Amended Safety Assessment of Fatty Acyl Sarcosines and Their Salts as Used in Cosmetics

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All interested persons are provided 60 days from the above release date to comment on this safety assessment and to identify additional published data that should be included or provide unpublished data which can be made public and included. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, will be available at the CIR office for review by any interested party and may be cited in a peer-reviewed scientific journal. Please submit data, comments, or requests to the CIR Director, Dr. Lillian Gill.

The 2016 Cosmetic Ingredient Review Expert Panel members are: Chairman, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Director is Lillian J. Gill, D.P.A. This safety assessment was prepared by Monice M. Fiume, Assistant Director/Senior Scientific Analyst/Writer.
ABSTRACT

The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) assessed the safety of 14 fatty acyl sarcosines and their salts as used in cosmetics; all of these ingredients are reported to function in cosmetics as hair conditioning agents and most also can function as surfactants – cleansing agents. The ingredients reviewed in this assessment are composed of an amide comprising a fatty acyl residue and sarcosine, and are either free acids or simple salts thereof. The Panel relied on relevant new data, including concentration of use, and considered data from the previous CIR report, such as the reaction of sarcosine with oxidizing materials possibly resulting in nitrosation and the formation of N-nitroso-N-methylglycine. The Panel concluded that these ingredients are safe as used in cosmetics when formulated to be non-irritating, but these ingredients should not be used in cosmetic products in which N-nitroso compounds may be formed.

INTRODUCTION

In 2001, the Cosmetic Ingredient Review (CIR) Expert Panel (Panel) published a safety assessment with the conclusion that the 5 fatty acyl sarcosines and 5 fatty acyl sarcosine salts listed below are safe as used in rinse-off products, safe for use in leave-on products at concentrations of ≤5%, and the data are insufficient to determine the safety for use in products where the fatty acyl sarcosines and their salts are likely to be inhaled.1 These ingredients should not be used in cosmetic products in which N-nitroso compounds may be formed.

Cocoyl Sarcosine
Lauroyl Sarcosine
Myristoyl Sarcosine
Oleoyl Sarcosine
Stearoyl Sarcosine

Ammonium Cocoyl Sarcosinate
Ammonium Lauroyl Sarcosinate
Sodium Cocoyl Sarcosinate
Sodium Lauroyl Sarcosinate
Sodium Myristoyl Sarcosinate

Concentration of use data were not provided at the time of the original safety assessment; because those values were not available, the concentration limit of 5% was established for leave-on products based upon the highest concentration tested in human repeat-insult patch tests. Concentration of use data are now available, and additional new relevant data have been discovered; therefore, the Panel re-opened this safety assessment to reassess the original conclusion.

The Panel determined that the following 4 additional fatty acyl sarcosine salts are structurally similar to the ingredients named above, and that the data in the original safety assessment, together with the new data presented in this report, supports the safety of these 4 additional fatty acyl sarcosine salts; therefore, these ingredients are included in this report:

Potassium Cocoyl Sarcosinate
Potassium Lauroyl Sarcosinate
Sodium Oleoyl Sarcosinate
Sodium Palmitoyl Sarcosinate

All of the ingredients included in this assessment are reported to function in cosmetics as hair conditioning agents, and most of these ingredients are reported to function as surfactants – cleansing agents2 (Table 1).

Excerpts from the summary of the 2001 report are disseminated throughout the text of this re-review document, as appropriate, and are identified by italicized text. (This information is not included in the summary section.)

Several previous CIR safety assessments are relevant to this safety assessment because they discuss the safety of components of the acyl sarcosines and sarcosinate amides. In 2011, the Panel concluded that Cocos Nucifera (Coconut) Oil and Elaeis Guineensis (Palm) Oil are safe in the present practices of use and concentration.3 In 1987, the Panel published a report with the conclusion that Oleic, Lauric, Palmitic, Myristic, and Stearic Acids are safe in present practices of use and concentration in cosmetics;4 this conclusion was reaffirmed in 2006.5

Much of the new toxicity data included in this safety assessment was found on the European Chemicals Agency (ECHA) website.6 The ECHA website provides summaries of information generated by industry, and it is those summary data that are reported in this safety assessment when ECHA is cited.

CHEMISTRY

Definition and Structure

Sarcosine, also known as N-methylglycine or N-methylaminoacetic acid, is derived from the decomposition of creatine or caffeine.1 Sarcosine is also a naturally occurring amino acid found in marine animals. It conforms generally to the formula:
The ingredients in this report are each an amide comprising a fatty acyl residue and sarcosine, with connectivity occurring via the nitrogen atom of sarcosine and the carbonyl of the fatty acyl residue. These ingredients are either free acids (the carboxylic functional group of the sarcosine residue), or are simple salts thereof. The salts in this report recite the term “sarcosinate” in the name, and were referred to in the previous report as “sarcosinates” or “sarcosinates amides.” Since these previously utilized terms could erroneously be interpreted to mean esters or amides with connectivity through the carbonyl of sarcosine, these salts are hereto referred to simply as fatty acyl sarcosine salts.

***Figure 1. Sarcosine***

![Sarcosine](image)

**Physical and Chemical Properties**

The ingredients included in this safety assessment are viscous liquids or waxy solids (Table 2). The free acids have molecular weights of approximately 280-350 Da. The salts are formed from the carboxylic acid moiety, and among the ingredients reviewed herein, are simple alkali metal (sodium, potassium) or ammonium salts.

The modification of the hydrocarbon chain imparts greater solubility and crystallinity to the molecule. Acyl sarcosines are somewhat stronger acids than the parent fatty acids, and they form salts in the neutral and mildly acidic pH range. The salts are similar physically and chemically to fatty acid soaps; the fatty acyl sarcosine salts are, however, more soluble in water and less affected by water hardness than are common soaps.

***Method of Manufacture***

The acyl sarcosines are the condensation products of sarcosine with natural fatty acids and are produced commercially by the reaction of sodium sarcosine and the parent fatty acid chlorides. The acyl sarcosines can then be neutralized to form the sodium or ammonium salts.

The acyl sarcosinates are often supplied as 30% or 95% aqueous solutions. According to a manufacturer, only internally prepared sodium sarcosinate is used as a starting material. The sodium sarcosinate is then reacted directly with the acyl chloride, which has been prepared from the free fatty acid by treatment with phosphorus trichloride.

***Impurities/Composition***

Thirty percent aqueous solutions of Lauroyl Sarcosine and Sodium Lauroyl Sarcosinate were analyzed for nitrosamines (test method unavailable). The detection limits were 65 ppb for N-nitrososarcosine in Lauroyl Sarcosine and 15 ppb in Sodium Lauroyl Sarcosinate, respectively; no nitrosamines were detected. The synthesis reaction is kept in a closed system for up to several days prior to the succeeding reaction to prevent contamination with nitrite precursors. The reaction conditions are not conducive to the formation of nitrosamines as contaminants, and neither nitrates nor nitrites are used in the manufacturing process.

