
Safety Assessment of Fatty Acids & Fatty Acid Salts as Used in Cosmetics

Status: Draft Final Report for Panel Review
Release Date: March 15, 2019
Panel Meeting Date: April 8-9, 2019

The 2019 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Christina L. Burnett, Senior Scientific Analyst/Writer.



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Memorandum

To: CIR Expert Panel Members and Liaisons
From: Christina L. Burnett, Senior Scientific Writer/Analyst
Date: March 15, 2019
Subject: Draft Final Safety Assessment on Fatty Acids and Fatty Acid Salts

Enclosed is the Draft Final Report of the Safety Assessment of Fatty Acids and Fatty Acid Salts as Used in Cosmetics. (It is identified as *facids042019FR* in the pdf document.) At the December 2018 meeting, the Panel issued a Tentative Report with the conclusion that 102 ingredients are safe in the present practices of use and concentration described in the safety assessment when formulated to be non-irritating and non-sensitizing, which may be based on a QRA.

CIR staff have received the 2019 VCRP data and the use table for these ingredients has been updated accordingly. Only minor changes were noted. Linoleic Acid has increased from 633 to 681 total uses in cosmetic products; the majority of these uses are still in leave-on skin care products. Stearic Acid, a previously reviewed ingredient, still has the most reported uses of the ingredients in this safety assessment, with a total of 6265 (previously 5738); the majority of these uses are in leave-on eye makeup preparations and skin care products. Stearic Acid 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, another previously reviewed ingredient, still has the second greatest number of reported uses in this safety assessment with 1532 (previously 1240); the majority of the uses were 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 were in rinse-off products such as shampoos, shaving products, and personal cleanliness products. Uses are now being reported for Sodium Undecylenate (1) and Ammonium Stearate (4), which previously did not have reported use.

Additional data from the published literature, including short-term toxicity, chronic toxicity and genotoxicity studies on Isomerized Safflower Acid, a phototoxicity study on damaged skin following exposure to Linoleic Acid, and genotoxicity studies on Magnesium Stearate, have been incorporated into the report and **highlighted** for your convenience. No new data have been received from the Council since the December Panel meeting.

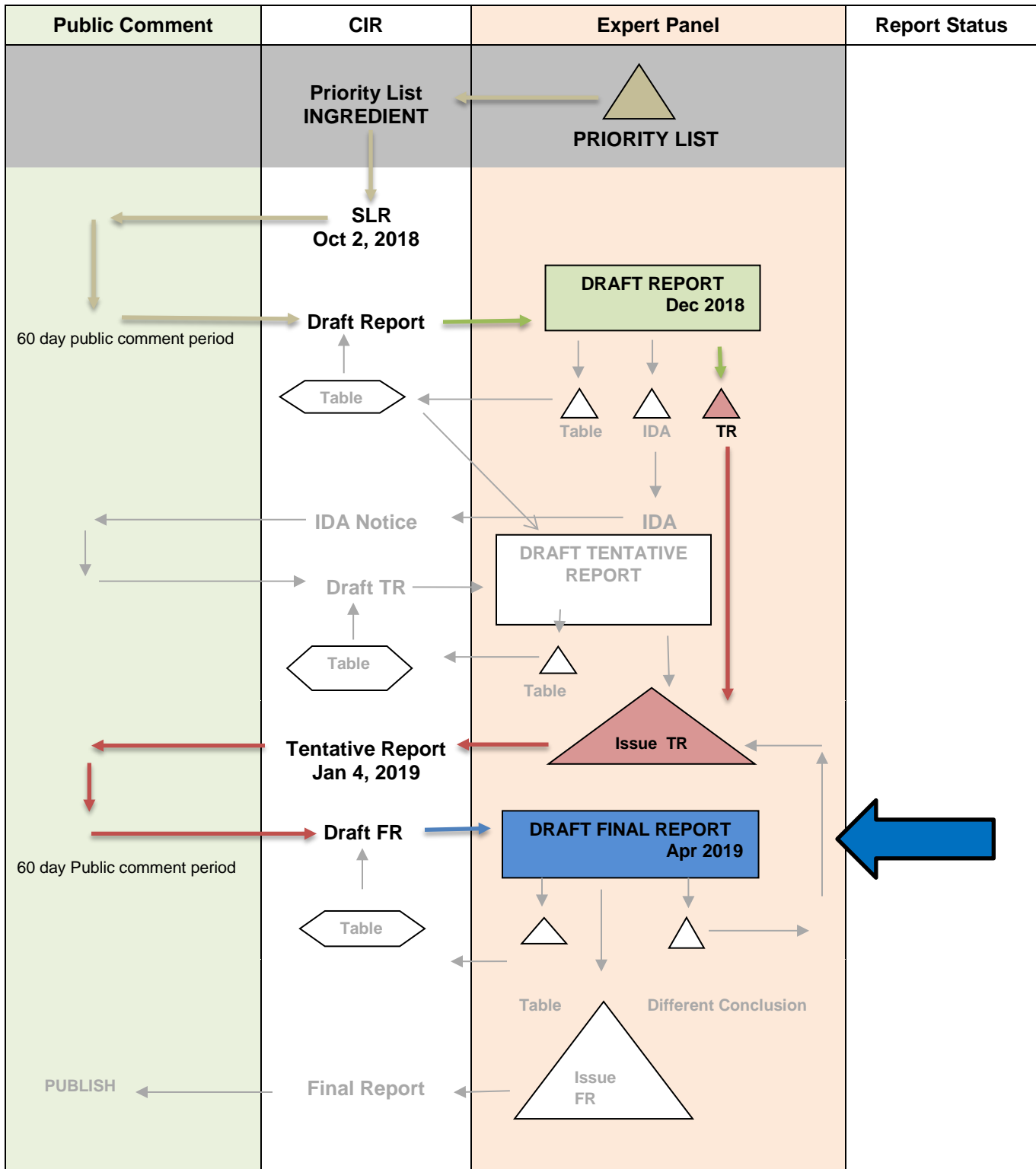
Comments provided by the Council prior to the December meeting and on the Tentative Report have been addressed (*facids042019pcpc1* and *facids042019pcpc2*, respectively). In the comments on the Tentative Report, the Council states that conjugated linoleic acid (CLA; the technical name for Isomerized Safflower Acid) received a GRAS determination from the FDA in 2008. Upon further research, however, there is only a GRAS designation for methyl esters of CLA (21CFR 573.637). Staff have found no reliable evidence to demonstrate that the free acids have received GRAS status.

The Panel should carefully review the Abstract, Discussion, and Conclusion of this safety assessment. If these are satisfactory, the Panel should issue a Final Report.

SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Fatty Acids and Fatty Acid Salts

MEETING April 2019



Fatty Acids and Fatty Acid Salts History

October 2, 2018 - Scientific Literature Review announced.

December 4, 2018 - The Panel issued a tentative report with the conclusion that the 102 ingredients are safe in the present practices of use and concentration described in the safety assessment when formulated to be non-irritating and non-sensitizing, which may be based on a QRA.

The Expert Panel recognized that these ingredients, particularly Myristic Acid, Oleic Acid, and Sodium Caprate, 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 otherwise a concern.

The Panel was concerned that the potential exists for dermal irritation with the use of products formulated using fatty acids and fatty acid salts. The Panel specified that products containing fatty acids and fatty acid salts must be formulated to be non-irritating. The Panel was also concerned about the potential for polyunsaturated fatty acids to undergo oxidation during the formulation, or storage of cosmetic products, that may produce compounds that are dermal sensitizers. The Panel advises industry to limit oxidative products in formulations containing fatty acids and fatty acid salts, and to utilize accepted methodologies, such as a QRA, to ensure formulations are non-sensitizing.

Fatty Acids and Fatty Acid Salts Data Profile –April 2019 – Writer, Christina Burnett																
	In-Use	Physical/Chemical Properties	Method of Manufacturing	Composition/Impurities	UV Absorption	Acute Toxicity	Repeated Dose Toxicity	Genotoxicity	Reproductive and Developmental	Carcinogenicity	Toxicokinetics	Irritation/Sensitization - Nonhuman	Irritation/Sensitization - Human	Ocular/Mucosal	Phototoxicity	Clinical/Case Studies
Aluminum Dilinoleate																
Aluminum Distearate	X	X										*		*		
Aluminum Isostearate																
Aluminum Isostearates/Palmitates																
Aluminum Isostearates/Stearates																
Aluminum Isostearates/Laurates/Palmitates																
Aluminum Isostearates/Laurates/Stearates																
Aluminum Lanolate																
Aluminum Stearate	X	X				*										
Aluminum Stearates	X															
Aluminum Tristearate	X	X										X				
Ammonium Isostearate																
Ammonium Oleate		X				X		X				X				
Ammonium Stearate	X	X				*						*	*	*		
Arachidic Acid	X	X														
Beeswax Acid				X												
Behenic Acid	X	X		X		X	X	X	X							
C14-28 Alkyl Acid	X															
C10-40 Isoalkyl Acid	X															
C14-28 Isoalkyl Acid	X															
C32-36 Isoalkyl Acid																
Calcium Behenate	X															
Calcium Laurate																
Calcium Stearate	X	X		X		X	X*	X	X		*					
Calcium Undecylenate		X														
Capric Acid	X	X				X	X	X	X			X				

Fatty Acids and Fatty Acid Salts Data Profile –April 2019 – Writer, Christina Burnett																
	In-Use	Physical/Chemical Properties	Method of Manufacturing	Composition/Impurities	UV Absorption	Acute Toxicity	Repeated Dose Toxicity	Genotoxicity	Reproductive and Developmental	Carcinogenicity	Toxicokinetics	Irritation/Sensitization - Nonhuman	Irritation/Sensitization - Human	Ocular/Mucosal	Phototoxicity	Clinical/Case Studies
Caproic Acid	X	X						X				X		X		
Caprylic Acid	X	X		X		X		X	X			X		X		
Dilinoleic Acid	X	X														
Dierucic Acid																
Eicosatrienoic Acid		X														
Erucic Acid		X														
Hydroxycapric Acid	X	X														
Hydroxycaprylic Acid	X	X														
10-Hydroxydecanoic Acid	X	X														
Hydroxylauric Acid		X														
Hydroxystearic Acid	X	X						*	*	*	*	X	*			X
10-Hydroxystearic Acid		X					*									
Isomerized Linoleic Acid	X	X				X		X								
Isomerized Safflower Acid							X	X								
Isostearic Acid	X	X				*					*	X*	*	*	*	
Lauric Acid	X	X	*	X		X*	*	X*	*	*	*	X*	*	X*	X	
Linoleic Acid	X	X		X			X	X				X			X	
Linolenic Acid	X	X										X				
Lithium Stearate	X	X				X*	X	X	X			X		X		
Magnesium Lanolate																
Magnesium Laurate	X															
Magnesium Palmitate		X														
Magnesium Stearate	X	X		X		*		*X	*	*		*		*		
Magnesium Tallowate																
Myristic Acid	X	X	*	X				X	*		*	*	*	*		
Methyl Myristic Acid		X														
Oleic Acid	X	X	*	X		*	*	*	*	*	X*	X*	*	X*	*	
Palmitic Acid	X	X	*	X		X*	*		*	*	*	X*	X*	X*	*	

[illegible]

Fatty Acids and Fatty Acid Salts Data Profile –April 2019 – Writer, Christina Burnett																
	In-Use	Physical/Chemical Properties	Method of Manufacturing	Composition/Impurities	UV Absorption	Acute Toxicity	Repeated Dose Toxicity	Genotoxicity	Reproductive and Developmental	Carcinogenicity	Toxicokinetics	Irritation/Sensitization - Nonhuman	Irritation/Sensitization - Human	Ocular/Mucosal	Phototoxicity	Clinical/Case Studies
Sodium Caprate											X					
Sodium Caprylate																
Sodium Castorate	X															
Sodium Dilinoleate																
Sodium Hydrogenated Tallowate																
Sodium Hydroxystearate																
Sodium Isostearate	X															
Sodium Lanolate																
Sodium Lardate																
Sodium Laurate	X														X	
Sodium Laurate/Linoleate/Oleate/Palmitate	X															
Sodium Linoleate																
Sodium Oleate	X	X								X						
Sodium Palmitate	X	X														
Sodium Stearate	X	X				*					*		*			
Sodium Tallowate	X															
Sodium Tamanuseedate																
Sodium Undecylenate	X	X					X					X		X		
Stearic Acid	X	X	*	X		X*	*	*	*	*	*	*	*	X*	X	
Trilinoleic Acid	X	X										X				
Undecanoic Acid	X	X														
Undecylenic Acid	X	X				X	X	X	X			X		X		X

X indicates that data were available in the category for that ingredient.

* indicates data were available in previous reports for that ingredient.

Fatty Acids & Soaps

[illegible]

[illegible]

Ingredient	CAS #	InfoB	SciFin	PubMed	TOXNET	FDA	EU	ECHA	IUCLID	SIDS	ECETOC	HPVIS	NICNAS	NTIS	NTP	WHO	FAO	NIOSH	FEMA	Web
Sodium Isostearate	64248-79-9	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Sodium Lanolate		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Sodium Lardate	68605-06-1	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Sodium Laurate	629-25-4	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Sodium Laurate/Linoleate/Oleate/Palmitate		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Sodium Linoleate	822-17-3	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Sodium Oleate	143-19-1; 166558-02-4	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Sodium Palmitate	408-35-5	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Sodium Stearate-RR	822-16-2	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Sodium Tallowate	8052-48-0	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Sodium Tamanuseedate		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Sodium Undecylenate	3398-33-2	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Stearic Acid-RR	57-11-4	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Trilinoleic Acid	68937-90-6; 7049-66-3	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Undecanoic Acid	112-37-8	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Undecylenic Acid	112-38-9 ; 1333-28-4	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

Botanical and/or Fragrance Websites (if applicable)

Ingredient	Dr. Duke's	Taxonomy	GRIN	Sigma-Aldrich	AHPA	EMA	AGRICOLA	SSA	IFRA	RIFM
Capric Acid	NA	NA	NA	NA	NA	NA	NA	NA	√	√
Caproic Acid	NA	NA	NA	NA	NA	NA	NA	NA	√	√
Caprylic Acid	NA	NA	NA	NA	NA	NA	NA	NA	√	√
Lauric Acid-RR	NA	NA	NA	NA	NA	NA	NA	NA	√	√
Linoleic Acid	NA	NA	NA	NA	NA	NA	NA	NA	√	√
Linolenic Acid	NA	NA	NA	NA	NA	NA	NA	NA	√	√
Myristic Acid-RR	NA	NA	NA	NA	NA	NA	NA	NA	√	√
Oleic Acid-RR	NA	NA	NA	NA	NA	NA	NA	NA	√	√
Palmitic Acid-RR	NA	NA	NA	NA	NA	NA	NA	NA	√	√
Stearic Acid-RR	NA	NA	NA	NA	NA	NA	NA	NA	√	√
Undecanoic Acid	NA	NA	NA	NA	NA	NA	NA	NA	√	√
Undecylenic Acid	NA	NA	NA	NA	NA	NA	NA	NA	√	√

NA= Not applicable

RR = Re-Review

Search Strategy

SciFinder and **PubMed** tallies are combined. SciFinder was searched by CAS# and INCI names, references were then narrowed by “adverse effects, including toxicity”. PubMed returns were limited when needed by “toxicity” or “dermal” or “sensitization” or “irritation”.

