Safety Assessment of Fatty Acids & Soaps as Used in Cosmetics

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All interested persons are provided 60 days from the above date to comment on this safety assessment and to identify additional published data that should be included or provide unpublished data which can be made public and included.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 All unpublished data submitted to CIR will be discussed in open meetings, will be available at the CIR office for review by any interested party and may be cited in a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 Executive Director, Dr. Bart Heldreth.

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INTRODUCTION

Most of the fatty acids and soaps (i.e. fatty acid salts) detailed in this safety assessment are reported to function as anticaking agents, emulsion stabilizers, viscosity increasing agents, opacifying agents, and surfactants, according to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI; *Dictionary*; see Table 1).[1] Additional functions included hair and skin conditioning agents, binders, slip modifier, antioxidants, fragrance ingredients, colorants, skin protectants, cosmetic biocide, and film formers. Functions such as oral health care drug (for Isomerized Safflower Acid) and antifungal agent (for Calcium Undecylenate and Undecylenic Acid) are not considered cosmetic functions in the United States (US) and, therefore, do not fall under the purview of the Cosmetic Ingredient Review (CIR). This assessment of the safety of the following 102 fatty acid and soap ingredients is based on the data contained in this report:

Aluminum Dilinoleate
Aluminum Distearate
Aluminum Isostearate
Aluminum Isostearates/Palmitates
Aluminum Isostearates/Stearates
Aluminum Isostearates/Laurates/Palmitates
Aluminum Isostearates/Laurates/Stearates
Aluminum Lanolate
Aluminum Stearate
Aluminum Stearates
Aluminum Tristearate
Ammonium Isostearate
Ammonium Oleate
Ammonium Stearate
Arachidic Acid
Beeswax Acid
Behenic Acid
C14-28 Alkyl Acid
C10-40 Isoalkyl Acid
C14-28 Isoalkyl Acid
C32-36 Isoalkyl Acid
Calcium Behenate
Calcium Laurate
Calcium Stearate
Calcium Undecylenate
Capric Acid
Caproic Acid
Caprylic Acid
Dilinoleic Acid
Dierucic Acid
Eicosatrienoic Acid
Erucic Acid
Hydroxycapric Acid
Hydroxycaprylic Acid
10-Hydroxydecanoic Acid
Hydroxylauric Acid
Hydroxystearic Acid
10-Hydroxystearic Acid
Isomerized Linoleic Acid
Isomerized Safflower Acid
Isostearic Acid
Lauric Acid
Linoleic Acid
Linolenic Acid
Lithium Stearate
Magnesium Lanolate
Magnesium Laurate
Magnesium Palmitate
Magnesium Stearate
Magnesium Tallowate
Myristic Acid
Methyl Myristic Acid
Oleic Acid
Palmitic Acid
Potassium Behenate
Potassium Borageate
Potassium Camelliate
Potassium Caprate
Potassium Caprylate
Potassium Caprylate/Caprate
Potassium Castorate
Potassium Hydrogenated Tallowate
Potassium Hydroxystearate
Potassium Isostearate
Potassium Lanolate
Potassium Laurate
Potassium Linoleate
Potassium Linseedate
Potassium Oleate
Potassium Olivate/Sunflowerseedate
Potassium Palmitate
Potassium Stearate
Potassium Sunflowerseedate
Potassium Tallate
Potassium Tallowate
Potassium Undecylenate
Sodium Arganate
Sodium Beeswax
Sodium Behenate
Sodium Camellia Japonica Seedate
Sodium Caprate
Sodium Caprylate
Sodium Castorate
Sodium Dilinoleate
Sodium Hydrogenated Tallowate
Sodium Hydroxystearate
Sodium Isostearate
Sodium Lanolate
Sodium Lardate
Sodium Laurate
Sodium Laurate/Linoleate/Oleate/Palmitate
Sodium Linoleate
Sodium Oleate
Sodium Palmitate
Sodium Stearate
Sodium Tallowate
Sodium Tamanuseedate
Sodium Undecylenate
Stearic Acid
Trilinoleic Acid
Undecanoic Acid
Undecylenic Acid

Several of the ingredients included in this report have been previously reviewed (denoted in red above) by the CIR Expert Panel (Panel);[2-10] moreover, several related ingredients have also been reviewed.[11-17] The conclusions of these reviews have been provided in Table 2. Pertinent data from the previously reviewed ingredient reports relevant to the evaluation of the safety of the ingredients in this report have been summarized in the appropriate sections in *italics.* Note: the Panel has previously reviewed the safety of Arachidonic Acid; however, this ingredient is not included in this assessment because the Panel found the data were insufficient to determine safety.[18] The conclusion was subsequently changed to "Use Not Supported by the Data and Information Submitted to the CIR," per the CIR Procedures.

The fatty acid ingredients described in this safety assessment are ubiquitous in food as dietary fats. The US Food and Drug Administration (FDA) determined that several of the fatty acids and salts of fatty acids are approved as food additives permitted for direct addition to food for human consumption (see the Non-Cosmetic Use section for the complete list). Daily consumption of these ingredients would result in much larger systemic exposures than what is expected from use in cosmetic products, even if there was 100% absorption. A sampling of the systemic toxicity via oral exposure has been included in this report; however, the primary focus of the safety assessment of the ingredients that are approved direct food additives is based on topical exposure and local effects.

The available data in the published literature on fatty acids is voluminous. For this scientific literature review, a representative sampling of the most pertinent data has been included. Additional relevant data may be added in subsequent drafts. This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an exhaustive search of the world's literature. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that CIR typically evaluates, is provided on the CIR website (http://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; http://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

Some chemical and toxicological data on the fatty acids and soaps included in this safety assessment were obtained from robust summaries of data submitted to the European Chemical Agency (ECHA) by companies as part of the REACH chemical registration process.[19-32] Additionally, some data were obtained from an assessment by the Organisation for Economic Co-Operation and Development Screening Information Data Sets (OECD SIDS).[33-35] These data summaries are available on the ECHA and OECD SIDS websites, respectively, and when deemed appropriate, information from the summaries has been included in this report.

CHEMISTRY

Definitions and Structures

The definitions and structures of the fatty acids and soaps in this safety assessment are detailed in Table 1. Fatty acids, or aliphatic acids, consist of a carboxylic acid group at the polar end and a non-polar hydrocarbon chain.[35] The general structure for these acids in mono form is:

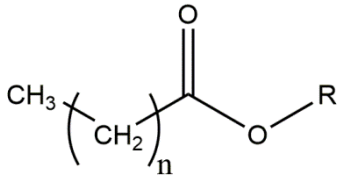


Figure 1. Generic fatty acid/salt structure (wherein R is a hydrogen atom or an ammonium, sodium, potassium, magnesium, or calcium cation. The chain lengths for fatty acids are 4 to 22 carbons in length (i.e. n is 2 to 20)).

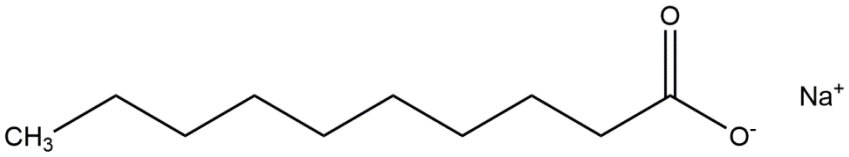


Figure 2. Specific example of a fatty acid salt (soap) with a 10 carbon chain length, Sodium Caprate

Physical and Chemical Properties

The available physical and chemical properties of many of the fatty acids in this report are found in Table 3. Generally, as alkyl chain lengths increase in fatty acids, melting points and boiling points increase, while water solubility and vapor pressure decrease.[35] Additionally, within a given carbon chain length, melting points increase with increasing saturation and decrease with increasing unsaturation.

Method of Manufacturing

Fatty acids occur naturally in animal and plant biochemistry, including synthesis in tissues such as the skin.[36] Fatty acids are usually produced by the hydrolysis of common animal and vegetable fats and oils followed by fractionation of the resulting fatty acids.[7] Fatty acids that are used in foods, drugs and cosmetics normally exist as mixtures of several fatty acids depending on the source and manufacturing process.

Lauric Acid

Lauric Acid is produced by the hydrolysis, usually via saponification, of animal or vegetable fats and oils followed by fractional distillation.[7] Lauric Acid is commonly isolated from coconut oil, and several patents describe its chemical synthesis.

Myristic Acid

The following methods have been used in the preparation of Myristic Acid: isolation from tail-oil fatty acids from 9-ketotetradecanoic acid, by electrolysis of a mixture of methyl hydrogen adipate and decanoic acid, by Maurer oxidation of myristanol, and from cetanol.[7] The most common means of preparation is by fractional distillation of hydrolyzed coconut oil, palm kernel oil, or coconut acids.

Oleic Acid

Oleic Acid is produced by the hydrolysis and fractionation (e.g., saponification and distillation) of animal or vegetable fats and oils.[7] Preparation of Oleic Acid from animal tallow and olive has been reported. It is also obtained as a by-product in the manufacture of solid Stearic and Palmitic Acids. Crude (i.e., unpurified, unbleached) Oleic Acid of commerce contains Stearic and Palmitic Acids in varying quantities.

Palmitic Acid

Palmitic Acid is produced by the hydrolysis and fractionation of palm oil, tallow oil, coconut oil, Japan wax, Chinese vegetable tallow, and spermaceti.[7] Fractionation is usually by distillation or crystallization. Palmitic Acid can also be obtained in the manufacturing process for Stearic Acid.

Stearic Acid

Methods of processing for Stearic Acid include hydrolysis of tallow or hydrogenation of unsaturated fatty acids (e.g., Oleic Acid) in cottonseed and other vegetable oils, followed by methods of isolation, such as fractional distillation or crystallization.[7] A successive series of pressing operations has been used to separate the liquid unsaturated fatty acids from the solid saturated fatty acids. The Palmitic Acid/Stearic Acid ratio obtained from tallow hydrolysis and triple-pressing or solvent crystallization is 55%/45%. Concentrations of Stearic Acid as high as 95-99% have been reported from the hydrogenation of unsaturated fatty acids.

Composition/Impurities

Beeswax Acid

Unhydrolyzed beeswax produced by the honeybee, *Apis melifera*, contains 23% hydrocarbons, 45% wax monoesters, 6% diesters of long chain alcohols with Palmitic Acid, 1% free alcohols, and 12% free acids.[37] Palmitic Acid is the major acid found in the ester fraction.

Behenic Acid

The major impurities reported for Behenic Acid (86% pure) are C_{12}-C_{20} fatty acids (~11%).[33]

USE

Cosmetic

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

According to 2018 VCRP data, Stearic Acid has the most reported uses in cosmetic products with a total of 5738; the majority of the uses are in leave-on eye makeup preparations and skin care products (Table 4 and Table 5).[38] The reported frequency of use of this ingredient has more than doubled since it was last reviewed; Stearic Acid had a total of 2133 reported uses in 2006, the majority of which were also in leave-on eye makeup preparations and skin care products.[8] Palmitic Acid has the second greatest number of reported uses with 1240; the majority of the uses are in leave-on eye makeup preparations and skin care products.[38] Again use of this ingredient has increased significantly since it was last reviewed; in 2006, Palmitic Acid had a total of 132 reported uses, the majority of those uses were in rinse-off products.[8]

The results of the concentration of use survey conducted in 2016 by the Council indicate that Sodium Laurate/Linoleate/Oleate/Palmitate is used at up to 84.7% in bath soaps and detergents and at up to 74.5% in leave-on baby products.[39] According to that survey, Stearic Acid was reported to be used at up to 37.4% in rinse-off products (bath soaps and detergents) and at up to 21% in leave-on products (eyebrow pencil). Use concentrations have slightly decreased since the last review of Stearic Acid in 2006, where Stearic Acid was reported to be used at up to 43% in rinse-off products (shaving cream) and 22% in leave-on products (eyeliners).[8] In 2016, Palmitic Acid was reported to be used at up to 21% in both rinse-off and leave-on products (skin cleansing preparations and fragrance products, respectively);[39] whereas in 2006, Palmitic Acid was reported to be used at up to 20% in rinse-off products (shaving cream) and 16% in leave-on products (lipsticks), indicating a slight increase in use concentration.[8] Since last reviewed, the highest concentration of use for Sodium Stearate in leave-on products has increased from 25% (in deodorants) to 84% (in fragrance preparations).[2,39] Ingredients with no reported uses in the VCRP or by Council are listed in Table 6.

Many of the fatty acid and soap ingredient described in this safety assessment may be used in products that can be incidentally ingested or come into contact with mucous membranes; for example, use is reported in lipsticks, bath preparations, and bath soaps and detergents. In 2016, Behenic Acid was reported to be used at up to 14% in lipstick and Sodium Laurate/Linoleate/Oleate/Palmitate was reported to be used at up to 84.7% in bath soaps and detergents.[39] Additionally, these ingredients have been reported to be used in products that may come into contact with the eyes, such as eyebrow pencils, eyeliners, mascara, and eye shadows. In 2016, Behenic Acid was reported to be used at up to 22% in eyebrow pencils and Hydroxystearic Acid was used at up to 14% in eyeshadows.

Fatty acids and soaps were reported to be used in cosmetic sprays and powders; including skin, deodorant, and fragrance products, and could possibly be inhaled. For example, Stearic Acid was reported to be in face and neck sprays at up to 3%, Oleic Acid was reported to be in spray deodorants at up to 1.5%, and Magnesium Stearate was reported to be in face powders at up to 7.2%.[39] 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 below 10 µm compared with pump sprays.[40-43] Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.[40,41] There is some evidence indicating that deodorant spray products can release substantially larger fractions of particulates having aerodynamic equivalent diameters in the range considered to be respirable.[40] However, the information is not sufficient to determine whether significantly greater lung exposures result from the use of deodorant sprays, compared to other cosmetic sprays. 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.[44-46]

In regulations on cosmetic products in the European Union, Aluminum Stearate, Calcium Stearate, and Magnesium Stearate are listed on Annex IV: list of colorants allowed in cosmetic products in the EU.[47] Calcium Undecylenate, Potassium Undecylenate, Sodium Undecylenate, and Undecylenic Acid are listed on Annex V: list of preservatives allowed in cosmetic products with the maximum concentration in ready for use preparation restricted to 0.2% as acid. The remaining fatty acid and soap ingredients listed in this report are not restricted from use in any way under the rules governing cosmetic products in the European Union.

According to Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the following ingredients are Tier I chemicals (not considered to pose an unreasonable risk to the health of workers and public health on the basis of the Tier I IMAP assessment): Ammonium Stearate, Arachidic Acid, Behenic Acid, Calcium Behenate, Calcium Laurate, Calcium Stearate, Erucic Acid, Hydroxystearic Acid, Isostearic Acid, Lauric Acid, Linoleic Acid, Linolenic Acid, Magnesium Laurate, Magnesium Palmitate, Magnesium Stearate, Myristic Acid, Oleic Acid, Palmitic Acid, Potassium Caprylate, Potassium Castorate, Potassium Hydrogenated Tallowate, Potassium Laurate, Potassium Oleate, Potassium Palmitate, Potassium Stearate, Potassium Tallate, Potassium Tallowate, Sodium Caprylate, Sodium Castorate, Sodium Hydrogenated Tallowate, Sodium Isostearate, Sodium Laurate, Sodium Oleate, Sodium Palmitate, Sodium Stearate, Sodium Tallowate, Stearic Acid, and Undecylenic Acid.[48] The remaining fatty acids and soaps listed in this report do not have a NICNAS determination.

Non-Cosmetic

Regulations applicable to the use of fatty acids and soaps in food, feed, drugs and pesticides in the US are summarized in Table 7. Non-cosmetic uses of the fatty acid and soap ingredients listed in this report are found in Table 8. According to 21 CFR §172.515, §172.615, §172.860, §172.862,§172.863, the US FDA determined that the following ingredients are food additives permitted for direct addition to food for human consumption: Aluminum Distearate, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearate, Calcium Laurate, Calcium Stearate, Capric Acid, Caprylic Acid, Caproic Acid, Lauric Acid, Magnesium Palmitate, Magnesium Stearate, Myristic Acid, Oleic Acid, Palmitic Acid, Potassium Caprate, Potassium Laurate, Potassium Oleate, Potassium Palmitate, Potassium Stearate, Sodium Caprate, Sodium Laurate, Sodium Oleate, Sodium Palmitate, Sodium Stearate, Stearic Acid, and Undecylenic Acid.

TOXICOKINETICS

Dermal Penetration

Sodium Stearate

Sodium Stearate is absorbed through both rat and human skin.[3]

Penetration Enhancement

Oleic Acid

Oleic Acid has been studied for its ability to act as a penetration enhancer for use in topical drug delivery.[49]

Sodium Caprate

Sodium Caprate is reported to be an oral absorption promoter that has potential for use in oral drug products containing poorly permeable molecules.[50]

Myristic Acid

Myristic acid enhanced the dermal penetration of several drugs.[7,9]

Absorption, Distribution, Metabolism, Distribution

Fatty acids share a common degradation pathway in which they are metabolized to acetyl-Coenzyme A (acetyl-CoA) or other key metabolites that are structurally similar breakdown products.[35] No differences in metabolism are expected between even and odd numbered carbon chain compounds or saturated and unsaturated compounds.

Calcium Stearate

Limited absorption studies indicated that Calcium Stearate is slightly absorbed by isolated dog intestine.[3]

Lauric Acid, Oleic Acid, Palmitic Acid, Stearic Acid

Fatty acids are absorbed, digested, and transported in animals and humans.[7] *Radioactivity from labeled fatty acids administered orally, intravenously, intraperitoneally, and intraduodenally has been found in various tissues and in blood and lymph. P-Oxidation of the fatty acids involves serial oxidation and reduction reactions yielding acetyl-CoA. High intake of dietary saturated fatty acids has been associated with the incidence of atherosclerosis and thrombosis.*

Hydroxystearic Acid

In male rats fed a diet containing hydrogenated castor oil, Hydroxystearic Acid was deposited in abdominal fat, as well as other body lipids, along with its metabolities (hydroxypalmitic acid, hydroxymyristic acid, and hydroxylauric acid).[4] *Hydroxystearic Acid has also been detected in the feces of 12 subjects who presumably ate a normal mixture of foods.*

Isostearic Acid

Studies with rat liver homogenate suggest Isostearic Acid is readily metabolized following ingestion.[5]

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Acute dermal and oral studies of several fatty acid and soap ingredients are summarized in Table 9. In dermal studies of Capric Acid, Lithium Stearate, Stearic Acid, and Undecylenic Acid, the LD_{50} values were greater than 200 mg/kg/bw.[22,27,29,31] The LD_{50} values in oral studies of numerous fatty acid and soap ingredients were well above the doses tested.[19,21,22,24-29,31,34,51]

Lauric Acid, Oleic Acid, Palmitic Acid, Stearic Acid

Little acute toxicity was observed when Oleic Acid, Lauric Acid, Palmitic Acid, Myristic Acid, or Stearic Acid, or cosmetic formulations containing these fatty acids at concentrations of 2.2 - 13% were given to rats orally at doses of 15,000 - 19,000 mg/kg body weight.[7]

Results from single topical applications of Oleic Acid (at concentrations up to 50%) to the skin of mice, rabbits, and guinea pigs ranged from no toxicity to signs of erythema, hyperkeratosis, and hyperplasia.[7] *An acute intradermal administration to guinea pigs of up to 25% Oleic Acid resulted in local inflammation and necrosis. A formulation containing 2.2% Palmitic Acid was considered nontoxic to rabbits in an acute dermal study. A single topically applied dose of 5 g/kg commercial grade Stearic Acid was not toxic to rabbits. An acute intradermal administration of 10-100 mM Stearic Acid to guinea pigs and rabbits resulted in mild erythema and slight induration.*

Aluminum Stearate, Ammonium Stearate, Lithium Stearate, Magnesium Stearate, and Sodium Stearate

Acute oral studies with rats showed that Aluminum, Ammonium, Lithium, Magnesium, and Sodium Stearates are practically nontoxic.[3] Studies with guinea pigs demonstrated that 100% Aluminum Stearate and 100% Ammonium Stearate have a low potential for acute dermal toxicity.

Isostearic Acid

In rats, the acute oral LD_{50} of Isostearic Acid is estimated to be greater than 32 ml/kg.[5]

Short-Term and Subchronic Toxicity Studies

Repeated dose short-term and subchronic dermal and oral studies of several fatty acid and soap ingredients are summarized in Table 10. The no-observable-adverse effect level (NOAEL) in a dermal study of Lithium Stearate in rats was $\geq$ 1000 mg/kg bw/day for systemic effects, but the NOAEL for local effects was 100 mg/kg bw/day.[27] The NOAEL for Behenic Acid, Calcium Stearate, and Capric Acid was greater than or equal to the highest doses tested in oral studies.[21,22,34] In oral gavage studies with Sodium Undecylenate, the NOAEL was $\leq$ 50 mg/kg bw/day with adverse effects including dose-dependent clinical signs of toxicity and adverse effects in the forestomaches of high dose groups.[31] Conjugated Linoleic Acid tested at 1% in feed did not cause adverse effects in rats.[52] An 8 week dietary study of up to 2.5% Undecylenic Acid reported "inhibition of growth."[51]

Lauric Acid, Oleic Acid, Palmitic Acid, Stearic Acid

In subchronic oral toxicity studies, Oleic Acid, Palmitic Acid, and Stearic Acid were fed to rats in diets at concentrations ranging from 5 to 50%.[7] Thrombosis, aortic atherosclerosis, anorexia, and mortality were observed. In a subchronic study, no signs of toxicity were observed in chicks fed 5% dietary Stearic and Oleic Acids.

No deaths or significant gross or microscopic alterations were observed among New Zealand White rabbits after 4 weeks of topical administration of product formulations containing 2.0% Stearic Acid.[7] No abnormal physiological parameters were noted in a 13-week dermal toxicity study in rats of 2 cosmetic product formulations containing, at most, 5% Stearic Acid.

Calcium Stearate

An emulsion of Calcium Stearate in egg yolk and water applied to the skin of guinea pigs for 14 days caused a significant decrease in body weight.[3] Calcium Stearate administered intratracheally to rats for 2 and 4 months caused varying degrees of lung pathology.

Hydroxystearic Acid

Reduced growth rate was noted in rats fed diets containing 8.7% and 17.3% Hydroxystearic Acid, but not in rats fed 4.3% Hydroxystearic Acid, in a 90-day subchronic oral toxicity study.[4] The results of a second 90-day experiment (no reduction in growth rate) confirmed that the reduction in growth rate previously observed was due to the lower caloric density of diets consisting of 8.7% and 17.3% Hydroxystearic Acid. In both experiments, the results of hematologic and microscopic evaluations were unremarkable.

Chronic Toxicity Studies

Oleic Acid

Feeding of 15% dietary Oleic Acid to rats in a chronic study resulted in normal growth and general health.[7]

Calcium Stearate

Calcium Stearate administered intratracheally to rats for 6 and 8 months caused varying degrees of lung pathology.[3]

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES

Dermal and oral DART studies of several fatty acid and soap ingredients are summarized in Table 11. Lithium Stearate caused no treatment-related adverse reproductive or developmental effects at doses up to 1000 mg/kg bw/day in dermal studies.[27] While non-reproductive effects were noted in parental animals in a few oral studies, no treatment-related adverse effects were observed on the reproductive cycles or development of offspring in rats exposed to Behenic Acid (up to 1000 mg/kg/day), Calcium Stearate (up to 1000 mg/kg/day), Capric Acid (up to 2000 mg/kg/day), Caprylic Acid (up to 1000 mg/kg/day), or Undecylenic Acid (up to 1000 mg/kg/day).[21,22,24,31,34,53]

Lauric Acid, Myristic Acid, Oleic Acid, Palmitic Acid, Stearic Acid

Although placental transfer of fatty acids has been documented in several species and fetal lipid metabolism has been studied, no studies on the teratogenicity of Oleic, Lauric, Palmitic, Myristic, or Stearic Acids were found.[7] Feeding of 15% dietary Oleic Acid to rats in a chronic study resulted in impairment in the reproductive capacity of female rats. Little or no

toxicity to sperm cells by Oleic Acid, Palmitic Acid, and Stearic Acid were observed in studies reported in the re-review of these ingredients.[8]

Magnesium Stearate

When fed to female rabbits 8 days post-coitus, a pharmaceutical vehicle containing 5.5% by weight Magnesium Stearate was not teratogenic.[3]

Hydroxystearic Acid

The dermal teratogenicity of two antiperspirant prototype formulations containing 7% Hydroxystearic Acid was evaluated using 2 groups of 30 Charles River Crl:CD VAF/Plus female rats.[4] *There were no test article-related or statistically significant differences in the incidence of fetal malformations or fetal developmental variations between experimental and control groups. Skin irritation reactions, however, were observed in greater than 50% of the dams in both experimental groups. No deaths were reported during the study.*

GENOTOXICITY STUDIES

Genotoxicity studies of several fatty acid and soap ingredients are summarized in Table 12. In vitro bacterial cell and mammalian cell assays were negative for genotoxicity, with and without metabolic activation, in Ammonium Oleate (up to 333 µg/plate), Behenic Acid (up to 5000 µg/plate), Calcium Stearate (up to 312.5 µg/plate), Capric Acid (up to 10, 000 µg/plate), Caproic Acid (up to 10,000 µg/plate), Caprylic Acid (up to 3333 µg/plate), Isomerized Linoleic Acid (up to 2500 µg/plate), Lauric Acid (up to 2500 µg/plate), Linoleic Acid (dose not reported), Lithium Stearate (up to 5000 µg/plate), Myristic Acid (dose not reported), and Undecylenic Acid (up to 750 µg/plate) .[19,21-23,23-27,31,34,54,55] No genotoxicity was detected in an oral micronucleus assay in mice with up to 4000 mg/kg Undecylenic Acid in 10% gum arabic.[31]

Lauric Acid, Oleic Acid, Stearic Acid

Although Oleic Acid and Lauric Acid induced mitotic aneuploidy in in vitro mutagenicity tests, both have been indicated as inhibitors of mutagenicity produced by positive controls, such as N-nitrosopyrrolidine and sodium azide, in other tests. Stearic Acid was inactive in aneuploidy induction tests and in the Ames test, and it did not inhibit mutagenicity, as did Oleic Acid and Lauric Acid. No increase of mitotic crossing-over events was induced by Oleic Acid, Lauric Acid, or Stearic Acid. Oleic Acid did not increase the number of sister chromatid exchanges over background.