Precursors necessary for the "hypothetical formation" for polynuclear aromatic hydrocarbons are also absent from the synthesis reactions and none of the starting materials are prepared or provided in a hydrocarbon solvent. Similarly, the
presence of dioxins was considered "exceedingly improbable," as no phenolic compounds were present in any of the synthesis reactions.

Oleoyl Sarcosine
Oleoyl Sarcosine is 97% pure. It may contain 2% free fatty acids.

Sodium Lauroyl Sarcosinate
According to several suppliers, sodium lauroyl sarcosinate (30% active) contains 1-1.5% (max.) sodium laurate, 2.5% (max.) free fatty acid, 0.2-0.5% (max.) inorganic salt, and 0.35% (max.) chloride.\(^7\)\(^8\)\(^9\)\(^10\)

Nitrosation
Sarcosine can react with oxidizing materials and can be nitrosated to form N-nitrososarcosine,\(^1\) a compound that is a liver carcinogen.\(^12\) N-Nitrososarcosine has been formed by the reaction of sarcosine with sodium nitrite in an acid solution and by passing nitric acid fumes through a sarcosine solution.\(^1\) N-Nitrososarcosine can also be produced by nitrosating N-methylsarcosine hydrochloride or by treating creatine in an acid medium with an aqueous solution of sodium nitrite. Primary routes of potential human exposure to N-nitrososarcosine are inhalation, ingestion, and dermal contact. N-nitrososarcosine has been detected in foodstuffs, particularly meat, at concentrations of 2-56 µg/kg of sample. It can be produced by various reactions in air, water, soil, food, and animal systems.

When 50 mg of Sodium Lauroyl Sarcosinate was incubated with 100 mg of sodium nitrite in 10% hydrochloric acid, investigators detected sarcosine, Lauroyl Sarcosine, and N-nitrososarcosine using thin-layer chromatography.\(^1\) The yield of N-nitrososarcosine was 6.0%.

USE
Cosmetic
The safety of the cosmetic ingredients included in this safety assessment is evaluated based on data received from the U.S. Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product category in FDA’s Voluntary Cosmetic Registration Program (VCRP) database. Use concentration data are submitted by industry in response to surveys, conducted by the Personal Care Products Council (Council), of maximum reported use concentrations by product category.

Based on 2016 VCRP data\(^13\) and the results of a 2015 Council survey,\(^14\) 10 of the 14 ingredients included in this safety assessment are currently in use. Sodium Lauroyl Sarcosinate has the highest frequency of use, with 485 reported uses; the majority of these uses are in rinse-off formulations, primarily bath soaps and detergents (230 uses) and shampooos (113 uses; Table 3). Sodium Lauroyl Sarcosinate also has the highest concentration of use, with maximum use concentrations up to 15% in rinse-off products. The highest reported leave-on concentration is 5% Sodium Myristoyl Sarcosinate in eye shadow formulations.

All but one of the in-use ingredients has been reviewed previously by the Panel, and the frequencies of use of these ingredients have not changed significantly. Concentration of use data were not provided at the time of the original safety assessment, therefore it is not apparent whether the concentration of use has changed. (Because those values were not available, a concentration limit of 5% was established for leave-on products, based upon the highest concentration tested in human repeat-insult patch tests.\(^1\))

Table 4 provides a listing of the fatty acyl sarcosines and salts not currently reported to be in use in use.

Several of the ingredients included in this assessment are used in products that can be ingested (e.g., <5% Sodium Myristoyl Sarcosinate in lipstick), used near the eye (e.g., 5% Sodium Myristoyl Sarcosinate in eye shadow), or come in contact with mucous membranes (e.g., ≤9% Sodium Lauroyl Sarcosinate in bath soaps and detergents). Additionally, some of the fatty acyl sarcosines and salts are listed in the VCRP in product types that can be sprays, but it is not known whether or not the reported uses are in sprays. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 µm, with propellant sprays yielding a greater fraction of droplets/particles <10 µm compared with pump sprays.\(^15\)\(^16\) 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., they would not enter the lungs) to any appreciable amount.\(^17\)\(^18\) Sodium Myristoyl Sarcosinate and Sodium Palmitoyl Sarcosinate were reported to be used in face powders at concentrations of 0.15% and 0.081%, respectively. Conservative estimates of inhalation exposures to respirable particles during the use of loose-powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.\(^19\)\(^21\)

All of the fatty acyl sarcosines and salts named in the report are listed in the European Union inventory of cosmetic ingredients, and none of the listed ingredients are restricted from use in any way under the rules governing cosmetic products in the European Union.
Non-Cosmetic
Several of the fatty acyl sarcosines and salts are approved for the following indirect food additive uses:

- N-Acyl sarcosines, where the acyl group is lauroyl, oleoyl, or derived from the combined fatty acids of coconut oil, are approved as antistatic and/or antifogging agents at levels not to exceed a total of 0.15% by weight of polyolefin film and ethylene-vinyl acetate copolymer film for which average thickness of the copolymer films shall not exceed 0.003 inches. [21CFR178.3130]
- In polymers (specifically, cellophane), N-acyl sarcosines, where the acyl group is lauroyl or stearoyl, are approved for use only as release agents in coatings at levels not to exceed a total of 0.3% by weight of the finished packaging cellophane, and Sodium Lauroyl Sarcosinate is approved for use at 0.35% only in vinylidene chloride copolymer coatings. [21CFR177.1200]
- Oleoyl Sarcosine is approved for use as a corrosion inhibitor in lubricants with incidental food contact at levels not to exceed 0.5% by weight of the lubricant. [21CFR178.3570]
- Sodium Lauroyl Sarcosinate is approved in adhesives without limitations. [21CFR175.105]

Oleoyl Sarcosine is used in lubricants and greases, metal working fluids, washing and cleaning products, hydraulic fluids, textile treatment products and dyes, metal surface treatment products, and leather treatment products. It is used in the formulation of mixtures and/or re-packaging, building and construction work and agriculture, forestry, and fishing. Also, Oleoyl Sarcosine is used for the manufacture of plastic products, mineral products (e.g. plasters, cement), fabricated metal products, machinery and vehicles, furniture and textiles, leather or fur.

TOXICOKINETICS

Dermal Penetration
The amount of transdermal penetration from 1% Lauroyl Sarcosine (0.5 g) in an ointment was ~1660 µg over 24 h in Wistar rat, as determined using high-performance liquid chromatography: addition of 30% vitamin E or 10% squalene enhanced Lauroyl Sarcosine penetration.1

Penetration Enhancement
Lauroyl Sarcosine (30%) increased the penetration of isosorbide dinitrate through the skin of the rat; the addition of 30% vitamin E or 10% squalene maintained or enhanced the effect of Lauroyl Sarcosine.1 In a study of the effects of surfactants on epidermal permeability, 30% Sodium Lauroyl Sarcosinate did not increase permeability.