Aluminum Tristearate (limited to 2000-2018) = 3335 hits, 3 relevant
Ammonium Stearate (limited to 2000-2018) = 3333 hits, 0 relevant
Arachidic Acid OR Eicosenoic Acid = 335 hits, 2 relevant
Calcium Stearate (limited to 2000-2018) = 3346 hits, 1 relevant
Capric Acid = 1012 hits, 5 relevant
Caproic Acid = 1411 hits, 1 relevant
Caprylic Acid = 2240 hits, 14 relevant
Dierucic Acid = 629 hits, 0 relevant
Eicosatrienoic Acid = 1889 hits, 4 relevant
Erucic Acid = 623 hits, 5 relevant
Hydroxystearic Acid (limited 2014-2018 due to RR in 2015) = 38 hits, 0 relevant
Lauric Acid = 1833 hits, 2 relevant
Linoleic Acid = 21,546 hits, 22 relevant
Linolenic Acid = 10,526 hits, 4 relevant
Lithium Stearate = 7 hits, 0 relevant
Magnesium Lanolate = 0 hits
Magnesium Laurate = 6 hits, 0 relevant
Magnesium Palmitate = 70 hits, 0 relevant
Magnesium Stearate (limited to 2000-2018) = 3574 hits, 2 relevant
Magnesium Tallowate = 0 hits
Myristic Acid (limited to 2008-2018 due to review in 2010) = 1046 hits, 0 relevant
Methyl Myristic Acid = 181 hits, 0 relevant
Oleic Acid (limited to 2003-2018 due to RR in 2004/2005) = 10,243 hits, 19 relevant
Palmitic Acid (limited to 2003-2018 due to RR in 2004/2005) = 6653 hits, 7 relevant
Potassium Behenate = 2 hits, 0 relevant
Potassium Borageate as borageate = 0 hits
Potassium Camelliate as camelliate = 0 hits
Potassium Caprate = 7 hits, 1 relevant
Potassium Caprylate = 7 hits, 2 relevant
Potassium Caprylate/Caprate = 0 hits
Potassium Castorate as castorate = 0 hits
Potassium Hydrogenated Tallowate = 0 hits
Potassium Hydroxystearate = 2 hits, 0 relevant
Potassium Isostearate = 1 hit, 0 relevant
Potassium Lanolate = 0 hits
Potassium Laurate = 1853 hits, 2 relevant
Potassium Linoleate = 301 hits, 0 relevant
Potassium Linseedate as linseedate = 0 hits
Potassium Oleate = 378 hits, 1 relevant

Potassium Olivatate/Sunflowerseedate = 0 hits
Potassium Palmitate = 143 hits, 0 relevant
Potassium Stearate (limited to 2000-2018) = 53 hits, 0 relevant
Potassium Sunflowerseedate as sunflowerseedate = 0 hits
Potassium Tallate (limited to 2009-2018) = 0 hits
Potassium Tallowate = 0 hits
Potassium Undecylenate = 4 hits, 1 relevant
Sodium Arganate as arganate = 0 hits
Sodium Beeswax = 26 hits, 0 relevant
Sodium Behenate = 14 hits, 0 relevant
Sodium Camellia Japonica Seedate = 0 hits
Sodium Caprate = 817 hits, 1 relevant
Sodium Caprylate = 1989 hits, 4 relevant
Sodium Castorate = 0 hits
Sodium Dilinoleate = 0 hits
Sodium Hydrogenated Tallowate = 0 hits
Sodium Hydroxystearate = 7 hits, 0 relevant
Sodium Isostearate = 7 hits, 0 relevant
Sodium Lanolate = 1 hit, 0 relevant
Sodium Lardate = 0 hits
Sodium Laurate = 1936 hits, 4 relevant
Sodium Laurate/Linoleate/Oleate/Palmitate = 1 hit, 0 relevant
Sodium Linoleate = 756 hits, 0 relevant
Sodium Oleate = 523 hits, 2 relevant
Sodium Palmitate = 15,433 hits, 0 relevant
Sodium Stearate (limited to 2000-2018) = 3477 hits, 0 relevant
Sodium Tallowate = 249,884 hits, 0 relevant
Sodium Tamanuseedate = 0 hits
Sodium Undecylenate = 10 hits, 0 relevant
Stearic Acid (limited to 2003-2018 due to RR in 2004/2005) = 3090 hits, 3 relevant
Trilinoleic Acid = 3 hits, 0 relevant
Undecanoic Acid = 247 hits, 0 relevant
Undecylenic Acid = 237 hits, 3 relevant

Typical Search Terms

- INCI names
- CAS numbers
- chemical/technical names
- additional terms will be used as appropriate

LINKS

Search Engines

- Pubmed (- <http://www.ncbi.nlm.nih.gov/pubmed>)
- Toxnet (<https://toxnet.nlm.nih.gov/>); (includes Toxline; HSDB; ChemIDPlus; DART; IRIS; CCRIS; CPDB; GENE-TOX)
- Scifinder (<https://scifinder.cas.org/scifinder>)

appropriate qualifiers are used as necessary

search results are reviewed to identify relevant documents

Pertinent Websites

- wINCI - <http://webdictionary.personalcarecouncil.org>
- FDA databases <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>
- FDA search databases: <http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm>;
- EAFUS: <http://www.accessdata.fda.gov/scripts/fcn/fcnavigation.cfm?rpt=eafuslisting&displayall=true>
- GRAS listing: <http://www.fda.gov/food/ingredientspackaginglabeling/gras/default.htm>
- SCOGS database: <http://www.fda.gov/food/ingredientspackaginglabeling/gras/scogs/ucm2006852.htm>
- Indirect Food Additives: <http://www.accessdata.fda.gov/scripts/fdcc/?set=IndirectAdditives>
- Drug Approvals and Database: <http://www.fda.gov/Drugs/InformationOnDrugs/default.htm>
- <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM135688.pdf>
- FDA Orange Book: <https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm>
- OTC ingredient list: <https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm135688.pdf>
- (inactive ingredients approved for drugs: <http://www.accessdata.fda.gov/scripts/cder/iig/>)
- HPVIS (EPA High-Production Volume Info Systems) - <https://ofmext.epa.gov/hpvis/HPVISlogin>
- NIOSH (National Institute for Occupational Safety and Health) - <http://www.cdc.gov/niosh/>
- NTIS (National Technical Information Service) - <http://www.ntis.gov/>
- NTP (National Toxicology Program) - <http://ntp.niehs.nih.gov/>
- Office of Dietary Supplements <https://ods.od.nih.gov/>
- FEMA (Flavor & Extract Manufacturers Association) - http://www.femaflavor.org/search/apachesolr_search/
- EU CosIng database: <http://ec.europa.eu/growth/tools-databases/cosing/>
- ECHA (European Chemicals Agency – REACH dossiers) – <http://echa.europa.eu/information-on-chemicals;jsessionid=A978100B4E4CC39C78C93A851EB3E3C7.live1>
- ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) - <http://www.ecetoc.org>
- European Medicines Agency (EMA) - <http://www.ema.europa.eu/ema/>
- IUCLID (International Uniform Chemical Information Database) - <https://iuclid6.echa.europa.eu/search>
- OECD SIDS (Organisation for Economic Co-operation and Development Screening Info Data Sets)- <http://webnet.oecd.org/hpv/ui/Search.aspx>
- SCCS (Scientific Committee for Consumer Safety) opinions: http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm
- NICNAS (Australian National Industrial Chemical Notification and Assessment Scheme)- <https://www.nicnas.gov.au/>

- International Programme on Chemical Safety <http://www.inchem.org/>
- FAO (Food and Agriculture Organization of the United Nations) - <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>
- WHO (World Health Organization) technical reports - http://www.who.int/biologicals/technical_report_series/en/
- www.google.com - a general Google search should be performed for additional background information, to identify references that are available, and for other general information

Botanical Websites, if applicable

- Dr. Duke's - <https://phytochem.nal.usda.gov/phytochem/search>
- Taxonomy database - <http://www.ncbi.nlm.nih.gov/taxonomy>
- GRIN (U.S. National Plant Germplasm System) - <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx>
- Sigma Aldrich plant profiler- <http://www.sigmaaldrich.com/life-science/nutrition-research/learning-center/plant-profiler.html>
- American Herbal Products Association Botanical Safety Handbook (database) - <http://www.ahpa.org/Resources/BotanicalSafetyHandbook.aspx>
- European Medicines Agency Herbal Medicines - http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_search.jsp
- National Agricultural Library NAL Catalog (AGRICOLA) <https://agricola.nal.usda.gov/>
- The Seasoning and Spice Association List of Culinary Herbs and Spices http://www.seasoningandspice.org.uk/ssa/background_culinary-herbs-spices.aspx

Fragrance Websites, if applicable

- IFRA (International Fragrance Association) – <http://www.ifraorg.org/>
- Research Institute for Fragrance Materials (RIFM)

Note: ChemPortal can be used to search several of the above databases simultaneously - http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en

Fatty Acids and Fatty Acid Salts
December 3-4, 2018 Minutes

Dr. Belstio's Team

DR. BELSITO: Christina is right there. Hi, Christina. Okay. So this is the first time we're looking at this report, and it was based upon high frequency. I thought safe as used, discussion pesticides, heavy metal, animal-derived, but the animal-derived as tallow and we have that usual verbiage for tallow; but formulated to be non-irritating and non-sensitizing.

DR. LIEBLER: Is there any evidence of sensitization?

DR. BELSITO: I think so.

DR. LIEBLER: I mean, the only possibility, I guess, would be due to oxidation products of the polyunsaturated fatty acids. Because those could be directly protein reactive.

DR. BELSITO: In vitro, direct peptide reactivity predicted that linoleic acid and linolenic acid were skin sensitizers. Hydroxystearic acid, up to 50 percent, linoleic acid 25, linolenic 25, oleic 10, and undecylenic acid 25 indicate that these ingredients may induce sensitization. In guinea pig studies, reactions observed to ammonium oleate, up to 50 percent, hydroxystearic acid, up to 10 percent, may have been due to irritation. So, there's some equivocal data.

DR. LIEBLER: Yeah, I had a comment on this, Don. Polyunsaturated fatty acids, like linolenic and linoleic, can undergo oxidation to yield peptide protein reactive oxidation products. In this DPRA, the test concentrations were really high, a hundred millimolar. So, even if you had one percent oxidation, that would be millimolar oxidation product available to react with the peptide, which could give you a positive result, but I think it's --

DR. BELSITO: But then you have a whole bunch of positive LLNAs.

DR. LIEBLER: Again, it depends on the purity of the compound and the concentration used in the test. So, you could say formulated to be non-sensitizing, and in the discussion, you could explain -- because I think we would understand the mechanistic basis for that. So, it could certainly be explained that polyunsaturated fatty acids would autoxidize, and you should take care to ensure the purity of the polyunsaturated fatty acids that are used to minimize adverse effects of oxidation products.

DR. BELSITO: So, do you want to get rid of the conclusion non-sensitizing?

DR. LIEBLER: I suppose formulating them to include pure, fresh linoleic acid and linolenic acid, if it is used, would fall under formulation to be non-sensitizing.

DR. BELSITO: Except that these products could be put in a jar where they are opened, and oxidized, during the course of use.

DR. LIEBLER: Right. For the life of me I don't see why they'd use linoleic acid, but it's got a lot of uses. And oleic acid would be just as good; it's very similar physical properties, but it's not very oxidizable at all. So, I guess, no, I don't object to formulated to be non-sensitizing. But I think this needs to be addressed in the discussion. And that's why I sent you that review, Christina.

MS. BURNETT: I got it. Thank you.

DR. BELSITO: So safe -- I had non-irritating and non-sensitizing.

DR. LIEBLER: Correct.

DR. BELSITO: And then, if you want to add Dan's to the discussion, that we also need pesticides, heavy metal, and the animal tallow in the discussion.

Then, again, for these EU restrictions that I didn't understand, do you have any idea why they were -- so it says European Union, the stearates, aluminum, calcium, and magnesium, are listed in Annex IV, list of colorants allowed in cosmetic products in the EU. Does that mean they're not allowed for other functions, because we have them as other functions? And then the undecylenate salts are restricted to 0.2 percent acid.

MS. BURNETT: I'm not sure on the Annex IV, or how Europe works. Because it's a colorant, they have to list which ones are approved, maybe? It wasn't on the restricted list for other uses.

DR. BELSITO: Okay. I just -- any idea why they restricted undecylenic salts and the acid to 0.2 percent free acid?

MS. BURNETT: Unless it has to do with its antifungal properties. I don't know.

DR. BELSITO: Then it gets into a -- the FDA has not approved undecylenic acid as an antifungal. Is that correct?

MS. BURNETT: It's an OTC.

DR. BELSITO: Is it an OTC antifungal in the US?

MS. BURNETT: It's in my big list of -- oh yeah.

DR. BELSITO: They may be in Europe. Maybe that's why they restricted it, I don't know.

MS. BURNETT: Is approved over-the-counter drug, calcium undecylenate for dandruff, dermatitis, psoriasis as long as the total undecylenate concentrations of 10 to 15 percent. And then undecylenic acid, the same. It's in table eight, on PDF, page 60.

DR. BELSITO: I mean, I was just curious as to if there was any information of why they limited it.

MS. BURNETT: But what I had, I don't --

DR. BELSITO: Okay.

DR. SNYDER: Don, it's a penetration enhancement discussion.

DR. BELSITO: Oh, I missed that. Where is that, Paul? Well, yeah, then it definitely needs to be in the discussion. Both are celecoxib?

DR. SNYDER: Oleic acid. Page 24. Topical delivery of --

DR. BELSITO: Yeah, it just said has been studied for its ability to act as a penetration enhancer. It didn't say whether it was.

DR. SNYDER: Yeah, that's true. And the reference 53 says, "in vitro and in vivo influence of penetration enhancers in the topical application." We checked reference 53 to see whether it was or wasn't?

DR. BELSITO: Yeah.

DR. SNYDER: It looks like it was evaluated.

DR. BELSITO: Myristic acid was to, yeah. So, in the discussion penetration enhancement.

MS. BURNETT: It might have been in comparison with other things.

DR. SNYDER: It was.

MS. BURNETT: It might be. There was a reason why I didn't put in more details. I have a feeling they weren't pertinent.

DR. BELSITO: Anything else?

DR. HELDRETH: So, then the conclusion would be safe and non-irritating and non-sensitizing, which may be based on a qualitative risk assessment? Okay. I just wanted to make sure of that last question.

Dr. Marks' Team

DR. MARKS: The first review of the fatty acids and fatty acid salts. There were just a few of these. To be precise, Christina tells me it's 102 ingredients. So, the first thing we need to decide, do we like the ingredients. And then, the second thing will be what needs do we have?

I have 4 pages of ingredients. Ron, Ron, and Tom, how do you like these? Ron Shank, you usually have a very logical way of taking large groups, like this, and dividing them into smaller bites.

DR. SHANK: You probably won't like this, but --

MS. BURNETT: Is that why you were avoiding me during the break? Take them out.

DR. SHANK: Sorry. But I think, based on the FDA-approved use of several of these ingredients as food additives, and based on the completed reviews of several of the ingredients by the panel, and based on the low concentrations of use for most of the ingredients, the whole group can be considered safe when formulated, of course, to be non-irritating.

DR. SLAGA: Well, we do have irritation data.

DR. MARKS: Yeah. That's what he said, formulated to be.

DR. SHANK: Yeah. That's why I said formulated to be non-irritating, not to be irritating.

DR. MARKS: I may differ slightly, but that's okay, Ron. I like your approach. So, you like all 109 [sic] and I can -- I like the way you did it.

DR. SHANK: I have three basis. One, the FDA approved use of several of these ingredients as food additives. Also, based on the completed reviews of several of the ingredients, by the panel; and also based on the low concentrations of use for most of the ingredients, the whole group can be considered safe as used, when formulated to be non-irritating.

DR. MARKS: So, I'll just -- first, let's -- ingredients okay? Tom? Ron Hill?

DR. HILL: I had concerns about including these dimeric ones, partly because we have no basis for which to do any read-across. They're structurally dissimilar.

DR. MARKS: So, which ones are these? The dimeric.

DR. HILL: There's just two. Hang on. I've probably got them listed in here. Otherwise, I'd have to go to the -- and then there are a couple others I want to talk about, at least, based on Dr. Shank's assertion.

DR. SHANK: Yeah, the first two of the aluminum dilinoleate and distearate.

DR. HILL: Yeah. I think that there's just two dimeric structures. I think it's the dilinoleate, and there's a salt of that. And then there's one more that's not in use.

MS. BURNETT: Dierucic?

DR. HILL: Diarasic [sic]. Diaruxic [sic]. I don't know how you say that actually, honestly. I'm embarrassed.

DR. MARKS: Where is that? Which ones -- what's the preface of that? So, there's the aluminum dilinoleate -- that's the one --

MS. BURNETT: No, go down.

DR. HILL: And there's actually three of those, I think, that have it. I just did a search on dilino --

MS. BURNETT: Well, he's looking at the parent one, I think. The parents of dilinoleic and dierucic. And, like, it's the associated salts with those, Dr. Hill?

DR. HILL: What's that?

MS. BURNETT: The associated salts with those?

DR. HILL: Yeah. I think there's two salts, aren't there? Or three. Aluminum --

MS. BURNETT: Aluminum dilinoleate.

DR. HILL: Maybe calcium and sodium. Or -- I apologize. I have them flagged somewhere, I just didn't know which spot I did it.

DR. MARKS: So, Ron Shank, do you have -- looking at those now, this is on the second page. The dilinoleic acid and the di--

MS. BURNETT: He's looking at the profile page.

DR. MARKS: Right. This would be page -- it's on -- yeah, the profile page.

DR. HILL: They're all listed on one page in the beginning of the report.

DR. MARKS: Yeah. I like to look at it with the profile page.

DR. HILL: I do, too.

MS. BURNETT: He's looking starting on PDF page 6.

DR. MARKS: So, Ron Shank, what do you think about that, using your reasoning?

DR. HILL: I said that we have to have some sensitization on that if we keep it.

DR. MARKS: Yeah. I had sensitization. Actually, it's interesting. I wanted sensitization on palmitic acid and stearic acid at 21 percent. Both of them have over 1000 uses, one over 1000, that's the palmitic, and the stearic is over 5000 uses. Their leave-on is 21 percent, the highest concentration, particularly around the eye.

And, Ron, you're right, it was previously found to be safe. But when I looked at the details, the sensitization was at 13 percent, not 21 percent. So, I don't know if that difference is enough to warrant asking for more sensitization data.

DR. SLAGA: Especially, when we said it was safe before.

DR. MARKS: Well, you know, we've done that before in some other ingredients. When we've gone back and looked at the original report.

DR. SLAGA: We didn't like it.

DR. MARKS: Yeah. That, to me, was the only sensitization I was really concerned about. The others, as you said, are low concentrations and such.

DR. SLAGA: I had safe.

DR. MARKS: Yeah.

Dr. HILL: Well, again, in terms of the grouping, I, personally, don't feel like I can read across to those dimeric ones. And again, we're not going to get data on the eruxic [sic] -- eroxic [sic] acid. I have to figure out how exactly you're supposed to say that, but E-R-U-C-I-C, there's just one of those, I believe. And then, there's two salts plus the dilinoleic acid. And part of it related to the production process, which is a little bit -- the information we have is a little bit sketch. That's a technical term, sketch.

And then, there was a set of iso that I want to talk about. But also, I was gonna ask Dr. Shank, while you were on there, do we feel like we know enough about the beeswax? Well, it's not in use -- reported in use, is it? The beeswax fatty acids?

DR. SHANK: The sodium beeswax, no reported use.

DR. HILL: And then the other one I wondered about was the safflower oil, because there's conflicting information.

DR. SHANK: Safflower oil, we've reviewed.