Magnesium Stearate

Magnesium Stearate was not mutagenic in microbial tests with Salmonella typhimurium or Saccharomyces cerevisiae.[3]

Hydroxystearic Acid

Hydroxystearic Acid was not mutagenic in S. typhimurium strainsTA1535, TA100, TA1537, TA1538, and TA98.[4] *However, Hydroxystearic Acid was classified as mutagenic in Escherichia coli strain Hs30. Hydroxystearic Acid was not mutagenic in the L5178Y TK +/- mouse lymphoma assay, with or without metabolic activation, nor did it produce chromosome aberrations in Chinese hamster ovary cells, with or without metabolic activation.*

CARCINOGENICITY STUDIES

Sodium Oleate

In a 108 week drinking water study, groups of 50 male and 50 female F344 rats received 0%, 2.5%, or 5.0% Sodium Oleate.[56] Water consumption was recorded twice weekly and the rats were weighted every two or four weeks. Blood and urine samples were taken from 10 rats per sex per dose group prior to study termination for biochemical and hematological analyses. A necropsy was performed at study termination to examine for tumors or other lesions in the major organs and tissues.

Survival rates for the treated rats were comparable to the controls. While there was a slight reduction in body weight gains in male rats, there were no significant differences in growth curved of treated and control rats of either sex. Water consumption was slightly, but not significantly, depressed in both female treatment groups. The mean liver weight in the 5% male test group was statistically significantly lower than that of the males in the control and 2.5% test group. The mean thymus weight in the 5% female test group was statistically significantly higher than that of the females in the control and 2.5% test group. No statistically significant differences were observed between the treated rats of either sex and the control rats in the results of urine and serum analyses, hematology parameters, or in tumor incidences, except for pancreatic tumors. An increase in the incidence of pancreatic tumors was observed in both male dose groups when compared to the control group, but these were not significantly different from reported spontaneous incidences of these tumors in this strain of rat. The authors concluded that Sodium Oleate did not induce tumors in this drinking water study in rats.[56]

Lauric Acid, Oleic Acid, Palmitic Acid, Stearic Acid

In carcinogenicity studies, no malignant tumors were induced by repeated subcutaneous injections of 1-16.5 mg Oleic Acid in two species of mice. Intestinal and gastric tumors were found in mice receiving dietary Oleic Acid at daily concentrations up to 200 mg/mouse. Treatment of mice with repeated subcutaneous injections of 25 and 50 mg Lauric Acid was not carcinogenic. Low incidences of carcinomas, sarcomas, and lymphomas were observed in mice receiving single or repeated subcutaneous injections of 25 and 50 mg Palmitic Acid and up to 82 mg Stearic Acid. Feeding of up to 50 g/kg/day dietary Stearic Acid to mice was not carcinogenic.

Magnesium Stearate

Mice surviving 30-week implants of Magnesium Stearate pellets in the bladder had a bladder tumor incidence of 5.0%, but the incidence was no different than that caused by glass beads.

Hydroxystearic Acid

In an 18-month carcinogenicity study (subcutaneous study), Hydroxystearic Acid was classified as tentatively carcinogenic in Swiss-Webster mice.[4] Subcutaneous sarcomas were observed at the site of injection in 9 of the 28 mice (14 per dose group) that were alive at 6 months. All of the sarcomas were observed in the low-dose group (total dose of 4 mg delivered in a total of 8 ml tricaprylin for 80 weeks). The high-dose group received a total dose of 80 mg delivered in a total of 8 ml of tricaprylin. In a second study in which 9 A/He male mice received a total intraperitoneal dose of 60 mg Hydroxystearic Acid over a period of 4 weeks, the frequency of lung tumors was within the spontaneous occurrence.

OTHER RELEVANT STUDIES

Comedogenicity

Oleic Acid

Oleic Acid and its UVA-induced peroxides were associated with increased comedo formation on the treated ears of two species of rabbits.[7]

Isostearic Acid

A product formulation both with and without 2.5% Isostearic Acid was tested in a rabbit ear comedogenicity assay. The formulation without Isostearic Acid was irritating but did not produce comedones; however, the formulation with Isostearic Acid was both irritating and comedogenic.

Hepatotoxicity

Hydroxystearic Acid

In an in vitro study, Hydroxystearic Acid interfered with oxidative phosphorylation in rat liver mitochondria.[4] Oxidative phosphorylation was uncoupled and mitochondria were damaged.

DERMAL IRRITATION AND SENSITIZATION STUDIES

Dermal irritation and sensitization studies of several fatty acid and soap ingredients are summarized in Table 13. Several in vitro assays and animal irritation studies indicate that Caproic Acid, Caprylic Acid, Isostearic Acid, Lauric Acid, and Trilinoleic Acid may be irritating and/or corrosive, especially when used at high concentrations.[19,23,24,26,28,30,57-60] The salts Aluminum Tristearate and Lithium Stearate, however, were predicted to be not irritating and/or corrosive human epidermis models.[20,27] In human irritation studies, Lauric Acid at 50% induced erythema, edema, and scaling in a closed epicutaneous test; however, only slight erythema was observed in an open epicutaneous test of Lauric Acid at 80%.[26] No dermal irritation was observed in subjects exposed to Palmitic Acid at 50%.[28]

In local lymph node assays (LLNAs), Lithium Stearate (up to 10%) was not sensitizing; however, the results of tests with Hydroxystearic Acid (up to 50%) and Ammonium Oleate (up to 50%) indicate that these ingredients may induce sensitization. In guinea pig studies, reactions observed to Ammonium Oleate (up to 50%) and Hydroxystearic Acid (up to 10%) may have been due to irritation.[19,32] No sensitization was observed in guinea pig studies with Capric Acid (up to 40%), Lauric Acid (up to 2.5%), Sodium Undecylenate (up to 0.1%), Trilinoleic Acid (up to 75%), or Undecylenic Acid (up to 100%).[22,26,30,31]

Lauric Acid, Oleic Acid, Palmitic Acid, Myristic Acid, and Stearic Acid

In single insult occlusive patch tests for primary irritation, Stearic Acid at doses of 35-65% in vehicles and Lauric, Oleic, Palmitic, and Myristic Acids at 1-13% in cosmetic product formulations produced no to moderate erythema and slight, if any, edema in the skin of rabbits.[7] Slight increases in irritation were observed in the short-term repeated patch tests (daily for 3-14 days) of Oleic Acid (5%) and Myristic Acid (concentration not reported). Eighteen mmol% concentrations of the fatty acids topically applied to the of the external ear canals of albino rabbits for 6 weeks produced a range of responses, varying from no irritation with Stearic Acid to slight irritation with Myristic Acid and Palmitic Acid to defined erythema, desquamation, and persistent follicular keratosis with Oleic Acid and Lauric Acid. Slight local edema was observed among

New Zealand White rabbits after 4 weeks of topical administration of product formulations containing 2.0% Stearic Acid. In 13-week dermal toxicity studies, 2 cosmetic product formulations containing, at most, 5% Stearic Acid produced moderate skin irritation in rats receiving 4.0 ml/kg and 227 mg/kg doses.

In maximization studies with 2 cosmetic product formulations containing 5.08% Oleic Acid and 1.0% Stearic Acid, slight reactions were observed to challenge patches.[7] These formulations were considered weak, grade 1, sensitizers. In another maximization study, after intradermal induction and booster injections of a formulation containing 3.5% Stearic Acid, reactions to topical challenge applications of the formulation were few and minimal in intensity.

In clinical primary and cumulative irritation studies, 50% Oleic Acid, 50% Myristic Acid, and 40% Stearic Acid in mineral oil were nonirritating.[7] Mild to intense erythema in single insult occlusive patch tests, soap chamber tests, and 21-day cumulative irritation studies were produced by cosmetic product formulations containing Oleic Acid (up to 30%), Palmitic Acid (2.2%), Myristic Acid (up to 8%), or Stearic Acid (up to 13%). In clinical repeated insult patch tests (open, occlusive, and semiocclusive), maximization tests, and prophetic patch tests with cosmetic product formulations containing Oleic Acid, Lauric Acid, Palmitic Acid, and Stearic Acid at concentrations ranging from < 1 to 13%, no primary or cumulative irritation or sensitization was reported. Slight, if any, reactions were observed after challenge patching at original or adjacent sites on the upper backs or forearms of some subjects (approximately < 2%). Intensity of observed reactions to the formulations was not directly related to the concentrations of the fatty acid ingredients.

Myristic Acid

Myristic Acid (concentration not reported) was nonirritating in a single insult occlusive patch test and slightly irritating in a repeat open patch test on rabbits.[7,9] In clinical primary and cumulative irritation studies, Myristic Acid at up to 50% was nonirritating.

Stearate Salts

Skin irritation studies with rabbits demonstrated that 10% Aluminum Distearate in corn oil and 100% Ammonium Stearate were minimal and slight irritants, respectively, whereas 100% Magnesium Stearate and Sodium Stearate were non-irritating. When tested on rabbit skin at concentrations of 100%, Magnesium Stearate was found to be noncorrosive. In human studies, 7 out of 20 subjects exhibited minimal to mild skin erythema when tested with an aqueous solution of 1.5% Ammonium Stearate in a single-insult, 24 h patch test. In a similar study with 0.5% Sodium Stearate in aqueous solution, 4 out of 20 subjects demonstrated minimal to moderate skin erythema. In a 21 day patch test with 10 subjects, an aqueous bath soap and detergent solution containing 0.1% to 0.25% Sodium Stearate caused minimal skin irritation. An aqueous solution of the same formulation containing 0.3% to 0.75% Sodium Stearate caused no sensitization in 100 subjects. A stick deodorant containing 7% Sodium Stearate demonstrated low potential for human skin irritation and sensitization.

Hydroxystearic Acid

Skin irritation reactions to each of 3 antiperspirant prototype formulations, each containing 7% Hydroxystearic Acid, were observed in a human primary irritation patch test using 35 volunteers.[4] Semi-occluded patches produced reactions in as many as 9 of the subjects, whereas occluded patches produced reactions in as many as 17 individuals. Only 2 reactions were noted in the semi-occluded patch controls and only 1 in the occluded patch controls. Although the formulations reportedly contained the same concentration of Hydroxystearic Acid, there were small differences in the numbers of individuals reacting to each.

Isostearic Acid

Isostearic Acid at up to 100% produced no significant skin irritation in Draize rabbit irritation tests, whereas variable degrees of irritation were produced by product formulations containing Isostearic Acid.[5] In clinical studies, 100 subjects showed no signs of irritation after a 24 h single insult skin patch with undiluted Isostearic Acid, and product formulations containing up to 4% Isostearic Acid produced, at most, minimal irritation when similarly tested on a total of 221 subjects. In another study, 35% Isostearic Acid in mineral oil was neither an irritant nor a sensitizer in 168 subjects. Isostearic Acid at 10% in mineral oil was similarly not irritating or sensitizing to 103 subjects. Product formulations containing 2.5% to 2.85% Isostearic Acid produced no evidence of contact sensitization when tested in repeated insult patch tests on a total of 333 subjects.

PHOTOTOXICITY AND PHOTOSENSITIZATION

In Vitro

Lauric Acid and Sodium Laurate

In a validation study of the in vitro reactive oxygen species (ROS) assay and the 3T3 neutral red uptake phototoxicity test (3T3 NRU PT), Lauric Acid and Sodium Laurate were not predicted to cause phototoxicity or photoallergy.[61] These findings were supported by the results of an ultraviolet/visible light (UV/VIS) spectral analysis.

Animal and Human

Oleic Acid, Palmitic Acid, Stearic Acid

Skin lotion formulations containing 2.8% Stearic Acid were not photosensitizing to the skin of Hartley guinea pigs. Cosmetic product formulations containing 1 - 13% Oleic Acid, Palmitic Acid, or Stearic Acid produced no photosensitization in human subjects. There were slight reactions to a few induction patches.

Isostearic Acid

In a subset population of 25 individuals in an irritation and sensitization study in humans, 35% Isostearic Acid in mineral oil with exposure to UVA + UVB was not a photosensitizer.

OCULAR IRRITATION STUDIES

Ocular irritation studies for several fatty acid and soap ingredients are summarized in Table 14. Caproic Acid at 50% was corrosive in bovine corneas, but Lithium Stearate (concentration not reported) was predicted to be non-irritating in a human corneal model.[23,27] In rabbits, Caproic Acid (concentration not reported), Caprylic Acid (70%), Lauric Acid (up to 100%), Lithium Stearate (concentration not reported), Stearic Acid (iso-form; 100%), Sodium Undecylenate (33.2%), and Undecylenic Acid (concentration not reported) were mild to moderate ocular irritants.[22-24,26,27,31,62] Oleic Acid (at up to 0.1%) Palmitic Acid (concentration not reported) were not ocular irritants.[28,63]

Lauric Acid, Oleic Acid, Palmitic Acid, Myristic Acid, and Stearic Acid

In ocular irritation studies, Oleic Acid, Lauric Acid, Palmitic Acid, Myristic Acid, and Stearic Acid neat and at concentrations ranging from 1 to 19.4% in cosmetic product formulations produced no to minimal irritation after single and multiple (daily, 14-day) instillations into the eyes of albino rabbits. Irritation was primarily in the form of very slight conjunctival erythema. A single instillation of Lauric Acid also produced cornea1 opacity and iritis. In humans, there was no treatment-related ocular irritation in female subjects, some of whom were contact lens wearers, involved in two 3-week exaggerated-use studies of mascara formulations containing 2% and 3% Oleic Acid. These formulations were used in combination with other eye area cosmetics.

Myristic Acid

Myristic Acid in product formulations at a concentration of 1.5% was minimally irritating to the eyes of rabbits.[7,9]

Stearate Salts

Eye irritation studies with rabbits showed that 10% Aluminum Distearate in corn oil and 100% Ammonium Stearate and 100% Sodium Stearate were minimal to mild irritants; 100% Magnesium Stearate was non-irritating.

Isostearic Acid

Undiluted Isostearic Acid produced no significant eye irritation in Draize rabbit irritation tests, whereas variable degrees of irritation were produced by product formulations containing Isostearic Acid.

CLINICAL STUDIES

Case Reports

Hydroxystearic Acid

A patient presented with pruritic edematous erythema and scaling on the lips, and positive patch test reactions were reported with three of her lip gloss formulations.[64] Subsequent patch tests were performed with 21 lip gloss ingredients, and only Hydroxystearic Acid and C18-36 acid triglyceride, both tested at 10% in petrolatum and both present in all three lip gloss formulations, produced positive reactions (+ reaction on day 2 and day 3). Patch tests of these substances in 6 control subjects were negative.

In another case report, a patient presented with severe contact dermatitis from a lip balm and from a solid-stick underarm antiperspirant/deodorant.[65] Patch testing with ingredients from the lip balm resulted in positive results at 10% Hydroxystearic Acid in petrolatum. Subsequent patch testing with serial dilutions of Hydroxystearic Acid (99.7% pure) were positive to 0.001% in petrolatum. (A patch test with hydrogenated castor oil, an ingredient present in the deodorant formulation, was positive at 1% in petrolatum.)

Undecylenic Acid and Potassium Undecylenate

A 52-year-old white male patient present with intermittent scaling and itching between the toes following application of a therapeutic topical cream containing 10% Undecylenic Acid as free acid and potassium salt on two consecutive days.[66] On the third day, the dorsa of the feet became erythematous, edematous, and exudative. When application of the cream was halted, gradual healing occurred with local therapy. Slight residual erythema and fissuring at the base of the left third toe was apparent on day 10 post-application. When the patient resumed use of the cream on his feet, marked erythema, edema, and pruritus occurred within 24 h on the toes and dorsa of the feet. Pruritus and lesions disappeared three weeks after the second

discontinuation of the cream. Patch tests with materials from the patient's shoes were negative. Marked positive reactions were observed to the topical cream and a similar powder formulation. Patch tests with Potassium Undecylenate gave a marked positive reaction, but reactions to other preparations containing Undecylenic Acid, zinc undecylenate, copper undecylenate, potassium chloride, and potassium permanganate were negative

SUMMARY

Most of the 102 fatty acids and soap ingredients detailed in this safety assessment are reported to function as anticaking agents, emulsion stabilizers, viscosity increasing agents, opacifying agents, and surfactants. Additional functions included hair and skin conditioning agents, binders, slip modifier, antioxidants, fragrance ingredients, colorants, skin protectants, cosmetic biocide, and film formers.

The fatty acids that are used to derive the ingredients described in this safety assessment are ubiquitous in food as components of dietary fats. The US FDA determined that several of the fatty acids and salts of fatty acids are approved as food additives permitted for direct addition to food for human consumption. Daily consumption of these ingredients would result in much larger systemic exposures than what is expected from use in cosmetic products, even if there was 100% absorption. A sampling of the systemic toxicity via oral exposure has been included in this report; however, the primary focus of the safety assessment is the review of safety based on topical exposure and local effects.

Fatty acids occur naturally in animal and plant biochemistry, including synthesis in tissues such as the skin. Fatty acids are usually produced by the hydrolysis of common animal and vegetable fats and oils followed by fractionation of the resulting fatty acids. Fatty acids that are used in foods, drugs and cosmetics normally exist as mixtures of several fatty acids depending on the source and manufacturing process.

According to 2018 VCRP data, Stearic Acid has the most reported uses in cosmetic products with a total of 5738; the majority of the uses are in leave-on eye makeup preparations and skin care products. This ingredient had a total of 2133 reported uses in 2006; the majority of the uses were also in leave-on eye makeup preparations and skin care products. Palmitic Acid had the second greatest number of reported uses with 1240; the majority of the uses are in leave-on eye makeup preparations and skin care products. In 2006, Palmitic Acid had a total of 132 reported uses; the majority of the uses in rinse-off products such as shampoos, shaving products, and personal cleanliness products. The results of the concentration of use survey conducted in 2016 by the Council indicate that Sodium Laurate/Linoleate/Oleate/Palmitate is used at up to 84.7% in bath soaps and detergents and at up to 74.5% in leave-on baby products. Stearic Acid was reported to be used at up to 37.4% in rinse-off products (bath soaps and detergents) and at up to 21% in leave-on products (eyebrow pencil); and Palmitic Acid was reported to be used at up to 21% in both rinse-off and leave-on products (skin cleansing preparations and fragrance products, respectively). In 2006, Stearic Acid was reported to be used at up to 43% in rinse-off products (shaving cream) and 22% in leave-on products (eyeliners); and Palmitic Acid was reported to be used at up to 20% in rinse-off products (shaving cream) and 16% in leave-on products (lipsticks).

Fatty acids share a common degradation pathway in which they are metabolized to acetyl-CoA or other key metabolites that are structurally similar breakdown products. No differences in metabolism are expected between even and odd numbered carbon chain compounds or saturated and unsaturated compounds.

In dermal studies of Capric Acid, Lithium Stearate, Stearic Acid, and Undecylenic Acid, the LD_{50} values were greater than 200 mg/kg/bw. The LD_{50} values in oral studies of numerous fatty acid and soap ingredients were well above the doses tested.

The NOAEL in a dermal study of Lithium Stearate in rats was $\geq$ 1000 mg/kg bw/day for systemic effects, but the NOAEL for local effects was 100 mg/kg bw/day. The NOAEL for Behenic Acid, Calcium Stearate, and Capric Acid was greater than or equal to the highest doses tested in oral studies. In oral gavage studies with Sodium Undecylenate, the NOAEL was $\leq$ 50 mg/kg bw/day with adverse effects including dose-dependent clinical signs of toxicity and adverse effects in the forestomaches of high dose groups. A dated dietary study of Undecylenic Acid reported "inhibition of growth."

Lithium Stearate caused no treatment-related adverse reproductive or developmental effects at doses up to 1000 mg/kg bw/day in dermal studies. While non-reproductive effects were noted in parental animals in a few oral studies, no treatment-related adverse effects were observed on the reproductive cycles or development of offspring in rats exposed to Behenic Acid, Calcium Stearate, Capric Acid, Caprylic Acid, or Undecylenic Acid.

In vitro bacterial cell and mammalian cell assays were negative for genotoxicity in several different fatty acids and fatty acid salts. No genotoxicity was detected in a micronucleus assay in mice with Undecylenic Acid.

Several in vitro assays and animal irritation studies indicate that fatty acids may be irritating and/or corrosive, especially when used at high concentrations. The salts Aluminum Tristearate and Lithium Stearate, however, were predicted to be not irritating and/or corrosive human epidermis models. In human irritation studies, Lauric Acid at 50% induced erythema, edema, and scaling in a closed epicutaneous test; however, only slight erythema was observed in an open epicutaneous test of Lauric Acid at 80%. No dermal irritation was observed in subjects exposed to Palmitic Acid at 50%. In LLNAs, Lithium Stearate (up to 10%) was not sensitizing; however, the results of tests with Hydroxystearic Acid (up to 50%) and Ammonium Oleate (up to 50%) indicate that these ingredients may induce sensitization. In guinea pig studies, reactions observed to Ammonium Oleate (up to 50%) and Hydroxystearic Acid (up to 10%) may have been due to irritation. No sensitization was observed in guinea pig studies with Capric Acid (up to 40%), Lauric Acid (up to 2.5%), Sodium Undecylenate (up to 0.1%), Trilinoleic Acid (up to 75%), or Undecylenic Acid (up to 100%).

Caproic Acid at 50% was corrosive in bovine corneas, but Lithium Stearate (concentration not reported) was predicted to be non-irritating in a human corneal model. In rabbits, Caproic Acid (concentration not reported), Caprylic Acid (70%), Lauric Acid (concentration not reported), Lithium Stearate (concentration not reported), and Undecylenic Acid (concentration not reported) were ocular irritants of varying severity. Oleic Acid (up to 0.1%) and Palmitic Acid (concentration not reported) were not ocular irritants.

Case reports of reactions to Hydroxystearic Acid in lip products and deodorants and to Potassium Undecylenate in a topical cream have been reported.

PREVIOUS DISCUSSIONS

Lauric Acid, Oleic Acid, Palmitic Acid, Myristic Acid, and Stearic Acid

Although insufficient data were available for Myristic Acid, the Expert Panel included it in this safety assessment due to its structural similarity with the other fatty acids of this group.

Applications of Laurie and Oleic Acids to the skin of rabbits resulted in follicular keratosis and/or formation of comedones. These effects were considered by members of the Expert Panel in their safety assessment of the fatty acids reviewed in this report.

In the re-review summary, the Panel noted that these fatty acids may be plant-derived. In such cases, established limits for pesticide and heavy metal residues should not be exceeded (lead $\leq$ 10 ppm, arsenic $\leq$ 3 ppm, mercury $\leq$ 1 ppm, total PCB/pesticide $\leq$ 40 ppm, with $\leq$ 10 ppm for any specific pesticide residue).

The Panel also noted in the re-review summary that these fatty acids may also be derived from animal sources, including beef. The Panel agrees with the Food and Drug Administration's position that tallow derivatives, including these fatty acids, would not present any risk of transmissible encephalopathies.

Myristic Acid and Related Salts and Esters

The data on Butyl Myristate and the related salts and esters, coupled with the data on the related chemicals (Myristic Acid, Myristyl Myristate, and Isopropyl Myristate), are a sufficient basis for a safety assessment. The CIR Expert Panel believes that there is little toxicological and chemical difference between Myristic Acid and any of its inorganic salts included in this report. The salts are expected to dissociate in any product formulation, independent of whether the salt is aluminum, calcium, magnesium, potassium, sodium, or zinc. For the various esters of fatty alcohols and Myristic Acid, the CIR Expert Panel considers that these fatty acid esters are subject to hydrolysis to from Myristic Acid and the component fatty alcohols. It is the experience of the Panel in its review of fatty alcohols of varying length of carbon chains that there is little difference in toxicity. Accordingly, the available data were considered supportive of the safety of the entire group as used in cosmetics.

The Expert Panel recognized that use concentration data are not available for all ingredients in this group and that some ingredients in the group are not in current use. The Expert Panel considered that the use concentrations for the ingredients that are in use are not likely to be different from the use concentrations for other myristates. Were those ingredients not in current use to be used in the future, the Panel expects that they would be used in products and at concentrations similar to those reported.

The Expert Panel recognized that these ingredients 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.

A number of the ingredients in this report—Cetyl Myristate, Octyldodecyl Myristate, and Sodium Myristate—have uses that include sprays. There are no data available on inhalation toxicity for these ingredients or the other ingredients in this assessment. The Expert Panel determined that there is sufficient inhalation toxicity data on Isopropyl Myristate in its assessment demonstrating no inhalation toxicity. In addition to the inhalation toxicity data, the Panel determined that Butyl Myristate and the salts and esters can be used safely in hair sprays, because the ingredient particle size is not respirable. The Panel reasoned that the particle size of aerosol hair sprays (~38 µm) and pump hair sprays (>80 µm) is large compared with respirable particulate sizes (10 µm).

There are no data on the reproductive or developmental toxicity of Myristic Acid or its component parts for the derivatives. Based on structure-activity relationships, the Expert Panel considered that these chemicals had little potential for such toxicity when used as cosmetic ingredients.

Isopropyl Myristate was not genotoxic in the Ames assay. The Expert Panel determined this to be sufficient carcinogenicity data for the related ingredients in this safety assessment.

Aluminum Distearate, Aluminum Stearate, Aluminum Tristearate, Ammonium Stearate, Calcium Stearate, Lithium Stearate, Magnesium Stearate, Potassium Stearate, and Sodium Stearate

The opinion expressed in the [previous] conclusion is based on a composite of available animal and human data. However, the Panel felt that a number of the reported clinical studies for primary skin irritation and sensitization were suboptimal or inadequate in terms of number of subjects tested, concentrations tested, and/or test protocols employed. Data for the purpose of assessing the human skin sensitization potential of the Stearates were also limited in that only product formulation data were available. Further, no clinical studies relating to phototoxicity or photocontact allergenicity were

reported. Despite these limitations and/or deficiencies in the clinical data, it is the Panel's opinion that sufficient animal and human data are available to assess the safety of the Stearates as cosmetic ingredients.