Lauroyl Sarcosine
The effect of Lauroyl Sarcosine (98% pure) on transdermal fluorescein delivery across the epidermis of human cadaver skin was determined using Franz cells.24 The vehicles were phosphate buffered solution (PBS; in which Lauroyl Sarcosine was generally insoluble) and aq. ethanol solution. A 0.7 cm² skin surface was exposed to 0.3 ml of test solution. Lauroyl Sarcosine only did not significantly enhance transdermal flux. With ethanol, skin permeability increased with increasing Lauroyl Sarcosine concentrations (1-3%) in 25-50% ethanol solution, and transdermal delivery of fluorescein was increased by 47-fold using formulations containing 3% Lauroyl Sarcosine in aq. 50% ethanol solutions. The effects of higher concentrations of ethanol (i.e., 75% or 100%) as the vehicle resulted in weaker enhancement effects. Lauroyl Sarcosine and ethanol synergistically increased skin permeability, and the researchers concluded that permeability was increased due to a mechanism that involved synergistic lipid-fluidization activity in the stratum corneum.

Sodium Lauroyl Sarcosinate
In the study described above, the researchers also examined the effect of Sodium Lauroyl Sarcosinate on transdermal fluorescein delivery across human cadaver skin epidermis.24 Sodium Lauroyl Sarcosinate was completely dissolved in PBS. Only a “very small increase in transdermal flux” (0.061±0.013 µg) was observed.

Absorption, Distribution, Metabolism, and Excretion
When [14C]Sodium Lauroyl Sarcosinate was administered to rats (route of administration not available) during a metabolism study, 82-89% of the 50 mg/kg dose was excreted in the urine and feces within 24 h.1 For the next 24 hours, 1-2% was excreted. Nearly all of the excreted material was found in the urine. In a study in which [14C]Sodium Lauroyl Sarcosinate was applied to the teeth, oral mucosa, and tongue of rats, the mean distribution of [14C] was 1.12% in the teeth, 2.22% in the oral mucosa, and 2.95% in the tongue immediately after dosing. At 24 h, the mean distribution was 0.79% in the teeth, 0.92% in the oral mucosa, 0.57% in the tongue, 1.6% in the liver, 0.8% in the kidneys, 1.8% in the feces, and 42.2% in the urine. The data indicated that Sodium Lauroyl Sarcosinate was not absorbed by the tissues of the mouth, but was swallowed and absorbed into the blood. Approximately 34% of the radioactivity was excreted in the urine over a period of 4 h, and 42% was excreted within 24 h.
Sarcosine is a natural amino acid found in muscles and other body tissues; it is found naturally as an intermediate in the metabolism of choline to glycine. Oleoyl Sarcosine is a normal metabolite in man.

**TOXICOLOGICAL STUDIES**

The [fatty acyl] sarcosines and sarcosinates [salts] have low oral toxicity. The oral LD$_{50}$ values of Sodium Lauroyl Sarcosinate, Cocoyl Sarcosine, and Sodium Cocoyl Sarcosinate were 4.2 to 6.0 g/kg in rats. The oral LD$_{50}$ of Cocoyl Sarcosine in mice was 2.1 g/kg. Ten male Yale Sherman Wistar rats per group were given a single dose (gavage) of 2.5% aqueous Sodium Lauroyl Sarcosine; no deaths occurred in groups given up to 1000 mg/kg, 1 rat each died in the 1200- and 1500-mg/kg groups, 2 died in the 1750 mg/kg group, 4 died after treatment with 2000 mg/kg, 7 died in the 2250 mg/kg group, and all 10 rats died in the group given 2500 g/kg. Weanling rats fed 0.5 - 2% Sodium Lauroyl Sarcosinate for up to 6 mos had no signs of toxicity. During a 2-yr feeding study using Wistar rats, the no-observed-effect level of Sodium Lauroyl Sarcosinate was 1000 mg/kg/day.

### Acute Toxicity Studies

#### Dermal

**Sodium Myristoyl Sarcosinate**

A dose of 2000 mg/kg bw Sodium Myristoyl Sarcosinate in arachis oil BP was applied for 24h to the backs and flanks of 5 male and 5 female RCC Han:WIST rats using semi-occlusive patches. Approximately 10% of the body was covered. Observations were made 0.5, 1, 2, and 4 h after dosing, and then once daily for 14 days. All animals survived until study termination. Very slight erythema, which was observed in 7/10 animals, was fully reversible within 5 days. The dermal LD$_{50}$ of Sodium Myristoyl Sarcosinate was >2000 mg/kg bw in male and female rats.

#### Oral

**Oleoyl Sarcosine**

One study reported that the oral LD$_{50}$ of Oleoyl Sarcosine was >5000 mg/kg bw, by gavage, in male and female Sprague-Dawley rats, and another reported it as 9200 mg/kg bw in the rat. (Details were not provided.)

**Sodium Lauroyl Sarcosinate**

Male and female Sprague-Dawley rats were given a single dose by gavage of 5000 mg/kg bw aq. Sodium Lauroyl Sarcosinate. One female died on day 2; clinical signs were not observed in any of the remaining animals. The oral LD$_{50}$ was >5000 mg/kg bw.

**Sodium Oleoyl Sarcosinate**

The oral LD$_{50}$ of Sodium Oleoyl Sarcosinate in rats was 6000 mg/kg.

#### Inhalation

**Oleoyl Sarcosine**

Ten male and 10 female Sprague-Dawley rats were exposed nose/head only to Oleoyl Sarcosine in 10% ethanol for 4 h, according to Organisation for Economic Development (OECD) Guideline 403 (acute inhalation study). The LC$_{50}$ for male and female rats was >1.0-1.85 mg/l air. Shallow respiration was noted in all animals of these 2 groups. Some treatment-related gross and microscopic lesions were observed in the lungs of some animals at all test concentrations. The LC$_{50}$ of Sodium Lauroyl Sarcosinate (34.5% pure) was between 1 and 5% for male and female rats.

The acute inhalation toxicity of Sodium Lauroyl Sarcosinate (96.2% pure) was evaluated in Wistar rats following a 4-h nose-only exposure; the test was performed according to EPA OPPTS 870.1300 guideline for acute inhalation toxicity. Groups of 5 males were exposed to 0.05 or 0.5 mg/l, and 5 males and 5 females were exposed to 1 or 5 mg/l. The MMAD of the aerosol particles at target concentrations of 0.5, 1, and 5 mg/l were 2.6-3.1 µm, 2.0-2.7 µm, and 2.5-4.5 µm, respectively; the researchers stated that at 5 mg/L, the MMAD measurements showed an abnormal distribution, which may have been caused by the high test substance concentration in relation with high relative humidity, but the results were sufficient to conclude that the droplets size was suitable to warrant a correct exposure with sufficient distribution over the lungs. Two females and 3 males of the 5 mg/l group were found dead immediately after exposure, and the remaining animals were killed within 1 h after exposure for humane reasons; death was attributed to acute respiratory tract irritancy. No mortality occurred in the 0.5 or 1.0 mg/l groups; shallow respiration was noted in all animals of these 2 groups. Some treatment-related gross and microscopic lesions were observed in the lungs of some animals at all test concentrations. The LC$_{50}$ of Sodium Lauroyl Sarcosinate (34.5% pure) was between 1 and 5% for male and female rats.