DR. HILL: Yeah. But that was the oil. That wasn't the basis of my concern. Hang on. There was language about -- it related to this conjugated linoleic acid, the technical name for isomerized safflower oil. So, I actually focused on the ones that said isomerized, for a while, based on we don't know what the results of those are. But my comment about beeswax acids was, do we know anything about any potential sensitization? Because, as I remember, there are some less common fatty acids in there. It's not in use. I mean, it's beeswax.

So, you're a dermatologist. You don't -- people are putting beeswax stuff on themselves all the time. You've not seen anything suggestive that there's any sensitization issues, right?

DR. MARKS: Not really.

DR. HELDRETH: They're primarily long chain, C-24 to --

DR. HILL: I know. There are big long chain ones, and some of them have double bonds in unusual places. But that's -- I didn't -- this was a question for the group. But the isomerized ones, that was one I spent some time looking at, because we don't have complete information. So, that was part of my informational needs is, what's in that stuff?

And particularly, one that said -- on page 25, it says conjugated linoleic acids. So, conjugated suggests it should be conjugated with what? And then, a technical name for isomerized safflower acid, that didn't make any sense at all. Is it truly conjugated? Is that conjugated as phospholipids or sunflower proteins? That's not one of the ingredients, but it related to what was on page 25.

DR. MARKS: So, Ron Hill, it's interesting, I could take a look at my sensitization concern in another way, as there's so many uses of both palmitic and stearic acid. And even though the concentration use now is reported significantly higher than in the previous reports, where we have sensitization data, the number of case reports is -- and there's no significant clinical alerts that we could move forward with a safe conclusion.

DR. SHANK: I thought so, but --

DR. HILL: Yeah. We'll see what the other team --

DR. SHANK: -- if you want sensitization in higher test concentrations, it's okay.

DR. SLAGA: Yeah. Belsito has it, so we can see what they do.

DR. HILL: I wrote also, in terms of needs, impurities in any and all with synthetic sidechain; and composition profile for the ones that are likely to be a mixture of fatty acid chain links or multiple isos, especially if we're intending to read across. And there were a couple in particular. Let's see. All the impurities information we have are ones given in the food codex; and we have no necessity to believe that these are necessarily food-produced materials.

On page 38, I asked, is that first hydroxystearic structure versus -- there's a hydroxystearic, and then after that is a 10-hydroxystearic. What's the story there? That's page 38.

DR. HELDRETH: So, the hydroxystearic acid -- typically, when the Nomenclature Committee will do a hydroxy fatty acid, they always mean the placement shown. The 10-hydroxystearic acid is called out, because it's different from their standard practice.

DR. HILL: I know. So, then, what do we know about that? That was my question.

DR. HELDRETH: Okay.

DR. HILL: Yeah, Hydroxystearic acid, that's one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve. And I know that stearic acids, hydroxylated, are naturally occurring, hydroxylated in multiple positions. The question is, is that structure in there known to be a for sure -- are those two actually the same? I mean, it's a lack of clarity, I think. And then, what do the use table look like on that again?

DR. MARKS: Okay. So, Ron, you --

DR. HILL: I'm looking for the use data on those. Are they in use? And if so, at what concentrations do we know?

DR. MARKS: The use is Page 51, Table 5.

DR. HILL: Yeah. I don't see --

MS. BURNETT: Hydroxystearic acid is in use.

DR. HILL: But I don't see it in the table here that summarizes use data, unless it's -- I see 10-hydroxydecanoic.

MS. BURNETT: They're both used. Oh, wait. No.

DR. HILL: I'm looking at table 5. Table 5, I don't see it in there.

MS. BURNETT: It's not there, no.

DR. HILL: So, that suggests it's in the -- well, it would still show up there, if it was even just the VCRP.

MS. BURNETT: Yes, the 10-hydroxystearic acid is not reported in use. The Hydroxystearic acid is reported in use.

DR. HILL: It's not in this table, though.

MS. BURNETT: Which --

DR. HILL: Table 5.

MS. BURNETT: It's in Table 6. The one that -- because it was previously reviewed. The previously reviewed ones are in a different table.

DR. HILL: Okay, yeah. Okay. I'm sorry. I forgot about that. Okay, yeah. So, up to what concentration. So, my question really relate up to -- 2016, up to 14 percent in the leave-on. So, my question related to, do we really know, for sure, what that stuff is? And do we have sensitization data to cover it directly on that compound? Not that I think it should sensitize, but then again, once you have hydroxy, you can have ketone, and then you can react.

So, hydroxystearic acid, we have irritation, sensitization, non-human. And then human with a star, so that's old data, but it seems like we are covered with that. So, we're good there. As well as genotox -- I'm not worried about any of that.

DR. MARKS: Okay.

DR. HILL: Hang on. Iso. There's iso. I don't know which one it was. There's no chronic toxicology data for isostearic, which is reported to be a mixture of branched chains. And it was written off with some toxicokinetics information, in a previous report, that completely lacks credibility.

In the 1983 report, the "toxicokinetic" info appears to only be general knowledge of omega-branched biotransformation, not the other branching. FDA has approved only indirect food additive use for that particular substance, not direct.

And isostearic is in pretty common use at, I think, fairly high concentrations. And that would be Table 6, right? Yeah, up to 26 percent -- 16 percent in leave-on and 26 in rinse-off. 26 percent in leave-ons -- I'm sorry, 16 percent in leave-ons. So, I had concerns about isostearic.

DR. MARKS: Isostearic acid?

DR. HILL: Isostearic acid, yes. So, that's a mixture --

DR. MARKS: So it was safe before to use 6 percent. Is that right, or 16?

DR. HILL: But I looked back at the previous report as to why it was cleared for safety, and there's nothing to hang your hat on.

DR. MARKS: There wasn't an issue with sensitization?

DR. HILL: No, I'm not worried about sensitization with isostearics. I'm worried about chronic tox possibilities.

DR. MARKS: Tom, Ron Shank?

DR. SLAGA: I have no problem.

DR. MARKS: You're not concerned?

DR. SLAGA: No.

DR. SHANK: Sorry.

DR. MARKS: No, you don't have to -- so, with tomorrow, I'll be seconding a motion. And as you can tell, at least the discussion from the sensitization can go either way, insufficient data announcement. And for me it would be do we go up to 21 percent in HRIPT for palmitic and stearic acids? They were previously reported safe, but the highest concentration that was tested was 13 percent. The lack of clinical alerts would suggest that they are safe at 21 percent used around the eye.

So, a tentative report with a safe to formulate to be non-irritating is okay, too. I'm fine to go either way. Ron Hill, when it comes to the discussion, we'll let you go ahead and --

DR. HILL: I'm not done yet, by the way.

DR. MARKS: Oh, okay.

DR. HILL: I have a few more. So, Eicosatrienoic Acid is almost Arachidonic Acid, which Arachidonic Acid's a precursor for prostaglandins -- and Arachidonic Acid was specifically excluded from an earlier report, in terms of conclusion of safety, because of that issue. The question is, what do we know about - and I think this is one that's not in current use. Isn't that correct, Christina?

MS. BURNETT: I'm sorry. Which --

DR. HILL: Eicosatrienoic Acid. Eicosatrienoic. That's one double bond short of Arachidonic Acid.

MS. BURNETT: Arachidic Acid? Or --

DR. HILL: No. Eicosatrienoic.

MS. BURNETT: E-I-C-O -- okay.

DR. HILL: E-I-C-O.

MS. BURNETT: In my head, I was pronouncing it differently. That's why I wasn't looking for -- not use.

DR. HILL: Okay. So, we won't get any information about that. But I can't conclude sufficient without knowing about that. What about the two alpha hydroxy acids? Did that cause any question marks with anybody?

DR. MARKS: No, I think, Ron, you've already heard Tom's and Ron's --

DR. HILL: Okay. I did. I did. I'm asking them again, specifically, about those.

DR. MARKS: I think, tomorrow, just list the ones which you have concerns about, and then we'll react from that.

DR. HILL: So, this was a more --

DR. MARKS: It's a first review, so we'll have another look at it.

DR. HILL: All right. Great. There is a need to distinguish with the undecylenic acid, it is an anti-fungal OTC drug. We do have cosmetic products that don't list it as that use, but in a concentration range it puts it up there. Maybe we need to ban -- and actually preservative is listed in language somewhere, but I'm not sure it's listed for any of those as preservative function in the dictionary.

But that was just a general issue that I saw in all of this, just kind of ignoring that it's there. And it does have pharmacology as an anti-fungal and bacteriostatic which, in one case, I think it does -- they do describe its use as bacteriostatic effect.

MS. BURNETT: Yeah. The dictionary list the undecylenic acid as anti-fungal and cosmetic biocide.

DR. HILL: So, the reason I asked that question is because in the OTC function, it appears that we're in the 10 to 25 percent range. And somewhere in the report, we have a nail product, up to 25 percent, in nail creams and lotions. But then, somewhere else, it looked like that use had disappeared.

So, I didn't know is it, in fact, used at 25 percent in nail creams and lotions? Because, arguably, even if it doesn't say OTC drug, wouldn't it be de facto an OTC drug?

MS. BURNETT: It also was reported to be a surfactant.

DR. HILL: Sure. It would be. That's how it kills the -- or at least stops the growth of the fungus. I think it wrecks their -- well, no, there's a cell wall -- or cell membrane, I'm sorry -- function in fungi. It also reported testing undecylenic acid for sensitization at 100 percent; and I wondered how you do that, given that it's a solid, although it melts at 26 percent. So, I'm wondering, did they butter it on? And if it hadn't said nail product use up to 25 percent, then the next highest use is .2 percent. So, perhaps this is really verifying that that reported use is cosmetic. I don't know how you deal with that.

DR. MARKS: Okay. Any other -- Ron Hill, I'm going to retract something I said earlier when you said beeswax, not a sensitizer, and it's yes. Actually, that's not true. Propolis, which is a mixture derived from the bees' hive and such, is a sensitizer.

DR. HILL: Yeah. But if this is -- if it's -- I mean, we don't have method of manufacturer for that, because it's not in use. So, we're not going to get it.

DR. MARKS: Right. I just wanted to be clear on that. Any other comments? Ron Hill.

DR. HILL: Well, just from the European Annex V, Calcium Undecylenate, Potassium Undecylenate, Sodium Undecylenate, and Undecylenic Acid are listed on Annex V: list of preservatives allowed in cosmetic products; the maximum concentration in ready for use preparations is restricted to 0.2 percent as Undecylenic Acid. But we've got a nail product saying 25 percent.

What I said about the sensitization of Undecylenic Acid and why I asked about testing it, is because we wouldn't expect direct reactivity. So, there's a protein reactivity study in there that doesn't have any merit with that molecule; because we would expect it to react once an epoxide is made of that terminal alkyne moiety. Otherwise, we don't expect sensitization. So, anyway, I mean, it's in use as an OTC drug product, so that, to me, mitigates any concern about that, honestly.

DR. MARKS: Exactly. Good. Okay. If nothing more, Ron Hill, tomorrow morning --

DR. HILL: I'm good for now.

DR. MARKS: -- when we discuss this, Wilma will be asking for discussion points. And I'll go ahead and call on you if you want, and you can just react when Wilma asks for discussion.

DR. HILL: And also, for Christina, just to note that we need the penetration enhancement language captured in the discussion, because some of these are known penetration enhancers. It'd be really nice to know -- it seemed like there ought to be literature out there about the SAR penetration enhancement by fatty acids, but there may not be. And I didn't do that search myself.

DR. MARKS: So, I didn't really ask you, Ron Hill, do you favor insufficient data announcement --

DR. HILL: Yes, sir.

DR. MARKS: -- versus a tentative report with safe, formulated to be non-irritating? I assume the insufficient data announcement with all the things you brought up.

DR. HILL: Yes. And I'll make sure I can concisely give my insufficient that can shoot down one, or not.

DR. MARKS: Okay. Great. Any other comments? Okay. Let me see this.

Full Panel

DR. BELSITO: This is the first time that we're looking at this report on fatty acids and fatty acid salts. Very well put together. We thought that, based upon the data presented here, we could go safe as used when formulated to be non-irritating and non-sensitizing, again, using QRA or other methodologies. And then there are some discussion points.

DR. BERGFELD: Okay. Dr. Marks' team.

DR. MARKS: Second.

DR. BERGFELD: Second. Do you want to take up the discussion points now?

DR. BELSITO: Yeah, pesticides, heavy metal, animal-derived, but it's tallow and so used the usual tallow caveat. Let's see if there's anything else, penetration enhancement. Thank you, Paul.

DR. BERGFELD: Dr. Marks' team, any additions to the discussion?

DR. MARKS: No, I think you covered it with the non-sensitizing. I was concerned that palmitic and stearic acids, even though it had been in a previous report and felt to be safe, the sensitization data was significantly less. It was previously 13 percent was non-sensitizing, whereas now it's being used in a lot of ingredients, up to 21 percent, particularly around the eyes. So, you're non-sensitizing caveat in the conclusion reassures me there.

DR. BERGFELD: Dan?

DR. LIEBLER: I just want to bring out something that I'm sure is pretty evident to you guys, but I want to make sure it's mentioned in the full panel discussion. The sensitizing issue, particularly that positive DPRA data they had, is most likely related to oxidation products of the polyunsaturated fatty acids, linoleic and linolenic. Those are two high-used ingredients in this family; and even a small amount of oxidation could give rise to protein modifications and initiate a series of events that would lead to a sensitization response. That's, I think, one of the issues. The formulation to be non-sensitizing, in the discussion, I think we need to raise the point of paying attention to the degree of oxidation of the fatty acids incorporated in the susceptibility to oxidation in the formulation.

DR. BERGFELD: Thank you for adding that. I think that the preceding ingredient we also clarified why we put non-sensitizing and non-irritating in the discussion. And this particular discussion is very important for the discussion in the document. Ron Hill, did you --

DR. HILL: I'm sorry. I had a number of things, which we did talk about some of them yesterday.

DR. BERGFELD: Okay.

DR. HILL: We have synthetic fatty acids in here where we don't really know what the composition is; so I focused on the ones where we had process-type isomerization, where we didn't necessarily know what

we got after that. And also, the ones that are iso that are described to be mixtures of chain links. I think we need to get away from this way of thinking, that if something has 18 carbons, however it is branched or constructed, that it is the same. Again, the more we learn about what happens with membrane structure and membrane microdomains, and what happens if we have something built up in those that are not normal, the more we really need to have some idea about chronic things.

Let's start with what, actually, is in this stuff. I think it's reasonable to expect that, if we have something that's a mixture of isos, we have modern technology that can tell us what isos are in there, what are the branchings. We're engineered to metabolize fatty acids that are omega branched and some other branchings, specifically, but, if the branching is different, that's an issue.

The other thing that we discussed, a little while yesterday, was the Undecylenic Acid because we have one product in there that is up to 25 percent in a nail lotion. Ten to 25 percent is OTC antifungal products of Undecylenic Acid. So, what happens if we call it a bacteriostat or fungistat or a preservative, which is what's in the dictionary in some cases, how does that fall? I mean, that's really the FDA's call and not our purview. But I wanted to point out that we do have Undecylenic Acid, in most cases at .2 percent or below, but there's this one case that says 25 percent if that's accurate. So, just to pay attention to the three undecylenates that are in there, and know if there's any consequences related to that.

I had concern with these dimeric ones. We're not going to get any data on -- is it Erucic Acid, E-R-U-C-I-C? I'm not sure how you say that, but I think that's correct. So, there's a Dierucic Acid that's listed in there, but it's not reported to be in use, we wouldn't see the data. And the Dilinoleic Acid is -- Linoleic Acid -- excuse me -- Dilinoleic Acid is structurally quite disparate from these others, and we're trying to read across to that, and that bugs me.

DR. BERGFELD: So, are you asking for clarification of the chemistry, again, for this group? Or are your specific questions about the chemistry?

DR. HILL: I wondered why we leave the Dilinoleic Acid and the Dierucic Acid in there. Why do they stay in the group? And if they do, how do we feel we can read across to those, because I sure don't feel that I can.

DR. BERGFELD: Dan, you want to respond?

DR. LIEBLER: I felt it was reasonable to include those at this point in the report. You know I don't really have concerns about these molecules. I would agree that their metabolism would have to be a little different. And honestly, I don't know off the top of my head what that is. These have not been -- I'm trying to think if any of the dimer ingredients, they're not red in Christina's list, so they have -- oh, Aluminum Distearate has been safe as used, Aluminum Tristearate also. That's what I was looking for earlier. So, these have already been found safe. I'd like to know more about them.

DR. HILL: But the Aluminum Distearate is not that. Aluminum Distearate is one aluminum with two stearic acids.

DR. LIEBLER: Oh, they're not the dimer structures. They're not the carbon dimers --

DR. HILL: No.

DR. LIEBLER: Okay, I take that back. Thank you. You know, this is a judgment call. I don't feel I'd support removing them from the report.

DR. BERGFELD: Ron Shank, any comments on the chemistry or the tox?

DR. SHANK: No, no comments.

DR. BERGFELD: Tom?

DR. SLAGA: No.

DR. BERGFELD: Paul?

DR. SNYDER: No.

DR. BERGFELD: Curt?

DR. KLAASSEN: No.

DR. BERGFELD: Well, coming back to the fatty acids. It's been seconded? Any do we have any other discussion? For the discussion points, we need to have -- Christina, do you have the list? Could you read it off to make sure they're complete?

MS. BURNETT: I have inclusion of the pesticides boilerplate, heavy metals boilerplate, the tallow animal boilerplate, penetration enhancement boilerplate. And then a discussion about limiting the oxidation products of polyunsaturated fats, to limit sensitization and formulations, or something to that degree.