Hydroxystearic Acid

Because of the paucity of information on Hydroxystearic Acid, the Expert Panel considered in its original assessment that the available data on related compounds might be used (e.g. Stearic Acid). Findings on long-chain aliphatic acids were taken from the published CIR report on Oleic Acid, Lauric Acid, Palmitic Acid, Myristic Acid, and Stearic Acid. Slight local edema and no deaths were observed among New Zealand White rabbits after 4 weeks of topical administration (dorsal skin) of product formulations containing 2.0% Stearic Acid. There were no significant gross or microscopic lesions that were considered treatment related. In 13-week dermal toxicity studies, two cosmetic product formulations containing, at most 5% Stearic Acid produced moderate skin irritation (dorsal skin) in rats receiving 4.0 ml/kg and 227 mg/kg doses. All other physiologic parameters were normal. Low incidences of carcinomas, sarcomas, and lymphomas were observed in mice receiving single or repeated subcutaneous injections of 25 and 50 mg Palmitic Acid and up to 82 mg Stearic Acid. Stearic Acid was not carcinogenic in mice fed dietary doses up to 50 g/kg/day. In clinical primary and cumulative irritation studies, Oleic, Myristic, and Stearic Acids at concentrations of 100% or 40 % to 50% in mineral oil were non-irritating. Mild to intense erythema in single insult occlusive patch tests, soap chamber tests, and 21-day cumulative irritation studies were produced by cosmetic product formulations containing 2%-93% Oleic, Palmitic, Myristic, or Stearic Acid and were generally not related to the fatty acid concentrations in the formulations. In clinical repeated insult patch tests, maximization tests, and prophetic patch tests with cosmetic product formulations containing Oleic, Lauric, Palmitic, and Stearic Acids at concentrations ranging from less than 1% to 13%, no primary or cumulative irritation or sensitization was reported. Additionally, cosmetic product formulations containing 1% to 13% Oleic, Palmitic, or Stearic Acid did not induce photosensitization; however, there were slight reactions to some induction patches.

Because of the possible influence of the hydroxyl group on toxicity, however, the Expert Panel determined that these data are not pertinent to the safety assessment of Hydroxystearic Acid. Accordingly, the CIR Expert Panel issued a Final Report in March 1995 concluding that the available data were insufficient to support the safety of Hydroxystearic Acid. The following data were considered necessary to make a safety assessment: (1) concentration of use; (2) chemical characterization; (3) a dermal teratogenicity study; (4) one genotoxicity test using a mammalian system (if the results of the genotoxicity test are positive, a dermal carcinogenicity test by NTP standards will be requested); and (5) skin irritation data.

Subsequently, new data inclusive of all of the above data needs were received. The Expert Panel, with data now available on the use of the ingredient, received the reproduction and developmental toxicity and genotoxicity data that found no significant effects at exposures likely to exceed that seen from expected cosmetic use concentrations. The sarcomas produced by subcutaneous injection of Hydroxystearic Acid were considered to be a physical phenomenon unrelated to the specific material injected and not relevant to the use of this ingredient in cosmetics. Under semi-occluded and occluded patch testing conditions, the Expert Panel recognized irritation was found with antiperspirant prototype formulations. It is the experience of the Expert Panel that such formulations under those exaggerated conditions do produce irritation, but are not generally irritating in actual use.

Isostearic Acid

The Panel expressed concern regarding the production of comedones in the rabbit ear assay by a product formulation containing commercially available Isostearic Acid.[5] *The Panel recognized that currently available tests are inadequate to predict the potential for human comedogenicity of an ingredient used in a product formulation. However, it is a potential health effect that should be considered when Isostearic Acid is used in cosmetic formulations.*

Tall Oil Acid, Sodium Tallate, Potassium Tallate, and Ammonium Tallate

The CIR Expert Panel recognized that there are limited animal and human toxicity data and dermal irritation/sensitization studies for Tall Oil Acid. Tall Oil Acid is, however, known to be composed of fatty acids for which safety test data were available.

When considered with the subchronic and chronic oral toxicity, reproductive and developmental toxicity, genotoxicity, carcinogenicity, and photosensitization studies available for Oleic Acid, Lauric Acid, Palmitic Acid, Myristic Acid, and Stearic Acid, the available data for Tall Oil Acid itself are a sufficient basis for reaching a conclusion regarding Tall Oil Acid. It is the experience of the Panel in its review of fatty acids of varying carbon chain lengths that there is little difference in toxicity.

The Panel also considered that there is little difference between members of this family of salts of Tall Oil Acid. The salts are expected to be dissociated in any product formulation independent of whether the salt is sodium, potassium, or ammonium. Accordingly, the available data for Tall Oil Acid are considered supportive of the safety of the entire group as used in cosmetics.

The CIR Expert Panel recognized that there are data gaps regarding use and concentration of these ingredients. However, the overall information available on the types of products in which these ingredients are used and at what concentrations indicates a pattern of use, which was considered by the Expert Panel in assessing safety.

DATA NEEDS

CIR is seeking any additional toxicological data, specifically dermal and ocular irritation and sensitization data on these cosmetic ingredients at use concentrations, which would help the CIR Expert Panel assess the safety of these ingredients as they are used in cosmetics and would improve the resulting safety assessment.

TABLES

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. [1,CIR Staff]

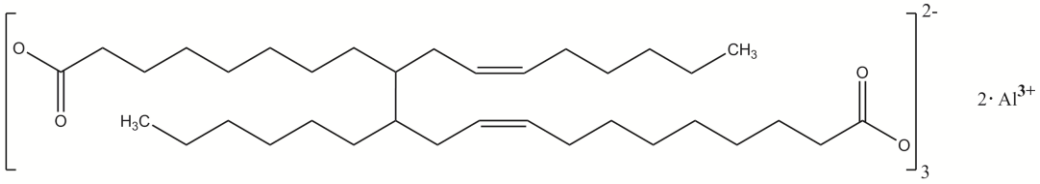
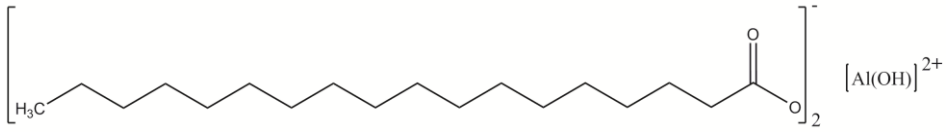
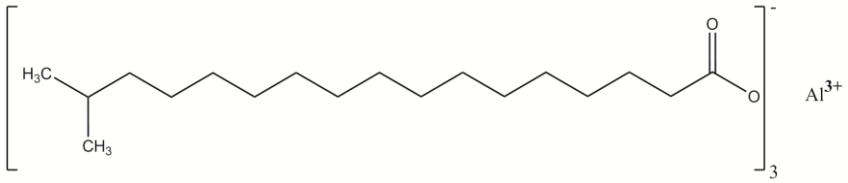
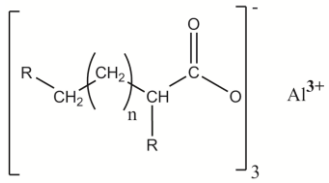
Ingredient & CAS No.	Definition & Structure	Function(s)
Aluminum Dilinoleate 53202-37-2	Aluminum Dilinoleate is the aluminum salt of Dilinoleic Acid 	anticaking agent; emulsion stabilizer; viscosity increasing agent – nonaqueous
Aluminum Distearate 300-92-5	Aluminum Distearate is an aluminum salt of stearic acid that conforms to the formula: 	anticaking agent; emulsion stabilizer; viscosity increasing agent – nonaqueous
Aluminum Isostearate 72277-75-9	Aluminum Isostearate is the aluminum salt of isostearic acid.  [one example of an "iso"]	anticaking agent; emulsion stabilizer; viscosity increasing agent – nonaqueous
Aluminum Isostearates/Palmitates	Aluminum Isostearates/Palmitates is the aluminum salt of a mixture of palmitic acid and isostearic acid.	anticaking agent; emulsion stabilizer; viscosity increasing agent – nonaqueous
Aluminum Isostearates/Stearates	Aluminum Isostearates/Stearates is the aluminum salt of a mixture of stearic acid and isostearic acid.	anticaking agent; emulsion stabilizer; viscosity increasing agent – nonaqueous
Aluminum Isostearates/Laurates/ Palmitates	Aluminum Isostearates/Laurates/Palmitates is the aluminum salt of a mixture of isostearic acid, lauric acid, and palmitic acid.	anticaking agent; emulsion stabilizer; viscosity increasing agent – nonaqueous
Aluminum Isostearates/Laurates/ Stearates	Aluminum Isostearates/Laurates/Stearates is the aluminum salt of a mixture of isostearic acid, lauric acid, and stearic acid.	anticaking agent; emulsion stabilizer; viscosity increasing agent – nonaqueous
Aluminum Lanolate	Aluminum Lanolate is the aluminum salt of lanolin acid. [The length of the Lanolin fatty acid chain varies from 7 to 41 carbon atoms, with the main fatty acids being palmitic (Cl6), stearic (Cl8) and longer molecules (C20 to C32).][13]  [wherein "n" is variable for the fatty acid composition of lanolin acid, and is in the range of 4 to 38; R is, in each case, hydrogen or hydroxyl, wherein at least one R is hydrogen; some fatty acids from lanolin acid may be branched][13]	anticaking agent; emulsion stabilizer; viscosity increasing agent – nonaqueous

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. [1,CIR Staff]

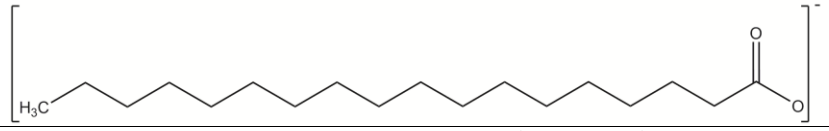
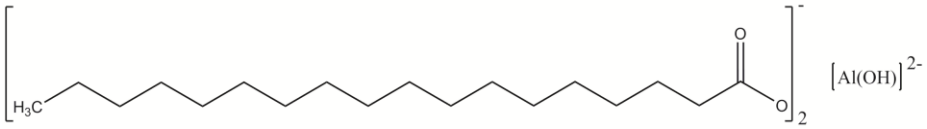
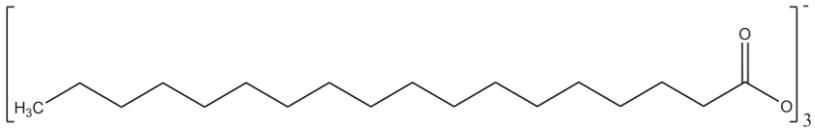
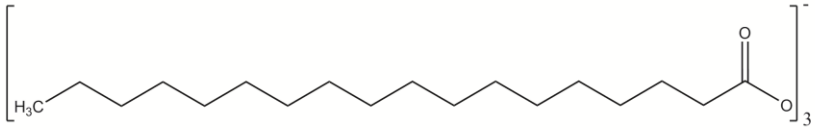
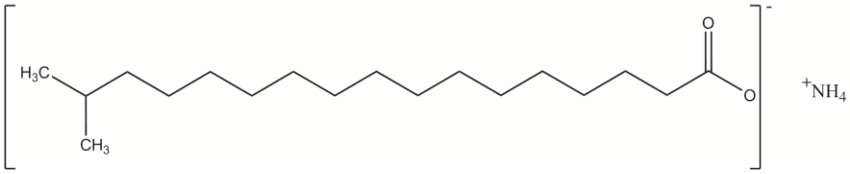
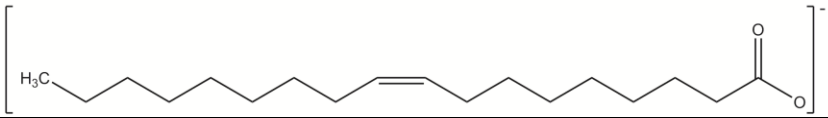
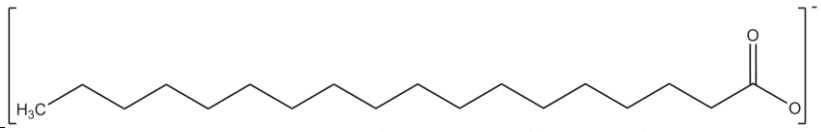
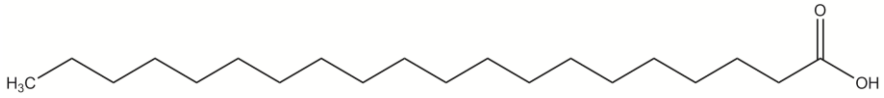
Ingredient & CAS No.	Definition & Structure	Function(s)
Aluminum Stearate 7047-84-9	Aluminum Stearate is the aluminum salt of stearic acid that conforms to the formula:  	anticaking agent; colorants; emulsion stabilizer; viscosity increasing agent – nonaqueous
Aluminum Stearates	Aluminum Stearates is a mixture of equal parts of aluminum distearate and aluminum tristate.  and  	anticaking agent; emulsion stabilizer; viscosity increasing agent – nonaqueous
Aluminum Tristearate 637-12-7	Aluminum Tristearate is the aluminum slat of stearic acid that conforms generally to the formula:  	anticaking agent; emulsion stabilizer; viscosity increasing agent – nonaqueous
Ammonium Isostearate	Ammonium Isostearate is the ammonium salt of isostearic acid.  one example of an "iso"	surfactant – cleansing agent
Ammonium Oleate 544-60-5	Ammonium Oleate is the ammonium salt of oleic acid that conforms to the formula:  	surfactant – cleansing agent
Ammonium Stearate 1002-89-7	Ammonium Stearate is the ammonium salt of stearic acid. It conforms to the formula:  	surfactant – cleansing agent
Arachidic Acid 506-30-9	Arachidic Acid is the fatty acid that conforms to the formula:  	opacifying agent; surfactant – cleansing agent

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. [1,CIR Staff]

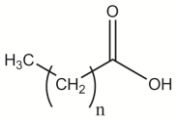
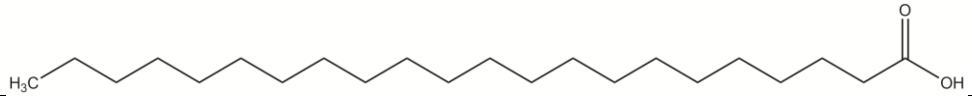
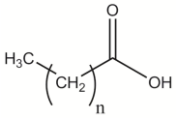
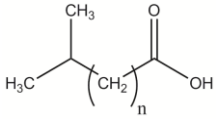
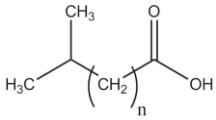
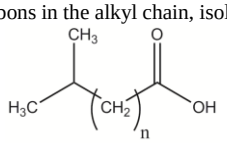
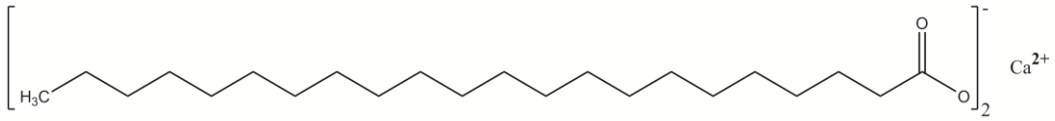
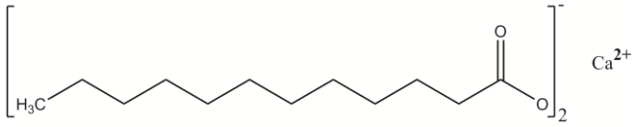
Ingredient & CAS No.	Definition & Structure	Function(s)
Beeswax Acid	Beeswax Acid is the acid portion obtained by the saponification of beeswax. It is composed of C24 to C36 straight-chain acids.  [wherein "n" is 22 to 34]	surfactant- cleansing agent; surfactant – emulsifying agent
Behenic Acid 112-85-6	Behenic Acid is the fatty acid that conforms generally to the formula: 	opacifying agent; surfactant – cleansing agent
C14-28 Alkyl Acid	C14-28 Alkyl Acid is a mixture of saturated fatty acids containing 14 to 28 carbons in the alkyl chain.  [wherein "n" is 12 to 26]	hair conditioning agent
C10-40 Isoalkyl Acid	C10-40 Isoalkyl Acid is a mixture of branched, saturated fatty acids with 10 to 40 carbons in the alkyl chain, isolated from lanolin acid.  [one example of an "iso"; wherein "n" is 7 to 37]	hair conditioning agent; skin-conditioning agent - emollient
C14-28 Isoalkyl Acid	C14-28 Isoalkyl Acid is a mixture of branched chain, saturated fatty acids containing 14 to 28 carbons in the alkyl chain.  [one example of an "iso"; wherein "n" is 11 to 25]	hair conditioning agent
C32-36 Isoalkyl Acid	C32-36 Isoalkyl Acid is a mixture of branched, saturated fatty acids with 32 to 36 carbons in the alkyl chain, isolated from lanolin acid.  [one example of an "iso"; wherein "n" is 29 to 33]	skin-conditioning agent – misc.
Calcium Behenate 3578-72-1	Calcium Behenate is the calcium salt of Behenic Acid. 	anticaking agent; viscosity increasing agent - nonaqueous
Calcium Laurate 4696-56-4	Calcium Laurate is the calcium salt of Lauric Acid. 	anticaking agent; emulsion stabilizer; viscosity increasing agent - nonaqueous

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. [1,CIR Staff]

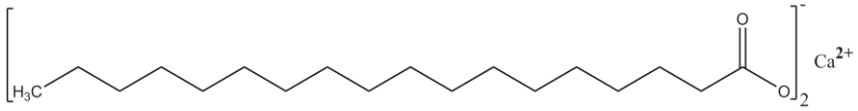
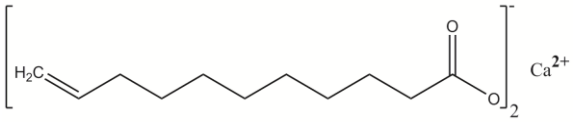
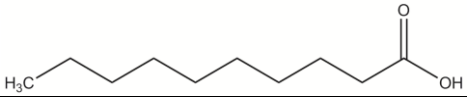
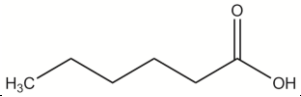
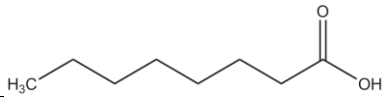
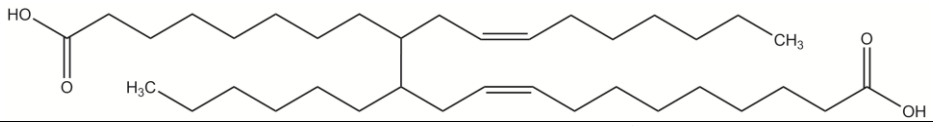
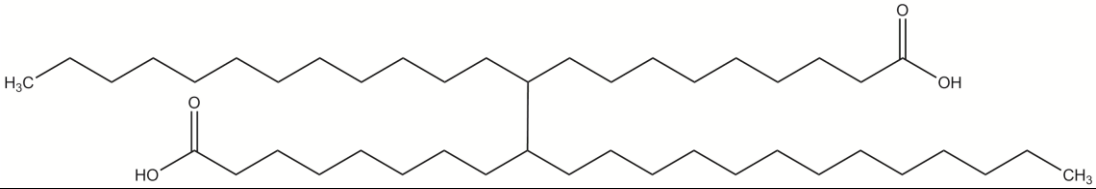
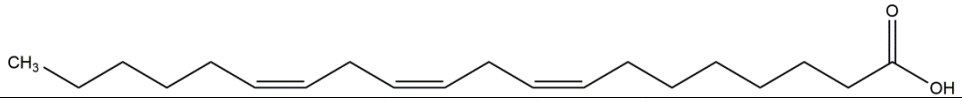
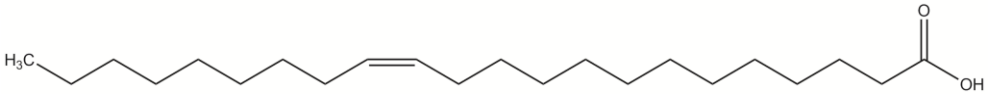
Ingredient & CAS No.	Definition & Structure	Function(s)
Calcium Stearate 1592-23-0	Calcium Stearate is the calcium salt of stearic acid. It conforms to the formula: 	anticaking agent; colorant; emulsion stabilizer; viscosity increasing agent - nonaqueous
Calcium Undecylenate 1322-14-1	Calcium Undecylenate is the organic salt that conforms to the formula: 	antifungal agent; viscosity increasing agent - nonaqueous
Capric Acid 334-48-5	Capric Acid is the fatty acid that conforms to the formula: 	fragrance ingredient; surfactant – cleansing agent
Caproic Acid 142-62-1	Caproic Acid is the aliphatic acid that conforms to the formula: 	fragrance ingredient; surfactant – cleansing agent
Caprylic Acid 124-07-2	Caprylic Acid is the fatty acid that conforms to the formula: 	fragrance ingredient; surfactant – cleansing agent
Dilinoleic Acid 26085-09-6 6144-28-1	Dilinoleic Acid is the 36-carbon dicarboxylic acid formed by the catalytic dimerization of linoleic acid. 	skin-conditioning agent – occlusive
Dierucic Acid 63541-50-4	Dierucic Acid is the 44-carbon dicarboxylic acid formed by the dimerization of Erucic Acid. 	skin-conditioning agent - occlusive
Eicosatrienoic Acid 1783-84-2	Eicosatrienoic Acid is the organic compound that conforms to the formula: 	skin-conditioning agent – misc.
Erucic Acid 112-86-7	Erucic Acid is the fatty acid that conforms to the formula: 	skin-conditioning agent – misc.

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. [1,CIR Staff]

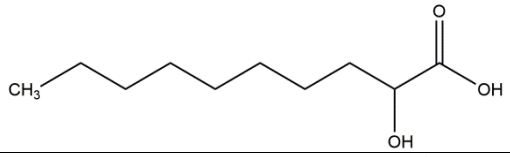
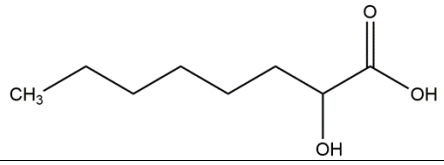
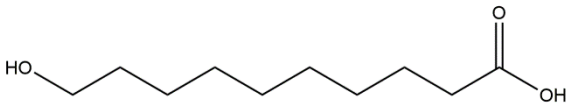
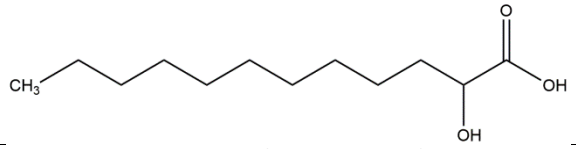
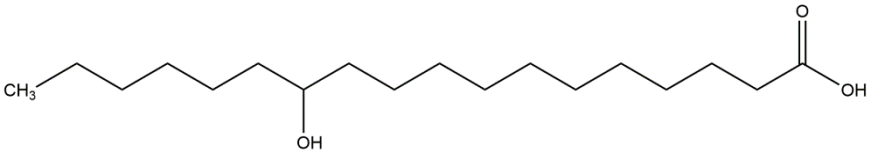
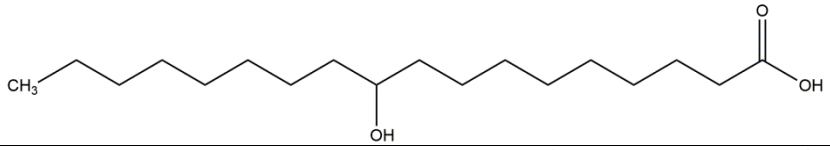
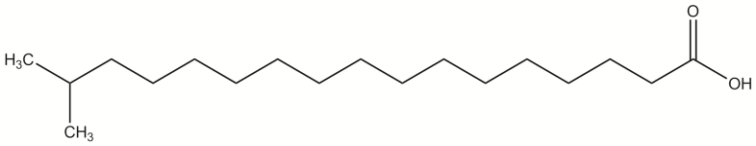
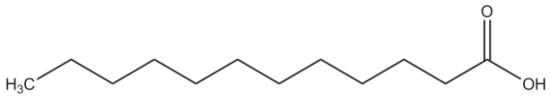
Ingredient & CAS No.	Definition & Structure	Function(s)
Hydroxycapric Acid 5393-81-7	Hydroxycapric Acid is the organic acid that conforms to the formula: 	skin-conditioning agent – misc.
Hydroxycaprylic Acid 617-73-2	Hydroxycaprylic Acid is the organic acid that conforms to the formula: 	skin-conditioning agent – misc.
10-Hydroxydecanoic Acid 1679-53-4	10-Hydroxydecanoic Acid is the organic compound that conforms to the formula: 	skin-conditioning agent - occlusive
Hydroxylauric Acid 2984-55-6	Hydroxylauric Acid is the organic compound that conforms to the formula: 	skin-conditioning agent – misc.
Hydroxystearic Acid 106-14-9 1330-70-7	Hydroxystearic Acid is the fatty acid that conforms generally to the formula: 	surfactant – cleansing agent
10-Hydroxystearic Acid 638-26-6	10-Hydroxystearic Acid is the organic compound that conforms to the formula: 	skin protectant; skin-conditioning agent – misc.
Isomerized Linoleic Acid 67701-06-8	Isomerized Linoleic Acid is the end-product of the controlled isomerization of Linoleic Acid.	film former; skin-conditioning agent - occlusive
Isomerized Safflower Acid 121250-47-3	Isomerized Safflower Acid is the end-product of the controlled isomerization of Safflower Acid. [Carthamus Tinctorius (Safflower) Seed Oil is mainly comprised of C18:2 and C18:1 fatty acids].[11]	oral health care drug; skin-conditioning agent – misc.
Isostearic Acid 2724-58-5 30399-84-9	Isostearic Acid is a mixture of branched chain 18 carbon aliphatic acids.  one example of an “iso”	binder; surfactant – cleansing agent
Lauric Acid 143-07-7	Lauric Acid is the fatty acid that conforms generally to the formula: 	fragrance ingredient; surfactant – cleansing agent

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. [1,CIR Staff]

