrane	NR					
Baby Products	NR					
Duration of Use						
Leave-On	NR					
Rinse-Off	4					
Diluted for (bath) use	NR					
Totals/Conc. Range	4					

NR = Not Reported; Totals = Rinse-off + Leave-on Product Uses.
Notes: Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure type uses may not equal the sum total uses. Omission of Conc.(%) column indicates the absence of ingredient use concentration data;

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