DR. MARKS: To me, I view that -- and, Dan, I think you really elucidated -- that's the reason for the quantitative risk assessment, because we're concerned about the oxidative products. Is that correct?

DR. LIEBLER: I think so. That's the only mechanism, I can find, that would plausibly drive sensitization with this family of molecules.

DR. BERGFELD: Could I ask, Ron Hill, is there something you wish to add to this list?

DR. HILL: I mean I think more information. Are we going safe? Is that's what's going on?

DR. BERGFELD: The conclusion that's on the table is safe.

DR. HILL: We can at least -- we would at least -- I'm not voting for safe for all of these, that's not going to happen.

DR. BERGFELD: Okay.

DR. HILL: But at least, in any case, if that goes through that way, we need to discuss the general uncertainties with regard to the actual compositions in some of the synthetic fatty acids. Number one.

DR. BERGFELD: Okay.

DR. HILL: You talk about oxidation products, we can make those oxidation products in our skin. We have P450s in the skin, so if there's a double bond there, we can certainly make an epoxide and react. I don't think, based on the fact that we have those fatty acids, at least the natural ones in our body, that we have a problem there. But that, again, is why I look at things like the one that's almost arachidonic acid in there. The eicosatrienoic Acid -- eicosatetraenoic acid is arachidonic acid, which we didn't clear before. I don't think the trienoic can be converted. It would be nice to know if can or can't, but I don't think so.

Anyway, when we have an endogenous fatty acid with a double bond in it, we know our biochemistry can handle that and we shouldn't sensitize. But when there's something artificial, we don't know that for sure. So, we should at least discuss that sensitization can happen and here's a mechanism by where it can happen. People that are using these should take note of that, and take steps to ensure that sensitization is studied. And if we're going to require it, then we're okay still.

DR. BERGFELD: Yeah, that is -- it's to be non-sensitizing. All right. Any other comments? Going to call the question. Dr. Belsito, restate the conclusion that you proposed?

DR. BELSITO: Sure, safe as used when formulated to be non-irritating, non-sensitizing, QRA, other methodologies.

DR. BERGFELD: All right. I'm going to call the question. All those in favor? Opposed? Okay. One opposed.

MS. BURNETT: Am I removing Dilinoleic Acid and di --

DR. BELSITO: No.

MS. BURNETT: It stays? Okay. All right.

DR. BERGFELD: So, we have one opposing vote. Thank you very much for that discussion.

Safety Assessment of Fatty Acids & Fatty Acid Salts as Used in Cosmetics

Status: Draft Final Report for Panel Review
Release Date: March 15, 2019
Panel Meeting Date: April 8-9, 2019

The 2019 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Christina L. Burnett, Senior Scientific Analyst/Writer.

ABSTRACT

The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) assessed the safety of 102 fatty acids and fatty acid salts, most of which are reported to function as anticaking agents, emulsion stabilizers, viscosity increasing agents, opacifying agents, and surfactants in cosmetic products. The Panel reviewed the available data to determine the safety of these ingredients, noting that these ingredients may cause dermal irritation. Further, the Panel also noted the potential for polyunsaturated fatty acids to undergo oxidation during the formulation of cosmetic products, which may produce compounds that may be dermal sensitizers. The Panel concluded that fatty acids and fatty acid salts are safe in cosmetics in the present practices of use and concentration described in this safety assessment when formulated to be non-irritating and non-sensitizing, which may be determined based on a quantitative risk assessment (QRA).

INTRODUCTION

This report addresses the safety of 102 fatty acid and fatty acid salts (listed below) as used in cosmetics. Most of the fatty acids and 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 reported 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).

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

Sodium Caprate	Sodium Linoleate
Sodium Caprylate	Sodium Oleate
Sodium Castorate	Sodium Palmitate
Sodium Dilinoleate	Sodium Stearate
Sodium Hydrogenated Tallowate	Sodium Tallowate
Sodium Hydroxystearate	Sodium Tamanuseedate
Sodium Isostearate	Sodium Undecylenate
Sodium Lanolate	Stearic Acid
Sodium Lardate	Trilinoleic Acid
Sodium Laurate	Undecanoic Acid
Sodium Laurate/Linoleate/Oleate/Palmitate	Undecylenic Acid

While most of the fatty acids (such as Linoleic Acid, with reported use in 633 cosmetic formulations)² and fatty acid salts have not been previously reviewed by the Panel, several previously assessed ingredients have been included herein (denoted in **red** above) as they fit within this grouping of fatty acids and salts and can be appropriately re-reviewed here within.³⁻¹¹ Each of the ingredients in this report comprises a carboxylic acid functional group and an aliphatic (fatty) chain. Pertinent data from the reports on the previously reviewed fatty acids and fatty acid salts are summarized in the appropriate sections of this report 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.¹² Dermal absorption data were needed, and if absorbed, additional data are required. The conclusion was subsequently reclassified as “Use Not Supported by the Data and Information Submitted to the CIR,” per the CIR Procedures. Additionally, several related ingredients have also been reviewed and are referred to herein as supplemental information.¹³⁻¹⁹ The conclusions for the previously assessed fatty acids and fatty acid salts and the other related ingredients have been provided in Table 2.

Most of the fatty acid ingredients described in this safety assessment are ubiquitous in food as dietary fats. The US Food and Drug Administration (FDA) has affirmed that Calcium Stearate, Caprylic Acid, Linoleic Acid, Magnesium Stearate, Sodium Oleate, Sodium Palmitate, and Stearic Acid are generally recognized as safe (GRAS) as direct or indirect food substances. The US FDA has also affirmed that Oleic Acid is GRAS as a substance migrating from food packaging. Additionally, the US FDA has 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 safety for 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 report, a representative sampling of the most pertinent published data, as identified by conducting an exhaustive search of the world’s literature, has been included for each endpoint that is evaluated. This safety assessment also includes unpublished data. 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 (<https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites>; <https://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 fatty acid salts 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.²⁰⁻³³ Additionally, some data were obtained from an assessment by the Organisation for Economic Co-Operation and Development Screening Information Data Sets (OECD SIDS).³⁴⁻³⁶ 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 fatty acid salts included 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.³⁶ The general structure for these acids in mono form is:

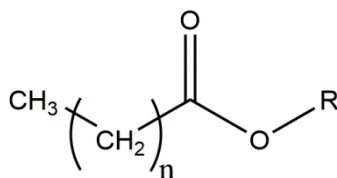


Figure 1. Generic fatty acid/salt structure (wherein R is a hydrogen atom or an ammonium, sodium, potassium, magnesium, or calcium cation. The chain lengths for fatty acids are 4 to 40 carbons in length (i.e. n is 2 to 38)).

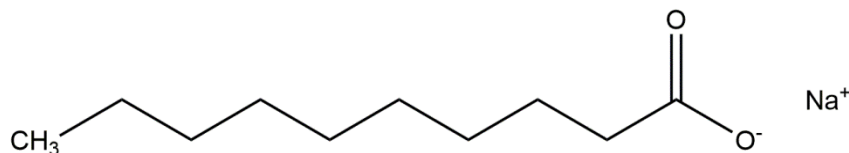


Figure 2. Specific example of a fatty acid salt with a 10 carbon chain length, Sodium Caprate

While some of these ingredients are comprised of straight (i.e., not branched) alkanes (saturated chains; i.e., no double bonds) like Sodium Caprate (Figure 2), some others are comprised of varying degrees of unsaturation (alkenes; e.g., Oleic Acid: 1, Linoleic Acid: 2, and Linolenic Acid: 3) and/or branching (e.g., Methyl Myristic Acid). Table 3 lists the parent fatty acid ingredients by increasing carbon chain length, for the straight chain alkanes and alkenes.

Physical and Chemical Properties

The available physical and chemical properties of many of the fatty acids in this report are found in Table 4. Generally, as alkyl chain lengths increase in fatty acids, melting points and boiling points increase, while water solubility and vapor pressure decrease.³⁶ Additionally, within a given carbon chain length, melting points increase with increasing saturation and decrease with increasing unsaturation. Unsaturation, especially two or more double bonds, increases the rates of fatty acid auto-oxidation, which yields hydroperoxides and other oxidation products.³⁷

Method of Manufacturing

Most fatty acids occur naturally in animal and plant biochemistry, including synthesis in tissues such as the skin.³⁸ Fatty acids are usually produced by the hydrolysis of common animal and vegetable fats and oils followed by fractionation of the resulting fatty acids.⁸ Fatty acids that are used in foods, drugs, and cosmetics normally exist as mixtures of several fatty acids, and the actual composition is dependent on the source of the acid 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.⁸ 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 tall-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.⁸ 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.⁸ Preparation of Oleic Acid from animal tallow and olive oil 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.⁸ 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.⁸ 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

Available information on composition and impurities, including *Food Chemicals Codex* specifications, of several of the fatty acids and fatty acid salts in this report are found in Table 5.

USE**Cosmetic**

The safety of the cosmetic ingredients included in this assessment is evaluated based on data received from the US FDA and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product category in 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.

While this report comprises, in part, a number of previously-reviewed ingredients, it was prioritized based on the high frequency of use of a previously unreviewed ingredient, Linoleic Acid. According to 2019 VCRP data, Linoleic Acid has 681 total uses in cosmetic products; the majority of the uses are in leave-on skin care products (Table 6).³⁹ Stearic Acid, a previously reviewed ingredient, has the most reported uses in this safety assessment with a total of 6265 uses; the majority of the uses are in leave-on eye makeup preparations and skin care products (Table 7). The reported frequency of use of this ingredient has almost tripled 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.⁹ Palmitic Acid, another previously reviewed ingredient, has the second greatest number of reported uses in this safety assessment with 1532 uses; the majority of these uses are in leave-on eye makeup preparations and skin care products.³⁹ Again use of this ingredient has increased significantly since it was last reviewed; in 2006, Palmitic Acid had a total of 132 reported uses, and the majority of those uses were in rinse-off products.⁹

The results of the concentration of use survey conducted in 2016 by the Council indicate that Linoleic Acid is used at up to 21.8% in rinse-off skin cleansing products and at up to 3.4% in face, neck, body, and hand skin care products.² 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.² 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).⁹ 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);² 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.⁹ 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).^{2,3} Ingredients with no reported uses in the VCRP or by Council are listed in Table 8.

Many of the ingredients included 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. According to concentration of use survey data from 2016, Behenic Acid is reported to be used at up to 14% in lipstick and Sodium Laurate/Linoleate/Oleate/Palmitate is reported to be used at up to 84.7% in bath soaps and detergents.² Additionally, these ingredients are reported to be used in products that may

come into contact with the eyes, such as eyebrow pencils, eyeliners, mascara, and eye shadows. For example, Behenic Acid is reported to be used at up to 22% in eyebrow pencils and Hydroxystearic Acid is used at up to 14% in eyeshadows.

Fatty acids and fatty acid salts 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 is reported to be in face and neck sprays at up to 3%, Oleic Acid is reported to be in spray deodorants at up to 1.5%, and Magnesium Stearate is reported to be in face powders at up to 7.2%.² 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; the maximum concentration in ready for use preparations is restricted to 0.2% as acid. The remaining fatty acids and fatty acid salts 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 not considered to pose an unreasonable risk to the health of workers and public health: 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 fatty acid salts listed in this report do not have a NICNAS determination.

Non-Cosmetic

Most of the fatty acid ingredients described in this safety assessment are components of dietary fats found in both plant and animal food sources.⁴⁹ Linoleic Acid and Linolenic Acid are essential fatty acids for biological processes that must be obtained from the diet as they are not synthesized in the human body. The US Department of Agriculture (USDA) recommends that the daily intake of fatty acids (as unsaturated fats) in adults should be 27 g per day based on a 2000 calorie diet, and that saturated fat intake should be limited to less than 10% of daily caloric intake.

Regulations applicable to the use of fatty acids and fatty acid salts in human food, animal feed, drugs, and pesticides in the US are summarized in Table 9. Non-cosmetic uses of the ingredients listed in this report are found in Table 10.

Several potassium fatty acid have been investigated for use as antibacterial agents in oral care products and anti-amoeba agents in contact lens disinfectants.^{50,51}

TOXICOKINETICS

Dermal Penetration

Sodium Stearate

*Sodium Stearate is absorbed through both rat and human skin.*⁴

Penetration Enhancement

Oleic Acid

The penetration enhancing ability of Oleic Acid (up to 10% in propylene glycol) has been studied for use in the topical delivery of celecoxib, lumiracoxib, and **zaltoprofen**.⁵²⁻⁵⁴ The results of these studies indicated that Oleic Acid increases penetration enhancement of these drugs.

Sodium Caprate

Sodium Caprate (100 mM; 0.2 ml/100 g bodyweight) is reported to be an oral absorption promoter that has potential for use in oral drug products containing poorly permeable molecules.⁵⁵

Myristic Acid

*Myristic Acid enhanced the dermal penetration of several drugs (e.g., bupropion and nitrendipine).*¹⁰

Absorption, Distribution, Metabolism, Excretion

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.³⁶ No significant differences in metabolic clearance are expected between even and odd numbered carbon chain compounds, saturated and unsaturated compounds, or branched chain compounds, although different reaction sequences accommodate different structures.

Arachidic Acid and Palmitic Acid

The blood and tissue distribution of 1-[¹⁴C]-Arachidic Acid and 9,10-[³H]-Palmitic Acid were studied in rats.⁵⁶ The test materials were simultaneously injected into fasted or fed male rats. Arachidic Acid was found to follow the same principal pathways as Palmitic Acid, although the radiolabeled Arachidic Acid disappeared more slowly from the blood than radiolabeled Palmitic Acid. Two minutes after the injection, slightly less radiolabeled Arachidic Acid than radiolabeled Palmitic Acid was recovered from the whole animal. In the liver, more of the esterified Arachidic Acid radioactivity was present in triglycerides and less in phospholipids than that of the Palmitic Acid radioactivity.

Calcium Stearate

*Limited absorption studies indicated that Calcium Stearate is slightly absorbed by isolated dog intestine.*⁴

Lauric Acid, Oleic Acid, Palmitic Acid, Stearic Acid

*Fatty acids are absorbed, digested, and transported in animals and humans.*⁸ *Radioactivity from labeled fatty acids administered orally, intravenously, intraperitoneally, and intraduodenally has been found in various tissues and in blood and lymph. β -Oxidation of the fatty acids involves serial oxidation and reduction reactions yielding acetyl-CoA.*

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 metabolites (hydroxypalmitic acid, hydroxymyristic acid, and hydroxylauric acid).*⁵ *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.*⁶

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Acute dermal and oral studies of several fatty acids and fatty acid salts are summarized in Table 11. In dermal studies of Capric Acid, Lithium Stearate, Stearic Acid, and Undecylenic Acid, the LD₅₀ values were greater than 2000 mg/kg/bw.^{23,28,30,32} The LD₅₀ values in oral studies of Ammonium Oleate (up to 64 ml/kg), Behenic Acid (up to 5000 mg/kg bw), Calcium Stearate (2000 mg/kg bw), Capric Acid (up to 5000 mg/kg bw), Caprylic Acid (up to 5000 mg/kg bw), Isomerized Linoleic Acid (2000 mg/kg bw), Lauric Acid (up to 10,000 mg/kg bw), Lithium

Stearate (up to 5000 mg/kg bw), Palmitic Acid (5000 mg/kg bw), Stearic Acid (up to 6000 mg/kg bw), and Undecylenic Acid (up to 2000 mg/kg bw) were above the doses tested.^{20,22,23,25-30,32,35,57}

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.⁸

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.⁸ 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 (5.0 g/kg), Ammonium (5.0 g/kg), Lithium (tested up to 15.0 g/kg, but no effects at up to 3.0 g/kg), Magnesium (up to 10.0 g/kg), and Sodium (up to 5 g/kg) Stearates are practically nontoxic.⁴ 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 LD₅₀ of Isostearic Acid is estimated to be greater than 32 ml/kg.⁶

Short-Term and Subchronic Toxicity Studies

Repeated dose short-term and subchronic dermal and oral studies of several fatty acid and fatty acid salt ingredients are summarized in Table 12. The no-observable-adverse effect level (NOAEL) in a dermal study of Lithium Stearate in rats was ≥ 1000 mg/kg bw/day for systemic effects, but the NOAEL for local effects was 100 mg/kg bw/day.²⁸ The NOAELs for Behenic Acid (up to 1000 mg/kg bw/day), Calcium Stearate (up to 2000 mg/kg bw/day), and Capric Acid (up to 1000 mg/kg bw/day) were greater than or equal to the highest doses tested in oral studies.^{22,23,35} In oral gavage studies with Sodium Undecylenate, the NOAEL was ≤ 50 mg/kg bw/day with adverse effects including dose-dependent clinical signs of toxicity and adverse effects in the forestomachs of high dose groups.³² Hepatocellular hypertrophy was observed in rats fed up to 15% Isomerized Safflower Acid in a proprietary blend for 90 days. An 8-week dietary study of up to 2.5% Undecylenic Acid reported "inhibition of growth" in rats.⁵⁷

Lauric Acid, Oleic Acid, Palmitic Acid, Stearic Acid

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.⁸ 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.

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%.⁸ 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.

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.⁴ Calcium Stearate (10 or 50 mg in 0.5 ml of saline and 0.01 ml of egg yolk) 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.⁵ 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

Isomerized Safflower Acid

In a 36-week dietary study of Isomerized Safflower Acid, groups of 20 male Fischer 344 rats were given either a control diet or the same diet supplemented with 1.5% Isomerized Safflower Acid.⁵⁸ Feed consumption and body weights measurements and clinical observations of toxicity were made weekly. At termination, 15 major organs from 10 animals in each treatment group were excised, weighed, and evaluated histopathologically. No clinical signs of toxicity were observed from treatment. No treatment-related effects in feed consumption, body weight gains, or in the histopathological investigations were observed. There was no significant difference in hematological measurements in cardiac blood from the treated rats when compared to the control animals.