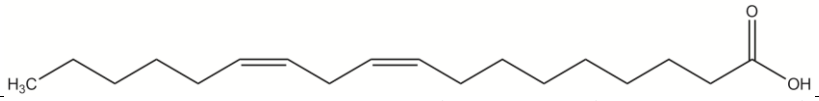
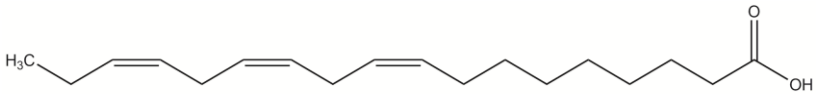
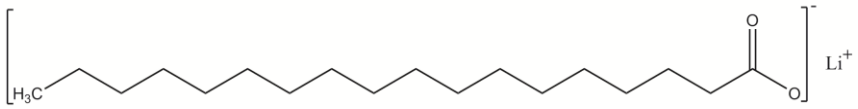
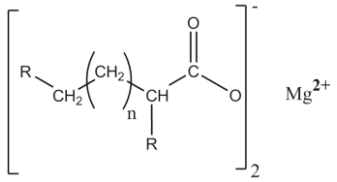
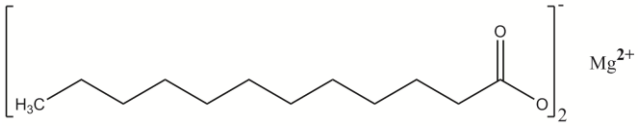
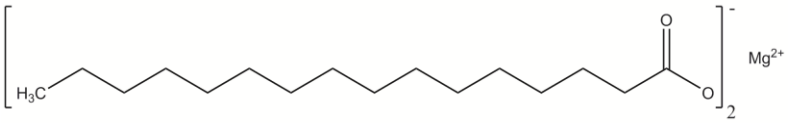
Ingredient & CAS No.	Definition & Structure	Function(s)
Linoleic Acid 342889-37-6 60-33-3	Linoleic Acid is the unsaturated fatty acid that conforms generally to the formula: 	fragrance ingredient; hair conditioning agent; skin-conditioning agent – misc.; surfactant – cleansing agent
Linolenic Acid 463-40-1	Linolenic Acid is the unsaturated fatty acid that conforms generally to the formula: 	fragrance ingredient; hair conditioning agent; skin-conditioning agent – misc.; surfactant – cleansing agent
Lithium Stearate 4485-12-5	Lithium Stearate is the lithium salt of stearic acid. It conforms generally to the formula: 	anticaking agent; binder; opacifying agent; slip modifier; viscosity increasing agent - nonaqueous
Magnesium Lanolate	Magnesium Lanolate is the magnesium salt of Lanolin Acid.  [wherein "n" is variable for the fatty acid composition of lanolin acid, and is in the range of 4 to 38; R is, in each case, hydrogen or hydroxyl, wherein at least one R is hydrogen; some fatty acids from lanolin acid may be branched][13]	anticaking agent; skin-conditioning agent – misc.; viscosity increasing agent - nonaqueous
Magnesium Laurate 4040-48-6	Magnesium Laurate is the magnesium salt of Lauric Acid. It conforms generally to the formula: 	binder
Magnesium Palmitate 2601-98-1	Magnesium Palmitate is the magnesium salt of palmitic acid. It conforms generally to the formula: 	anticaking agent; slip modifier; viscosity increasing agent - nonaqueous

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. [1,CIR Staff]

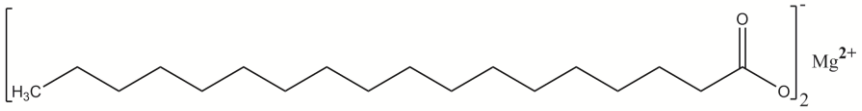
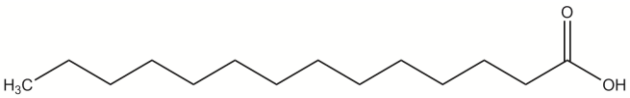
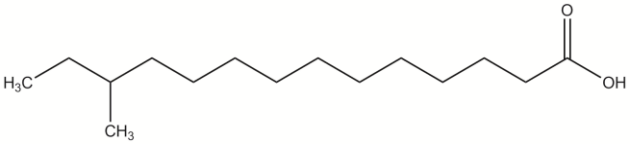
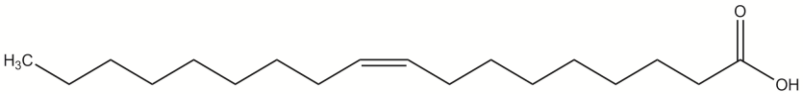
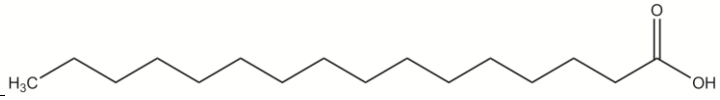
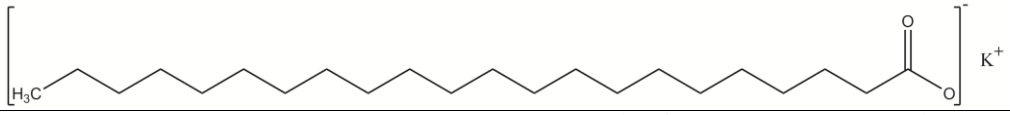
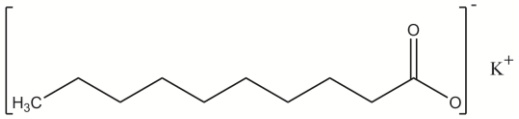
Ingredient & CAS No.	Definition & Structure	Function(s)
Magnesium Stearate 557-04-0	Magnesium Stearate is the magnesium salt of stearic acid. It conforms generally to the formula: 	anticaking agent; bulking agent; colorant; viscosity increasing agent - nonaqueous
Magnesium Tallowate 68953-41-3	Magnesium Tallowate is the magnesium salt of Tallow Acid. [Tallow is mainly comprised of C14, C16, C18, C18:1, and C18:2 fatty acid glycerides].[16]	anticaking agent; bulking agent; viscosity increasing agent - nonaqueous
Myristic Acid 544-63-8	Myristic Acid is the organic acid that conforms generally to the formula: 	fragrance ingredient; opacifying agent; surfactant – cleansing agent
Methyl Myristic Acid 73679-18-2	Methyl Myristic Acid is the organic compound that conforms to the formula: 	antioxidant
Oleic Acid 112-80-1 2027-47-6	Oleic Acid is the unsaturated fatty acid that conforms generally to the formula: 	fragrance ingredient; surfactant – cleansing agent
Palmitic Acid 57-10-3	Palmitic Acid is the fatty acid that conforms generally to the formula: 	fragrance ingredient; opacifying agent; surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Behenate 7211-53-2	Potassium Behenate is the potassium salt of Behenic Acid. 	surfactant – cleansing agent
Potassium Borageate	Potassium Borageate is the potassium salt of the fatty acids derived from Borago Officinalis Seed Oil. [Borago Officinalis Seed Oil is mainly comprised of C16, C18, C18:1, and C18:2 fatty acids].[11]	surfactant – cleansing agent
Potassium Camelliate	Potassium Camelliate is the potassium salt of the fatty acids derived from Camellia Seed Oil. [Camellia Seed Oil obtained from various species of *Camellia* is mainly comprised of C18:1 and C18:2 fatty acids].[11]	surfactant – cleansing agent
Potassium Caprate 13040-18-1	Potassium Caprate is the potassium salt of Capric Acid. 	surfactant – cleansing agent

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. [1,CIR Staff]

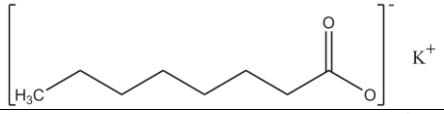
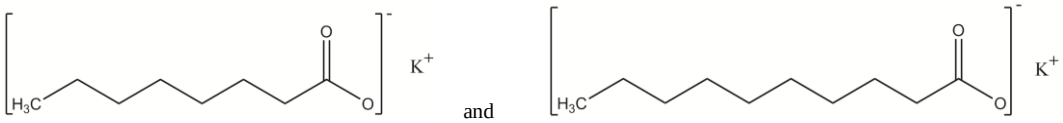
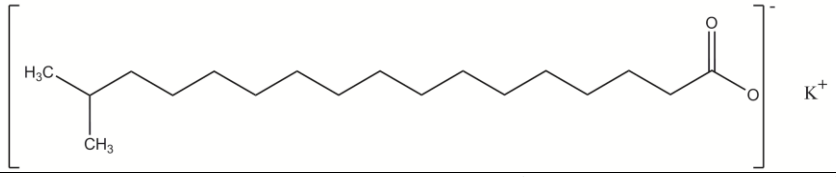
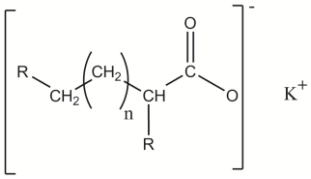
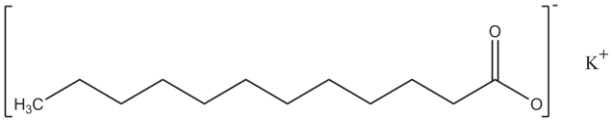
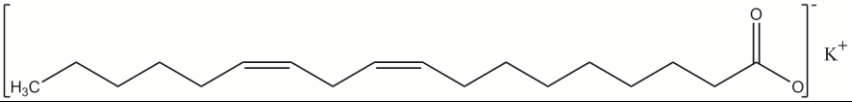
Ingredient & CAS No.	Definition & Structure	Function(s)
Potassium Caprylate 764-71-6	Potassium Caprylate is the potassium salt of Caprylic Acid that conforms to the formula: 	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Caprylate/Caprate	Potassium Caprylate/Caprate is the potassium salt of a mixture of Caprylic Acid and Capric Acid. 	surfactant – cleansing agent; surfactant - hydrotropes
Potassium Castorate 8013-05-6	Potassium Castorate is the potassium salt of the fatty acids derived from Ricinus Communis (Castor) Seed Oil. [Ricinus Communis (Castor) Seed Oil is mainly comprised of C18:1(OH), C18:1, and C18:2 fatty acids].[15]	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Hydrogenated Tallowate	Potassium Hydrogenated Tallowate is the potassium salt of Hydrogenated Tallow Acid. [Tallow is mainly comprised of C14, C16, C18, C18:1, and C18:2 fatty acid glycerides].[16]	surfactant – cleansing agent
Potassium Hydroxystearate 34326-46-0	Potassium Hydroxystearate is the potassium salt of Hydroxystearic Acid.	surfactant – cleansing agent
Potassium Isostearate 68413-46-7	Potassium Isostearate is the potassium salt of Isostearic Acid. 	surfactant – cleansing agent
Potassium Lanolate	Potassium Lanolate is the potassium salt of Lanolin Acid.  [wherein "n" is variable for the fatty acid composition of lanolin acid, and is in the range of 4 to 38; R is, in each case, hydrogen or hydroxyl, wherein at least one R is hydrogen; some fatty acids from lanolin acid may be branched][13]	surfactant – cleansing agent
Potassium Laurate 10124-65-9	Potassium Laurate is the potassium salt of lauric acid. It conforms generally to the formula: 	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Linoleate 3414-89-9	Potassium Linoleate is the potassium salt of Linoleic Acid. 	surfactant – cleansing agent; surfactant – emulsifying agent; viscosity increasing agent - nonaqueous
Potassium Linseedate	Potassium Linseedate is the potassium salt of the fatty acids derived from Linum Usitatissimum (Linseed) Seed Oil.[Linum Usitatissimum (Linseed) Seed Oil is mainly comprised of C16, C18, C18:1, C18:2, and C18:3 fatty acids].[11]	surfactant – cleansing agent

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. [1,CIR Staff]

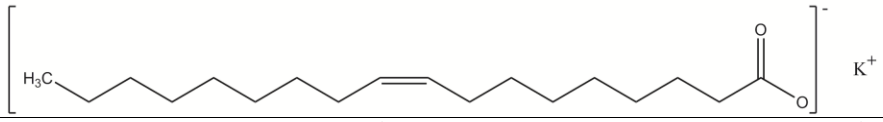
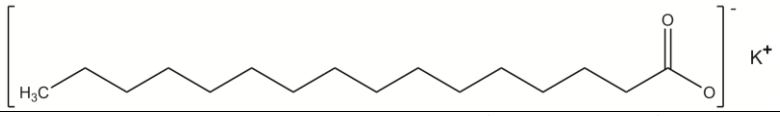
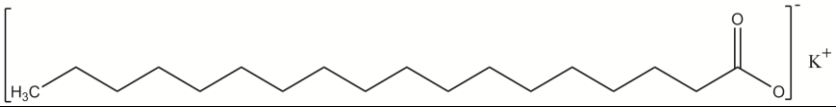
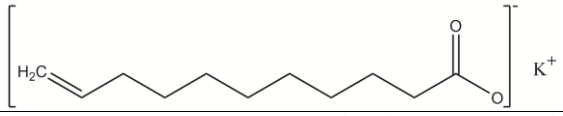
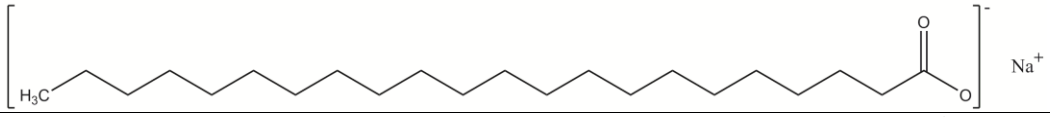
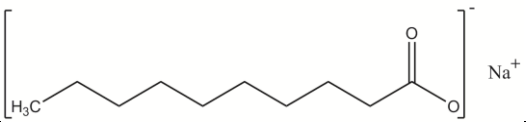
Ingredient & CAS No.	Definition & Structure	Function(s)
Potassium Oleate 143-18-0 23282-35-1	Potassium Oleate is the potassium salt of oleic acid. It conforms generally to the formula: 	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Olivate/ Sunflowerseedate	Potassium Olivate/Sunflowerseedate is the product obtained by the hydrolysis of a mixture of Olea Europaea (Olive) Fruit Oil and Helanthus Annuus (Sunflower) Seed Oil with potassium hydroxide. [Olea Europaea (Olive) Fruit Oil and Helanthus Annuus (Sunflower) Seed Oil are mainly comprised of C16, C18, C18:1, and C18:2 fatty acids].[11]	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Palmitate 2624-31-9	Potassium Palmitate is the potassium salt of palmitic acid. It conforms generally to the formula: 	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Stearate 593-29-3	Potassium Stearate is the potassium salt of stearic acid. It conforms generally to the formula: 	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Sunflowerseedate	Potassium Sunflowerseedate is the potassium salt of Sunflower Seed Acid. [Sunflower Seed Acid is mainly comprised of C16, C18, C18:1, and C18:2 fatty acids].[11]	surfactant – cleansing agent
Potassium Tallate 61790-44-1	Potassium Tallate is the potassium salt of Tall Oil Acid. [Tall Oil Acid is mainly comprised of C18:1 and C18:2 fatty acids].[10]	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Tallowate 61790-32-7	Potassium Tallowate is the potassium salt of Tallow Acid. [Tallow is mainly comprised of C14, C16, C18, C18:1, and C18:2 fatty acid glycerides].[16]	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Undecylenate 6159-41-7	Potassium Undecylenate is the potassium salt of Undecylenic Acid. 	surfactant – cleansing agent; surfactant – emulsifying agent
Sodium Arganate	Sodium Arganate is the sodium salt of the fatty acids derived from Argania Spinosa Kernel Oil. [Argania Spinosa Kernel Oil is mainly comprised of C16, C18, C18:1, and C18:2 fatty acids].[11]	surfactant – cleansing agent
Sodium Beeswax	Sodium Beeswax is the sodium salt of the fatty acids derived from Beeswax. [Beeswax is mainly comprised of even numbered C14 to C32 alcohols].[12]	surfactant – emulsifying agent
Sodium Behenate 5331-77-1	Sodium Behenate is the sodium salt of Behenic Acid. 	surfactant – cleansing agent
Sodium Camellia Japonica Seedate	Sodium Camellia Japonica Seedate is the product obtained by the hydrolysis of Camellia Japonica Seed Oil by sodium hydroxide. [Camellia Japonica Seed Oil is mainly comprised of C18:1 fatty acids].[11]	surfactant – cleansing agent
Sodium Caprate 1002-62-6	Sodium Caprate is the sodium salt of Capric Acid. 	surfactant – cleansing agent

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. [1,CIR Staff]

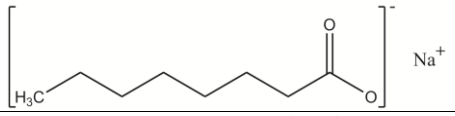
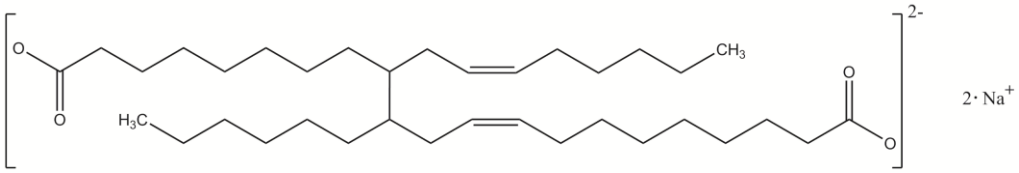
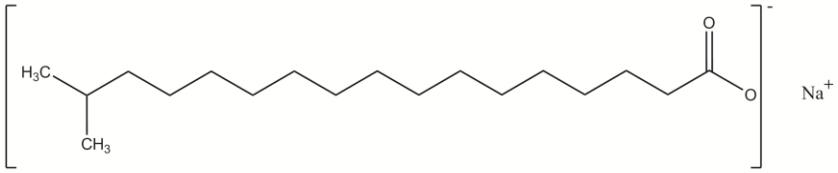
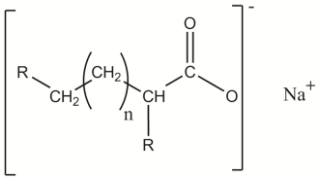
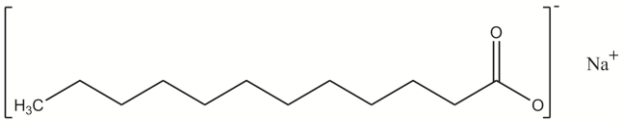
Ingredient & CAS No.	Definition & Structure	Function(s)
Sodium Caprylate 1984-06-1	Sodium Caprylate is the sodium salt of caprylic acid that conforms to the formula: 	surfactant – cleansing agent; surfactant – emulsifying agent
Sodium Castorate 8013-06-7 96690-37-8	Sodium Castorate is the sodium salt of the fatty acids derived from Ricinus Communis (Castor) Seed Oil. [Ricinus Communis (Castor) Seed Oil is mainly comprised of C18:1(OH), C18:1, and C18:2 fatty acids].[15]	surfactant – cleansing agent; surfactant – emulsifying agent
Sodium Dilinoleate 67701-20-6	Sodium Dilinoleate is the sodium salt of Dilinoleic Acid. 	surfactant – cleansing agent
Sodium Hydrogenated Tallowate	Sodium Hydrogenated Tallowate is the sodium salt of Hydrogenated Tallow Acid. [Tallow is mainly comprised of C14, C16, C18, C18:1, and C18:2 fatty acid glycerides].[16]	surfactant – cleansing agent
Sodium Hydroxystearate 13329-67-4	Sodium Hydroxystearate is the sodium salt of Hydroxystearic Acid .	surfactant – cleansing agent
Sodium Isostearate 64248-79-9	Sodium Isostearate is the sodium salt of Isostearic Acid.  one example of an "iso"	surfactant – cleansing agent; surfactant – emulsifying agent
Sodium Lanolate	Sodium Lanolate is the sodium salt of Lanolin Acid.  [wherein "n" is variable for the fatty acid composition of lanolin acid, and is in the range of 4 to 38; R is, in each case, hydrogen or hydroxyl, wherein at least one R is hydrogen; some fatty acids from lanolin acid may be branched][13]	surfactant – cleansing agent
Sodium Lardate 68605-06-1	Sodium Lardate is the sodium salt of the fatty acids derived from Lard. [Lard is mainly comprised of C16, C18, and C18:1 fatty acids].[14]	surfactant – cleansing agent; surfactant – emulsifying agent; surfactant – foam booster
Sodium Laurate 629-25-4	Sodium Laurate is the sodium salt of lauric acid that conforms generally to the formula: 	surfactant – cleansing agent; surfactant – emulsifying agent
Sodium Laurate/Linoleate/ Oleate/Palmitate	Sodium Laurate/Linoleate/Oleate/Palmitate is the sodium salt of a mixture of lauric, linoleic, oleic and pamitic acids.	skin protectant; skin-conditioning agent – emollient; skin-conditioning agent – misc.
Sodium Linoleate 822-17-3	Sodium Linoleate is the sodium salt of Linoleic Acid.	surfactant – cleansing agent; surfactant – emulsifying agent; viscosity increasing agent - nonaqueous

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. [1,CIR Staff]

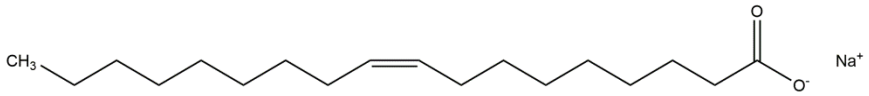
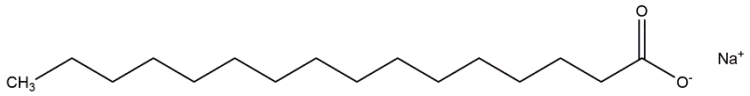
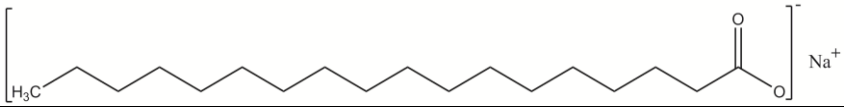
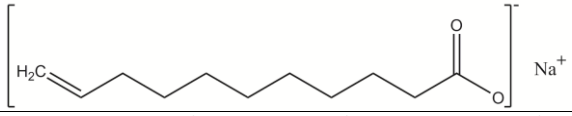
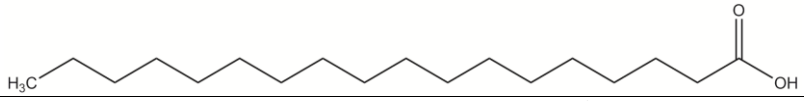
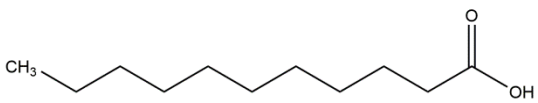
Ingredient & CAS No.	Definition & Structure	Function(s)
Sodium Oleate 143-19-1 166558-02-4	Sodium Oleate is the sodium salt of oleic acid that conforms generally to the formula: 	surfactant – cleansing agent; surfactant – emulsifying agent; viscosity increasing agent - aqueous
Sodium Palmitate 408-35-5	Sodium Palmitate is the sodium salt of palmitic acid that conforms generally to the formula: 	surfactant – cleansing agent; surfactant – emulsifying agent; viscosity increasing agent - aqueous
Sodium Stearate 822-16-2	Sodium Stearate is the sodium salt of stearic acid that conforms generally to the formula: 	surfactant – cleansing agent; surfactant – emulsifying agent; viscosity increasing agent - aqueous
Sodium Tallowate 8052-48-0	Sodium Tallowate is the sodium salt of Tallow Acid. [Tallow is mainly comprised of C14, C16, C18, C18:1, and C18:2 fatty acid glycerides].[16]	surfactant – cleansing agent; surfactant – foam booster; viscosity increasing agent - aqueous
Sodium Tamanuseedate	Sodium Tamanuseedate is the sodium salt of the fatty acids derived from Calophyllum Inophyllum Seed Oil.	surfactant – cleansing agent; surfactant – emulsifying agent; viscosity increasing agent - nonaqueous
Sodium Undecylenate 3398-33-2	Sodium Undecylenate is the sodium salt of Undecylenic Acid that conforms generally to the formula: 	surfactant – cleansing agent; surfactant – emulsifying agent
Stearic Acid 57-11-4	Stearic Acid is the fatty acid that conforms generally to the formula: 	fragrance ingredient; surfactant – cleansing agent; surfactant – emulsifying agent
Trilinoleic Acid 68937-90-6 7049-66-3	Trilinoleic Acid is the 54-carbon tricarboxylic acid formed by the catalytic tirmerization of Linoleic Acid.	skin-conditioning agent – occlusive; viscosity increasing agent - nonaqueous
Undecanoic Acid 112-37-8	Undecanoic Acid is the aliphatic acid that conforms to the formula: 	fragrance ingredient; surfactant – cleansing agent; surfactant – emulsifying agent

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. [1,CIR Staff]

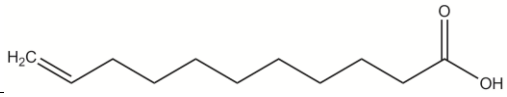
Ingredient & CAS No.	Definition & Structure	Function(s)
Undecylenic Acid 112-38-9 1333-28-4	Undecylenic Acid is the aliphatic acid that conforms generally to the formula: 	antifungal agent; cosmetic biocide; fragrance ingredient; surfactant – cleansing agent; surfactant – emulsifying agent

Table 2. Previously reviewed and related reviewed ingredients

Ingredients	Conclusion	Assessment Publication Status	Reference
Previously Reviewed Ingredients			
Aluminum Distearate	Safe as used	published in1982; re-review published in 2003 – not reopened	[2,3]
Aluminum Stearate	Safe as used	published in1982; re-review published in 2003 – not reopened	[2,3]
Aluminum Tristearate	Safe as used	published in1982; re-review published in 2003 – not reopened	[2,3]
Ammonium Stearate	Safe as used	published in1982; re-review published in 2003 – not reopened	[2,3]
Calcium Stearate	Safe as used	published in1982; re-review published in 2003 – not reopened	[2,3]
Hydroxystearic Acid	Safe as used	published in 1999	[4]
Isostearic Acid	Safe as used	published in 1983; re-review published in 2005 – not reopened	[5,6]
Lauric Acid	Safe as used	published in 1987; re-review published in 2006 – not reopened	[7,8]
Lithium Stearate	Safe as used	published in1982; re-review published in 2003 – not reopened	[2,3]
Magnesium Stearate	Safe as used	published in1982; re-review published in 2003 – not reopened	[2,3]
Myristic Acid	Safe as used	published in 1987; re-review published in 2006 – not reopened; included in expanded report with salts and esters published in 2010	[7-9]
Oleic Acid	Safe as used	published in 1987; re-review published in 2006 – not reopened	[7,8]
Palmitic Acid	Safe as used	published in 1987; re-review published in 2006 – not reopened	[7,8]
Potassium Stearate	Safe as used	published in1982; re-review published in 2003 – not reopened	[2,3]
Potassium Tallate	Safe as used	published in 2009	[10]
Sodium Stearate	Safe as used	published in1982; re-review published in 2003 – not reopened	[2,3]
Stearic Acid	Safe as used	published in 1987; re-review published in 2006 – not reopened	[7,8]
Related Reviewed Ingredients			
Argania Spinosa Kernel Oil	Safe as used	published in 2017	[11]
Beeswax	Safe as used	published in1984; re-review published in 2005 – not reopened	[6,12]
Borago Officinalis Seed Oil	Safe as used	published in 2017	[11]
Camellia Japonica Seed Oil	Safe as used	published in 2017	[11]
Helianthus Annuus (Sunflower) Seed Oil and Sunflower Seed Acid	Safe as used	published in 2017	[11]
Lanolin and Lanolin Acid	Safe as used	published in 1980; re-review published in 2005 – not reopened	[6,13]
Lard	Safe as used provided established limits on heavy metals and pesticides are not exceeded	published in 2001; re-reviewed in 2017 – not reopened	[14]
Linum Usitatissimum (Linseed) Seed Oil	Safe as used	published in 2017	[11]
Olea Europaea (Olive) Fruit Oil	Safe as used	published in 2017	[11]
Ricinus Communis (Castor) Seed Oil	Safe as used	published in 2007	[15]
Tallow	Safe as used	published in 1990; re-review published in 2008 – not reopened	[16,17]