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signs were noted in the low or high dose groups; lethargy, flat/hunched posture, labored respiration, piloerection and red
discoloration of the mouth and nose among the males of the 0.5 mg/l group and most females (but not males) in the 1 mg/l
group. At necropsy, red foci were noted on the lungs in animals of all groups except the lowest dose group. The LC50 of
Sodium Lauroyl Sarcosinate in rats was 0.05-0.5 mg/l air following the 4-h exposure.

**Short-Term Toxicity Studies**

**Oral**

**Sodium Lauroyl Sarcosinate**

Groups of 15 male and 15 female Sprague-Dawley albino rats were dosed orally by gavage daily with 0, 30, 100, and 250
mg/kg bw Sodium Lauroyl Sarcosinate in distilled water for 91 or 92 days.25 Body weight gains were decreased in males of
the 100 and 250 mg/kg bw groups; the decrease was statistically significant compared to controls for 5 of 13 wks in the mid-
dose group and 8 of 13 wks in the high doses group. Absolute stomach weights (in males), stomach-to-body weight ratios,
and stomach-to-brain-weight ratios (in males and females) were statistically significantly increased in the 100 and 250 mg/kg
bw dose groups, there was an increase in stomach wall thickness and yellow discoloration of non-glandular gastric mucosa,
and histopathology revealed an increase in incidence and severity of squamous cell hyperplasia, hyperkeratosis/parakeratosis,
inflammation and edema of the non-glandular gastric mucosa in both male and females of these groups. Weights of several
other organs that were statistically significantly different from control values were not considered toxicologically significant.
There were no toxicologically significant changes in hematology or clinical chemistry parameters. No test material-related
mortality was reported. The no-observed effect level (NOEL), lowest observable adverse effect level (LOAEL), and no-
observable adverse effect level (NOAEL) for male and female animals were 30, 100, and 250 mg/kg bw/day, respectively.

**Inhalation**

**Oleoyl Sarcosine**

In a 28-day inhalation study performed according to OECD Guideline 412 (Repeated Dose Inhalation Toxicity: 28/14-Day),
groups of 3 male and 3 female Fischer 344 rats were exposed nose/head-only to 0, 0.006, 0.02, or 0.06 mg/l Oleoyl Sarcosine
in <10% ethanol.22 The daily exposure time was not specified; however, according to OECD Guideline 412, daily exposure
is 6 h in this type of study. The MMAD of the aerosol particles were 1.11, 1.15 and 1.22 μm for the low, mid and high
concentrations, respectively. All test concentrations caused effects at several sites of the respiratory system with indications
for a local irritation, squamous metaplasia and epithelium proliferation and submucous acute inflammation at the basis of the
epiglottis; these changes may be explained by the amounts of inert material deposited within the respiratory system. In the
lungs and bronchi, the most prominent finding was a focal early stage of fibrosis. The researchers stated that due to the high
amount of test substance deposits in the lungs, especially in the 0.02 and 0.06 mg/l groups, these changes may be explained
as an overloading of the tissue, and do not necessarily imply an intrinsic toxicity of the test material; an intrinsic toxicity is
unlikely because the test material is insoluble and the shape of the particles is not fibrous. There was an effect on testes,
thyroid, brain, lung and kidneys weights, but details were not provided. The NOEL was <0.006 mg/l air in males and
females; the basis for the effect level was local irritation. The no-observed adverse effect concentration (NOAEC) was >0.06
mg/l air in males, and the basis for that effect level was an effect on organ weight.

**DEVELOPMENTAL AND REPRODUCTIVE TOXICITY**

The feeding of up to 1000 mg/kg/day Sodium Lauroyl Sarcosinate did not adversely affect fertility of albino Sherman Wistar
rats during a 2-year oral toxicity study.1

**Sodium Lauroyl Sarcosinate**

A prenatal developmental toxicity study (OECD Guideline 414) was conducted for Sodium Lauroyl Sarcosinate (95% pure)
in Sprague-Dawley rats.26 Groups of 24 gravid female rats were dosed once daily by gavage with 0, 30, 100 and 250 mg/kg
bw/day of the test article in distilled water on days 5-10 of gestation, and the animals were killed on day 20 of gestation.
Sodium Lauroyl Sarcosinate was not embryotoxic or teratogenic. Maternal body weight gains (adjusted) in the mid- and
high-dose group were decreased during gestation as compared to the controls. Feed consumption was decreased in the high
dose group; the decrease was statistically significantly between days 8-11 and days 14-17 of gestation. Two high-dose dams
died during the study; one on day 10 and one on day 18 of gestation. The dam that died on day 18 of gestation had sloughing
on the non-glandular region of the stomach, 7 dead fetuses had sloughing in the right uterine horn, and 5 dead fetuses had
sloughing in the left uterine horn, and the high-dose females killed at study termination all had sloughing on the non-
glandular region of the stomach; this effect was not observed in the low or mid-dose groups. The NOAEL (maternal
toxicity), LOAEL (maternal toxicity), and NOEL (developmental toxicity) were 30, 100, and ≥250 mg/kg bw/day Sodium
Lauroyl Sarcosinate, respectively.
GENOTOXICITY

In Vitro
Natrium Lauroyl Sarcosinate was not considered mutagenic in five strains of Salmonella typhimurium during plate incorporation assays and spot tests. In addition, Natrium Lauroyl Sarcosinate did not induce double-strand DNA breaks in the comet assay using human white blood cells and V79 Chinese Hamster cells, but the compound was cytotoxic.

Oleoyl Sarcosine
Oleoyl Sarcosine in dimethyl sulfoxide at concentrations of ≥5000 µg/plate, with or without metabolic activation, was not mutagenic in an Ames test with S. typhimurium TA1535, TA1537, TA100 and TA98, or in an Ames test with S. typhimurium TA97a, TA98, TA100, TA102, or TA1535. Positive and vehicle controls gave expected results.

Sodium Lauroyl Sarcosinate
The genotoxic potential of Sodium Lauroyl Sarcosinate (96.2% pure) was evaluated in an in vitro mammalian chromosomal aberration assay in lymphocytes. Cells were treated with 22.5 – 360 µg/ml for 4 h with or without metabolic activation, and with 22.5 – 270 µg/ml for 24 h without metabolic activation. Minimal essential media (MEM) served as the vehicle. Sodium Lauroyl Sarcosinate was not genotoxic. Solvent and positive controls gave expected results.

CARCINOGENICITY

Oleoyl Sarcosine
Carcinogenicity data of the fatty acyl sarcosines and their salts were not available; however, the ingredients were not considered likely carcinogens as they and their metabolites "do not belong to any class of compounds that contains a significant number of mutagens or oncogens."