In another dietary study, Isomerized Safflower Acid tested given to 11 male Fischer 344 rats at 1% in semi-purified feed for 18 months.⁵⁹ A control group of 10 male rats received regular diet. The rats were observed closely for clinical signs of toxicity. Body weights and feed intake were measured weekly and twice a week, respectively. Three rats from each group were randomly selected to measure body fat after 12 weeks. Clinical chemistry and hematological analyses were performed at 72 weeks, and necropsy and histopathology performed at study end.

Four 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. The study authors concluded that the test material did not cause adverse effects in rats.⁵⁹

Oleic Acid

*Feeding of 15% dietary Oleic Acid to rats in a chronic study resulted in normal growth and general health.*⁸

Calcium Stearate

*Calcium Stearate (10 or 50 mg in 0.5 ml of saline and 0.01ml of egg yolk) administered intratracheally to rats for 6 and 8 months caused varying degrees of lung pathology.*⁴

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES

Dermal and oral DART studies of several fatty acid and fatty acid salt ingredients are summarized in Table 13. Lithium Stearate caused no treatment-related adverse reproductive or developmental effects at doses up to 1000 mg/kg bw/day in dermal studies where male rats were treated for 43 days and female rats were treated for 33 days until gestation day 19.²⁸ 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; males were treated 42 days and females were treated ~39 days until lactation day 3),²² Calcium Stearate (up to 1000 mg/kg/day; males were treated 28 days and females were treated ~39 days until lactation day 3),³⁵ Capric Acid (up to 2000 mg/kg/day; females were treated up to ~33 days until lactation day 4),²³ Caprylic Acid (up to 1000 mg/kg/day; females were treated for up to 9 days during gestation starting on gestation day 12),^{25,60} or Undecylenic Acid (up to 1000 mg/kg/day; males were treated up to 28 days and females were treated up to 40 days until lactation day 4).³²

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.*⁸ *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 in whole semen samples by serial dilutions of Oleic Acid, Palmitic Acid, and Stearic Acid were observed in studies of these ingredients.*⁹

Magnesium Stearate

*When fed to female rabbits at 8 days post-coitus, a pharmaceutical vehicle containing 5.5% by weight Magnesium Stearate was not teratogenic.*⁴

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 on gestation days 6 through 15.⁵ 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 fatty acid salt ingredients are summarized in Table 14. 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),²⁰ Behenic Acid (up to 5000 µg/plate),²² Calcium Stearate (up to 312.5 µg/plate),³⁵ Capric Acid (up to 10,000 µg/plate),^{23,61} Caproic Acid (up to 10,000 µg/plate),²⁴ Caprylic Acid (up to 3333 µg/plate),^{25,61} Isomerized Linoleic Acid (up to 2500 µg/plate),²⁶ **Isomerized Safflower Acid (up to 5000 µg/plate),⁶² Lauric Acid (up to 2500 µg/plate),^{27,61} Linoleic Acid (dose not reported),⁶³ Lithium Stearate (up to 5000 µg/plate),²⁸ Magnesium Stearate (up to 5000 µg/plate),⁶⁴ Myristic Acid (dose not reported),⁶¹ and Undecylenic Acid (up to 750 µg/plate).³² In vivo, no genotoxicity was detected in a mouse micronucleus assay after oral exposure up to **2000 mg/kg Magnesium Stearate in 0.5% sodium carboxymethyl cellulose** or 4000 mg/kg Undecylenic Acid in 10% gum arabic.^{32,64}**

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 (concentration tested not reported) was not mutagenic in microbial tests with Salmonella typhimurium or Saccharomyces cerevisiae.*⁴

Hydroxystearic Acid

Hydroxystearic Acid was not mutagenic in S. typhimurium strains TA1535, TA100, TA1537, TA1538, and TA98.⁵ 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.⁶⁵ Water consumption was recorded twice weekly and the rats were weighed 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 curve 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.⁶⁵

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 strains of mice. Intestinal and gastric tumors were found in mice receiving dietary Oleic Acid at daily doses 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 (duration not reported).

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.⁵ 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 tricaprilyn for 80 weeks). The high-dose group received a total dose of 80 mg delivered in a total of 8 ml of tricaprilyn. 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 (99%) and its UVA-induced peroxides were associated with increased comedo formation on the treated ears of two species of rabbits.⁸

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 (30 μ M) interfered with oxidative phosphorylation in rat liver mitochondria.⁵ Oxidative phosphorylation was uncoupled and mitochondria were damaged.

DERMAL IRRITATION AND SENSITIZATION STUDIES

Dermal irritation and sensitization studies of several fatty acid and fatty acid salt ingredients are summarized in Table 15. Several in vitro assays and animal irritation studies indicate that Caproic Acid and Caprylic Acid are corrosive at concentrations of 70% and 99%, respectively, and Capric Acid (concentration not reported) Isostearic Acid (tested at 100%), Lauric Acid (concentration not reported), Trilinoleic Acid (concentration not reported), and Undecylenic Acid (concentration not reported) may be irritating.^{20,24,25,27,29,31,66-70} Aluminum Tristearate, Lauric Acid, Lithium Stearate, however, were predicted to be not irritating and/or corrosive in human epidermis models.^{21,28,70} 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%.²⁷ No dermal irritation was observed in subjects exposed to Palmitic Acid at 50%.²⁹

In chemico direct peptide reactivity assays (DPRAs) predicted that Linoleic Acid (100 mM) and Linolenic Acid (100 mM) were skin sensitizers, while Oleic Acid (100 mM) and Undecylenic Acid (100 mM) were not.⁷¹ In local lymph node assays (LLNAs) and modified LLNAs, Lithium Stearate (up to 10%) was not sensitizing; however, the results of tests with Ammonium Oleate (up to 50%), Hydroxystearic Acid (up to 50%); Linoleic Acid (25%), Linolenic Acid (25%), Oleic Acid (10%), and Undecylenic Acid (25%) indicate that these ingredients may induce sensitization.^{20,28,33,71} In guinea pig studies, reactions observed to Ammonium Oleate (up to 50%) and Hydroxystearic Acid (up to 10%) may have been due to irritation.^{20,33} 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%).^{23,27,31,32}

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

In single insult occlusive patch tests for primary irritation, Stearic Acid at concentrations 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.⁸ Slight increases in irritation were observed in rabbits in short-term repeated patch tests (daily for 3-14 days) of Oleic Acid (5%) and Myristic Acid (concentration not reported). Approximately 5% (w/v; 18 mmol%) alcohol solution of the fatty acids topically applied to the skin 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 guinea pig maximization studies with 2 cosmetic product formulations containing 5.08% Oleic Acid and 1.0% Stearic Acid, slight reactions were observed to challenge patches.⁸ 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.⁸ 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 semi-occlusive), 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 non-irritating in a single insult occlusive patch test and slightly irritating in a repeat open patch test on rabbits.^{8,10} In clinical primary and cumulative irritation studies, Myristic Acid at up to 50% was nonirritating.

Aluminum Distearate, Ammonium Stearate, Magnesium Stearate, and Sodium Stearate

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.⁴ 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.⁵ 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 up to 35% Isostearic Acid.⁶ 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 PHOTSENSITIZATION

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.⁷² These findings were supported by the results of an ultraviolet/visible light (UV/VIS) spectral analysis.

Animal

Stearic Acid

Skin lotion formulations containing 2.8% Stearic Acid were not photosensitizing to the skin of Hartley guinea pigs.⁸

Human

Linoleic Acid

In a study to evaluate skin response to UV following exposure to lipid ingredients in moisturizers, human volunteers received a 20 µl aliquot of 20 mg/ml Linoleic Acid dissolved in octyldodecanol on tape-stripped buttock skin.⁷³ The test sites were occluded. Two days after application of the test material, the areas were irradiated with UV (Waldmann UV800 phototherapy device and a Philips TL-20W/23 fluorescent sun lamp with emission spectrum between 285 and 350 nm; mid- to long-wavelength UV (UVB and UVA, respectively)) and skin samples were obtained 24 hours later. The histologic features and expression of markers of collagen metabolism and inflammatory mediators were evaluated. When compared to the vehicle, Linoleic Acid increased the induction of apoptotic cells and the expression of MMP- and IL-6 mRNA. The authors concluded that topical Linoleic Acid followed by UV exposure has the potential to aggravate damaged skin.

Oleic Acid, Palmitic Acid, Stearic Acid

Cosmetic product formulations containing 1 - 13% Oleic Acid, Palmitic Acid, or Stearic Acid produced no photosensitization in human subjects.⁸ 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.⁶

OCULAR IRRITATION STUDIES

Ocular irritation studies for several fatty acid and fatty acid salt ingredients are summarized in Table 16. 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.^{24,28} 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.^{23-25,27,28,32,74} Oleic Acid (at up to 0.1%) and Palmitic Acid (concentration not reported) were not ocular irritants.^{29,75}

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.^{8,10} Irritation was primarily in the form of very slight conjunctival erythema. A single instillation of Lauric Acid also produced corneal 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 in product formulations at a concentration of 1.5% was minimally irritating to the eyes of rabbits.

Aluminum Distearate, Ammonium Stearate, and Magnesium Stearate

Eye irritation studies with rabbits showed that 10% Aluminum Distearate in corn oil and undiluted Ammonium Stearate and Sodium Stearate were minimal to mild irritants; 100% Magnesium Stearate was non-irritating.⁴

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.⁶

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.⁷⁶ 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.⁷⁷ 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 presented 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.⁷⁸ 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 fatty acid salts 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. While some of these ingredients have not been previously reviewed by the Panel, such as Linoleic Acid, several previously assessed ingredients have been included herein as they fit within this grouping of fatty acids and salts and can be appropriately re-reviewed herewith. Each of the ingredients in this report comprises a carboxylic acid functional group and an aliphatic (fatty) chain.

Most of the fatty acid 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 2019 VCRP data, Linoleic Acid has 681 total uses in cosmetic products; the majority of these uses is in leave-on skin care products. Stearic Acid, a previously reviewed ingredient, has the most reported uses in this safety assessment with a total of 6265; the majority of these 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, another previously reviewed ingredient, had the second greatest number of reported uses in this safety assessment with 1532; the majority of the uses were 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 were 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 Linoleic Acid is used at up to 21.8% in rinse-off skin cleansing products and at up to 3.4% in face, neck, body, and hand skin care products. 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 is 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); Palmitic Acid is 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 LD₅₀ values were greater than 2000 mg/kg/bw. The LD₅₀ values in oral studies of numerous fatty acid and fatty acid salt ingredients were above the doses tested.

The NOAEL in a dermal study of Lithium Stearate in rats was ≥ 1000 mg/kg bw/day for systemic effects, but the NOAEL for local effects was 100 mg/kg bw/day. The NOAELs for Behenic Acid, Calcium Stearate, and Capric Acid were greater than or equal to the highest doses tested in oral studies. In oral gavage studies with Sodium Undecylenate, the NOAEL was ≤ 50 mg/kg bw/day with adverse effects including dose-dependent clinical signs of toxicity and adverse effects in the forestomachs of high dose groups. An 8-week dietary study of up to 2.5% Undecylenic Acid reported "inhibition of growth" in rats. Isomerized Safflower Acid tested at 1% and 1.5% in feed for 18 and 9 months, respectively, did not cause adverse effects in rats, but hepatocellular hypertrophy was observed in rats fed up to 15% in a proprietary blend in a 90-day study.

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 (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).

In vitro bacterial cell and mammalian cell assays were negative for genotoxicity in Ammonium Oleate, Behenic Acid, Calcium Stearate, Capric Acid, Caproic Acid, Caprylic Acid, Isomerized Linoleic Acid, Isomerized Safflower Acid, Lauric Acid, Linoleic Acid, Lithium Stearate, Magnesium Stearate, Myristic Acid, and Undecylenic Acid. No genotoxicity was detected in a micronucleus assay in mice with Undecylenic Acid.

Several in vitro assays and animal irritation studies indicate that Caproic Acid and Caprylic Acid are corrosive at concentrations of 70% and 99%, respectively, and Capric Acid (concentration not reported), Isostearic Acid (100%), Lauric Acid (concentration not reported), Trilinoleic Acid (concentration not reported), and Undecylenic Acid (concentration not reported) may be irritating. Aluminum Tristearate, Lauric Acid, 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 chemico DPRAs predicted that Linoleic Acid (100 mM) and Linolenic Acid (100 mM) were skin sensitizers, while Oleic Acid (100 mM) and Undecylenic Acid (100 mM) were not. 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%).

Lauric Acid and Sodium Laurate were not predicted to cause phototoxicity or photoallergy in in vitro assays. In human studies, topical application of Linoleic Acid followed by UV exposure was determined to have the potential to aggravate damaged skin.

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.

DISCUSSION

Each of the ingredients in this report comprises a carboxylic acid functional group and an aliphatic (fatty) chain. Most of the fatty acids (such as Linoleic Acid) and fatty acid salts have not been previously reviewed by the Panel. However, several previously assessed ingredients are included in this report as they fit within this grouping of fatty acids and salts, and pertinent data from the previous reports were considered by the Panel.

The Panel acknowledged that some of the fatty acids and fatty acid salts may be formed from plant-derived or animal-derived constituents. The Panel thus expressed concern regarding pesticide residues and heavy metal that may be present in botanical ingredients. They stressed that the cosmetics industry should continue to use the necessary procedures to sufficiently limit amounts of such impurities in an ingredient before blending them into cosmetic formulations. Additionally, the Panel considered the risks inherent in using animal-derived ingredients, namely the transmission of infectious agents. While tallow may be used in the manufacture of some ingredients in this safety assessment and is clearly animal-derived, the Panel notes that tallow is highly processed, and tallow derivatives even more so. The Panel agrees with determinations by the US FDA that tallow derivatives are not risk materials for transmission of infectious agents.

The Panel also recognized that these ingredients, particularly Myristic Acid, Oleic Acid, and Sodium Caprate, 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 otherwise a concern.

The Panel was concerned that the potential exists for dermal irritation with the use of products formulated using fatty acids and fatty acid salts. The Panel specified that products containing fatty acids and fatty acid salts must be formulated to be non-irritating. The Panel was also concerned about the potential for polyunsaturated fatty acids to undergo oxidation during the formulation, or storage of cosmetic products, that may produce compounds

that are dermal sensitizers. The Panel advises industry to limit oxidative products in formulations containing fatty acids and fatty acid salts, and to utilize accepted methodologies, such as a QRA, to ensure formulations are non-sensitizing.

Fatty acids and fatty acid salts were reported to be used in spray and powder products that could possibly be inhaled. For example, Stearic Acid is reported to be in face and neck sprays at up to 3%, Oleic Acid is reported to be in spray deodorants at up to 1.5%, and Magnesium Stearate is reported to be in face powders at up to 7.2%. There were no inhalation toxicity data available. Although the Panel noted that droplets/particles from spray and loose-powder cosmetic products would not be respirable to any appreciable amount, the potential for inhalation toxicity is not limited to respirable droplets/particles deposited in the lungs. In principle, inhaled droplets/particles deposited in the nasopharyngeal and thoracic regions of the respiratory tract may cause toxic effects depending on their chemical and other properties. However, coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at <https://www.cir-safety.org/cir-findings>.

CONCLUSION

The CIR Expert Panel concluded that the following ingredients are safe in the present practices of use and concentration described in the safety assessment when formulated to be non-irritating and non-sensitizing, which may be based on a QRA.

Aluminum Dilinoleate*	10-Hydroxydecanoic Acid
Aluminum Distearate	Hydroxylauric Acid*
Aluminum Isostearate*	Hydroxystearic Acid
Aluminum Isostearates/Palmitates*	10-Hydroxystearic Acid*
Aluminum Isostearates/Stearates*	Isomerized Linoleic Acid
Aluminum Isostearates/Laurates/Palmitates*	Isomerized Safflower Acid*
Aluminum Isostearates/Laurates/Stearates*	Isostearic Acid
Aluminum Lanolate*	Lauric Acid
Aluminum Stearate	Linoleic Acid
Aluminum Stearates	Linolenic Acid
Aluminum Tristearate	Lithium Stearate
Ammonium Isostearate*	Magnesium Lanolate*
Ammonium Oleate*	Magnesium Laurate
Ammonium Stearate	Magnesium Palmitate*
Arachidic Acid	Magnesium Stearate
Beeswax Acid*	Magnesium Tallowate*
Behenic Acid	Myristic Acid
C14-28 Alkyl Acid	Methyl Myristic Acid*
C10-40 Isoalkyl Acid	Oleic Acid
C14-28 Isoalkyl Acid	Palmitic Acid
C32-36 Isoalkyl Acid*	Potassium Behenate
Calcium Behenate	Potassium Borageate*
Calcium Laurate*	Potassium Camelliate*
Calcium Stearate	Potassium Caprate*
Calcium Undecylenate*	Potassium Caprylate*
Capric Acid	Potassium Caprylate/Caprate*
Caproic Acid	Potassium Castorate
Caprylic Acid	Potassium Hydrogenated Tallowate
Dilinoic Acid	Potassium Hydroxystearate*
Dierucic Acid*	Potassium Isostearate
Eicosatrienoic Acid*	Potassium Lanolate*
Erucic Acid*	Potassium Laurate
Hydroxycapric Acid	Potassium Linoleate*
Hydroxycaprylic Acid	Potassium Linseedate*

Potassium Oleate	Sodium Hydroxystearate*
Potassium Oliviate/Sunflowerseedate*	Sodium Isostearate
Potassium Palmitate	Sodium Lanolate*
Potassium Stearate	Sodium Lardate*
Potassium Sunflowerseedate*	Sodium Laurate
Potassium Tallate	Sodium Laurate/Linoleate/Oleate/Palmitate
Potassium Tallowate	Sodium Linoleate*
Potassium Undecylenate*	Sodium Oleate
Sodium Arganate*	Sodium Palmitate
Sodium Beeswax*	Sodium Stearate
Sodium Behenate	Sodium Tallowate
Sodium Camellia Japonica Seedate*	Sodium Tamanuseedate*
Sodium Caprate*	Sodium Undecylenate
Sodium Caprylate*	Stearic Acid
Sodium Castorate	Trilinoleic Acid
Sodium Dilinoleate*	Undecanoic Acid
Sodium Hydrogenated Tallowate*	Undecylenic Acid

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

Ingredients denoted in red were previously reviewed by the Panel.