Table 3. Physical and chemical properties

Property	Value	Reference
	Aluminum Distearate	
Physical Form	White powder	[67]
Molecular Weight Da	610	[3]
Specific gravity	1.009	[3]
Melting Point º C	120-145	[3]
	Aluminum Stearate	
Physical Form	White powder	[67]
Molecular Weight Da	344	[3]
Specific gravity	1.010	[3]
Melting Point º C	173	[3]
	Aluminum Tristearate	
Physical Form	White powder	[20]
Molecular Weight Da	877.35	[3]
Density g/cm^3 @ 20º C	1.066	[20]
Vapor Pressure mmHg @ 25º C	0	[20]
Melting Point º C at 760 mmHg	179.5	[20]
Boiling Point ºC at 760 mm Hg	250	[20]
Water Solubility mg/L @ 25ºC	0 (insoluble)	[20]
Log P	22.69	[20]
	Ammonium Oleate	
Physical Form	Yellow-brown paste	[68]
Molecular Weight Da	299.50	[68]
Melting Point º C	70-72F	[68]
	Ammonium Stearate	
Physical Form	Yellow-white powder or tan, wax-like solid	[67,68]
Molecular Weight Da	301.5	[3]
Specific gravity @ 22º C	0.89	[3]
Melting Point º C	73-87	[3]
	Arachidic Acid	
Physical Form	Shining, white, crystalline leaflets	[67]
Molecular Weight Da	312.5	[68]
Density g/cm^3 @ 20º C and 760 mmHg	0.884 (estimated)	[69]
Melting Point º C	75.5	[68]
Boiling Point ºC at 760 mm Hg	328	[68]
	Behenic Acid	
Physical Form	White to off-white waxy solid	[21]
Molecular Weight Da	340.59	[68]
Density g/cm^3 @ 100º C	0.82	[68]
Vapor Pressure mmHg @ 100º C	$< 4.875 \times 10^{-5}$	[33]
Melting Point º C	79.95	[68]
Boiling Point ºC at 60 mm Hg	306	[68]
Water Solubility mg/L @ 25ºC	0.016	[21]
Log P @ 25ºC	> 5.11	[21]
	Calcium Stearate	
Physical Form	Granular, fatty powder	[68]
Molecular Weight Da	607.00	[3]
Melting Point º C	129-180	[3]
	Calcium Undecylenate	
Physical Form	Fine, white powder	[67]
Melting Point º C	155	[67]
	Capric Acid	
Physical Form	White to pale yellow crystals or needles	[22]
Molecular Weight Da	172.27	[68]
Density g/cm^3 @ 20º C	0.89	[22]
Vapor Pressure mmHg @ 25º C	3.66×10^{-4}	[22]
Melting Point º C at 760 mmg Hg	31.65	[22]
Boiling Point ºC at 760 mm Hg	268.7	[22]
Water Solubility mg/L @ 25ºC	61.8	[22]
Log P @ 20ºC	4.1	[22]
	Caproic Acid	
Physical Form	Colorless to light brown liquid	[23]
Molecular Weight Da	116.16	[68]
Density g/cm^3 @ 20º C	0.93	[23]
Vapor Pressure mmHg @ 25º C	0.044	[23]
Melting Point º C at 760 mmg Hg	- 4	[23]
Boiling Point ºC at 760 mm Hg	203	[23]
Water Solubility g/L @ 25ºC	10.3	[23]
Log P_{ow}	1.92	[23]

Table 3. Physical and chemical properties

Property	Value	Reference
	Caprylic Acid	
Physical Form	Colorless liquid	[24]
Molecular Weight Da	144.21	[68]
Density g/cm^3 @ 20º C	0.91	[24]
Vapor Pressure mmHg @ 25º C	0.00368	[24]
Melting Point º C at 760 mmg Hg	16.5	[24]
Boiling Point ºC at 760 mm Hg	237	[24]
Water Solubility mg/L @ 20ºC	680	[24]
Log P @ 20ºC	3.05	[24]
	Dilinoleic Acid	
Physical Form	Light yellow, viscous liquid	[67]
Density g/cm^3 @ 100º C	0.921	[67]
	Eicosatrienoic Acid	
Molecular Weight Da	306.48	[69]
Density g/cm^3 @ 20º C and 760 mmHg	0.917 (estimated)	[69]
Vapor Pressure mmHg @ 25º C	6.77 x 10^{-9} (estimated)	[69]
Boiling Point ºC at 760 mm Hg	438.0 (estimated)	[69]
Log P @ 25ºC	7.541 (estimated)	[69]
	Eruric Acid	
Molecular Weight Da	338.58	[68]
Density g/cm^3 @ 55º C	0.860	[68]
Vapor Pressure mmHg @ 25º C	4.91 x 10^{-7} (estimated)	[69]
Melting Point º C	33.8	[68]
	381.5 (decomp.)	[68]
Log P @ 25ºC	9.459	[69]
Boiling Point ºC at 760 mm Hg	***Hydroxycapric Acid***	
Molecular Weight Da	188.26	[69]
Density g/cm^3 @ 20º C and 760 mm Hg	1.011 (estimated)	[69]
Vapor Pressure mmHg @ 25º C	2.90 x 10^{-5} (estimated)	[69]
Boiling Point ºC at 760 mm Hg	318.9 (estimated)	[69]
Log P @ 25ºC	2.716 (estimated)	[69]
	Hydroxycaprylic Acid	
Molecular Weight Da	160.21	[69]
Density g/cm^3 @ 20º C and 760 mmHg	1.046 (estimated)	[69]
Vapor Pressure mmHg @ 25º C	2.49 x 10^{-4} (estimated)	[69]
Melting Point º C	70	[70]
Boiling Point ºC at 760 mm Hg	289.0 (estimated)	[69]
Log P @ 25ºC	1.697	[69]
	10-Hydroxydecanoic Acid	
Molecular Weight Da	188.26	[69]
Density g/cm^3 @ 20º C and 760 mmHg	1.013 (estimated)	[69]
Vapor Pressure mmHg @ 25º C	1.18 x 10^{-5} (estimated)	[69]
Boiling Point ºC at 760 mm Hg	330.8 (estimated)	[69]
Log P @ 25ºC	1.847 (estimated)	[69]
	Hydroxylauric Acid	
Molecular Weight Da	216.32	[69]
Density g/cm^3 @ 20º C and 760 mmHg	0.987 (estimated)	[69]
Vapor Pressure mmHg @ 25º C	3.05 x 10^{-6} (estimated)	[69]
Boiling Point ºC at 760 mm Hg	348.5 (estimated)	[69]
Log P @ 25ºC	3.735 (estimated)	[69]
	Hydroxystearic Acid	
Molecular Weight Da	300.48	[4]
Density g/cm^3 @ 20 ºC and 760 mmHg	0.944 (estimated)	[69]
Vapor Pressure mmHg @ 25 ºC	1.92 x 10^{-9} (estimated)	[69]
Melting Point ºC	75-82	[4]
Boiling Point ºC at 760 mm Hg	436.3 (estimated)	[69]
Log P @ 20 ºC	5.767 (estimated	[69]
	10-Hydroxystearic Acid	
Molecular Weight Da	300.48	[69]
Density g/cm^3 @ 20º C and 760 mmHg	0.944 (estimated)	[69]
Vapor Pressure mmHg @ 25º C	1.92 x 10^{-9} (estimated)	[69]
Boiling Point ºC at 760 mm Hg	436.3 (estimated)	[69]
Log P @ 25ºC	5.767 (estimated)	[69]
	Isomerized Linoleic Acid	
Physical Form	paste	[25]
Molecular Weight Da	228.291	[71]
Density g/cm^3 @ 20º C	0.84-0.89	[25]
Melting Point º C	44-48	[25]
Boiling Point ºC at 7.5 mm Hg	225	[25]

Table 3. Physical and chemical properties

Property	Value	Reference
	Isostearic Acid	
Physical Form	Clear, oily liquid	[5]
Molecular Weight Da	284.48	[69]
Specific gravity @ 25º C	0.89-0.906	[5]
Vapor Pressure mmHg @ 25º C	1.52×10^{-7} (estimated)	[69]
Boiling Point ºC at 760 mm Hg	400.8 (estimated)	[69]
Log P @ 25ºC	7.674 (estimated)	[69]
	Lauric Acid	
Physical Form	White or slightly yellow, somewhat glossy crystalline solid or powder/colorless solid	[7]
Molecular Weight Da	200.32	[7]
Density g/cm^3 @ 50º C	0.8679	[7]
Vapor Pressure mmHg @ 25º C	6.61×10^{-4} (estimated)	[69]
Melting Point º C	44 or 48	[7]
Boiling Point ºC	225	[7]
Log P @ 25ºC	4.773 (estimated)	[69]
	Linoleic Acid	
Physical Form	Colorless oil	[68]
Molecular Weight Da	280.45	[68]
Density g/cm^3 @ 15º C	0.905	[67]
Vapor Pressure mmHg @ 25º C	3.54×10^{-6} (estimated)	[69]
Melting Point º C	-12	[68]
Boiling Point ºC @ 14 mmHg	228	[67]
Log P @ 25ºC	7.017 (estimated)	[69]
	Linolenic Acid	
Physical Form	Colorless liquid	[68]
Molecular Weight Da	278.44	[68]
Density g/cm^3 @ 20 º C	0.916	[67]
Vapor Pressure mmHg @ 25º C	4.24x 10-9 (estimated)	[69]
Melting Point º C	-11	[67]
Boiling Point ºC @ 17 mmHg	230	[67]
Log P @ 25ºC	6.522 (estimated)	[69]
	Lithium Stearate	
Physical Form	White solid	[27]
Molecular Weight Da	290.41	[3]
Specific gravity	1.025	[3]
Melting Point º C	108	[3]
	Magnesium Palmitate	
Physical Form	Crystalline needles or white lumps	[67]
Melting Point º C	121.5	[67]
	Magnesium Stearate	
Physical Form	White powder	[68]
Molecular Weight Da	591.27	[3]
Specific gravity	1.028	[3]
Melting Point º C	86-132	[3]
	Methyl Myristic Acid	
Molecular Weight Da	242.40	[69]
Density g/cm^3 @ 20º C and 760 mmHg	0.894 (estimated)	[69]
Vapor Pressure mmHg @ 25º C	5.19×10^{-6} (estimated)	[69]
Boiling Point ºC at 760 mm Hg	355.5 (estimated)	[69]
Log P @ 25 ºC	6.146 (estimated)	[69]
	Myristic Acid	
Physical Form	Solid	[7]
Molecular Weight Da	228.36	[7]
Density g/cm^3 @ 70º C	0.8528	[7]
Vapor Pressure mmHg @ 25º C	1.39×10^{-4} (estimated)	[69]
Melting Point º C	54.4-58.5	[7]
Boiling Point ºC	250.5	[7]
Log P @ 25ºC	5.792 (estimated)	[69]
	Oleic Acid	
Physical Form	Colorless to pale yellow, oily liquid above 5-7 ºC	[7]
Molecular Weight Da	282.45	[7]
Density g/cm^3 @ 25º C	0.895	[7]
Vapor Pressure mmHg @ 25º C	3.70×10^{-6} (estimated)	[69]
Melting Point º C	16.3	[7]
Boiling Point ºC at 11 mm Hg	286	[7]
Log P @ 25ºC	7.421 (estimated)	[69]

Table 3. Physical and chemical properties

Property	Value	Reference
	Palmitic Acid	
Physical Form	White or faintly yellow, slightly glossy crystalline solid/white or yellow-white powder/white crystalline scales/colorless crystals	[7]
Molecular Weight Da	256.43	[7]
Density g/cm^3 @ 62º C	0.8527	[7]
Melting Point º C	63-64	[7]
Boiling Point ºC	215	[7]
Water Solubility mg/L @ 20ºC	< 0.05	[28]
	Potassium Laurate	
Physical Form	Light tan paste	[67]
	Potassium Linoleate	
Physical Form	Light tan paste	[67]
	Potassium Oleate	
Physical form	Yellowish or brownish soft mass or gray-tan paste	[67,68]
	Potassium Stearate	
Physical Form	White to pale yellow powder	[68]
Molecular Weight Da	322.58	[3]
Density g/cm^3 @ 75º C	1.037	[68]
	Potassium Undecylenate	
Physical Form	Finely divided, white powder	[67]
	Sodium Oleate	
Physical Form	White powder	[68]
Molecular Weight Da	304.45	[68]
Melting Point º C	232-235	[67]
	Sodium Palmitate	
Physical Form	White to yellow powder	[67]
Melting Point º C	270	[70]
	Sodium Stearate	
Physical Form	White powder	[68]
Molecular Weight Da	306.47	[3]
	Sodium Undecylenate	
Physical Form	White powder	[67]
	Stearic Acid	
Physical Form	White or faintly yellow crystals or leaflets/white or yellow-white powder	[7]
Molecular Weight Da	284.48	[7]
Density g/cm^3 @ 70º C	0.847	[7]
Vapor Pressure mmHg @ 25º C	4.28 x 10^{-8}	[29]
Melting Point º C	69-71.2	[7]
Boiling Point ºC at 760 mmHg	232	[29]
Water Solubility mg/L @ 25ºC	0.597	[29]
Log P @ 25ºC	8.23	[29]
	Trilinoleic Acid	
Physical Form	Dark brown liquid	[30]
Molecular Weight Da	801.036	[71]
Density g/cm^3 @ 19º C	0.967	[30]
Melting Point º C	- 3	[30]
Water Solubility mg/L @ 20ºC	< 0.37	[30]
	Undecanoic Acid	
Molecular Weight Da	186.29	[69]
Density g/cm^3 @ 80 ºC	0.805	[67]
Vapor Pressure mmHg @ 25º C	1.51 x 10^{-3} (estimated)	[69]
Melting Point º C	28.5	[67]
Boiling Point ºC at 760 mmHg	284.0	[67]
Log P @ 25ºC	4.263 (estimated)	[69]
	Undecylenic Acid	
Physical Form	Colorless or white solid	[31]
Molecular Weight Da	184.28	[68]
Density g/cm^3 @ 24.4º C	1.0024	[31]
Vapor Pressure mmHg @ 20º C	0.000143	[31]
Melting Point º C at 760 mmg Hg	26.4	[31]
Boiling Point ºC at 760 mm Hg	293.75	[31]
Water Solubility mg/L @ 20ºC	38.46	[31]
Log P_{ow} @ 20ºC	4.0	[31]

Table 4. Frequency (2018) and concentration of use (2016) according to duration and type of exposure for fatty acids and soaps[38,39]

	# of Uses	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*
	Aluminum Stearates		**Arachidic Acid**		**Behenic Acid**		**C14-28 Alkyl Acid**	
Totals[†]	**3**	**NR**	**9**	**0.000001-0.065**	**125**	**0.024-22**	**26**	**0.0095-0.075**
Duration of Use								
Leave-On	3	NR	7	0.000001-0.065	89	0.024-22	1	NR
Rinse Off	NR	NR	2	0.0002	36	0.9-6	25	0.0095-0.075
Diluted for (Bath) Use	NR	NR	NR	NR	NR	0.044	NR	NR
Exposure Type								
Eye Area	1	NR	5	0.065	16	0.024-22	NR	NR
Incidental Ingestion	NR	NR	NR	NR	3	0.48-14	NR	NR
Incidental Inhalation-Spray	NR	NR	1[b]	0.000001[a]	2; 8[a]; 9[b]	0.5; 12[a]	NR	NR
Incidental Inhalation-Powder	NR	NR	1[b]	NR	2[c]; 9[b]	0.5-2[c]	NR	NR
Dermal Contact	2	NR	3	0.0002	99	0.042-22	1	NR
Deodorant (underarm)	NR	NR	NR	NR	29[a]	0.75	NR	NR
Hair - Non-Coloring	NR	NR	NR	0.000001	11	2-12	23	0.0095-0.075
Hair-Coloring	NR	NR	NR	NR	1	NR	2	NR
Nail	NR	NR	1	NR	NR	0.5	NR	NR
Mucous Membrane	NR	NR	NR	0.0002	7	0.044-14	NR	NR
Baby Products	NR	NR	NR	NR	2	NR	NR	NR

	C10-40 Isoalkyl Acid		**C14-28 Isoalkyl Acid**		**Calcium Behenate**		**Capric Acid**	
Totals[†]	**NR**	**0.02-0.18**	**25**	**0.029-0.075**	**1**	**NR**	**2**	**0.0036-4**
Duration of Use								
Leave-On	NR	0.18	NR	NR	1	NR	NR	0.01-4
Rinse Off	NR	0.02	25	0.029-0.075	NR	NR	2	0.0036-0.2
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure Type								
Eye Area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	0.18[a]	NR	NR	1	NR	NR	NR
Incidental Inhalation-Powder	NR	NR	NR	NR	NR	NR	NR	0.01[c]
Dermal Contact	NR	NR	NR	NR	NR	NR	2	0.0036-4
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	0.02-0.18	23	0.0.29-0.075	1	NR	NR	NR
Hair-Coloring	NR	NR	2	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	NR	NR	0.07-0.1
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR

Table 4. Frequency (2018) and concentration of use (2016) according to duration and type of exposure for fatty acids and soaps[38,39]

	# of Uses	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*
	Caproic Acid		**Caprylic Acid**		**Dilinoleic Acid**		**Hydroxycapric Acid**	
Totals[†]	**NR**	**0.011**	**6**	**0.0018-4**	**71**	**0.14-2.5**	**1**	**0.7**
Duration of Use								
Leave-On	NR	NR	6	0.23-4	NR	0.14	1	0.7
Rinse Off	NR	0.011	NR	0.0018-0.1	71	2.5	NR	0.7
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure Type								
Eye Area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	0.011	2	NR	NR	0.14	NR	NR
Incidental Inhalation-Spray	NR	NR	3[a]	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	NR	NR	NR	NR	NR	NR	NR	0.7[c]
Dermal Contact	NR	NR	3	0.0018-4	NR	NR	1	0.7
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	1	0.23	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	71	2.5	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	0.011	2	0.0018-0.1	NR	0.14	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR

	Hydroxycaprylic Acid		**10-Hydroxydecanoic Acid**		**Isomerized Linoleic Acid**		**Linoleic Acid**	
Totals[†]	**4**	**0.076**	**11**	**0.0084-0.1**	**22**	**0.1-0.75**	**633**	**0.00033-21.8**
Duration of Use								
Leave-On	4	0.076	9	0.0084-0.1	19	0.1-0.75	557	0.00085-3.4
Rinse Off	NR	0.076	2	NR	3	NR	76	0.00033-21.8
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	0.0012
Exposure Type								
Eye Area	NR	NR	NR	0.1	7	NR	70	0.01-0.76
Incidental Ingestion	NR	NR	NR	NR	NR	NR	96	0.0075-1
Incidental Inhalation-Spray	1[a]; 2[b]	NR	5[a]; 2[b]	NR	6[a]; 4[b]	NR	210[a]; 105[b]	0.0038-0.25; 0.003-0.67[a]; 0.2[b]
Incidental Inhalation-Powder	2[b]	0.076[c]	2[b]	0.02; 0.1[c]	4[b]	0.1-0.75[c]	8; 105[b]	0.2; 0.0015-3.4[c]; 0.2[b]
Dermal Contact	4	NR	11	0.0084-0.1	22	0.1-0.75	475	0.00085-21.8
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	0.07
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR	52	0.0009-0.67
Hair-Coloring	NR	NR	NR	NR	NR	NR	5	0.00033-0.31
Nail	NR	NR	NR	NR	NR	NR	2	2
Mucous Membrane	NR	NR	NR	NR	1	NR	103	0.001-1.1
Baby Products	NR	NR	NR	NR	NR	NR	NR	0.043

Table 4. Frequency (2018) and concentration of use (2016) according to duration and type of exposure for fatty acids and soaps[38,39]

	# of Uses	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*
	Linolenic Acid		**Magnesium Laurate**		**Potassium Behenate**		**Potassium Castorate**	
Totals[†]	**205**	**0.000007-1**	**3**	**NR**	**5**	**NR**	**2**	**0.52**
Duration of Use								
Leave-On	170	0.00005-1	NR	NR	NR	NR	NR	NR
Rinse Off	35	0.000007-0.44	3	NR	5	NR	2	0.52
Diluted for (Bath) Use	NR	0.0002	NR	NR	NR	NR	NR	NR
Exposure Type								
Eye Area	17	0.001-0.084	NR	NR	NR	NR	NR	NR
Incidental Ingestion	6	0.0022-0.01	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	81[a]; 36[b]	0.00005-0.25; 0.001-1[a]	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	1; 36[b]	0.003-0.067[c]	NR	NR	NR	NR	NR	NR
Dermal Contact	161	0.000007-0.45	3	NR	5	NR	2	0.52
Deodorant (underarm)	NR	0.0045-0.07	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	36	0.00005-1	NR	NR	NR	NR	NR	NR
Hair-Coloring	1	NR	NR	NR	NR	NR	NR	NR
Nail	1	0.01	NR	NR	NR	NR	NR	NR
Mucous Membrane	10	0.000007-0.2	3	NR	2	NR	2	0.52
Baby Products	NR	0.005	NR	NR	NR	NR	NR	NR

	Potassium Hydrogenated Tallowate		**Potassium Isostearate**		**Potassium Laurate**		**Potassium Oleate**	
Totals[†]	**1**	**NR**	**5**	**1.6-3**	**24**	**0.001-9**	**19**	**0.25-23**
Duration of Use								
Leave-On	1	NR	2	NR	1	0.001-2	1	NR
Rinse Off	NR	NR	3	1.6-3	23	1.3-9	18	0.25-23
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure Type								
Eye Area	NR	NR	NR	NR	NR	0.001-0.0019	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	1[a]	NR	2[b]	NR	1[a]	NR	1[a]	NR
Incidental Inhalation-Powder	NR	NR	2[b]	NR	NR	0.0018-2[c]	NR	NR
Dermal Contact	1	NR	5	1.6-3	24	0.001-9	17	0.25-23
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	2	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	3	3	6	2-5.3	10	0.25-3
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR

Table 4. Frequency (2018) and concentration of use (2016) according to duration and type of exposure for fatty acids and soaps[38,39]

	# of Uses	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*
	Potassium Palmitate		**Potassium Tallowate**		**Sodium Behenate**		**Sodium Castorate**	
Totals[†]	**25**	**0.26-21.1**	**3**	**0.2-12.9**	**14**	**NR**	**2**	**NR**
Duration of Use								
Leave-On	6	0.26	NR	0.2	14	NR	NR	NR
Rinse Off	19	0.3-21.1	3	12.9	NR	NR	2	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure Type								
Eye Area	4	0.26	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	2[b]	NR	NR	0.2[a]	NR	NR	NR	NR
Incidental Inhalation-Powder	2[b]	NR	NR	NR	NR	NR	NR	NR
Dermal Contact	25	0.26-21.1	3	12.9	14	NR	2	NR
Deodorant (underarm)	NR	NR	NR	NR	14[a]	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	0.2	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	5	0.73	NR	NR	NR	NR	2	NR
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR

	Sodium Isostearate		**Sodium Laurate**		**Sodium Laurate/Linoleate/Oleate/Palmitate**		**Sodium Oleate**	
Totals[†]	**11**	**3**	**87**	**0.005-14**	**NR**	**74.5-84.7**	**62**	**0.000002-3.7**
Duration of Use								
Leave-On	8	NR	21	0.075-6	NR	74.5	58	0.000002-0.025
Rinse Off	3	3	66	0.005-14	NR	84.7	4	0.000025-3.7
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	0.35-0.38
Exposure Type								
Eye Area	2	NR	NR	NR	NR	NR	9	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	2[a]; 4[b]	NR	2[a]; 3[b]	NR	NR	NR	31[a]; 16[b]	NR
Incidental Inhalation-Powder	4[b]	NR	3[b]	6[c]	NR	NR	16[b]	NR
Dermal Contact	11	3	76	0.005-14	NR	74.5-84.7	62	0.000002-3.7
Deodorant (underarm)	NR	NR	14[a]	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	11	0.005-0.4	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	0.2
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	3	3	45	0.013-8.7	NR	84.7	2	0.000025-3.7
Baby Products	NR	NR	NR	0.01	NR	74.5	NR	NR

Table 4. Frequency (2018) and concentration of use (2016) according to duration and type of exposure for fatty acids and soaps[38,39]

	# of Uses	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*
	Sodium Palmitate		**Sodium Tallowate**		**Trilinoleic Acid**		**Undecanoic Acid**	
Totals†	**102**	**0.06-55.8**	**110**	**5.1-80**	**4**	**NR**	**NR**	**0.0014-0.14**
Duration of Use								
Leave-On	25	0.06-4.1	4	NR	3	NR	NR	0.0014-0.096
Rinse Off	75	1.3-55.8	106	5.1-80	1	NR	NR	0.016-0.14
Diluted for (Bath) Use	2	NR	NR	NR	NR	NR	NR	NR
Exposure Type								
Eye Area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	3[a]	NR	1[b]	NR	3[a]	NR	NR	0.0014
Incidental Inhalation-Powder	NR	NR	1[b]	NR	NR	NR	NR	NR
Dermal Contact	102	0.06-55.8	110	5.1-80	NR	NR	NR	0.0014-0.14
Deodorant (underarm)	21[a]	4.1	NR	NR	NR	NR	NR	0.0014-0.096
Hair - Non-Coloring	NR	NR	NR	NR	4	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	58	5.9-55.8	95	9-80	NR	NR	NR	0.016-0.14
Baby Products	1	0.06	2	NR	NR	NR	NR	NR

	Undecylenic Acid	
Totals†	**1**	**0.2-25**
Duration of Use		
Leave-On	1	0.2-25
Rinse Off	NR	NR
Diluted for (Bath) Use	NR	NR
Exposure Type		
Eye Area	NR	NR
Incidental Ingestion	NR	NR
Incidental Inhalation-Spray	1[a]	NR
Incidental Inhalation-Powder	NR	0.2
Dermal Contact	NR	0.2
Deodorant (underarm)	NR	NR
Hair - Non-Coloring	NR	NR
Hair-Coloring	NR	NR
Nail	NR	25
Mucous Membrane	NR	NR
Baby Products	NR	NR

NR = Not reported.

† 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.

[a.] It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.

[b.] Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.

[c.] It is possible these products may be powders, but it is not specified whether the reported uses are powders.