DERMAL IRRITATION AND SENSITIZATION

Sodium Lauroyl Sarcosinate
The irritation potential of Sodium Lauroyl Sarcosinate was evaluated in an in vitro mammalian chromosomal aberration assay in lymphocytes. Cells were treated with 22.5 – 360 µg/ml for 4 h with or without metabolic activation, and with 22.5 – 270 µg/ml for 24 h without metabolic activation. Minimal essential media (MEM) served as the vehicle. Sodium Lauroyl Sarcosinate was not genotoxic. Solvent and positive controls gave expected results.

Dermal Irritation

In Vitro
Sodium Lauroyl Sarcosinate
The irritation potential of Sodium Lauroyl Sarcosinate was evaluated in an In Vitro Skin Corrosion Human Skin Model Test (OECD Guideline 431) using reconstructed human epidermis. Twenty mg of the test material in 0.9% sodium chloride solution was applied to the tissue for 3, 60, or 240 min, and tissue viability was measured using 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) uptake. Sodium Lauroyl Sarcosinate was non-corrosive to reconstructed human epidermis. Appropriate negative and positive controls gave valid results.

Animal

Oleoyl Sarcosine
Oleoyl Sarcosine, 0.5 ml, was applied neat to the shaved intact and abraded skin of 3 male and 3 female New Zealand White rabbits under an occlusive patch for 24 h. The test sites were scored upon patch removal and over a 7-day period. The mean erythema score at 24 and 72 h was 2.5 – 2.8 and 2.7-3, respectively. Additionally, at 72 h, the treated areas developed slight necrosis and the skin hardened. Oleoyl Sarcosine was classified as irritating.

Sodium Lauroyl Sarcosinate
The dermal irritation potential of Sodium Lauroyl Sarcosinate was evaluated in 6 female New Zealand White rabbits. The test material was diluted 1:3 in water to give 10% active material, and occlusive patches containing 0.5 ml were applied for 24 h to shaved intact and abraded skin of each animal. Well-defined erythema was observed at both intact and abraded treatment sites of all 6 animals following the 24 h dosing period, and slight edema was observed at 4 intact and 2 abraded treatment sites. After 72 h, well-defined erythema remained at both the intact and abraded sites of 4 animals, and very slight erythema was observed at both sites in one animal. Slight edema was observed at the abraded site of one animal, and very slight edema was observed at 3 abraded sites and 3 intact sites. Test sites were scored at 24 and 72 h, and the mean scores for erythema and edema were 1.83/4 and 1.06/4, respectively; erythema and edema were not fully reversible within 72 h.
Sensitization

Animal
Oleoyl Sarcosine

In a guinea pig maximization test (GPMT) using groups of 10 male and 10 female Pirbright white guinea pigs, the intradermal induction consisted of 3 pairs of injections consisting of a 1:1 mixture of Freund’s Complete Adjuvant (FCA) and saline; 5% Oleoyl Sarcosine in saline; and a mixture of Oleoyl Sarcosine with FCA/saline. The epicutaneous induction concentration was 30% Oleoyl Sarcosine in petrolatum. The challenge was performed on day 20 and consisted of a 24-h patch at a concentration of 3% in petrolatum. The test site was evaluated after 48 h; 3 animals had very slight erythema and 2 had well-defined erythema. The researchers classified the test substance as not sensitizing.

Photosensitization

Animal
Oleoyl Sarcosine

A photosensitization study of Oleoyl Sarcosine was conducted using groups of 10 male and 10 female Pirbright White guinea pigs. Induction consisted of open applications of 0.1 ml of a 0.1% suspension of the test substance in 80% DAE (40% dimethylacetamide, 30% acetone, 30% ethanol) and 20% physiological saline that were applied topically to the shaved skin on the necks of the animals 4 times/wk for 3 wks. One h after each application, the animals were irradiated for 10 minutes; during wk 1, the animals were exposed to ultraviolet A (UVA) and visible light using a Schott WG 335, 3 mm, filter, and during wks 2 and 3 they were exposed to UVA, UVB, and visible light using a Schott WG 280, 3 mm, filter. The test sites were scored 24 h after each induction application during induction wk 1. The sites were not scored during induction wks 2 and 3; during this time, a total of four injections of 0.1 ml FCA/saline were made to the 4 corners of the application site on Monday and Wednesday of both wks.

The first challenge was performed 16 days after the last induction irradiation; open applications of 0.1 ml of the test substance was applied to the dorsal skin of the animals for 3 days, and the sites were irradiated 1 h after the application with a suberythematogenic dose of UVA, UVB, and visible light. The second challenge was performed after a 14-day non-treatment period; the test material was applied in the same manner as the first challenge, but this time the application was followed with 10 min irradiation with a suberythematogenic dose of UVA and visible light. The test sites were evaluated 24 h after each challenge application. Any animal in which the irritation score after challenge was 1+ point above the score from wk 1 of induction was considered to be photosensitized. The test animals were compared to the control group that was treated with the vehicle alone.

Three control animals and 2 test animals died during the study; the deaths were not related to dosing. Three of 17 control animals had slight erythema during the first challenge. However, 17 and 15 of the 18 test animals had positive results after the first and second challenges, respectively. Oleoyl Sarcosine was considered to possess a photocontact-allergic potential in guinea pigs.

OCULAR IRRITATION

Sodium Cocoyl Sarcosinate (10%) at neutral or slightly acid pH caused slight, temporary ocular irritation, but no corneal damage in rabbits according to the procedures of the Draize-Woodard test. In another ocular irritation study using rabbits, a 5% aqeous solution of Sodium Lauroyl Sarcosinate caused minimal conjunctival irritation and no apparent damage to the cornea.

In Vitro
Sodium Myristoyl Sarcosinate

The ocular irritation potential of 20% Sodium Myristoyl Sarcosinate (92.1% pure) in physiological saline was evaluated in the Bovine Corneal Opacity and Permeability (BCOP) test. The test article was considered to be an ocular corrosive or severe irritant in the BCOP test.

Animal
Oleoyl Sarcosine

Oleoyl Sarcosine was instilled into one eye of rabbits according to Environmental Protection Agency (EPA) guidelines; the eyes of half the rabbit were rinsed after 30 sec. Details on the dose and number of animals were not provided. Draize scores of 47 and 40 were reported for unrinsed and rinse eyes, respectively. Oleoyl sarcosine was classified as moderately irritating to rabbit eyes.

In another study, detachment and clouding of the cornea was seen in rabbits treated with either Oleoyl Sarcosine or its sodium salt. After treatment with the sodium salt, the effects on the cornea had worsened after 1 wk; this change was not reversible after 15 days.
Sodium Myristoyl Sarcosinate
One-tenth ml of a mixture of Sodium Myristoyl Sarcosinate and sodium myristate was instilled neat into the conjunctival sac of the right eye of 6 rabbits, and the contralateral eye served as the control. All animals had a positive response to the test article, and the maximum average eye irritation score was 55.3 at 24 h after instillation. The mixture of Sodium Myristoyl Sarcosinate and sodium myristate was extremely irritating to rabbit eyes and considered a primary eye irritant.