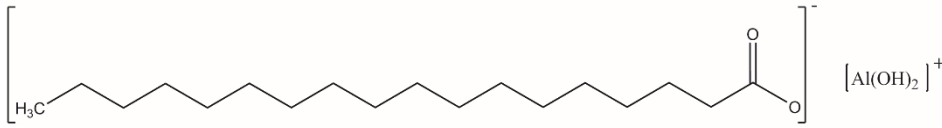
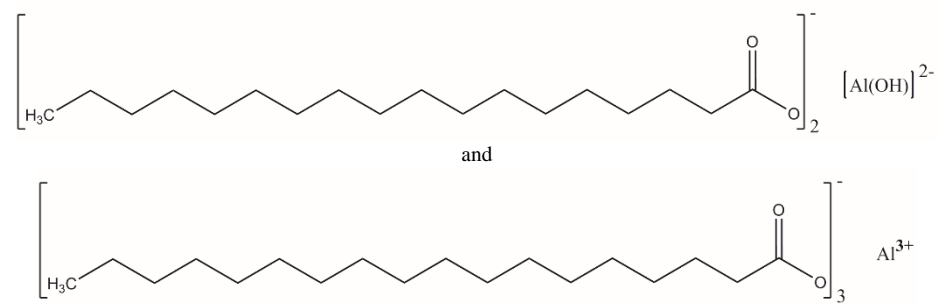
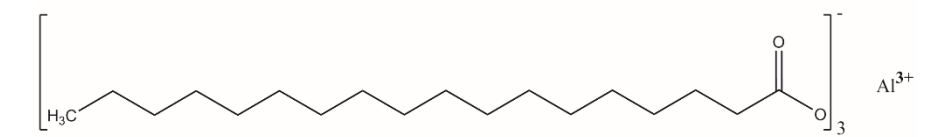
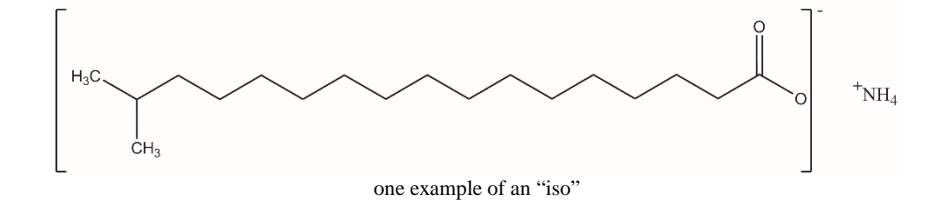
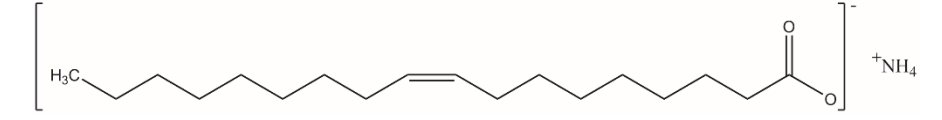
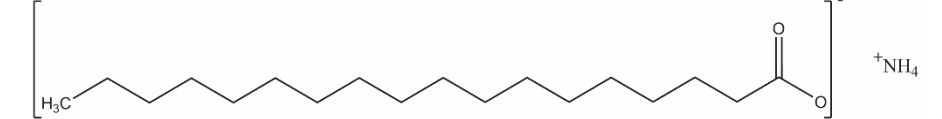
Ingredient & CAS No.	Definition & Structure	Function(s)
Aluminum Stearate 7047-84-9	Aluminum Stearate is the aluminum salt of stearic acid that conforms to the formula:	anticaking agent; colorants; emulsion stabilizer; viscosity increasing agent – nonaqueous
		
Aluminum Stearates	Aluminum Stearates is a mixture of equal parts of aluminum distearate and aluminum tristearate.	anticaking agent; emulsion stabilizer; viscosity increasing agent – nonaqueous
		
Aluminum Tristearate 637-12-7	Aluminum Tristearate is the aluminum salt 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.	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
		

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. ^{1,CIR Staff}

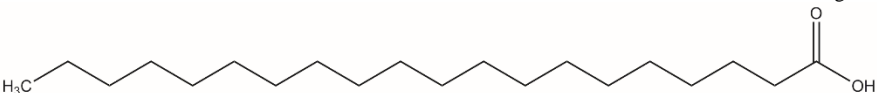
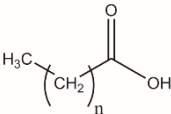
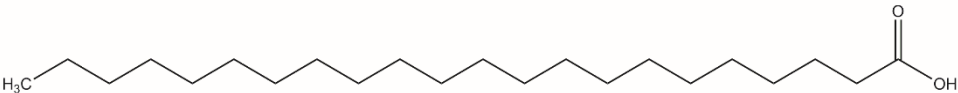
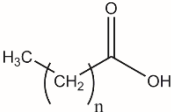
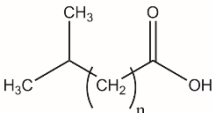
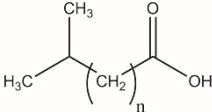
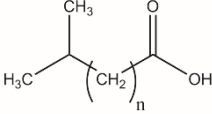
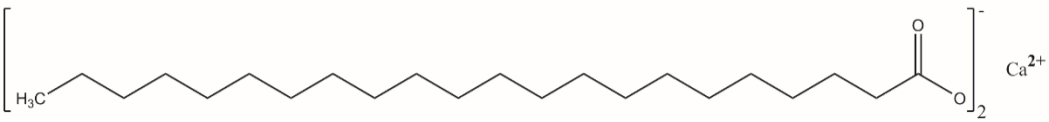
Ingredient & CAS No.	Definition & Structure	Function(s)
Arachidic Acid 506-30-9	Arachidic Acid is the fatty acid that conforms to the formula:	opacifying agent; surfactant – cleansing agent
		
Beeswax Acid	Beeswax Acid is the acid portion obtained by the saponification of beeswax. It is composed of C24 to C36 straight-chain acids.	surfactant- cleansing agent; surfactant – emulsifying agent
 <p data-bbox="704 556 914 581">[wherein “n” is 22 to 34]</p>		
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.	hair conditioning agent
 <p data-bbox="704 972 914 997">[wherein “n” is 12 to 26]</p>		
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.	hair conditioning agent; skin-conditioning agent - emollient
 <p data-bbox="602 1239 1016 1264">[one example of an “iso”; wherein “n” is 7 to 37]</p>		
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.	hair conditioning agent
 <p data-bbox="597 1463 1021 1488">[one example of an “iso”; wherein “n” is 11 to 25]</p>		
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.	skin-conditioning agent – misc.
 <p data-bbox="597 1688 1021 1713">[one example of an “iso”; wherein “n” is 29 to 33]</p>		
Calcium Behenate 3578-72-1	Calcium Behenate is the calcium salt of Behenic Acid.	anticaking agent; viscosity increasing agent - nonaqueous
		

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. ^{1, CIR Staff}

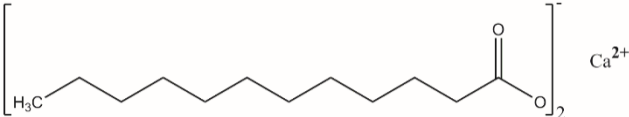
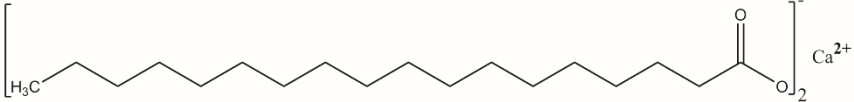
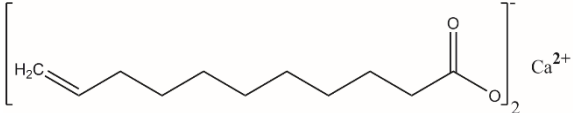
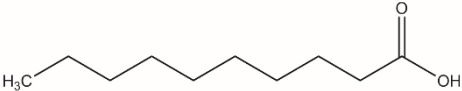
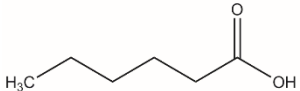
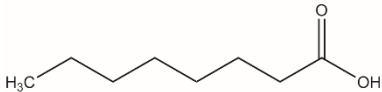
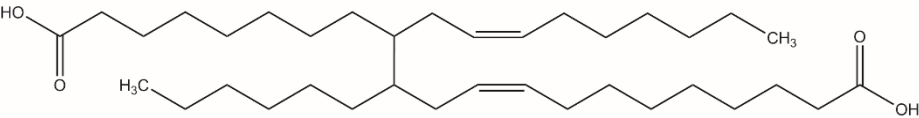
Ingredient & CAS No.	Definition & Structure	Function(s)
Calcium Laurate 4696-56-4	Calcium Laurate is the calcium salt of Lauric Acid.	anticaking agent; emulsion stabilizer; viscosity increasing agent - nonaqueous
		
Calcium Stearate 1592-23-0	Calcium Stearate is the calcium salt of stearic acid. It conforms 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
		
Dilinoic Acid 26085-09-6 6144-28-1	Dilinoic 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

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. ^{1,CIR Staff}

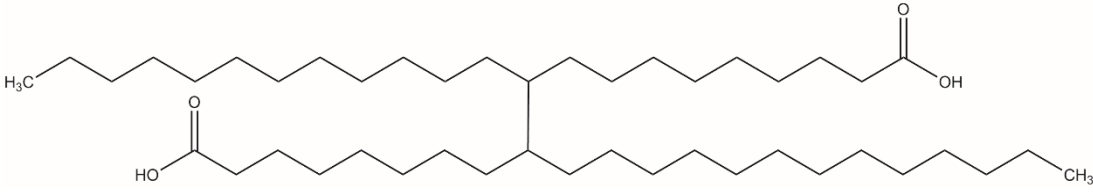
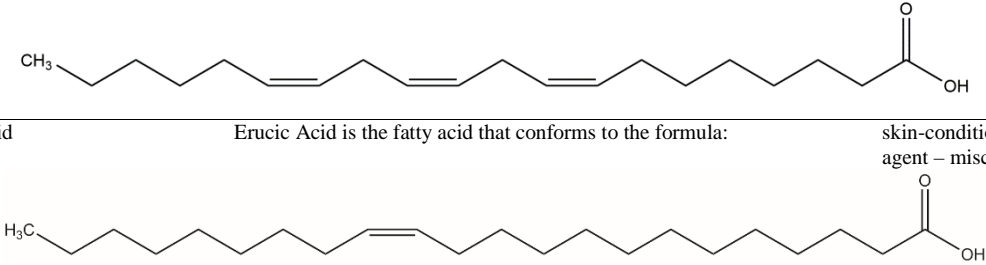
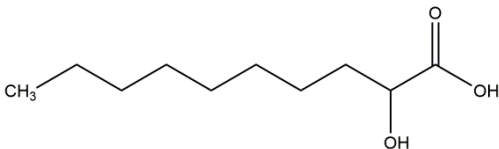
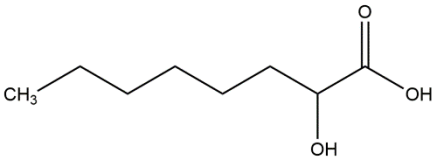
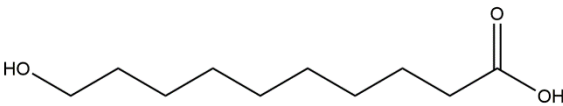
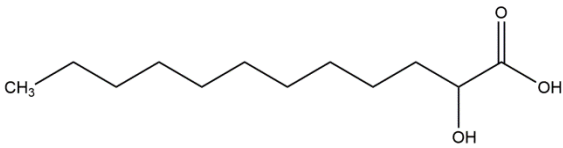
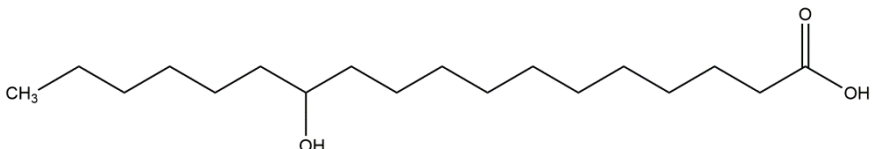
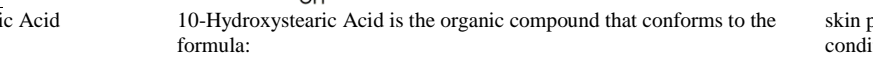
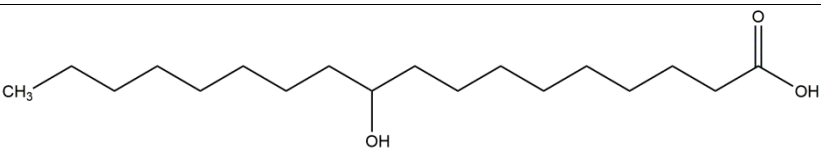
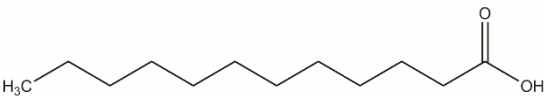
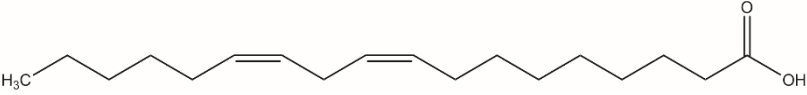
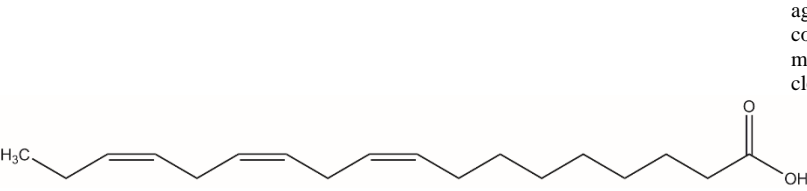
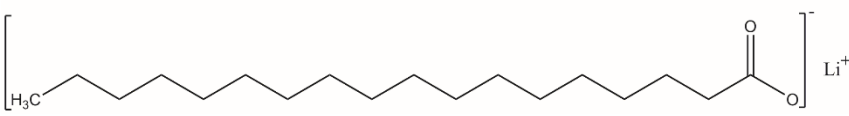
Ingredient & CAS No.	Definition & Structure	Function(s)
Eicosatrienoic Acid 1783-84-2	Eicosatrienoic Acid is the organic compound that conforms to the formula: 	skin-conditioning agent – misc.
Erucic Acid 112-86-7	Erucic Acid is the fatty acid that conforms to the formula: 	skin-conditioning agent – misc.
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.