Table 5. Current and historical frequency and concentration according to duration and type of exposure for previously reviewed fatty acids and soaps

	Aluminum Distearate				Aluminum Stearate			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2018[38]	**2001/2003[2]**	**2016[39]**	**2001/2003[2]**	**2018[38]**	**2001/2003[2]**	**2016[39]**	**2001/2003[2]**
Totals†	**23**	**50**	**0.004-5.5**	**0.1-5**	**50**	**3**	**0.00014-3.4**	**0.3-8**
Duration of Use								
Leave-On	*20*	*46*	*0.004-5.5*	*0.1-5*	*49*	*3*	*0.0099-3.1*	*0.3-8*
Rinse Off	*3*	*4*	*0.054-4*	*3*	*1*	*NR*	*0.00014-3.4*	*1-4*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	6	21	0.08-5.2	3	6	1	0.0099-1.8	0.5-7
Incidental Ingestion	1	1	0.36-0.4	5	NR	NR	NR	0.3-1
Incidental Inhalation-Spray	1[a]; 1[b]	1[a]; 1[b]	NR	0.1-0.5[a]	14[a]; 13[b]	1[b]	NR	0.4-8[a]; 0.3-0.4[b]
Incidental Inhalation-Powder	4; 1[b]	3; 1[b]	0.1-4.5; 0.048-1.5[c]	NR	13[b]	1[b]	3.1; 0.0099-1.3[c]	4; 0.3-0.4[b]
Dermal Contact	17	43	0.004-5.5	0.1-3	44	2	0.0099-3.1	0.3-8
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	2	NR	0.00014-0.00016	NR
Hair-Coloring	3	3	4	3	1	NR	3.4	NR
Nail	NR	NR	0.37	NR	1	NR	NR	NR
Mucous Membrane	1	1	0.36-0.4	5	NR	NR	NR	0.3-1
Baby Products	NR	NR	NR	NR	NR	NR	0.53	NR

	Aluminum Tristearate				Calcium Stearate			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2018[38]	**2001/2003[2]**	**2016[39]**	**2001/2003[2]**	**2018[38]**	**2001/2003[2]**	**2016[39]**	**2001/2003[2]**
Totals†	**2**	**12**	**NR**	**NR**	**263**	**107**	**0.000098-5**	**0.02-23**
Duration of Use								
Leave-On	*2*	*11*	*NR*	*NR*	*256*	*103*	*0.000098-5*	*0.02-23*
Rinse Off	*NR*	*1*	*NR*	*NR*	*7*	*4*	*0.00089-2.4*	*0.1-2*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	NR	4	NR	NR	211	72	0.01-4	0.2-20
Incidental Ingestion	NR	NR	NR	NR	3	3	0.1-2	1-23
Incidental Inhalation-Spray	1[b]	5[a]; 1[b]	NR	NR	1; 3[b]	1	0.000098-0.05; 0.005-0.025[a]	3
Incidental Inhalation-Powder	1[b]	1[b]	NR	NR	12; 3[b]	12	0.1-5; 0.65-5[c]	0.2-9
Dermal Contact	2	3	NR	NR	254	99	0.00089-5	0.02-20
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	5	0.02[a]
Hair - Non-Coloring	NR	5	NR	NR	NR	NR	0.000098-0.03	NR
Hair-Coloring	NR	NR	NR	NR	5	4	0.09-2.4	1
Nail	NR	NR	NR	NR	1	1	0.03-5	0.09-4
Mucous Membrane	NR	NR	NR	NR	4	3	0.1-2	1-23
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR

	Hydroxystearic Acid				Isostearic Acid			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2018[38]	**1996[4]**	**2016[39]**	**1995[4]**	**2018[38]**	**2002/2005[6]**	**2016[39]**	**2002/2005[6]**
Totals†	**124**	**2**	**0.00011-14**	**2.5-10**	**270**	**119**	**0.004-20**	**0.003-26**
Duration of Use								
Leave-On	122	2	0.005-14	2.5-10	233	113	0.012-16	0.003-16
Rinse Off	2	NR	0.00011-2	NR	37	6	0.004-20	1-26
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure Type								
Eye Area	13	NR	0.018-14	NR	80	13	0.013-9.5	0.01-3
Incidental Ingestion	60	NR	0.15-10	2.5	16	6	0.025-0.29	10
Incidental Inhalation-Spray	2; 7[a]; 3[b]	2[b]	NR	NR	39[a]; 47[b]	32[a]; 9[b]	0.032; 0.02-3[a]	0.5-3[a]; 0.3-2[b]
Incidental Inhalation-Powder	3[b]	2[b]	0.5; 0.001-2.6[c]	NR	1[c]; 47[b]	3; 9[b]	0.012-0.3; 0.045-3.8[c]	0.3-3; 0.3-2[b]
Dermal Contact	61	2	0.005-14	5-10	177	96	0.01-9.6	0.003
Deodorant (underarm)	9[a]	NR	NR	5-10[a]	2[a]	2[a]	NR	NR
Hair - Non-Coloring	2	NR	0.8-4	NR	5	4	0.004-2	1
Hair-Coloring	NR	NR	NR	NR	2	NR	0.75-20	18
Nail	1	NR	0.00011-0.038	NR	NR	2	3-16	2
Mucous Membrane	60	NR	0.15-10	2.5	34	6	0.025-0.29	2
Baby Products	NR	NR	NR	NR	1	NR	NR	NR

Table 5. Current and historical frequency and concentration according to duration and type of exposure for previously reviewed fatty acids and soaps

	Lauric Acid				Lithium Stearate			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2018[38]	**2006[8]**	**2016[39]**	**2006[8]**	**2018[38]**	**2001/2003[2]**	**2016[39]**	**2001/2003[2]**
Totals[†]	**517**	**121**	**0.0011-18**	**0.000004-11**	**85**	**17**	**0.1-4**	**2-3**
Duration of Use								
Leave-On	30	11	0.0011-13	0.00002-3	85	17	0.1-4	2-3
Rinse Off	485	90	0.005-18	0.000004-8	NR	NR	NR	NR
Diluted for (Bath) Use	2	20	0.11	2-11	NR	NR	NR	NR
Exposure Type								
Eye Area	1	NR	0.0048-0.8	NR	79	1	NR	2
Incidental Ingestion	3	1	0.0011	0.00003	4	1	NR	NR
Incidental Inhalation-Spray	4[a]; 9[b]	7[a]	0.2; 0.2[a]	0.00002-0.001; 0.00003-1[a]; 0.00006[b]	NR	NR	NR	3[a]
Incidental Inhalation-Powder	9[b]	NR	0.019-10[c]	0.00006[b]	NR	2	3	NR
Dermal Contact	322	70	0.0018-18	0.00002-11	81	16	0.1-4	2
Deodorant (underarm)	5[a]	3[a]	0.3	0.3[a]	NR	NR	NR	NR
Hair - Non-Coloring	35	7	0.005-4.2	0.000004-4	NR	NR	NR	3
Hair-Coloring	156	43	0.01-1.5	NR	NR	NR	NR	NR
Nail	1	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	136	40	0.0011-5	0.00003-11	4	1	NR	NR
Baby Products	1	NR	0.0018-0.31	NR	NR	NR	NR	NR

	Magnesium Stearate				Myristic Acid			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2018[38]	**2001/2003[2]**	**2016[39]**	**2001/2003[2]**	**2018[38]**	**2010[9]**	**2016[39]**	**2010[9]**
Totals[†]	**807**	**96**	**0.012-10**	**0.02-8**	**369**	**207**	**0.0005-28.7**	**0.00002-20**
Duration of Use								
Leave-On	754	92	0.012-10	0.02-8	162	61	0.0005-20.2	0.00002-20
Rinse Off	53	4	0.33-5	1	205	146	0.0031-28.7	0.00002-19
Diluted for (Bath) Use	NR	NR	NR	NR	2	NR	1	2
Exposure Type								
Eye Area	420	49	0.5-10	1-5	34	3	0.011-1	0.5
Incidental Ingestion	4	NR	0.012	1	2	5	NR	NR
Incidental Inhalation-Spray	2; 17[a]; 5[b]	6[a]; 8[b]	0.75; 0.15-0.6[a]	0.02-3[a]; 0.1[b]	1; 28[a]; 64[b]	11[a]; 14[b]	2.5; 0.002-7[a]	0.00002; 0.00002-2[a]; 0.8-20[b]
Incidental Inhalation-Powder	132; 5[b]	21; 8[b]	1-7.2; 0.12-1[c]	1-8; 0.1[b]; 2[c]	10; 64[b]	1; 14[b]	0.1-0.66; 0.03-20.2[c]	0.5; 0.8-20[b]
Dermal Contact	748	95	0.03-10	0.02-8	339	171	0.0005-28.7	0.005-20
Deodorant (underarm)	NR	NR	NR	NR	1[a]	1[a]	0.015	2[a]
Hair - Non-Coloring	7	NR	0.15-1	NR	13	29	0.002-7	0.00002-5
Hair-Coloring	44	NR	0.33-5	NR	NR	NR	0.2-0.33	0.00002
Nail	NR	NR	NR	NR	2	NR	0.04	NR
Mucous Membrane	8	5	0.012	1	34	16	0.0031-1.35	0.1-19
Baby Products	NR	NR	NR	2	NR	NR	0.05	NR

	Oleic Acid				Palmitic Acid			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2018[38]	**2006[8]**	**2016[39]**	**2006[8]**	**2018[38]**	**2006[8]**	**2016[39]**	**2006[8]**
Totals[†]	**1052**	**1131**	**0.0002-20.9**	**0.000004-20**	**1240**	**132**	**0.000000001-21**	**0.000006-20**
Duration of Use								
Leave-On	294	106	0.0002-17	0.00005-20	924	47	0.000000001-21	0.00003-16
Rinse Off	758	1014	0.0005-20.9	0.000004-19	312	74	0.00082-21	0.00002-20
Diluted for (Bath) Use	NR	11	0.0005-3	NR	2	11	NR	0.000006-2
Exposure Type								
Eye Area	69	49	0.01-5	0.1-5	204	3	0.011-5.3	0.003-4
Incidental Ingestion	87	5	0.0015-0.2	16	99	1	0.00033-1	0.2-16
Incidental Inhalation-Spray	72[a]; 29[b]	6; 14[a]; 2[b]	0.0007-1.5; 0.003-3.8[a]	0.001; 0.02-0.6[a]; 0.2-2[b]	3; 251[a]; 214[b]	1; 16[a]; 5[b]	0.0003-0.8; 0.000000001-8[a]	0.01-3; 0.00003-3[a]; 0.05-7[b]
Incidental Inhalation-Powder	1[c]; 29[b]	1[c]; 2[b]	0.24; 0.04-3.3[c]	0.0001; 1[c]; 0.2-2[b]	14; 2[c]; 214[b]	1; 5[b]	0.12; 0.03-8.6[c]	0.01-1; 0.5-7[b]
Dermal Contact	164	102	0.0002-20.9	0.000004-15	898	99	0.000005-21	0.000006-20
Deodorant (underarm)	3[a]	NR	0.64; 1.5[d]	0.0007-0.6[a]	35[a]	1[a]	0.06-3.5; 0.0021[d]	0.09-3[a]
Hair - Non-Coloring	21	10	0.001-3.8	0.000007-20	43	30	0.000000001-8	0.00002-3
Hair-Coloring	720	974	1.4-17	19	60	1	0.005-2	NR
Nail	7	2	0.0003-0.3	0.0008	4	NR	0.0042-7.5	0.02-0.03
Mucous Membrane	90	40	0.0005-10	0.000004-16	158	22	0.00033-9.7	0.000006-16
Baby Products	1	6	0.1-0.36	1-2	2	NR	0.98-1.7	NR

Table 5. Current and historical frequency and concentration according to duration and type of exposure for previously reviewed fatty acids and soaps

	Potassium Stearate				Potassium Tallate			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2018[38]	**2001/2003[2]**	**2016[39]**	**2001/2003[2]**	**2018[38]**	**2009[10]**	**2016[39]**	**2009[10]**
Totals†	**158**	**NR**	**0.0083-45**	**0.05-12**	**NR**	**9**	**NR**	**NR**
Duration of Use								
Leave-On	76	NR	0.0083-7.5	0.05	NR	NR	NR	NR
Rinse Off	82	NR	0.0097-45	12	NR	9	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure Type								
Eye Area	5	NR	0.033-0.8	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	28[a]; 24[b]	NR	0.2-7.5[a]	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	7; 1[c]; 24[b]	NR	0.0083; 0.18-1.8[c]	NR	NR	NR	NR	NR
Dermal Contact	136	NR	0.0083-45	0.05-12	NR	9	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	11	NR	0.0097-7.5	NR	NR	NR	NR	NR
Hair-Coloring	9	NR	3.1	NR	NR	NR	NR	NR
Nail	1	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	19	NR	0.59-3	NR	NR	9	NR	NR
Baby Products	1	NR	NR	NR	NR	NR	NR	NR

	Sodium Stearate				Stearic Acid			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2018[38]	**2001/2003[2]**	**2016[39]**	**2001/2003[2]**	**2018[38]**	**2006[8]**	**2016[39]**	**2006[8]**
Totals†	**519**	**184**	**0.000075-84**	**0.0001-25**	**5738**	**2133**	**0.00006-37.4**	**0.000002-43**
Duration of Use								
Leave-On	330	132	0.000075-84	0.0001-25	4616	1580	0.0001-21	0.00005-22
Rinse Off	189	51	0.000075-84	0.3-18	1119	539	0.00006-37.4	0.000002-43
Diluted for (Bath) Use	NR	1	NR	NR	3	14	0.02-1	0.000007-7
Exposure Type								
Eye Area	12	4	0.09-8.4	0.7-8	789	224	0.002-21	0.009-22
Incidental Ingestion	1	NR	7	0.1	103	40	0.0013-12	0.02-9
Incidental Inhalation-Spray	30[a]; 31[b]	6; 5[a]; 11[b]	0.13[a]	5-8; 7[a]	4; 1952[a]; 1180[b]	32; 490[a]; 409[b]	0.00015-3; 0.01-20[a]; 2.3-5.5[b]	1-16; 0.01-10[a]; 0.1-16[b]
Incidental Inhalation-Powder	1; 31[b]	2[c]; 11[b]	0.1-6[c]	NR	27; 28[c]; 1180[b]	6; 11[c]; 409[b]	0.36-2.1; 0.05-20[v]; 2.3-5.5[b]	0.1-1; 2-3[c]; 0.1-16[b]
Dermal Contact	475	170	0.000075-84	0.0001-25	4822	1819	0.0001-37.4	0.000007-43
Deodorant (underarm)	215[a]	101[a]	3.5-10	5-25[a]	54[a]	21[a]	0.05-4.1	0.2-9[a]
Hair - Non-Coloring	2	NR	0.00075-0.1	NR	124	29	0.00006-20	0.000002-7
Hair-Coloring	40	14	0.4-5.5	10-12	240	137	0.08-5	NR
Nail	NR	NR	7.5	NR	8	13	0.021-9.1	0.04-5
Mucous Membrane	106	32	0.001-34.3	0.1-18	331	101	0.0013-37.4	0.000007-19
Baby Products	NR	2	0.033	NR	30	18	0.03-2.1	0.1-3

NR = Not reported.

† 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.

[a] It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.

[b] Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.

[c] It is possible these products may be powders, but it is not specified whether the reported uses are powders.

[d] spray deodorant

Table 6. Ingredients not reported in use.

Aluminum Dilinoleate
Aluminum Isostearate
Aluminum Isostearates/Palmitates
Aluminum Isostearates/Stearates
Aluminum Isostearates/Laurates/Palmitates
Aluminum Isostearates/Laurates/Stearates
Aluminum Lanolate
Ammonium Isostearate
Ammonium Oleate
Ammonium Stearate
Beeswax Acid
C32-36 Isoalkyl Acid
Calcium Laurate
Calcium Undecylenate
Dierucic Acid
Eicosatrienoic Acid
Erucic Acid
Hydroxylauric Acid
10-Hydroxystearic Acid
Isomerized Safflower Acid
Magnesium Lanolate
Magnesium Palmitate
Magnesium Tallowate
Methyl Myristic Acid
Potassium Borageate
Potassium Camelliate
Potassium Caprate
Potassium Caprylate
Potassium Caprylate/Caprate
Potassium Hydroxystearate
Potassium Lanolate
Potassium Linoleate
Potassium Linseedate
Potassium Olivate/Sunflowerseedate
Potassium Sunflowerseedate
Potassium Undecylenate
Sodium Arganate
Sodium Beeswax
Sodium Camellia Japonica Seedate
Sodium Caprate
Sodium Caprylate
Sodium Dilinoleate
Sodium Hydrogenated Tallowate
Sodium Hydroxystearate
Sodium Lanolate
Sodium Lardate
Sodium Linoleate
Sodium Tamanuseedate
Sodium Undecylenate

Table 7. FDA and EPA regulations applicable to fatty acids and soaps

21 CFR §172.515 – Food Additives Permitted for Direct Addition to Food for Human Consumption: Synthetic flavoring substances and adjuvants
Caproic Acid, Undecylenic Acid
21 CFR §172.615 – Food Additives Permitted for Direct Addition to Food for Human Consumption: Chewing gum base
Potassium Stearate, Sodium Stearate, Stearic Acid
21 CFR §172.860 – Food Additives Permitted for Direct Addition to Food for Human Consumption: Fatty Acids
Capric Acid, Caprylic Acid, Lauric Acid, Myristic Acid, Oleic Acid, Palmitic Acid, Stearic Acid
21 CFR §172.862 – Food Additives Permitted for Direct Addition to Food for Human Consumption: Oleic acid derived from tall oil fatty acids
Oleic Acid
21 CFR §172.863 – Food Additives Permitted for Direct Addition to Food for Human Consumption: Salts of fatty acids
Aluminum Distearate, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearate, Calcium Laurate, Calcium Stearate, Magnesium Palmitate, Magnesium Stearate, Potassium Caprate, Potassium Laurate, Potassium Oleate, Potassium Palmitate, Potassium Stearate, Sodium Caprate, Sodium Laurate, Sodium Oleate, Sodium Palmitate, Sodium Stearate
21 CFR §173.315 – Secondary Direct Food Additives Permitted in Food for Human Consumption: Chemicals used in washing or to assist in the peeling of fruits and vegetables
Caproic Acid, Caprylic Acid, Oleic Acid
21 CFR §173.340 – Secondary Direct Food Additives Permitted in Food for Human Consumption: Defoaming agents
Aluminum Distearate, Aluminum Stearate, Aluminum Tristearate, Calcium Stearate, Capric Acid, Caprylic Acid, Lauric Acid, Magnesium Stearate, Myristic Acid, Oleic Acid, Palmitic Acid, Potassium Stearate, Stearic Acid,
21 CFR §175.105 – Approved Indirect Food Additives: Adhesives and Components of Coatings - Adhesives
Aluminum Dilinoleate, Aluminum Distearate, Aluminum Isostearates/Palmitates, Aluminum Isostearates/Laurates/Palmitates, Aluminum Isostearates/Laurates/Stearates, Aluminum Lanolate, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearate, Aluminum Isostearate, Ammonium Oleate, Ammonium Stearate, Calcium Behenate, Calcium Laurate, Calcium Stearate, Capric Acid, Caprylic Acid, Hydroxystearic Acid, Lauric Acid, Linoleic Acid, Magnesium Palmitate, Magnesium Stearate, Magnesium Tallowate, Myristic Acid, Oleic Acid, Palmitic Acid, Potassium Behenate, Potassium Caprate, Potassium Castorate, Potassium Isostearate, Potassium Laurate, Potassium Linoleate, Potassium Oleate, Potassium Palmitate, Potassium Stearate, Potassium Tallate, Potassium Tallowate, Sodium Behenate, Sodium Caprate, Sodium Caprylate, Sodium Dilinoleate, Sodium Isostearate, Sodium Laurate, Sodium Linoleate, Sodium Oleate, Sodium Palmitate, Sodium Stearate, Sodium Tallowate, Stearic Acid
21 CFR §175.210 – Approved Indirect Food Additives: Adhesives and Components of Coatings – Acrylate ester copolymer coating
Aluminum Stearate
21 CFR §175.300 – Approved Indirect Food Additives: Adhesives and Components of Coatings – Resinous and polymeric coatings
Aluminum Distearate, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearate, Calcium Stearate, Lithium Stearate, Magnesium Palmitate, Magnesium Stearate, Potassium Oleate, Potassium Stearate, Sodium Oleate, Sodium Stearate, Stearic Acid,
21 CFR §175.320 – Approved Indirect Food Additives: Adhesives and Components of Coatings – Resinous and polymeric coatings for polyolefin films
Aluminum Distearate, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearate, Ammonium Oleate, Ammonium Stearate, Calcium Stearate, Capric Acid, Caprylic Acid, Lauric Acid, Magnesium Palmitate, Magnesium Stearate, Myristic Acid, Oleic Acid, Palmitic Acid, Sodium Caprylate, Sodium Laurate, Sodium Oleate, Sodium Palmitate, Sodium Stearate, Sodium Tallowate, Stearic Acid,
21 CFR §176.170 – Approved Indirect Food Additives: Paper and Paperboard Components – Components for paper and paperboard in contact with aqueous and fatty foods
Aluminum Distearate, Aluminum Isostearates/Palmitates, Aluminum Isostearates/Stearates, Aluminum Isostearates/Laurates/Palmitates, Aluminum Isostearates/Laurates/Stearates, Aluminum Lanolate, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearate, Ammonium Isostearate, Ammonium Oleate, Ammonium Stearate, Behenic Acid, Calcium Behenate, Calcium Laurate, Calcium Stearate, Capric Acid, Caprylic Acid, Isostearic Acid, Lauric Acid, Linoleic Acid, Magnesium Lanolate, Magnesium Palmitate, Magnesium Stearate, Magnesium Tallowate, Myristic Acid, Oleic Acid, Palmitic Acid, Potassium Behenate, Potassium Caprate, Potassium Castorate, Potassium Isostearate, Potassium Lanolate, Potassium Laurate, Potassium Linoleate, Potassium Oleate, Potassium Palmitate, Potassium Stearate, Potassium Tallate, Potassium Tallowate, Sodium Behenate, Sodium Caprate, Sodium Caprylate, Sodium Castorate, Sodium Isostearate, Sodium Lanolate, Sodium Lardate, Sodium Laurate, Sodium Linoleate, Sodium Oleate, Sodium Palmitate, Sodium Stearate, Sodium Tallowate, Stearic Acid,
21 CFR §176.200 - Approved Indirect Food Additives: Paper and Paperboard Components –Defoaming agents used in coatings
Aluminum Distearate, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearate, Ammonium Oleate, Ammonium Stearate, Calcium Stearate, Capric Acid, Caprylic Acid, Dilinoleic Acid, Lauric Acid, Magnesium Palmitate, Magnesium Stearate, Myristic Acid, Oleic Acid, Palmitic Acid, Potassium Castorate, Potassium Laurate, Potassium Laurate, Potassium Oleate, Potassium Palmitate, Potassium Stearate, Potassium Tallowate, Sodium Caprylate, Sodium Castorate, Sodium Laurate, Sodium Oleate, Sodium Palmitate, Sodium Stearate, Sodium Tallowate, Stearic Acid, Trilinoleic Acid
21 CFR §176.210 - Approved Indirect Food Additives: Paper and Paperboard Components –Defoaming agents used in the manufacture of paper and paperboard
Aluminum Distearate, Aluminum Isostearates/Laurates/Palmitates, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearate, Ammonium Oleate, Ammonium Stearate, Calcium Laurate, Calcium Stearate, Capric Acid, Caprylic Acid, Dilinoleic Acid, Hydroxystearic Acid, Lauric Acid, Magnesium Palmitate, Magnesium Stearate, Magnesium Tallowate, Myristic Acid, Oleic Acid, Palmitic Acid, Potassium Castorate, Potassium Laurate, Potassium Oleate, Potassium Palmitate, Potassium Stearate, Sodium Caprylate, Sodium Castorate, Sodium Laurate, Sodium Oleate, Sodium Palmitate, Sodium Stearate, Stearic Acid
21 CFR §177.1010 – Indirect Food Additives; Acrylic and modified acrylic plastics, semirigid and rigid
Capric Acid, Caprlyci Acid, Lauric Acid, Myristic Acid, Oleic Acid, Palmitic Acid, Stearic Acid
21 CFR §177.1200 - Indirect Food Additives: Polymers – Cellophane
Aluminum Distearate, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearate, Ammonium Oleate, Ammonium Stearate, Calcium Stearate, Capric Acid, Caprylic Acid, Lauric Acid, Magnesium Palmitate, Magnesium Stearate, Myristic Acid, Oleic Acid, Palmitic Acid, Potassium Castorate, Potassium Laurate, Potassium Oleate, Potassium Palmitate, Potassium Stearate, Potassium Tallate, Potassium Tallowate, Sodium Caprylate, Sodium Laurate, Sodium Oleate, Sodium Palmitate, Sodium Stearate, Stearic Acid,
21 CFR §177.2260 –Indirect Food Additives: Polymers – Filters, resin-bonded
Aluminum Distearate, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearate, Ammonium Oleate, Ammonium Stearate, Calcium Stearate, Capric Acid, Caprylic Acid, Lauric Acid, Magnesium Palmitate, Magnesium Stearate, Myristic Acid, Oleic Acid, Palmitic Acid, Potassium Laurate, Potassium Oleate, Potassium Palmitate, Potassium Stearate, Potassium Tallowate, Sodium Caprylate, Sodium Laurate, Sodium Oleate, Sodium Stearate, Stearic Acid
21 CFR §177.2600 – Indirect Food Additives: Polymers – Rubber articles for repeated use