MUCOSAL IRRITATION
Sodium Lauroyl Sarcosinate (20% aq. solution, 2% in formulation, powder) was non-irritating to the gums and oral mucosa of rabbits.

CLINICAL REPORTS
Case Reports
Sodium Lauroyl Sarcosinate
A female patient developed an acute severe eczematous reaction on her hands, face, and neck, and the reaction was related to use of a hand soap. After open and unoccluded patch test resulted in a +3 bullous reaction to the product, patch testing with some of the individual constituents was performed. A +3 bullous reaction to a 30% aq. solution of Sodium Lauroyl Sarcosinate in sterile water was reported. In 2 subjects patch tested with the soap and Sodium Lauroyl Sarcosinate, negative results were obtained.

In another report, a female patient with recurrent hand dermatitis had a positive reaction to semi-open application of a liquid cleanser that contained Sodium Lauroyl Sarcosinate. Positive reactions were observed in follow-up patch testing with 0.1, 0.5, and 1% aq. Sodium Lauroyl Sarcosinate; at 98 h, the scores were “–”, “+/- “, and “ + “ at these concentrations, respectively.

SUMMARY
In 2001, the Panel published a safety assessment with the conclusion that 5 fatty acyl sarcosines and 5 salts are safe as used in rinse-off products, safe for use in leave-on products at concentrations of ≤5%, and the data are insufficient to determine the safety for use in products where the fatty acyl sarcosines and salts are likely to be inhaled. These ingredients should not be used in cosmetic products in which N-nitroso compounds may be formed. This assessment is a re-review of those original ingredients, as well as 4 additional salts.

Sarcosine (which is also known as N-methylglycine or N-methylaminoacetic acid) is a natural amino acid found in muscles and other body tissues, and it is found naturally as an intermediate in the metabolism of choline to glycine. Oleoyl Sarcosine is also a normal metabolite in man.

Ten of the 14 ingredients included in this safety assessment are currently in use. Sodium Lauroyl Sarcosinate has the highest frequency of use, with 485 reported uses; the majority of these uses are in rinse-off formulations, primarily bath soaps and detergents (230 uses) and shampoos (113 uses). Sodium Lauroyl Sarcosinate also has the highest concentration of use, with maximum use concentrations up to 15% in rinse-off products. The highest reported leave-on concentration is 5% Sodium Myristoyl Sarcosinate in eye shadow formulations.

Lauroyl Sarcosine and ethanol synergistically increased skin permeability, as demonstrated by up to a 47-fold increase in transdermal delivery of fluorescein across human cadaver epidermis using 3% Lauroyl Sarcosinate in aq. 50% ethanol. Lauroyl Sarcosine and Sodium Lauroyl Sarcosinate alone (in PBS) did not significantly affect penetration.

Sodium Myristoyl Sarcosinate had a dermal LD₅₀ of >2000 mg/kg bw in male and female rats. In acute oral studies in rats, Oleoyl Sarcosine had an LD₅₀ of 9200 mg/kg bw, Sodium Lauroyl Sarcosinate had an LD₅₀ of >5000 mg/kg bw, and Sodium Oleoyl Sarcosinate had an LD₅₀ of 6000 mg/kg. Acute inhalation studies were performed in rats; with a 4-h exposure, Oleoyl Sarcosine had a LC₅₀ of >1.01-1.85 mg/l air, Sodium Lauroyl Sarcosinate (34.5% pure) had an LC₅₀ between 1 and 5%, and Sodium Lauroyl Sarcosinate (96.2% pure) had an LC₅₀ of 0.05-0.5 mg/l air.

In a 3-mo gavage study of Sodium Lauroyl Sarcosinate in rats, the NOEL, LOAEL, and NOAEL were 30, 100, and 250 mg/kg bw/day, respectively. A 28-day inhalation study was performed in rats with Oleoyl Sarcosinate; the NOEL was <0.006 mg/l air, and the NOAEC was 0.06 mg/l air.

No embryotoxicity or teratogenicity was observed in a prenatal developmental toxicity study in which gravid rats were dosed by gavage with up to 250 mg/kg bw/day Sodium Lauroyl Sarcosinate on days 5-10 of gestation. The NOAEL and LOAEL for maternal toxicity were 30 and 100 mg/kg bw/day.

Oleoyl Sarcosine was not mutagenic in an Ames test (≥5000 µg/plate, with or without metabolic activation), and Sodium Lauroyl Sarcosinate (22.5 – 360 µg/ml for 4 h with or without metabolic activation; 22.5 – 270 µg/ml for 24 h without metabolic activation) was not genotoxic in an in vitro mammalian chromosomal aberration assay in lymphocytes.
Sodium Lauroyl Sarcosinate was non-corrosive to reconstructed human epidermis in an In Vitro Skin Corrosion Human Skin Model Test. Undiluted Oleoyl Sarcosine was irritating to rabbit skin, and Oleoyl Sarcosine was classified as not sensitizing in a GPMT in which 3 and 2/20 guinea pigs had very slight and well-defined erythema, respectively, 48 h after challenge with 3% Oleoyl Sarcosine in petrolatum. Oleoyl Sarcosine was also considered to possess photocontact-allergenic potential in guinea pigs. A single 24-h application of Sodium Lauroyl Sarcosinate (10% active material) produced mean erythema and edema scores of 1.83/4 and 1.06/4 in rabbits, and the effects were not fully reversible within 72 h.

Sodium Myristoyl Sarcosinate, 20%, was considered to be an ocular corrosive or severe irritant in vitro in the BCOP test, and a mixture of Sodium Myristoyl Sarcosinate and sodium myristate was extremely irritating to rabbit eyes and considered a primary eye irritant. Oleoyl Sarcosine was classified as moderately irritating to rabbit eyes.

**DISCUSSION**

A safety assessment of 5 fatty acyl sarcosines and 5 fatty acyl sarcosine salts was published in 2001 with the conclusions that these ingredients are safe as used in rinse-off products, safe for use in leave-on products at concentrations of ≤5%, and the data are insufficient to determine the safety for use in products where the fatty acyl sarcosines and their salts are likely to be inhaled. Also, the conclusion stated that these ingredients should not be used in cosmetic products in which N-nitrosocompounds may be formed. Concentration of use data were not provided at the time of the original safety assessment; because those values were not available, the concentration limit of 5% was established for leave-on products based upon the highest concentration tested in human repeat-insult patch tests. Concentration of use data are now available, and because sensitization is not observed in studies at the highest concentration currently reported to be used, the Panel re-opened the safety assessment to remove the 5% concentration limit for leave-on products.

The Panel also considered 4 previously unreviewed fatty acyl sarcosine salts for inclusion in this safety assessment. The Panel determined that these ingredients are structurally similar to the ingredients reviewed in the original assessment, and that the data from the original safety assessment, together with the new data presented in this report, support the safety of the 4 additional fatty acyl sarcosine salts. Therefore, the Panel included the 4 ingredients in this review.