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. ^{1, CIR Staff}

Ingredient & CAS No.	Definition & Structure	Function(s)
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. [A technical name for Isomerized Safflower Acid is conjugated linoleic acid; Carthamus Tinctorius (Safflower) Seed Oil comprises mainly C18:2 and C18:1 fatty acids. ¹³].	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.	binder; surfactant – cleansing agent
<div data-bbox="402 163 1218 310">  </div> <div data-bbox="708 726 912 751">one example of an “iso”</div>		
Lauric Acid 143-07-7	Lauric Acid is the fatty acid that conforms generally to the formula:	fragrance ingredient; surfactant – cleansing agent
<div data-bbox="539 846 1081 940">  </div>		
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
<div data-bbox="409 1119 1211 1213">  </div>		
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
<div data-bbox="409 1287 1211 1476">  </div>		
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
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Magnesium Lanolate	Magnesium Lanolate is the magnesium salt of Lanolin Acid.	anticaking agent; skin-conditioning agent – misc.; viscosity increasing agent - nonaqueous

Ingredient & CAS No.	Definition & Structure	Function(s)
	$\left[\begin{array}{c} \text{R}-\text{CH}_2-(\text{CH}_2)_n-\text{CH}-\text{C}(=\text{O})\text{O}^- \\ \\ \text{R} \end{array} \right]_2 \text{Mg}^{2+}$ <p>[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]¹⁵</p>	
Magnesium Laurate 4040-48-6	Magnesium Laurate is the magnesium salt of Lauric Acid. It conforms generally to the formula:	binder
	$\left[\text{H}_3\text{C}-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{C}(=\text{O})\text{O}^- \right]_2 \text{Mg}^{2+}$	
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
	$\left[\text{H}_3\text{C}-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{C}(=\text{O})\text{O}^- \right]_2 \text{Mg}^{2+}$	
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
	$\left[\text{H}_3\text{C}-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{C}(=\text{O})\text{O}^- \right]_2 \text{Mg}^{2+}$	
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]. ¹⁸	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
	$\text{H}_3\text{C}-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{C}(=\text{O})\text{OH}$	
Methyl Myristic Acid 73679-18-2	Methyl Myristic Acid is the organic compound that conforms to the formula:	antioxidant
	$\text{H}_3\text{C}-\text{CH}_2-\text{CH}(\text{CH}_3)-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{CH}_2-\text{C}(=\text{O})\text{OH}$	
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

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. ^{1, CIR Staff}

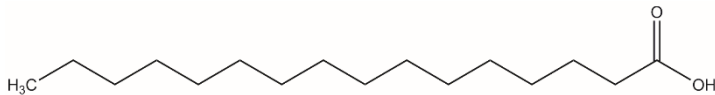
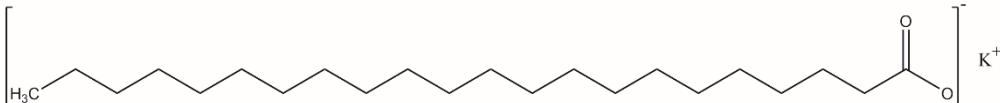
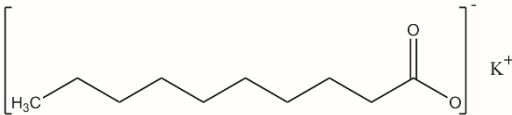
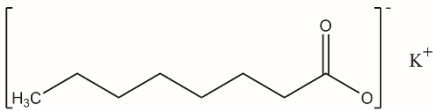
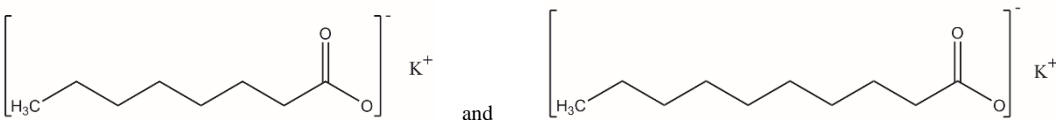
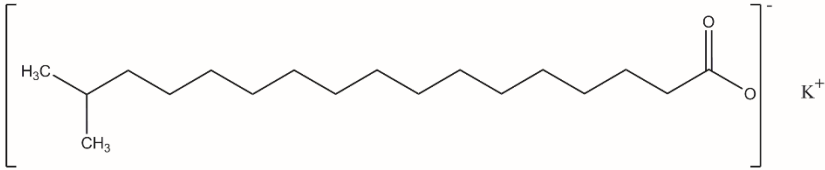
Ingredient & CAS No.	Definition & Structure	Function(s)
Palmitic Acid 57-10-3	Palmitic Acid is the fatty acid that conforms generally to the formula: 	fragrance ingredient; opacifying agent; surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Behenate 7211-53-2	Potassium Behenate is the potassium salt of Behenic Acid. 	surfactant – cleansing agent
Potassium Borageate	Potassium Borageate is the potassium salt of the fatty acids derived from <i>Borago Officinalis</i> Seed Oil. [<i>Borago Officinalis</i> Seed Oil is mainly comprised of C16, C18, C18:1, and C18:2 fatty acids]. ¹³	surfactant – cleansing agent
Potassium Camelliate	Potassium Camelliate is the potassium salt of the fatty acids derived from <i>Camellia</i> Seed Oil. [<i>Camellia</i> Seed Oil obtained from various species of <i>Camellia</i> is mainly comprised of C18:1 and C18:2 fatty acids]. ¹³	surfactant – cleansing agent
Potassium Caprate 13040-18-1	Potassium Caprate is the potassium salt of Capric Acid. 	surfactant – cleansing agent
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 <i>Ricinus Communis</i> (Castor) Seed Oil. [<i>Ricinus Communis</i> (Castor) Seed Oil is mainly comprised of C18:1(OH), C18:1, and C18:2 fatty acids]. ¹⁷	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]. ¹⁸	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.	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)
	$\left[\text{R}-\text{CH}_2-\left(\text{CH}_2\right)_n-\text{CH}\left(\text{R}\right)-\text{C}(=\text{O})\text{O} \right]^{-} \text{K}^{+}$ <p>[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]¹⁵</p>	
Potassium Laurate 10124-65-9	<p>Potassium Laurate is the potassium salt of lauric acid. It conforms generally to the formula:</p> $\left[\text{H}_3\text{C}-\left(\text{CH}_2\right)_{10}-\text{C}(=\text{O})\text{O} \right]^{-} \text{K}^{+}$	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Linoleate 3414-89-9	<p>Potassium Linoleate is the potassium salt of Linoleic Acid.</p> $\left[\text{H}_3\text{C}-\left(\text{CH}_2\right)_4-\text{CH}=\text{CH}-\left(\text{CH}_2\right)_4-\text{C}(=\text{O})\text{O} \right]^{-} \text{K}^{+}$	surfactant – cleansing agent; surfactant – emulsifying agent; viscosity increasing agent - nonaqueous
Potassium Linseedate	<p>Potassium Linseedate is the potassium salt of the fatty acids derived from <i>Linum Usitatissimum</i> (Linseed) Seed Oil.[<i>Linum Usitatissimum</i> (Linseed) Seed Oil is mainly comprised of C16, C18, C18:1, C18:2, and C18:3 fatty acids].¹³</p>	surfactant – cleansing agent
Potassium Oleate 143-18-0 23282-35-1	<p>Potassium Oleate is the potassium salt of oleic acid. It conforms generally to the formula:</p> $\left[\text{H}_3\text{C}-\left(\text{CH}_2\right)_7-\text{CH}=\text{CH}-\left(\text{CH}_2\right)_7-\text{C}(=\text{O})\text{O} \right]^{-} \text{K}^{+}$	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Oliviate/ Sunflowerseedate	<p>Potassium Oliviate/Sunflowerseedate is the product obtained by the hydrolysis of a mixture of <i>Olea Europaea</i> (Olive) Fruit Oil and <i>Helianthus Annuus</i> (Sunflower) Seed Oil with potassium hydroxide. [<i>Olea Europaea</i> (Olive) Fruit Oil and <i>Helianthus Annuus</i> (Sunflower) Seed Oil are mainly comprised of C16, C18, C18:1, and C18:2 fatty acids].¹³</p>	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Palmitate 2624-31-9	<p>Potassium Palmitate is the potassium salt of palmitic acid. It conforms generally to the formula:</p> $\left[\text{H}_3\text{C}-\left(\text{CH}_2\right)_{14}-\text{C}(=\text{O})\text{O} \right]^{-} \text{K}^{+}$	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Stearate 593-29-3	<p>Potassium Stearate is the potassium salt of stearic acid. It conforms generally to the formula:</p> $\left[\text{H}_3\text{C}-\left(\text{CH}_2\right)_{16}-\text{C}(=\text{O})\text{O} \right]^{-} \text{K}^{+}$	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium Sunflowerseedate	<p>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].¹³</p>	surfactant – cleansing agent
Potassium Tallate 61790-44-1	<p>Potassium Tallate is the potassium salt of Tall Oil Acid. [Tall Oil Acid is mainly comprised of C18:1 and C18:2 fatty acids].¹¹</p>	surfactant – cleansing agent; surfactant – emulsifying agent

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. ^{1, CIR Staff}

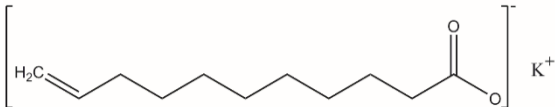
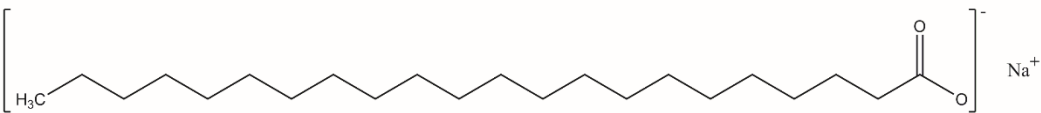
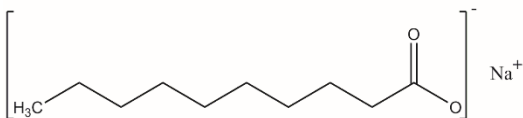
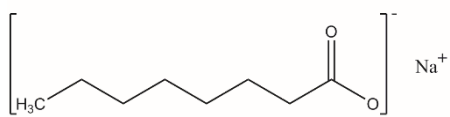
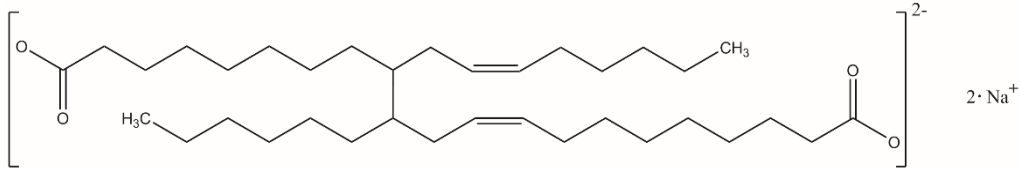
Ingredient & CAS No.	Definition & Structure	Function(s)
Potassium Tallowate 61790-32-7	Potassium Tallowate is the potassium salt of Tallow Acid. [Tallow is mainly comprised of C14, C16, C18, C18:1, and C18:2 fatty acid glycerides]. ¹⁸	surfactant – cleansing agent; surfactant – emulsifying agent
Potassium 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]. ¹³	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]. ¹⁴	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]. ¹³	surfactant – cleansing agent
Sodium Caprate 1002-62-6	Sodium Caprate is the sodium salt of Capric Acid. 	surfactant – cleansing agent
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]. ¹⁷	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]. ¹⁸	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.	surfactant – cleansing agent; surfactant – emulsifying agent

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. ^{1, CIR Staff}

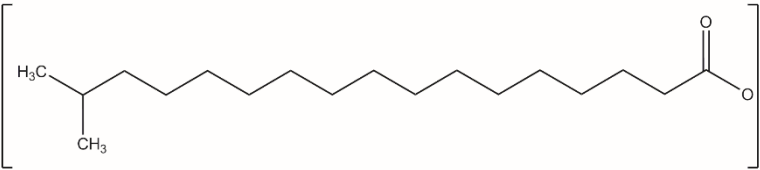
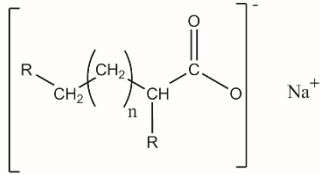
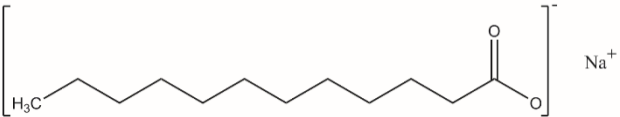
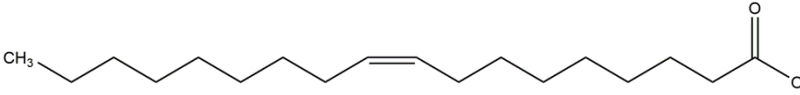
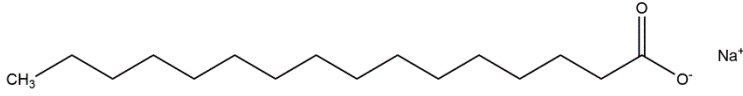
Ingredient & CAS No.	Definition & Structure	Function(s)
	 <p>one example of an “iso”</p>	Na ⁺
Sodium Lanolate	Sodium Lanolate is the sodium salt of Lanolin Acid.	surfactant – cleansing agent
	 <p>[wherein “n” is variable for the fatty acid composition of lanolin acid, and is in the range of 4 to 38; R is, in each case, hydrogen or hydroxyl, wherein at least one R is hydrogen; some fatty acids from lanolin acid may be branched]¹⁵</p>	
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]. ¹⁶	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
		Na ⁺
Sodium Laurate/Linoleate/ Oleate/Palmitate	Sodium Laurate/Linoleate/Oleate/Palmitate is the sodium salt of a mixture of lauric, linoleic, oleic and palmitic 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
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
		Na ⁺
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
		Na ⁺
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

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 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]. ¹⁸	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. [Calophyllum Inophyllum Seed Oil is mainly comprised of C18:1, C18:2, C18, and C16 fatty acids]. ⁷⁹	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 trimerization 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
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 fatty acids and fatty acid salts, and related ingredients

Ingredients	Conclusion	Assessment Publication Status	Reference
<i>Previously Reviewed Ingredients</i>			
Aluminum Distearate	Safe as used	published in 1982; re-review published in 2003 – not reopened	3,4
Aluminum Stearate	Safe as used	published in 1982; re-review published in 2003 – not reopened	3,4
Aluminum Tristearate	Safe as used	published in 1982; re-review published in 2003 – not reopened	3,4
Ammonium Stearate	Safe as used	published in 1982; re-review published in 2003 – not reopened	3,4
Calcium Stearate	Safe as used	published in 1982; re-review published in 2003 – not reopened	3,4
Hydroxystearic Acid	Safe as used	published in 1999	5
Isostearic Acid	Safe as used	published in 1983; re-review published in 2005 – not reopened	6,7
Lauric Acid	Safe as used	published in 1987; re-review published in 2006 – not reopened	8,9
Lithium Stearate	Safe as used	published in 1982; re-review published in 2003 – not reopened	3,4
Magnesium Stearate	Safe as used	published in 1982; re-review published in 2003 – not reopened	3,4
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	8,10
Oleic Acid	Safe as used	published in 1987; re-review published in 2006 – not reopened	8,9
Palmitic Acid	Safe as used	published in 1987; re-review published in 2006 – not reopened	8,9
Potassium Stearate	Safe as used	published in 1982; re-review published in 2003 – not reopened	3,4
Potassium Tallate	Safe as used	published in 2009	11
Sodium Stearate	Safe as used	published in 1982; re-review published in 2003 – not reopened	3,4
Stearic Acid	Safe as used	published in 1987; re-review published in 2006 – not reopened	8,9
<i>Related Ingredients</i>			
Argania Spinosa Kernel Oil	Safe as used	published in 2017	13
Beeswax	Safe as used	published in 1984; re-review published in 2005 – not reopened	7,14
Borago Officinalis Seed Oil	Safe as used	published in 2017	13
Camellia Japonica Seed Oil	Safe as used	published in 2017	13
Helianthus Annuus (Sunflower) Seed Oil and Sunflower Seed Acid	Safe as used	published in 2017	13
Lanolin and Lanolin Acid	Safe as used	published in 1980; re-review published in 2005 – not reopened	7,15
Lard	Safe as used provided established limits on heavy metals and pesticides are not exceeded	published in 2001; re-reviewed in 2017 – not reopened	16
Linum Usitatissimum (Linseed) Seed Oil	Safe as used	published in 2017	13
Olea Europaea (Olive) Fruit Oil	Safe as used	published in 2017	13
Ricinus Communis (Castor) Seed Oil	Safe as used	published in 2007	17
Tallow	Safe as used	published in 1990; re-review published in 2008 – not reopened	18,19

Table 3. Fatty acid ingredients by carbon chain length and degree of unsaturation

<i>Ingredient Name</i>	<i>Carbon Chain Length : Degree of Unsaturation</i>
Caproic Acid	6:0
Caprylic Acid	8:0
Capric Acid	10:0
Undecanoic Acid	11:0
Undecylenic Acid	11:1
Lauric Acid	12:0
Myristic Acid	14:0
Palmitic Acid	16:0
Stearic Acid	18:0
Oleic Acid	18:1
Linoleic Acid	18:2
Linolenic Acid	18:3
Arachidic Acid	20:0
Eicosatrienoic Acid	20:3
Behenic Acid	22:0
Erucic Acid	22:1

Table 4. Physical and chemical properties

Property	Value	Reference
<i>Aluminum Distearate</i>		
Physical Form	White powder	80
Molecular Weight Da	610	4
Specific gravity	1.009	4
Melting Point ° C	120-145	4
<i>Aluminum Stearate</i>		
Physical Form	White powder	80
Molecular Weight Da	344	4
Specific gravity	1.010	4
Melting Point ° C	173	4
<i>Aluminum Tristearate</i>		
Physical Form	White powder	21
Molecular Weight Da	877.35	4
Density g/cm ³ @ 20° C	1.066	21
Vapor Pressure mmHg @ 25° C	0	21
Melting Point ° C at 760 mmHg	179.5	21
Boiling Point °C at 760 mm Hg	250	21
Water Solubility mg/L @ 25°C	0 (insoluble)	21
Log P	22.69	21
<i>Ammonium Oleate</i>		
Physical Form	Yellow-brown paste	81
Molecular Weight Da	299.50	81
Melting Point ° C	21.1-22.2	81
<i>Ammonium Stearate</i>		
Physical Form	Yellow-white powder or tan, wax-like solid	80,81
Molecular Weight Da	301.5	4
Specific gravity @ 22° C	0.89	4
Melting Point ° C	73-87	4
<i>Arachidic Acid</i>		
Physical Form	Shining, white, crystalline leaflets	80
Molecular Weight Da	312.5	81
Density g/cm ³ @ 20° C and 760 mmHg	0.884 (estimated)	82
Melting Point ° C	75.5	81
Boiling Point °C at 760 mm Hg	328	81
<i>Behenic Acid</i>		
Physical Form	White to off-white waxy solid	22
Molecular Weight Da	340.59	81
Density g/cm ³ @ 100° C	0.82	81
Vapor Pressure mmHg @ 100° C	< 4.875 x 10 ⁻⁵	34
Melting Point ° C	79.95	81
Boiling Point °C at 60 mm Hg	306	81
Water Solubility mg/L @ 25°C	0.016	22
Log P @ 25°C	> 5.11	22
<i>Calcium Stearate</i>		
Physical Form	Granular, fatty powder	81
Molecular Weight Da	607.00	4
Melting Point ° C	129-180	4