Table 7. FDA and EPA regulations applicable to fatty acids and soaps

Behenic Acid, Calcium Stearate, Capric Acid, Caproic Acid, Caprylic Acid, Erucic Acid, Isostearic Acid, Lauric Acid, Linoleic Acid, Linolenic Acid, Myristic Acid, Oleic Acid, Palmitic Acid, Potassium Castorate, Potassium Laurate, Potassium Oleate, Potassium Palmitate, Potassium Stearate, Potassium Tallate, Potassium Tallowate, Sodium Caprylate, Sodium Castorate, Sodium Laurate, Sodium Oleate, Sodium Palmitate, Sodium Stearate, Sodium Tallowate, Stearic Acid
21 CFR §177.2800 – Indirect Food Additives: Polymers - Textiles and textile fibers
Aluminum Stearate, Capric Acid, Caprylic Acid, Lauric Acid, Myristic Acid, Oleic Acid, Palmitic Acid, Potassium Castorate, Potassium Laurate, Potassium Oleate, Potassium Palmitate, Potassium Stearate, Potassium Tallate, Potassium Tallowate, Sodium Caprylate, Sodium Castorate, Sodium Laurate, Sodium Oleate, Sodium Palmitate, Sodium Stearate, Sodium Tallowate, Stearic Acid
21 CFR §178.1010 – Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers – Sanitizing solutions
Calcium Stearate, Capric Acid, Caprylic Acid
21 CFR §178.2010 –Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers – Antioxidants and/or stabilizers for polymers
Calcium Stearate
21 CFR §178.3297 – Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers – Colorants for polymers
Aluminum Distearate, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearate
21 CFR §178.3570 – Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers – Lubricants with incidental food contact
Capric Acid, Caprylic Acid, Hydroxystearic Acid, Lauric Acid, Myristic Acid, Oleic Acid, Palmitic Acid, Stearic Acid
21 CFR §178.3910 – Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers – Surface lubricants used in the manufacture of metallic articles
Aluminum Distearate, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearate, Capric Acid, Caprylic Acid, Dilinoleic Acid, Lauric Acid, Magnesium Palmitate, Magnesium Stearate, Magnesium Tallowate, Myristic Acid, Oleic Acid, Palmitic Acid, Potassium Castorate, Potassium Laurate, Potassium Oleate, Potassium Palmitate, Potassium Stearate, Potassium Tallate, Potassium Tallowate, Sodium Caprylate, Sodium Castorate, Sodium Laurate, Sodium Oleate, Sodium Palmitate, Sodium Stearate, Sodium Tallowate, Stearic Acid, Trilinoleic Acid
21 CFR §179.45 – Irradiation in the Production, Processing and Handling of Food – Packaging materials for use during the irradiation of prepackaged foods (limit for stearates = not to exceed 1% by weight of the polymer)
Aluminum Distearate, Aluminum Stearate, Aluminum Stearates, Aluminum Tristearates, Calcium Stearate, Magnesium Stearate, Potassium Stearate, Sodium Stearate,
21 CFR §181.29 – Prior-Sanctioned Food Ingredients – Stabilizers
Aluminum Distearate, Aluminum Stearate, Aluminum Tristearate, Calcium Stearate, Magnesium Stearate, Potassium Oleate, Potassium Stearate, Sodium Stearate,
21 CFR §182.70 and §182.90– Substances Generally Recognized as Safe: Substances migrating from cotton and cotton fabrics used in dry food packaging and substances migrating from paper and paperboard products
Oleic Acid
21 CFR §184.1025, §184.1065, §184.1090, §184.1229, and §184.1440 – Direct Food Substances Affirmed as Generally Recognized as Safe
Calcium Stearate, Caprylic Acid, Linoleic Acid, Magnesium Stearate, Stearic Acid
21 CFR §186.1770 and §186.1771 – Indirect Food Substances Affirmed as Generally Recognized as Safe
Sodium Oleate, Sodium Palmitate
21 CFR §310.545 – New Drugs: Drug products containing certain active ingredients offered over-the-counter
Calcium Undecylenate (dandruff/seborrheic dermatitis/psoriasis drug product), Sodium Capyrlate (topical antifugal drug products for diaper rash drug products), Sodium Oleate (laxative drug products), Undecylenic Acid (dandruff/seborrheic dermatitis/psoriasis drug product)
21 CFR §333.210 – Topical Antimicrobial Drug Products for Over-the-Counter Human use: Antifugal active ingredients
Calcium Undecylenate and Undecylenic Acid (total undecylenate concentration of 10%-15%)
21 CFR §522.1610 – Implantation or Injectable Dosage Form New Animal Drugs
Sodium Oleate
21 CFR §573.280 – Food Additives Permitted in Feed and Drinking Water of Animals – Feed-grade
Calcium Stearate and Sodium Stearate
21 CFR §582.5065 – Substances Generally Recognized as Safe for Animals
Linoleic Acid
40 CFR §180.940 – Tolerances and Exemptions for Pesticide Chemical Residues in Food: Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions)
Calcium Stearate (no limit), Capric Acid (end-use concentration not to exceed 100 ppm), Caprylic Acid (end-use concentration not to exceed 52 ppm)
40 CFR §180.1068 – Tolerances and Exemptions for Pesticide Chemical Residues in Food: C_{12}-C_{18} fatty acid potassium salts; exemption from the requirement of a tolerance
Potassium Laurate, Potassium Oleate, Potassium Palmitate, Potassium Stearate

Table 8. Non-cosmetic uses of fatty acid and soaps[67,68]

Aluminum Distearate	Thickener in paints, inks and greases; water repellent; lubricant in plastics and cordages; in cement production
Aluminum Stearate	Paint and varnish drier; greases; waterproofing agent; cement additive; lubricants; cutting compounds; flatting agents; pharmaceuticals; defoaming agent in beet sugar and yeast processing
Aluminum Tristearate	Waterproofing fabrics and ropes; in paint and varnish driers; thickening lubricating oils; in cements; in light-sensitive photographic compositions
Ammonium Oleate	Detergent; solidifying alcohol; emulsifying agent
Ammonium Stearate	In waterproofing cements, concrete, stucco, paper, textiles, etc.
Arachidic Acid	Organic synthesis; lubricating greases; waxes and plastics, source of arachidyl alcohol; biochemical research
Behenic Acid	In lubricating oils; as solvent evaporation retarder in paint removers; waxes; plasticizers; chemicals; stabilizers
Calcium Stearate	For waterproofing fabrics, cement, stucco and explosives; as a releasing agent for plastic molding powders; as a stabilizer for polyvinyl chloride resins; lubricant in making tablets; in pencils and wax crayons; in food and pharmaceuticals as a conditioning agent; flatting agent in paints
Calcium Undecylenate	Bacteriostat and fungistat in pharmaceuticals
Capric Acid	Manufacture of esters for artificial fruit flavors and perfumes; as an intermediate in other chemical syntheses; base for wetting agents; plasticizer; resins; intermediate for food-grade additives
Caproic Acid	Manufacture of esters for artificial flavors and hexyl derivatives; analytical chemistry; manufacture of rubber chemicals; varnish driers, resins; pharmaceuticals
Caprylic Acid	An intermediate in manufacture of esters used in perfumery; in manufacture of dyes, drugs, antiseptics, and fungicides; ore separations; synthetic flavors
Dilinoleic Acid	Modifier in alkyd and polyamide resins; polyester or metallic soap for petroleum additive; emulsifying agent; adhesives; shellac substitute; to upgrade drying oils
Erucic Acid	Preparation of dibasic acids and other chemicals; polyethylene film additive; water-resistant nylon
Hydroxystearic Acid	Lithium greases; chemical intermediates
Lauric Acid	Alkyd resins; wetting agents; soaps; detergents; insecticides; food additives
Linoleic Acid	Manufacture of paints, coatings, emulsifiers, vitamins; soaps; special driers for protective coatings; feeds, geochemical research; dietary supplement; margarine
Linolenic Acid	Dietary supplement/nutrient; biochemical research; drying oils
Lithium Stearate	Plastics; waxes; greases; lubricant in powder metallurgy; corrosive inhibitor in petroleum; flatting agent in varnishes and lacquers; high-temperature lubricant
Magnesium Palmitate	Varnish drier; lubricant for plastics
Magnesium Stearate	Lubricant in making tablets; drier in paints and varnishes; flatting agent; stabilizer and lubricant for plastics; dietary supplement; in medicines
Myristic Acid	In lubricants; in coatings for anodized aluminum; antifoaming agent in pharmaceutic aids; soaps; synthesis of esters for flavors and perfumes; component of food-grade additives
Oleic Acid	In preparation of Turkey red oil; in polishing compounds; in waterproofing textiles and oiling wool; manufactured driers; thickening lubricating oils; emulsifying and solubilizing agent in pharmaceutic acids and a diagnostic aid for pancreatic function; soap base; manufacture of oleates; ointments; ore flotation; intermediate; surface coatings; food grade additives
Palmitic Acid	Manufacture of metallic palmitates; soaps; lubricating oils; waterproofing; food-grade additives
Potassium Laurate	Emulsifying agent
Potassium Linoleate	Emulsifying agent
Potassium Oleate	Detergent
Potassium Stearate	Anti-tack or release agent for elastomers; binder, emulsifier or anticaking agent in foods; stabilizer for chewing gum; base for textile softeners
Potassium Undecylenate	Bacteriostat and fungistat in pharmaceuticals
Sodium Oleate	Ore flotations; waterproofing textiles; emulsifier of oil-water systems

Table 8. Non-cosmetic uses of fatty acid and soaps[67,68]

Sodium Palmitate	Polymerization catalyst for synthetic rubbers; laundry soap; detergents; phamaceuticals; printing inks; emulsifier
Sodium Stearate	Industrial and household soap; emulsifying and stiffening agent in pharmaceutic acids; waterproofing and gelling agent, stabilizer in plastics
Sodium Undecylenate	Bacteriostat and fungistat in pharmaceuticals
Stearic Acid	For suppositories, coating enteric pills, ointments, and for coating bitter remedies; in the manufacture of metal stearate salts, stearin soap for opodeldoc, candles, phonograph records, insulators, and modeling compounds; impregnating plaster of Paris; stearates and stearate driers; lubricants; soaps; accelerator activator; dispersing agent and softener in rubber compounds; shoe and metal polishes; food packaging
Undecanoic Acid	Organic synthesis
Undecylenic Acid	Antifungal therapy; perfumery; flavoring; plastics; modifying agent (plasticizer, lubricant additive, etc.)

Table 9. Acute toxicity studies

Concentration/Vehicle	Dose/Study Protocol	Results	LD_{50} or LC_{50}	Reference
		Dermal		
Capric Acid in PEG 300	Acute dermal toxicity study in 5 male and 5 female HanRcc:WIST (SPF) rats; performed in accordance with OECD test guideline 402; test sites were clipped and semi-occluded; skin was rinsed with water after 24 h; 2000 mg/kg bw	4/5 males and 3/5 females were slightly to moderately sedated on day 2 after patch removal; at same time point, 3/5 males and 2/5 females had deep respiration and 3/5 males and 1/5 females had hunched posture; 1/5 females lost 2.3% body weight in the 1st week after treatment; no adverse effects observed at necropsy; slight to moderate erythema noted in all animals at patch removal; slight to moderate scaling in all animals and slight scabs observed in all but one female, which reversed by day 5	> 2000 mg/kg bw	22
Lithium Stearate; no vehicle used	Acute dermal toxicity study in 5 male and 5 female Wistar rats; performed in accordance with OECD test guideline 402; test sites were clipped and semi-occluded; test material was removed after 24 h; 2000 mg/kg bw	No clinical signs of toxicity or abnormal findings at necropsy were observed	> 2000 mg/kg bw	27
Stearic Acid; concentration and vehicle were not reported	Fixed dose dermal toxicity study in 3 male and 3 female New Zealand White rabbits; test sites were occluded; test material was removed after 24 h; 2000 mg/kg bw	Slight to moderate erythema observed at patch removal and remained, becoming severe in one female; 4 animals had slight to moderate desquamation; slight edema and escar formation was also noted in some animals during the 1st week; slight diarrhea in one female day 3 post-exposure; severe consolidation of the lungs in the only animal that died during the observation period; no other macroscopic abnormalities were observed	> 2000 mg/kg bw	29
Undecylenic Acid; concentration not reported, no vehicle used	Acute dermal toxicity study in 5 male and 5 female Sprague-Dawley rats per dose group; performed in accordance with OECD test guideline 402;test sites were semi-occluded 2000 mg/kg bw	No cutaneous reactions, clinical signs of toxicity, or abnormal findings at necropsy were observed	>2000 mg/kg bw	31
		Oral		
Ammonium Oleate; concentration not reported, no vehicle used	Gavage study in male and female rats (strain not reported); performed in accordance with OECD test guideline 401; 4, 8, 16, 32, 48, or 64 ml/kg; 5 animals per dose	Rats in the 16 mg/kg dose groups and greater experiences nasal hemorrhage, crusted ocular areas, oozed urine, and a debilitated appearance prior to death; mortalities occurred in the 40 ml/kg dose groups and greater	47.3 ml/kg bw or 42,097 mg/kg bw	19
Behenic Acid; 20% in corn oil	Gavage study in 5 male and 5 female Sprague-Dawley rats per dose group; performed in accordance with OECD test guideline 401; 2000 mg/kg bw	No adverse effects observed	> 2000 mg/kg bw	21
Behenic Acid; 50% in DMSO	Gavage study in 5 male and 5 female Wistar rats per dose group; performed in accordance with OECD test guideline 401; 5000 mg/kg bw	Ruffled fur and diminished activity approximately 20 min after treatment that cleared within 24 h; stomach mucosa was reddened and swollen, with remnants of test material undigested	> 5000 mg/kg bw	21
Calcium Stearate in corn oil	Gavage study in 3 female Sprague-Dawley rats; 2000 mg/kg bw; study performed with a 2nd confirmatory experiment (6 rats total)	Soiled perineal region, inanimation, prone position; no unscheduled deaths; no adverse effects at necropsy	> 2000 mg/kg bw	34

Table 9. Acute toxicity studies

Concentration/Vehicle	Dose/Study Protocol	Results	LD_{50} or LC_{50}	Reference
Capric Acid; concentration not reported; no vehicle used	Gavage study in 5 male and 5 female Wistar rats per dose group; performed in accordance with OECD test guideline 401; 2000 mg/kg bw	No clinical signs of toxicity; firm and/or small white/greyish patches in the forestomach observed during necropsy	> 2000 mg/kg bw	[22]
Capric Acid in water; concentration not reported	Gavage study in 5 male and 5 female Wistar rats per dose group; performed in accordance with OECD test guideline 401; 5000 mg/kg bw	Ruffled fur and diminished activity approximately 20 min after treatment that cleared within 24 h; slight reddening of gastric mucosa	> 5000 mg/kg bw	[22]
Caprylic Acid; concentration not reported; no vehicle used	Gavage study in 5 male and 5 female Wistar rats per dose group; performed in accordance with OECD test guideline 401; 2000 mg/kg bw	Firm and/or small white/greyish irregular patches in the forestomach observed in all animals	> 2000 mg/kg bw	[24]
Caprylic Acid; 25% in water	Gavage study in 5 male and 5 female Wistar rats per dose group; performed in accordance with OECD test guideline 401; 5000 mg/kg bw	Clinical signs of toxicity included salivation, reduced breathing and activity, and reduced state in both sexes, additionally ataxia, lateral position and reduced corneal reflex was observed in females; no abnormal findings were observed at necropsy	> 5000 mg/kg bw	[24]
Isomerized Linoleic Acid; concentration not reported; in propylene glycol	Gavage study in 5 male and 5 female Wistar rats per dose group; performed in accordance with OECD test guideline 401; 2000 mg/kg bw	One female rat had bloody eye encrustation and dacryorrhea; no abnormal findings were observed at necropsy	> 2000 mg/kg bw	[25]
Lauric Acid; concentration not reported; in water	Gavage study in 5 male and 5 female Wistar rats per dose group; performed in accordance with OECD test guideline 401; 5000 mg/kg bw	Slightly ruffled fur within 20 min after dosing that reversed within 24 h; slight reddening of gastric mucosa	> 5000 mg/kg bw	[26]
Lauric Acid; concentration not reported; in water and emulsifying agent	Gavage study with Wistar rats; 3 animals each at 2500 and 5000 mg/kg bw and 10 animals at 10,000 mg/kg bw; no further details provided	No mortality or clinical signs of toxicity noted	> 10,000 mg/kg bw	[26]
Lithium Stearate; concentration not reported, in water	Gavage fixed dose study in Wistar rats;1female at 300 mg/kg bw and 5 females at 2000 mg/kg bw; performed in accordance with OECD test guideline 420	Hunched posture, piloerection, ataxia, noisy respiration, sneezing, and increased salivation in rats that received 2000 mg/kg bw; no abnormal findings at necropsy	> 2000 mg/kg bw	[27]
Lithium Stearate; 16.66% in carboxymethyl cellulose	Gavage study in 5 or 10 male and 5 or 10 female Sprague-Dawley rats; 2, 3, 4, or 5 g/kg bw	Hemorrhagic lungs and thymus and reduced hemorrhagic and expanded caecum observed a necropsy	> 5000 mg/kg bw	[27]
Palmitic Acid; concentration not reported, in DMSO	Gavage study in 5 male and 5 female Wistar rats per dose group; performed in accordance with OECD test guideline 401; 5000 mg/kg bw	Clinical signs appeared after 20 min and included slightly diminished activity and ruffled fur; swelling of the gastric mucosa observed at necropsy	> 5000 mg/kg bw	[28]
Stearic Acid; concentration not reported, in DMSO	Gavage study in 5 male and 5 female Wistar rats per dose group; performed in accordance with OECD test guideline 401; 5000 mg/kg bw	Clinical signs appeared after 20 min and included ruffled fur, strong salivation and very diminished activity; swelling of the gastric mucosa observed at necropsy	> 5000 mg/kg bw	[29]
Stearic Acid; 20%, vehicle not reported	Gavage study in 5 male and 5 female Wistar rats per dose group; performed in accordance with OECD test guideline 401; 2000 mg/kg bw	Prior to death, 1 female exhibited dyspnea, lethargy, and bloody nose encrustation on dosing day; one other male had bloody eye encrustation; the female that died had petichiae in the thymus	> 2000 mg/kg bw	[29]
Stearic Acid; 20% w/v aqueous solution	Gavage study in 5 male and 5 female Sprague-Dawley rats per dose group; performed in accordance with OECD test guideline 401; 6000 mg/kg bw	No clinical signs of toxicity or abnormalities at necropsy were observed	> 6000 mg/kg bw	[29]

Table 9. Acute toxicity studies

Concentration/Vehicle	Dose/Study Protocol	Results	LD_{50} or LC_{50}	Reference
Undecylenic Acid; concentration not reported, in corn oil	Gavage study in 5 male and 5 female Sprague-Dawley rats per dose group; performed in accordance with OECD test guideline 401; 2000 mg/kg bw	Hypoactivity and piloerection was observed in 1 male and 1 female on day 1; no other clinical signs of toxicity or abnormal findings at necropsy were observed	>2000 mg/kg bw	[31]
Undecylenic Acid; concentration not reported, in sesame oil	Gavage study in 3-12 male and 3-12 female Carworth CF1 mice per dose group;0.034-0.29 g	Hyperirritability, spamodical jumping, shock-like collapse prior to death	8150 mg/kg bw	[31,51]

Table 10. Repeated dose toxicity studies

Concentration/Dose/Vehicle	Species	Study Protocol/Duration	Results	Reference
		Dermal		
Lithium Stearate; 0, 100, 300, or 1000 mg/kg/ day in water	10 male and 10 female Sprague-Dawley rats per dose group; recovery group had 5 rats per sex per dose	Dermal study in accordance with OECD test guideline 422;2.5 ml/kg applied daily for 6 h; semi-occluded; males treated for 43 days, started 14 days prior to mating, and females treated for 14 days prior to mating to gestation day 19 test sites washed with distilled water after exposure	NOAEL $\geq$ 1000 mg/kg bw/day in paternal animals for systemic effects ; NOAEL = 100 mg/kg bw/day for local effects; treatment-related increased incidence and/or severity of erosion/ulceration, epidermal hyperplasia and exudate, and acute to subacute/chronic inflammation and edema were observed in the mid- and high-dose groups; no treatment-related systemic adverse effects were observed	[27]
		Oral		
Behenic Acid;0, 100, 300, or 1000 mg/kg bw/day in corn oil	13 male and 13 female Sprague-Dawley rats per dose group	Gavage study in accordance with OECD test guideline 422; males were treated 42 days and females were treated for 14 days prior to mating to day 3 of lactation	NOAEL $\geq$ 1000 mg/kg bw/day; no treatment-related adverse effects observed	[21]
Calcium Stearate; 0, 500, 1000, or 2000 mg/kg bw/day in corn oil	10 male and 10 female Sprague-Dawley rats in the control and high dose groups and 5 of each sex in the low- and mid-dose groups	28 day gavage study	NOAEL $\geq$ 2000 mg/kg bw/day; no unscheduled deaths; no significant toxicological changes any test parameter	[34]
Capric Acid;0, 50, 150, or 1000 mg/kg bw/day in propylene glycol	5 male and 5 female Wistar rats per dose group	28 day gavage study in accordance with OECD test guideline 407	NOAEL $\geq$ 1000 mg/kg bw/day; slight to moderate breathing difficulties in several high dose animals only during week 3 of treatment were not considered treatment-related; irregularities in the forestomach were not considered toxicologically relevant	[22]
Capric Acid;0, 50, 250, or 1000 mg/kg bw/day in olive oil	10 male and 10 female Wistar rats per dose group	28 day gavage study in accordance with OECD test guideline 407	NOAEL $\geq$ 1000 mg/kg bw/day; no treatment-related effects were observed, including in the reproductive organs, some histopathologic edemas and ulcerations were attributed to the vehicle	[22]
Capric Acid; 0, 100, 300, or 1000 mg/kg bw/day in corn oil	13 male and 13 female Sprague-Dawley rats per dose group	Gavage study in accordance with OECD test guideline 422; males were treated 42 days and females were treated for 14 days prior to mating to day 3 of lactation	NOAEL $\geq$ 1000 mg/kg bw/day; no treatment-related adverse effects observed	[22]
Linoleic Acid (conjugated); 0% or 1% in semi-purified feed	10 and 11 weanling male Fischer 344 rats in the control and treatment groups, respectively	Dietary study for 18 months; rats were observed closely for clinical signs of toxicity; body weight and feed intake were measured weekly and twice a week, respectively; 3 rats from each group were randomly selected to measure body fat after 12 weeks; clinical chemistry and hematological analyses at 72 weeks; necropsy and histopathology performed at study end	Study authors concluded that test material did not cause adverse effects in rats; 4 control and 3 treatment animals died before study completion, these animals were found to have severe chronic renal disease and were observed to have either pituitary or testicular tumors; feed intake was lower in the treatment group than in the control group, but body weight and percent body fat, while lower, were not significantly different than the control group; clinical chemistry and hematology were within normal ranges for the treatment group except for increased blood urea nitrogen and cholesterol, which may be attributed to renal failure and age, respectively; no significant differences were observed in tissue weights at necropsy	[52]

Table 10. Repeated dose toxicity studies

Concentration/Dose/Vehicle	Species	Study Protocol/Duration	Results	Reference
Sodium Undecylenate; 50, 250, or 1000 mg/kg in water	6 male and 6 female Sprague-Dawley rats per dose group;	Gavage study in accordance with OECD test guideline 407; animals were treated for 14 days	NOAEL < 50 mg/kg bw/day; treatment-related mortality observed in high dose group; dose-dependent clinical signs of toxicity included ptyalism, loud breathing, swollen abdomen, sedation, soiled urogenital area, piloerection, round back and pallor of extremities; body weight gain and feed consumption reduced in dose-dependent manner; elevated urea levels observed in the high dose group along with slightly increased creatinine levels in females; thickened forestomaches due to epithelial cell hyperplasia/hyperkeratosis in high dose group	[31]
Sodium Undecylenate; 0, 20, 60, or180/360 mg/kg in water; high dose increased from 180 to 360 after day 50	10 male and 10 female Sprague-Dawley rats per dose group; included additional group of 10 for high dose recovery	Gavage study in accordance with OECD test guideline 408; animals were treated for 90 days	NOAEL = 60 mg/kg bw/day; LOAEL = 180 mg/kg bw/day; clinical signs of toxicity included ptyalism, loud breathing/respiratory difficulties and poor clinical condition; body weight gain and feed consumption were reduced in high dose group males, especially after dose increase at day 50; reduced glucose plasma levels (reversible) and reduced triglyceride levels (not reversible) observed in high dose females; high dose group also had reversible cardiomyopathy, forestomach edema/inflammatory cell infiltration; no treatment-related effects observed in low- and mid-dose groups	[31]
Undecylenic Acid; 0.5%, 1%, or 2.5%in feed	7 male Sprague-Dawley rats per dose group	8 week dietary study; bio-physical parameters studied not reported	Authors reported inhibition of growth, especially at 2.5%; no other bio-physical parameters reported	[51]

Table 11. DART studies

Concentration/Dose/Vehicle	Species	Study Protocol/Duration	Results	Reference
		Dermal		
Lithium Stearate; 0, 100, 300, or 1000 mg/kg/ day in water	10 male and 10 female Sprague-Dawley rats per dose group; recovery group had 5 rats per sex per dose	Dermal study in accordance with OECD test guideline 422 (same as repeated dose study described in Table 10); males treated for 43 days, started 14 days prior to mating, and females treated for 14 days prior to mating to gestation day 19	NOAEL $\geq$ 1000 mg/kg bw/day; no treatment-related adverse reproductive effects in parental animals and no treatment-related adverse effects in development of offspring	[27]
		Oral		
Behenic Acid;0, 100, 300, or 1000 mg/kg bw/day in corn oil	13 male and 13 female Sprague-Dawley rats per dose group	Gavage study in accordance with OECD test guideline 422 (same as repeated dose study described in Table 10); males were treated 42 days and females were treated for 14 days prior to mating to day 3 of lactation	NOAEL $\geq$ 1000 mg/kg bw/day; no treatment-related adverse effects observed in parental animals or offspring	[21]
Calcium Stearate; 0, 250, 500, or 1000 mg/kg bw/day in corn oil	10 male and 10 female Sprague-Dawley rats per dose group	Gavage study; males were treated 28 days and females were treated for 14 days prior to mating to day 3 of lactation	NOAEL = 1000 mg/kg bw/day for parental animals and for offspring; no treatment-related adverse effects observed	[34]
Capric Acid; 0, 200, 1000, or 2000 mg/kg bw/day in corn oil	10 female Crl:CD (SD)BR rats per dose group	Gavage study in accordance with OECD test guideline 421; females were treated for 7 days prior to mating to day 4 of lactation	Maternal NOAEL = 200 mg/kg bw/day and fetal NOAEL $\geq$ 2000 mg/kg bw/day; no treatment-related adverse effects observed in offspring; rales and excessive salivation observed in low-dose dams, ataxia, decreased motor activity, ungroomed and urine-stained coat, and mortalities observed in mid- and high-dose dams; decreased body weights and feed consumption observed in mid- and high-dose dams	[22]
Capric Acid; 0, 1000, or 1500 mg/kg bw/day in corn oil	22 female Crl:COBS, CD (SD) BR rats	Gavage study in accordance with OECD test guideline 414; dams received test material on gestation days 6 to15	Maternal and fetal NOAEL $\geq$ 1500 mg/kg bw/day; no treatment-related adverse effects observed in parental animals or offspring	[22]
Caprylic Acid; 0 or 1000 mg/kg bw/day in corn oil	22 female Crl:COBS, CD (SD) BR rats	Gavage study in accordance with OECD test guideline 414; dams received test material on gestation days 6 to 15	Maternal and fetal NOAEL $\geq$ 1000 mg/kg bw/day; no treatment-related adverse effects observed in parental animals or offspring	[24]
Caprylic Acid; 18.75 mmol/kg; undiluted	12 female Sprague-Dawley rats	Gavage teratology study; dams received test material on gestation days 12 to 20	Slight reduction of fetal weight likely due to severe maternal toxicity; no other significant embryotoxicity effects reported; low concentration of test material in maternal plasma	[53]
Undecylenic Acid;0, 50, 150, or 450 mg/kg bw/ day in corn oil	male and female Sprague-Dawley rats	Gavage study in accordance with OECD test guideline 421; males were treated 2 weeks prior to mating and during mating for a total of 4 weeks; females were treated 2 weeks prior to mating and during mating, pregnancy, and lactation until day 4 post-partum	NOAEL = 150 mg/kg bw/day for parental toxicity; NOEL = 450 mg/kg bw/day for reproductive performance; 2 males died on days 3 and 35 without clinical signs of toxicity and no evident cause of death at necropsy; hypersalivation was observed in both sexes in all dose groups along with respiratory difficulties in males in the high dose group; no treatment-related effects were observed to reproductive performance or in offspring	[31]