These ingredients, particularly Lauroyl Sarcosine, can enhance the penetration of other ingredients through the skin. The Panel cautioned that care should be taken in formulating cosmetic products that may contain these ingredients in combination with any ingredients whose safety was based on their lack of dermal absorption data, or when dermal absorption was a concern.

Sarcosine, a starting material in the manufacture of the sarcosines and sarcosinates, can react with oxidizing materials and can be nitrosated to form N-nitrososarcosine, a known animal liver carcinogen. As a result, the Panel concluded that fatty acyl sarcosines and their salts should not be used in cosmetic products in which N-nitrosocompounds can be formed.

The Panel was concerned that the potential exists for dermal irritation with the use of products formulated using fatty acyl sarcosines and their salts. The Panel specified that products containing these ingredients must be formulated to be non-irritating.

A photosensitization study indicated that Oleoyl Sarcosine may possess photocontact-allergenic potential in guinea pigs. The Panel noted that the chemical structure of Oleoyl Sarcosine does not have a chromophore, so there are no structural alerts for photosensitization. Additionally, the study did not indicate that an unirradiated control was used. The Panel stated that the allergic response observed in the study was most probably due to a contaminant, and not to Oleoyl Sarcosine.

The Panel acknowledged that some of the fatty acyl sarcosines and their salts may contain a cocoyl moiety, and expressed concern about pesticide residues and heavy metals that may be present in botanical ingredients. They stressed that the cosmetics industry should continue to use current good manufacturing practices (cGMPs) to limit impurities.

Additionally, the Panel discussed the issue of incidental inhalation exposure of fatty acyl sarcosines and their salts. Some of these ingredients are listed in the VCRP in product types that can be sprays, but it is not known whether or not the reported uses are in sprays. However, Sodium Myristoyl Sarcosinate and Sodium Palmitoyl Sarcosinate are reported to be used in face powders at concentrations of 0.15% and 0.081%, respectively, and these products may become airborne. Single dose, 4-h inhalation studies of 10% Oleoyl Sarcosine and Sodium Lauroyl Sarcosinate (96.2% pure) reported LC_{50} value of >1.01-1.85 mg/l air, and 0.05-0.5 mg/l, respectively; a 28-day inhalation study of Oleoyl Sarcosine in rats found that an intrinsic toxicity is unlikely because the test material is insoluble and the shape of the particles is not fibrous. The Panel also noted that droplets/particles from spray and loose-powder cosmetic products would not be respirable to any appreciable amount. Furthermore, droplets/particles deposited in the nasopharyngeal or bronchial regions of the respiratory tract present no toxicological concerns based on the chemical and biological properties of these ingredients. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. A detailed discussion and summary of the Panel’s approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at [http://www.cir-safety.org/cir-findings](http://www.cir-safety.org/cir-findings).
CONCLUSION

The CIR Expert Panel concluded that the following ingredients are safe as used in cosmetics when formulated to be non-irritating. The Expert Panel cautions that these ingredients should not be used in cosmetic products in which N-nitroso compounds can be formed.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cocoyl Sarcosine</td>
<td>Potassium Cocoyl Sarcosinate*</td>
</tr>
<tr>
<td>Lauroyl Sarcosine</td>
<td>Potassium Lauroyl Sarcosinate*</td>
</tr>
<tr>
<td>Myristoyl Sarcosine</td>
<td>Sodium Cocoyl Sarcosinate</td>
</tr>
<tr>
<td>Oleoyl Sarcosine</td>
<td>Sodium Lauroyl Sarcosinate</td>
</tr>
<tr>
<td>Stearoyl Sarcosine</td>
<td>Sodium Myristoyl Sarcosinate</td>
</tr>
<tr>
<td>Ammonium Cocoyl Sarcosinate*</td>
<td>Sodium Oleoyl Sarcosinate*</td>
</tr>
<tr>
<td>Ammonium Lauroyl Sarcosinate</td>
<td>Sodium Palmitoyl Sarcosinate</td>
</tr>
</tbody>
</table>

*Not reported to be in current use. 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 to others in this group.
Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment\(^2\) (CIR Staff)

<table>
<thead>
<tr>
<th>Ingredient CAS No.</th>
<th>Definition &amp; Structure</th>
<th>Function(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fatty Acyl Sarcosines</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Cocoyl Sarcosine (68411-97-2) | the N-cocoyl derivative of sarcosine that conforms generally to the formula: \[
\begin{align*}
\text{RC} - & \text{N}\text{H}_2\text{COOH} \\
\text{CH}_3 & 
\end{align*}
\] where \(\text{RCO-}\) represents the fatty acids derived from coconut oil. The fatty acids in Cocoyl Sarcosine have the following composition: 2-4\% \(C_{10}\), 55\% \(C_{12}\), 19-22\% \(C_{14}\), 0-7\% \(C_{16}\), 4-21\% \(C_{18}\), 0-8\% oleic acid, and 0-3\% unsaturated fatty acid.\(^1\) | hair conditioning agent; surfactant – cleansing agent |
| Lauroyl Sarcosine (97-78-9) | the N-lauroyl derivative of N-methylglycine that conforms generally to the formula: \[
\begin{align*}
\text{CH}_2\text{(CH}_3\text{)C-} & \text{N}\text{H}_2\text{COOH} \\
\text{CH}_3 & 
\end{align*}
\] | hair conditioning agent; surfactant – cleansing agent |
| Myristoyl Sarcosine (52558-73-3) | the N-myristoyl derivative of N-methylglycine that conforms to the formula: \[
\begin{align*}
\text{CH}_2\text{(CH}_3\text{)C-} & \text{N}\text{H}_2\text{COOH} \\
\text{CH}_3 & 
\end{align*}
\] | hair conditioning agent; surfactant – cleansing agent |
| Oleoyl Sarcosine (110-25-8) | the condensation product of oleic acid with N-methylglycine. It conforms generally to the formula: \[
\begin{align*}
\text{CH}_3\text{(CH}_2\text{)CH=CH(CH}_3\text{)C-} & \text{N}\text{H}_2\text{COOH} \\
\text{CH}_3 & 
\end{align*}
\] The fatty acid composition of Oleoyl Sarcosine is typically 4 to 5\% \(C_{14}\), 93\% \(C_{12}\), 3\% \(C_{14}\), 0-1\% \(C_{16}\), and 0-1\% oleic acid.\(^1\) | hair conditioning agent; surfactant – cleansing agent |
| Stearoyl Sarcosine (142-48-5) | the N-stearoyl derivative of N-methylglycine that conforms generally to the formula: (structure): \[
\begin{align*}
\text{CH}_3\text{(CH}_2\text{)C} - & \text{N}\text{H}_2\text{COOH} \\
\text{CH}_3 & 
\end{align*}
\] The fatty acid composition of Stearoyl Sarcosine is generally 0-2\% \(C_{14}\), 50\% \(C_{16}\), 4\% to 49\% \(C_{18}\), and 1\% oleic acid.\(^1\) | hair conditioning agent; surfactant – cleansing agent |
| **Fatty Acyl Sarcosine Salts** | | |
| Ammonium Cocoyl Sarcosinate | the ammonium salt of Cocoyl Sarcosine | hair conditioning agent; surfactant – cleansing agent |
| Ammonium Lauroyl Sarcosinate (68003-46-3) | the ammonium salt of Lauroyl Sarcosine. It conforms to the formula: \[
\begin{align*}
\text{CH}_3\text{(CH}_3\text{)C-} & \text{N}\text{H}_2\text{CONH}_4 \\
\text{CH}_3 & 
\end{align*}
\] | hair conditioning agent; surfactant – cleansing agent |
| Sodium Cocoyl Sarcosinate (61791-59-1) | the sodium salt of Cocoyl Sarcosine | hair conditioning agent; surfactant – cleansing agent |
| Sodium Lauroyl Sarcosinate (137-16-6) | the sodium salt of Lauroyl Sarcosine. It conforms generally to the formula: \[
\begin{align*}
\text{CH}_3\text{(CH}_3\text{)C-} & \text{N}\text{H}_2\text{COONa} \\
\text{CH}_3 & 
\end{align*}
\] The fatty acid composition of Sodium Lauroyl Sarcosinate is typically 95\% \(C_{12}\), 3\% \(C_{14}\), 0-1\% \(C_{16}\), and 0-1\% oleic acid.\(^1\) | hair conditioning agent; surfactant – cleansing agent |