Table 11. DART studies

Concentration/Dose/Vehicle	Species	Study Protocol/Duration	Results	Reference
Undecylenic Acid; 0, 150, 450, or 750 mg/kg bw/day in corn oil	24 female Sprague-Dawley rats per dose group	Gavage study in accordance with OECD test guideline 414; received test material from day 6 to day of gestation	Maternal NOAEL = 150 mg/kg bw/day and maternal LOAEL = 450 mg/kg bw/day; fetal NOAEL = 450 mg/kg bw/day; high dose group treatment was terminated due to high mortality; dams in mid-dose group were observed with hypersalivation and significantly reduced body weight gain compared to control; no treatment-related adverse effects observed in offspring	[31]
Undecylenic Acid; 0, 150, 450, or 1000 mg/kg bw/day in corn oil	7 female Sprague-Dawley rats per dose group	Gavage study in accordance with OECD test guideline 414; dams received test material from day 6 to day 20 of gestation	Maternal NOEL = 450 mg/kg bw/day; maternal LOAEL = 1000 mg/kg bw/day; hypersalivation was observed from gestation day 12 in all dose groups in a dose-dependent manner; 3 dams in the high dose group died on gestation day 7 without clinical signs of toxicity or adverse effects at necropsy; no treatment-related adverse effects observed in offspring	[31]

Table 12. Genotoxicity

Concentration/Dose	Species/Strain/Cell	Method	Results	Reference
		In Vitro		
Ammonium Oleate; 0.1 to 333 µg/plate with and without metabolic activation	*Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537	Ames test	Not genotoxic	[19]
Behenic Acid; 156 to 5000 µg/plate with and without metabolic activation in DMSO	*S. typhimurium* strains TA98, TA100, TA1535, and TA1537 and *Escherichia coli* strain WP2 uvr A	Ames test	Not genotoxic	[21]
Behenic Acid; up to 3500 µg/ml with and without metabolic activation in 1% carboxymethylcellulose sodium	Chinese hamster lung cells	Mammalian chromosome aberration test	Not genotoxic	[21]
Calcium Stearate; up to 312.5 µg/plate with and without metabolic activation in tetrahydrofuran	*S. typhimurium* strains TA98, TA100, TA1535, and TA1537 and *E. coli* strain WP2 uvr A	Ames test	Not genotoxic	[34]
Calcium Stearate; up to 2.0 µg/ml with and without metabolic activation in tetrahydrofuran	Chinese hamster lung cells	Mammalian chromosome aberration test	Not genotoxic	[34]
Capric Acid; 500 to 5000 µg/plate with and without metabolic activation in DMSO	*S. typhimurium strains* TA98 and TA100, *E. coli* strain WP2 uvr A pKM 101, and *E. coli strain* – not specified	Ames test	Not genotoxic	[22]
Capric Acid; 1000 to 10,000 µg/plate with and without metabolic activation in DMSO	*S. typhimurium strains* TA98 and TA100 and *E. coli* strain WP2 uvr A pKM 101	Ames test	Not genotoxic	[22]
Capric Acid; concentration and vehicle not reported; with and without metabolic activation	*S. typhimurium* strains TA97, TA98, TA100, TA1535, and TA1537	Ames test	Not genotoxic	[55]
Capric Acid; up to 1.84 mM with metabolic activation for 4 h; up to 1.18 mM without metabolic activation for 4h; up to 0.30 mM without metabolic activation for 24 h; all in RPMI cell culture medium	Mouse lymphoma L5178Y cells	Mammalian cell gene mutation assay at the TK locus	Not genotoxic	[22]
Capric Acid; up to 3500 µg/ml with and without metabolic activation in 1.0% carboxymethylcellulose sodium	Chinese hamster lung cells	Mammalian chromosome aberration test	Not genotoxic	[22]
Capric Acid; 5 to20 µg/ml with metabolic activation and 39 to 156 µg/ml without metabolic activation; vehicle = DMSO	Chinese hamster ovary cells	Mammalian chromosome aberration test	Not genotoxic	[22]
Caproic Acid; 3.1 to 5000 µg/plate with and without metabolic activation in Tween 80/double distilled water	*S. typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538	Ames test	Not genotoxic	[23]
Caproic Acid; 1000 to 10,000 µg/plate with and without metabolic activation in DMSO	*S. typhimurium* strains TA98 and TA100 and *E.coli* strain WP2 uvr A pKM 101	Ames test	Not genotoxic	[23]

Table 12. Genotoxicity

Concentration/Dose	Species/Strain/Cell	Method	Results	Reference
Caproic Acid; 10 to 1000 µg/plate with and without metabolic activation in DMSO	*S. typhimurium* strains TA97 and TA102	Ames test	Not genotoxic	[23]
Caprylic Acid; 10 to 3333 µg/plate with and without metabolic activation in DMSO	*S. typhimurium* strains TA97, TA98, TA100, TA1535, and TA1537	Ames test	Not genotoxic	[24]
Caprylic Acid; 4 to 2500 µg/plate with and without metabolic activation in Tween 80/double distilled water	*S. typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538	Ames test	Not genotoxic	[24]
Caprylic Acid; concentration and vehicle not reported; with and without metabolic activation	*S. typhimurium* strains TA97, TA98, TA100, TA1535, and TA1537	Ames test	Not genotoxic	[55]
Isomerized Linoleic Acid; up to 2500 µg/plate with and without metabolic activation in water/Tween 80	*S. typhimurium strains* TA98, TA100, TA1535, TA1537, and TA1538	Ames test	Not genotoxic	[25]
Lauric Acid; 4 to 2500 µg/plate with and without metabolic activation in DMSO	*S. typhimurium strains* TA98, TA100, TA1535, TA1537, and TA1538	Ames test	Not genotoxic	[26]
Lauric Acid; concentration and vehicle not reported; with and without metabolic activation	*S. typhimurium* strains TA97, TA98, TA100, TA1535, and TA1537	Ames test	Not genotoxic	[55]
Linoleic Acid; concentrations and vehicle not reported, with and without metabolic activation	*S. typhimurium strains* TA98, TA100, TA1535, TA1537; may have included TA97	Ames test	Not genotoxic	[54]
Lithium Stearate; 5 to 5000 µg/plate with and without metabolic activation in acetone	*S. typhimurium* strains TA98, TA100, TA1535, and TA1537 and *E. coli* strain WP2 uvr A	Ames test	Not genotoxic	[27]
Lithium Stearate; up to 80 µt/ml without metabolic activation and up to 120 µg/ml with metabolic activation; in acetone	Mouse lymphoma L5178Y cells	Mammalian cell gene mutation assay at the TK locus	Not genotoxic	[27]
Lithium Stearate; up to 320 µg/ml without metabolic activation and up to 480 µg/ml with metabolic activation; in DMSO	Human lymphocytes	Mammalian chromosome aberration test	Not genotoxic	[27]
Myristic Acid; concentration and vehicle not reported; with and without metabolic activation	*S. typhimurium* strains TA97, TA98, TA100, TA1535, and TA1537	Ames test	Not genotoxic	[55]
Undecylenic Acid; up to 750 µg/ml with and without metabolic activation; in DMSO	*S. typhimurium strains* TA98, TA100, TA1535, TA1537, and TA1538	Ames test	Not genotoxic	[31]
Undecylenic Acid; up to 600 µg/ml with and without metabolic activation; in DMSO	Chinese hamster lung fibroblasts (V79)	Mammalian gene mutation assay	Not genotoxic	[31]
Undecylenic Acid; up to 500 µg/ml without metabolic activation; in DMSO	Primary rat hepatocytes	DNA damage and repair assay (unscheduled DNA synthesis)	Not genotoxic	[31]

Table 12. Genotoxicity

Concentration/Dose	Species/Strain/Cell	Method	Results	Reference
Undecylenic Acid; up to 500 µg/ml with and without metabolic activation; in DMSO	Human lymphocytes	Mammalian chromosome aberration test	Not genotoxic	[31]
		In Vivo		
Undecylenic Acid; 0, 1000, 2000, or 4000 mg/kg in 10% gum arabic	15 male and 15 female CD-1 mice per dose group	Micronucleus assay; test material administered via gavage in a single treatment	Not genotoxic	[31]

Table 13. Dermal irritation and sensitization

Concentration/Dose/Vehicle	Test System	Method	Results	Reference
Irritation – In Vitro				
Aluminum Tristearate; undiluted	Human epidermis	Mat Tek EpiDerm™ model	Predicted to be not irritating	[20]
Capric Acid; at least 99% pure	Full-thickness Wistar rat dorsal and flank tissue	In vitro corrosivity test	Predicted to be not corrosive	[58]
Capric Acid; at least 99% pure	Full-thickness human mammary tissue	In vitro corrosivity test	Predicted to be not corrosive	[58]
Caproic Acid; at least 99% pure	Full-thickness Wistar rat dorsal and flank tissue	In vitro corrosivity test	Predicted to be corrosive	[58]
Caproic Acid; at least 99% pure	Full-thickness human mammary tissue	In vitro corrosivity test	Predicted to be corrosive	[58]
Caproic Acid; 50% to 70% in sesame oil, 50 µl applied	Human epidermis	Mat Tek EpiDerm™ model	Predicted to be corrosive at 70%, non-corrosive at 50% and 60%	[23]
Caproic Acid; 100%	Human epidermis	Episkin™ test	Predicted to be corrosive	[23]
Caproic Acid; 100%	Wistar rat skin disks	Transcutaneous electrical resistance (TER) test	Predicted to be corrosive	[23]
Caproic Acid; 100%	Reconstituted collagen matrix	CORROSITEX™ assay	Predicted to be corrosive in 1 out of 3 laboratories	[23]
Caproic Acid; 100%	Intact human skin equivalent	Skin 2TM ZK1350 assay	Predicted to be corrosive in 2 out of 3 laboratories	[23]
Caprylic Acid; concentration not reported, no vehicle used	Wistar rat disks	TER test	Predicted to be corrosive	[24]
Caprylic Acid; at least 99% pure	Full-thickness Wistar rat dorsal and flank tissue	In vitro corrosivity test	Predicted to be corrosive	[58]
Caprylic Acid; at least 99% pure	Full-thickness human mammary tissue	In vitro corrosivity test	Predicted to be not corrosive	[58]
Caprylic Acid; 99% pure	Reconstructed human epidermis (RHE)	SkinEthic™ RHE skin corrosion test	Predicted to be corrosive	[59]
Caprylic Acid; concentration not reported	Human skin keratinocytes	Modified EpiSkin™ full thickness skin model	Predicted to be corrosive	[60]
Caprylic Acid; concentration not reported	Human skin fibroblasts	Modified SkinEthic™ RHE skin model	Predicted to be corrosive	[60]
Isostearic Acid; 99% pure	RHE	SkinEthic™ RHE skin corrosion test	Predicted to be not corrosive	[59]
Lauric Acid; at least 99% pure	Full-thickness Wistar rat dorsal and flank tissue	In vitro corrosivity test	Predicted to be not corrosive	[58]
Lauric Acid; at least 99% pure	Full-thickness human mammary tissue	In vitro corrosivity test	Predicted to be not corrosive	[58]
Lithium Stearate; concentration not reported, no vehicle used	Human epidermis	Episkin test	Predicted to be not corrosive	[27]
Lithium Stearate; concentration not reported, no vehicle used	Human epidermis	Episkin test	Predicted to be not irritating	[27]
Irritation – Animal				
Ammonium Oleate; concentration not reported, no vehicle, ~ 0.5 ml applied to test site	6 rabbits, strain and sex not reported	Acute dermal irritation study in accordance with OECD test guideline 404; test sites occluded, with and without abrasion; 4 h exposure on 1.5 in^2 site followed by washing with solvent	Primary dermal irritation index (PDII) = 0.04; mean erythema score = 0.04 with effects fully reversed at 48 h; mean edema score = 0	[19]
Caproic Acid; concentration not reported, no vehicle, ~ 0.5 ml applied to test site	5 New Zealand White rabbits; sex not reported	Acute dermal irritation study in accordance with OECD test guideline 404; test sites shaved and occluded; 4 h exposure on 3 cm^2 site followed by washing	Corrosive; intensive erythema and edema observed after patch removal, edema disappeared after 7 days while erythema persisted and became full thickness necrosis; scar tissue observed after 21 days	[23]
Caprylic Acid; 100%	3 New Zealand White rabbits; sex not reported	Acute dermal irritation study in accordance with OECD test guideline 404; test sites clipped and semi-occluded; 4 h exposure followed by wiping off material with tissue	Corrosive; mean erythema score was 3 and mean edema score was 1.8	[24]

Table 13. Dermal irritation and sensitization

Caprylic Acid; 30%, 50%, 60%, and 70% in PEG 200/water and 100%	6 New Zealand White rabbits; sex not reported	Acute dermal irritation study; test sites clipped and occluded; 3 h exposure on 0.65 in^2	Corrosive at 100%with mean erythema and edema scores of $\geq$ 3.3 and 3.2, respectively; non-irritating at 30% through 70%	[24]
Caprylic Acid; 4%, 7.5%, 10%, and 15% in PEG 200/water and 100%	6 New Zealand White rabbits; sex not reported	Acute dermal irritation study; test sites clipped and occluded; 3 h exposure	Corrosive at 100%with mean erythema and edema scores of 3.3 and 2.5, respectively; non-irritating at 4% through 15%	[24]
Caprylic Acid; 55%, 60%, 65% and 80% in PEG/water	5 New Zealand White rabbits; sex not reported	Acute dermal irritation study; test sites clipped and occluded; 3 h exposure	Non-irritating at 55% and 60%; moderate to severe erythema and slight to moderate edema observed in 2aniamls at 65% and 80%	[24]
Caprylic Acid; 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD test guideline 404; 4 h exposure	Necrosis and eschar observed at day 2 and 3; PII = 4.44	[57]
Caprylic Acid/Capric Acid mix (55:45); 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD test guideline 404; 4 h exposure	Necrosis and eschar observed at day 2 and 3; PII = 5.11	[57]
Caprylic Acid/ Capric Acid mix (60:40); 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD test guideline 404; 4 h exposure	Eschar at day 1 in 2 animals; new skin formation with or without scaliness at day 14 in all animals; PII could not be calculated	[57]
Caprylic Acid/ Capric Acid mix (65:35); 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD test guideline 404; 4 h exposure	Eschar at day 1 in 2 animals; new skin formation or scaliness day 14 in all animals; PII could not be calculated	[57]
Caprylic Acid/ Capric Acid mix (65:35); 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD test guideline 404; 4 h exposure	Reactions observed outside of test site in all animals starting 4.5 h; PII = 5.33	[57]
Isostearic Acid; 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD test guideline 404; 4 h exposure	Reactions outside of test site in all animals starting on day 1; PII = 4.33	[57]
Lauric Acid; concentration not reported; in water	3 New Zealand White rabbits; sex not reported	Acute dermal irritation study in accordance with OECD test guideline 404; test sites shaved and semi-occluded; 4 h exposure on 10 cm^2 test site followed by wiping off material with tissue	Non-irritating; mean erythema and edema scores were 0.4 and 0, respectively	[26]
Lauric Acid; concentration not reported; no vehicle used	4 Kleinrussen rabbits; sex not reported	Acute dermal irritation study in accordance with OECD test guideline 404; test sites shaved and occluded; 4 h exposure on 2.5 cm^2 test site	Irritating; mean erythema and edema scores were 3.1 and 2, respectively	[26]
Lauric Acid; 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD test guideline 404; 4 h exposure	PII = 0.44	[57]
Palmitic Acid; concentration not reported; no vehicle used	4 Kleinrussen rabbits; sex not reported	Acute dermal irritation study in accordance with OECD test guideline 404; test sites shaved and occluded; 4 h exposure on 2.5 cm^2 test site	Non-irritating; mean erythema and edema scores were 0 and 0, respectively	[28]
Sodium Undecylenate; 33% aq	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD test guideline 404; 4 h exposure	PII = 1.67	[57]
Trilinoleic Acid; concentration not reports; no vehicle used	6 New Zealand White rabbits; sex not reported	Acute dermal irritation study; test sites intact and abraded; occlusive patch for 24 h	Slightly irritating	[30]
Undecylenic Acid; 100%	4 rabbits; details not provided	Acute dermal irritation study in accordance with OECD test guideline 404; 4 h exposure	PII = 2.42	[57]

Table 13. Dermal irritation and sensitization

Irritation – Human				
Lauric Acid; 50%; vehicle not reported	20 volunteers	Closed epicutaneous test; 10 µl applied to the back for 24 h in large Finn chambers	Substance induced erythema, edema, and scaling	[26]
Lauric Acid; 80%; vehicle not reported	10 volunteers	Open epicutaneous test on lower forearm; procedure repeated every 30 sec for 30 min; substance was not washed	3 subjects had erythema (score 1) after 30 min that disappeared after 30 min; no other reactions were observed	[26]
Palmitic Acid; 50%; vehicle not reported	20 volunteers	Closed epicutaneous test; 10 µl applied to the back for 24 h in large Finn chambers	Not irritating; skin scores for erythema, edema, scaling, and fissures were all 0	[28]
Sensitization - Animal				
Ammonium Oleate; 5% in physiological saline for intradermal induction; 25% or 50% in Vaseline® for topical induction; 25% in Vaseline® for topical challenge	10 female Hsd Poc:DH guinea pigs per dose group; 5 females in control	Guinea pig maximization study	All animals, including controls, exhibited grade 1 skin reactions during challenge, only animals with greater than 1 reaction counted as + reaction; 0, 1, and 4 animals had reactions at 24, 48, and 72 h post-challenge, respectively; 2, 3, and 3 animals had reaction at 24, 48, and 72 h post-rechallenge, respectively.	[19]
Ammonium Oleate; 10%, 25%, or 50% in acetone/olive oil (4:1 v/v)	5 female CBA/Ca mice/dose group	LLNA	Stimulation indices (SI) were 2.6, 14.9, and 6.9 for 10%, 25%, and 50%, respectively; according to test standards, the test material was sensitizing at 25% and 50%	[19]
Capric Acid; induction with 40% in distilled water, challenge and re-challenge with 20% in distilled water	10 male and 10 female Dunkin-Hartley albino guinea pigs/dose	Buehler test; occlusive	Not sensitizing; observed effects of confluent or moderate erythema in 6 animals at re-challenge was determined to be due to irritation	[22]
Capric Acid; induction with 5% in ethanol, challenge with 5% in acetone	20 guinea pigs, strain and sex not specified	Buehler test; occlusive	Not sensitizing	[22]
Hydroxystearic Acid; 0%, 10%, or 50% (containing 86% 12-hydroxystearic acid) in dimethyl sulfoxide	5 female CBA mice per group	LLNA	Sensitizing; EC3 value calculated to be 16%	[32]
Hydroxystearic Acid; intradermal induction with 2.5% in corn oil or 50% Freund's complete adjuvant/0.9% saline, topical induction with 10% in corn oil, challenge with 2.5% in corn oil	10 male and 10 female Dunkin-Hartley guinea pigs	Maximization test; occlusive	At 24-h post challenge, discrete or moderate erythema observed in 7/20 animals; at 48- and 72-h readings, increase in incidence and severity of cutaneous reactions at test sites correlated with the flanks being shaved after the 24-h reading; not possible to determine incidence of sensitization due to cutaneous reactions; test concentration used at challenge may have been too high and caused irritation	[32]

Table 13. Dermal irritation and sensitization

Hydroxystearic Acid; intradermal induction with 2.5% in corn oil or 50% Freund's complete adjuvant/0.9% saline, topical induction with 10% in corn oil, 1st challenge with 0.5% in corn oil and 2nd challenge with 1% and 5% in acetone	10 male and 10 female Dunkin-Hartley guinea pigs	Maximization test; occlusive	Not sensitizing; at 24-h post challenge, discrete erythema present at the vehicle patch site in 6/10 control animals, the test article patch sites of 4/10 control animals, the vehicle patch site of 7/20 test animals, and the test article patch site of 6/10 test animals; at 48-h reading, the incidences at the same sites were 6/10, 9/10, 4/20, and 6/20 animals, respectively; no cutaneous reactions at the 24-h reading of 2nd challenge and discrete erythema in 2/10 animals at the 48-h reading ; no reactions at the test article patch sites of any of the animals in either group	[32]
Lauric Acid; induction and challenge with 2.5% in ethanol	20 Pirbright white guinea pigs; sex not reported	Maximization test; occlusive	Not sensitizing	[26]
Lithium Stearate; 2.5%, 5%, or 10% in ethanol/distilled water (7:3)	4 female CBA/Ca mice per group	LLNA	Not sensitizing; SI were 0.86, 1.48, and 1.68 for 2.5%, 5%, and 10%, respectively	[27]
Sodium Undecylenate; intradermal induction with 0.1%; topical induction and challenge with 0.05%; in physiological saline	10 male and 10 female Dunkin-Hartley guinea pigs	Maximization test; occlusive	Not sensitizing	[31]
Trilinoleic Acid; induction undiluted, challenge with 50% or 75% in corn oil	20 guinea pigs per group, strain and sex not specified	Buehler test; no further details provided	Not sensitizing	[30]
Undecylenic Acid; intradermal induction with 1%; topical induction with 100%; challenge with 2.5%; in corn oil	10 male and 10 female Dunkin-Hartley guinea pigs	Maximization test; occlusive	Not sensitizing	[31]

Table 14. Ocular irritation studies

Concentration/Dose	Test System	Method	Results	Reference
In Vitro				
Caproic Acid; 50% in sesame oil	Bovine corneas	Bovine Corneal Opacity and Permeability test	Corrosive	[23]
Lithium Stearate; concentration not reported, no vehicle used	Corneal epithelial tissue reconstruct	Reconstructed Human Corneal model	Predicted to be non-irritating	[27]
Animal				
Caproic Acid; concentration not reported, no vehicle used	6 rabbits; no further details provided	Ocular irritation study; details not provided	Ocular irritant; corneal opacity and moderate conjunctivitis reported that did not reverse within 72 h	[22]
Caprylic Acid; 70% in Vaseline	3 female New Zealand White rabbits	Ocular irritation study; 0.1 ml instilled; eyes were rinsed with physiological saline after 24 h	Ocular irritant; conjunctival redness, chemosis, and discharge observed in all animals; corneal lesions observed in 2/3 animals	[24]
Caprylic Acid; concentration not reported, no vehicle used	6 rabbits; no further details provided	Ocular irritation study; details not provided	Ocular irritant; corneal opacity and moderate conjunctivitis that persisted until 72 h	[24]
Lauric Acid; concentration not reported, no vehicle used	3 New Zealand White rabbits; sex not reported	Ocular irritation study in accordance with OECD test guideline 405; details not provided	Ocular irritant; lacrimation and corneal epithelial damage in all animals; no corrosion observed	[26]
Lauric Acid; concentration not reported, no vehicle used	3 New Zealand White rabbits; sex not reported	Ocular irritation study in accordance with OECD test guideline 405;0.1 g instilled; eyes were rinsed with physiological saline	Not irritating	[26]
Lauric Acid; concentration not reported, no vehicle used	1 Kleinrussen rabbit; sex not reported	Ocular irritation study in accordance with OECD test guideline 405; eyes were not rinsed; no further details provided	Ocular irritant; slight to moderate reactions observed on the cornea that did not disappear within 21 days; reversible reactions in the iris and conjunctivae were observed	[26]
Lauric Acid; 100%	3 rabbits; strain and sex not reported	Draize ocular irritation study; 0.1 ml instilled	Modified maximum average score = 38.0; opacity and conjunctival redness was not resolved by day 21	[62]
Lithium Stearate; concentration not reported, no vehicle used	2 New Zealand White rabbits; sex not reported	Ocular irritation study in accordance with OECD test guideline 405; 0.1 ml instilled; eyes were not rinsed;	Mild ocular irritant; moderate conjunctival irritation observed	[27]
Oleic Acid; 0%, 0.02%, 0.05%, and 0.1% (v/v) in phosphate buffer at pH 7.4 and 1% Tween--80	6 New Zealand White rabbits per dose group; sex not reported	Modified Draize ocular irritation study; 100 µl instilled in left eye every 4 h and 4 times/day for 7 days; right eye received phosphate buffer; observation up to 72-h after last instillations	Not irritating	[63]
Palmitic Acid; concentration not reported, no vehicle used	4 Kleinrussen rabbits; sex not reported	Ocular irritation study in accordance with OECD test guideline 405; 0.1 ml instilled; eyes were not rinsed	Not irritating	[28]
Sodium Undecylenate; 33.2% in water	1 rabbit; strain and sex not reported	Draize ocular irritation study; 0.1 ml instilled	Moderately irritating; modified maximum average score = 45; corneal opacity and conjunctival redness and chemosis not resolved until day 9	[62]
Stearic Acid (iso-); 100%	3 rabbits; strain and sex not reported	Draize ocular irritation study; 0.1 ml instilled	Minimally irritating; modified maximum average score = 3.3; conjunctival redness resolved by day 3	[62]

Table 14. Ocular irritation studies

Concentration/Dose	Test System	Method	Results	Reference
Undecylenic Acid; concentration not reported, no vehicle used	3 male New Zealand White rabbits	Ocular irritation study in accordance with OECD test guideline 405; 100 mg instilled; no further details provided	Irritating; very slight to moderate conjunctival reactions observed in all animals from day 1 that persisted to day 14; slight iritis observed in 2 animals on day 2 that lasted to day 4 or 10, respectively; very slight or slight corneal opacity observed in all animals on day 2 that lasted until day 4 in 2 animals and to day 12 in the other	[31]

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