\(^1\) Data from the literature.
Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment (CIR Staff)

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS No.</th>
<th>Definition &amp; Structure</th>
<th>Function(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Myristoyl Sarcosinate</td>
<td>(30364-51-3)</td>
<td>the sodium salt of Myristoyl Sarcosine. It conforms generally to the formula:</td>
<td>hair conditioning agent; surfactant – cleansing agent</td>
</tr>
<tr>
<td>Potassium Cocooyl Sarcosinate</td>
<td></td>
<td>the potassium salt of Cocooyl Sarcosine</td>
<td>hair conditioning agent; surfactant – cleansing agent</td>
</tr>
<tr>
<td>Potassium Lauroyl Sarcosinate</td>
<td>(38932-32-0)</td>
<td>the potassium salt of Lauroyl Sarcosine. It conforms to the formula:</td>
<td>hair conditioning agent; surfactant – cleansing agent</td>
</tr>
<tr>
<td>Sodium Oleoyl Sarcosinate</td>
<td>(14351-62-3)</td>
<td>the sodium salt of oleoyl sarcosine that conforms to the formula:</td>
<td>skin conditioning agent - miscellaneous</td>
</tr>
<tr>
<td>Sodium Palmitoyl Sarcosinate</td>
<td>(4028-10-8)</td>
<td>the sodium salt of palmitoyl sarcosine that conforms to the formula:</td>
<td>hair conditioning agent; skin-conditioning agent - miscellaneous; surfactant - cleansing agent</td>
</tr>
<tr>
<td>Property</td>
<td>Description</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-----------</td>
<td></td>
</tr>
<tr>
<td><strong>Cocoyl Sarcosine</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>physical characteristics</td>
<td>yellow, viscous, oily liquid</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>molecular weight</td>
<td>280 - 290 Da</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>solubility</td>
<td>insoluble in water; soluble in most organic solvents, including glycols, glycerin, silicones, phosphate esters, and aliphatic hydrocarbons.</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>melting point</td>
<td>22-28°C</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>specific gravity</td>
<td>0.965 to 0.975 (25° /25°C)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Lauroyl Sarcosine</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>physical characteristics</td>
<td>white to off-white waxy solid to semisolid with a mild, fatty acid odor</td>
<td>1</td>
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<tr>
<td>molecular weight</td>
<td>280 - 290 Da</td>
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<tr>
<td>solubility</td>
<td>insoluble in water; soluble in most organic solvents, including glycols, glycerin, silicone, phosphate esters, and aliphatic hydrocarbons</td>
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<tr>
<td>melting point</td>
<td>28-36°C</td>
<td>1</td>
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<tr>
<td>specific gravity</td>
<td>0.969</td>
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<td></td>
</tr>
<tr>
<td>density</td>
<td>0.996 g/cm^3 (25°C)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>log P ow</td>
<td>4.1 (QSAR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Oleoyl Sarcosine</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>physical characteristics</td>
<td>amber-colored viscous liquid</td>
<td>22,7</td>
<td></td>
</tr>
<tr>
<td>molecular weight</td>
<td>353.55</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>solubility</td>
<td>insoluble in water; soluble in most organic solvents</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>melting point</td>
<td>0°C (solidification point)</td>
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</tr>
<tr>
<td>density</td>
<td>0.95 g/cm^3</td>
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<td></td>
</tr>
<tr>
<td>log P ow</td>
<td>&gt;6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td><strong>Stearoyl Sarcosine</strong></td>
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<td></td>
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<tr>
<td>molecular weight</td>
<td>340-350 Da</td>
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<tr>
<td>specific gravity</td>
<td>0.924</td>
<td>1</td>
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</tr>
<tr>
<td><strong>Sodium Lauroyl Sarcosinate</strong></td>
<td>available commercially as a colorless to slightly yellow, 30% aqueous solution, as solid flakes, or as a substantially anhydrous white powder with 97% active content white powder (≥95% active content)</td>
<td>26,11</td>
<td></td>
</tr>
<tr>
<td>particle size distribution</td>
<td>&lt;75µ, 15%; 75,µ, 52.2%; 125,µ, 28.4%; 250,µ, 5.6%; 500,µ, 0.6%; 1000,µ, 0.2%</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>solubility</td>
<td>soluble in water</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>melting point</td>
<td>140°C (powder form)</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>specific gravity</td>
<td>0.99 to 1.03 (25° /25°C)</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>Exposure Type</td>
<td># of Uses</td>
<td>Max Conc of Use (%)</td>
<td># of Uses</td>
</tr>
<tr>
<td>------------------------</td>
<td>-----------</td>
<td>---------------------</td>
<td>-----------</td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Incidental Inhalation</td>
<td>16</td>
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Table 3. Current and historical frequency and concentration of use according to duration and exposure
Table 3. Current and historical frequency and concentration of use according to duration and exposure

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<tr>
<th></th>
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<th># of Uses</th>
<th>Max Conc of Use (%)</th>
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<td>2015**</td>
<td>2016**</td>
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<tr>
<td>Baby Products</td>
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</tr>
</tbody>
</table>

*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.

**Concentration of use data were not available at the time of the original assessment.

* Includes products that can be sprays, but it is not known whether the reported uses are sprays

† Not specified whether this product is a spray or a powder or neither, but it is possible it may be a spray or a powder, so this information is captured for both categories of incidental inhalation

‡ Includes products that can be powders, but it is not known whether the reported uses are powders

NR – not reported

Table 4. Ingredients Currently Not Reported to be Used

Ammonium Cocoyl Sarcosinate
Potassium Cocoyl Sarcosinate†
Potassium Lauroyl Sarcosinate‡
Sodium Oleoyl Sarcosinate‡

*not previously reviewed
REFERENCES