Table 4. Physical and chemical properties

Property	Value	Reference
Calcium Undecylenate		
Physical Form	Fine, white powder	80
Melting Point °C	155	80
Capric Acid		
Physical Form	White to pale yellow crystals or needles	23
Molecular Weight Da	172.27	81
Density g/cm ³ @ 20° C	0.89	23
Vapor Pressure mmHg @ 25° C	3.66 x 10 ⁻⁴	23
Melting Point °C at 760 mmg Hg	31.65	23
Boiling Point °C at 760 mm Hg	268.7	23
Water Solubility mg/L @ 25°C	61.8	23
Log P @ 20°C	4.1	23
Caproic Acid		
Physical Form	Colorless to light brown liquid	24
Molecular Weight Da	116.16	81
Density g/cm ³ @ 20° C	0.93	24
Vapor Pressure mmHg @ 25° C	0.044	24
Melting Point °C at 760 mmg Hg	- 4	24
Boiling Point °C at 760 mm Hg	203	24
Water Solubility g/L @ 25°C	10.3	24
Log P _{ow}	1.92	24
Caprylic Acid		
Physical Form	Colorless liquid	25
Molecular Weight Da	144.21	81
Density g/cm ³ @ 20° C	0.91	25
Vapor Pressure mmHg @ 25° C	0.00368	25
Melting Point °C at 760 mmg Hg	16.5	25
Boiling Point °C at 760 mm Hg	237	25
Water Solubility mg/L @ 20°C	680	25
Log P @ 20°C	3.05	25
Dilinoleic Acid		
Physical Form	Light yellow, viscous liquid	80
Density g/cm ³ @ 100° C	0.921	80
Eicosatrienoic Acid		
Molecular Weight Da	306.48	82
Density g/cm ³ @ 20° C and 760 mmHg	0.917 (estimated)	82
Vapor Pressure mmHg @ 25° C	6.77 x 10 ⁻⁹ (estimated)	82
Boiling Point °C at 760 mm Hg	438.0 (estimated)	82
Log P @ 25°C	7.541 (estimated)	82
Eruric Acid		
Molecular Weight Da	338.58	81
Density g/cm ³ @ 55° C	0.860	81
Vapor Pressure mmHg @ 25° C	4.91 x 10 ⁻⁷ (estimated)	82
Melting Point °C	33.8	81
	381.5 (decomp.)	81
Log P @ 25°C	9.459	82
Boiling Point °C at 760 mm Hg	Hydroxycapric Acid	
Molecular Weight Da	188.26	82
Density g/cm ³ @ 20° C and 760 mm Hg	1.011 (estimated)	82
Vapor Pressure mmHg @ 25° C	2.90 x 10 ⁻⁵ (estimated)	82
Boiling Point °C at 760 mm Hg	318.9 (estimated)	82
Log P @ 25°C	2.716 (estimated)	82
Hydroxycaprylic Acid		
Molecular Weight Da	160.21	82
Density g/cm ³ @ 20° C and 760 mmHg	1.046 (estimated)	82
Vapor Pressure mmHg @ 25° C	2.49 x 10 ⁻⁴ (estimated)	82
Melting Point °C	70	83
Boiling Point °C at 760 mm Hg	289.0 (estimated)	82
Log P @ 25°C	1.697	82
10-Hydroxydecanoic Acid		
Molecular Weight Da	188.26	82
Density g/cm ³ @ 20° C and 760 mmHg	1.013 (estimated)	82
Vapor Pressure mmHg @ 25° C	1.18 x 10 ⁻⁵ (estimated)	82
Boiling Point °C at 760 mm Hg	330.8 (estimated)	82
Log P @ 25°C	1.847 (estimated)	82

Table 4. Physical and chemical properties

Property	Value	Reference
<i>Hydroxylauric Acid</i>		
Molecular Weight Da	216.32	82
Density g/cm ³ @ 20° C and 760 mmHg	0.987 (estimated)	82
Vapor Pressure mmHg @ 25° C	3.05 x 10 ⁻⁶ (estimated)	82
Boiling Point °C at 760 mm Hg	348.5 (estimated)	82
Log P @ 25°C	3.735 (estimated)	82
<i>Hydroxystearic Acid</i>		
Molecular Weight Da	300.48	5
Density g/cm ³ @ 20 °C and 760 mmHg	0.944 (estimated)	82
Vapor Pressure mmHg @ 25 °C	1.92 x 10 ⁻⁹ (estimated)	82
Melting Point °C	75-82	5
Boiling Point °C at 760 mm Hg	436.3 (estimated)	82
Log P @ 20 °C	5.767 (estimated)	82
<i>10-Hydroxystearic Acid</i>		
Molecular Weight Da	300.48	82
Density g/cm ³ @ 20° C and 760 mmHg	0.944 (estimated)	82
Vapor Pressure mmHg @ 25° C	1.92 x 10 ⁻⁹ (estimated)	82
Boiling Point °C at 760 mm Hg	436.3 (estimated)	82
Log P @ 25°C	5.767 (estimated)	82
<i>Isomerized Linoleic Acid</i>		
Physical Form	paste	26
Molecular Weight Da	228.291	84
Density g/cm ³ @ 20° C	0.84-0.89	26
Melting Point ° C	44-48	26
Boiling Point °C at 7.5 mm Hg	225	26
<i>Isostearic Acid</i>		
Physical Form	Clear, oily liquid	6
Molecular Weight Da	284.48	82
Specific gravity @ 25° C	0.89-0.906	6
Vapor Pressure mmHg @ 25° C	1.52 x 10 ⁻⁷ (estimated)	82
Boiling Point °C at 760 mm Hg	400.8 (estimated)	82
Log P @ 25°C	7.674 (estimated)	82
<i>Lauric Acid</i>		
Physical Form	White or slightly yellow, somewhat glossy crystalline solid or powder/colorless solid	8
Molecular Weight Da	200.32	8
Density g/cm ³ @ 50° C	0.8679	8
Vapor Pressure mmHg @ 25° C	6.61 x 10 ⁻⁴ (estimated)	82
Melting Point ° C	44 or 48	8
Boiling Point °C	225	8
Log P @ 25°C	4.773 (estimated)	82
<i>Linoleic Acid</i>		
Physical Form	Colorless oil	81
Molecular Weight Da	280.45	81
Density g/cm ³ @ 15° C	0.905	80
Vapor Pressure mmHg @ 25° C	3.54 x 10 ⁻⁶ (estimated)	82
Melting Point ° C	-12	81
Boiling Point °C @ 14 mmHg	228	80
Log P @ 25°C	7.017 (estimated)	82
<i>Linolenic Acid</i>		
Physical Form	Colorless liquid	81
Molecular Weight Da	278.44	81
Density g/cm ³ @ 20 °C	0.916	80
Vapor Pressure mmHg @ 25° C	4.24 x 10 ⁻⁹ (estimated)	82
Melting Point ° C	-11	80
Boiling Point °C @ 17 mmHg	230	80
Log P @ 25°C	6.522 (estimated)	82
<i>Lithium Stearate</i>		
Physical Form	White solid	28
Molecular Weight Da	290.41	4
Specific gravity	1.025	4
Melting Point ° C	108	4
<i>Magnesium Palmitate</i>		
Physical Form	Crystalline needles or white lumps	80
Melting Point ° C	121.5	80
<i>Magnesium Stearate</i>		
Physical Form	White powder	81
Molecular Weight Da	591.27	4
Specific gravity	1.028	4
Melting Point ° C	86-132	4

Table 4. Physical and chemical properties

Property	Value	Reference
<i>Methyl Myristic Acid</i>		
Molecular Weight Da	242.40	82
Density g/cm ³ @ 20° C and 760 mmHg	0.894 (estimated)	82
Vapor Pressure mmHg @ 25° C	5.19 x 10 ⁻⁶ (estimated)	82
Boiling Point °C at 760 mm Hg	355.5 (estimated)	82
Log P @ 25 °C	6.146 (estimated)	82
<i>Myristic Acid</i>		
Physical Form	Solid	8
Molecular Weight Da	228.36	8
Density g/cm ³ @ 70° C	0.8528	8
Vapor Pressure mmHg @ 25° C	1.39 x 10 ⁻⁴ (estimated)	82
Melting Point ° C	54.4-58.5	8
Boiling Point °C	250.5	8
Log P @ 25°C	5.792 (estimated)	82
<i>Oleic Acid</i>		
Physical Form	Colorless to pale yellow, oily liquid	8
Molecular Weight Da	282.45	8
Density g/cm ³ @ 25° C	0.895	8
Vapor Pressure mmHg @ 25° C	3.70 x 10 ⁻⁶ (estimated)	82
Melting Point ° C	16.3	8
Boiling Point °C at 11 mm Hg	286	8
Log P @ 25°C	7.421 (estimated)	82
<i>Palmitic Acid</i>		
Physical Form	White or faintly yellow, slightly glossy crystalline solid/white or yellow-white powder/white crystalline scales/colorless crystals	8
Molecular Weight Da	256.43	8
Density g/cm ³ @ 62° C	0.8527	8
Melting Point ° C	63-64	8
Boiling Point °C	215	8
Water Solubility mg/L @ 20°C	< 0.05	29
<i>Potassium Laurate</i>		
Physical Form	Light tan paste	80
<i>Potassium Linoleate</i>		
Physical Form	Light tan paste	80
<i>Potassium Oleate</i>		
Physical form	Yellowish or brownish soft mass or gray-tan paste	80,81
<i>Potassium Stearate</i>		
Physical Form	White to pale yellow powder	81
Molecular Weight Da	322.58	4
Density g/cm ³ @ 75° C	1.037	81
<i>Potassium Undecylenate</i>		
Physical Form	Finely divided, white powder	80
<i>Sodium Oleate</i>		
Physical Form	White powder	81
Molecular Weight Da	304.45	81
Melting Point ° C	232-235	80
<i>Sodium Palmitate</i>		
Physical Form	White to yellow powder	80
Melting Point ° C	270	83
<i>Sodium Stearate</i>		
Physical Form	White powder	81
Molecular Weight Da	306.47	4
<i>Sodium Undecylenate</i>		
Physical Form	White powder	80
<i>Stearic Acid</i>		
Physical Form	White or faintly yellow crystals or leaflets/white or yellow-white powder	8
Molecular Weight Da	284.48	8
Density g/cm ³ @ 70° C	0.847	8
Vapor Pressure mmHg @ 25° C	4.28 x 10 ⁻⁸	30
Melting Point ° C	69-71.2	8
Boiling Point °C at 760 mmHg	232	30
Water Solubility mg/L @ 25°C	0.597	30
Log P @ 25°C	8.23	30
<i>Trilinoleic Acid</i>		
Physical Form	Dark brown liquid	31
Molecular Weight Da	801.036	84
Density g/cm ³ @ 19° C	0.967	31
Melting Point ° C	- 3	31
Water Solubility mg/L @ 20°C	< 0.37	31

Table 4. Physical and chemical properties

Property	Value	Reference
Undecanoic Acid		
Molecular Weight Da	186.29	82
Density g/cm ³ @ 80 °C	0.805	80
Vapor Pressure mmHg @ 25° C	1.51 x 10 ⁻³ (estimated)	82
Melting Point ° C	28.5	80
Boiling Point °C at 760 mmHg	284.0	80
Log P @ 25°C	4.263 (estimated)	82
Undecylenic Acid		
Physical Form	Colorless or white solid	32
Molecular Weight Da	184.28	81
Density g/cm ³ @ 24.4° C	1.0024	32
Vapor Pressure mmHg @ 20° C	0.000143	32
Melting Point ° C at 760 mmHg	26.4	32
Boiling Point °C at 760 mmHg	293.75	32
Water Solubility mg/L @ 20°C	38.46	32
Log P _{ow} @ 20°C	4.0	32

Table 5. Composition and impurities of fatty acid and fatty acid salt ingredients

Ingredient	Composition and/or Impurities	References
Beeswax Acid	Unhydrolyzed beeswax produced by the honeybee, <i>Apis mellifera</i> , contains 23% hydrocarbons, 45% wax monoesters, 6% diesters of long chain alcohols with Palmitic Acid, 1% free alcohols, and 12% free acids; Palmitic Acid is the major acid found in the ester fraction	85
Behenic Acid (86% pure)	Major impurities are C ₁₂ -C ₂₀ fatty acids (~11%)	34
Calcium Stearate	Described as a compound of calcium with a mixture of solid organic acids obtained from edible sources and consisting chiefly of variable proportions of Calcium Stearate and Calcium Palmitate; should not contain more than 2 mg/kg lead	86
Caprylic Acid	Should not contain more than 0.2% unsaponifiable matter	86
Lauric Acid	Should not contain more than 0.1 mg/kg lead and not more than 0.3% unsaponifiable matter	86
Linoleic Acid	Should not contain more than 2 mg/kg lead and not more than 2.0% unsaponifiable matter	86
Magnesium Stearate	Described as a compound of magnesium with a mixture of solid organic acids obtained from edible sources and consisting chiefly of variable proportions of Magnesium Stearate and Magnesium Palmitate; should not contain more than 5 mg/kg lead	86
Myristic Acid	Obtained from coconut oil and other fats; should not contain more than 2 mg/kg lead and not more than 1% unsaponifiable matter	86
Oleic Acid	Should not contain more than 0.1 mg/kg lead and not more than 2.0% unsaponifiable matter	86
Palmitic Acid	Described as a mixture of solid organic acids obtained from fats consisting chiefly of Palmitic Acid with varying amounts of Stearic Acid; should not contain more than 0.1 mg/kg lead and not more than 1.5% unsaponifiable matter	86
Stearic Acid	Described as a mixture of solid organic acids obtained from fats consisting chiefly of Stearic Acid and Palmitic Acid; should not contain more than 2 mg/kg lead and not more than 1.5% unsaponifiable matter	86

Table 6. Frequency (2019) and concentration of use (2016) according to duration and type of exposure for fatty acids and fatty acid salts.^{2,39}

	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>
	Aluminum Stearates		Arachidic Acid		Behenic Acid		C14-28 Alkyl Acid	
Totals[†]	3	NR	12	0.000001-0.065	158	0.024-22	29	0.0095-0.075
<i>Duration of Use</i>								
Leave-On	3	NR	9	0.000001-0.065	122	0.024-22	3	NR
Rinse Off	NR	NR	3	0.0002	36	0.9-6	26	0.0095-0.075
Diluted for (Bath) Use	NR	NR	NR	NR	NR	0.044	NR	NR
<i>Exposure Type</i>								
Eye Area	1	NR	6	0.065	44	0.024-22	NR	NR
Incidental Ingestion	NR	NR	NR	NR	3	0.48-14	NR	NR
Incidental Inhalation-Spray	NR	NR	2 ^b	0.000001 ^a	2; 9 ^a ; 10 ^b	0.5; 12 ^a	NR	NR
Incidental Inhalation-Powder	NR	NR	2 ^b	NR	2 ^c ; 10 ^b	0.5-2 ^c	NR	NR
Dermal Contact	2	NR	5	0.0002	131	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	26	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	28	0.029-0.075	1	NR	6	0.0036-4
<i>Duration of Use</i>								
Leave-On	NR	0.18	2	NR	1	NR	1	0.01-4
Rinse Off	NR	0.02	26	0.029-0.075	NR	NR	5	0.0036-0.2
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR
<i>Exposure Type</i>								
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	1	NR
Incidental Inhalation-Powder	NR	NR	NR	NR	NR	NR	NR	0.01 ^c
Dermal Contact	NR	NR	NR	NR	NR	NR	6	0.0036-4
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	0.02-0.18	26	0.029-0.075	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

<i>Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>
d	Hydroxycapric Acid	
0.14-2.5	1	0.7
0.14	1	0.7
2.5	NR	0.7
NR	NR	NR
NR	NR	NR
0.14	NR	NR
NR	NR	NR
NR	NR	0.7 ^c
NR	1	0.7
NR	NR	NR
NR	NR	NR
2.5	NR	NR
NR	NR	NR
0.14	NR	NR
NR	NR	NR
c Acid	Linoleic Acid	
0.1-0.75	681	0.00033-21.8
0.1-0.75	600	0.00085-3.4
NR	81	0.00033-21.8
NR	NR	0.0012
NR	71	0.01-0.76
NR	118	0.0075-1
NR	225 ^a ; 110 ^b	0.0038-0.25; 0.003-0.67 ^a ; 0.2 ^b
0.1-0.75 ^c	8; 110 ^b	0.2; 0.0015-3.4 ^c ; 0.2 ^b
0.1-0.75	493	0.00085-21.8
NR	NR	0.07
NR	61	0.0009-0.67
NR	4	0.00033-0.31
NR	2	2
NR	125	0.001-1.1
NR	NR	0.043

Table 6. Frequency (2019) and concentration of use (2016) according to duration and type of exposure for fatty acids and fatty acid salts.^{2,39}

	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>
	Linolenic Acid		Magnesium Laurate		Potassium Behenate		Potassium Castorate	
Totals[†]	214	0.000007-1	4	NR	5	NR	2	0.52
<i>Duration of Use</i>								
Leave-On	176	0.00005-1	NR	NR	NR	NR	NR	NR
Rinse Off	38	0.000007-0.44	4	NR	5	NR	2	0.52
Diluted for (Bath) Use	NR	0.0002	NR	NR	NR	NR	NR	NR
<i>Exposure Type</i>								
Eye Area	18	0.001-0.084	NR	NR	NR	NR	NR	NR
Incidental Ingestion	8	0.0022-0.01	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	85 ^c ; 34 ^b	0.00005-0.25; 0.001-1 ^a	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	1; 34 ^b	0.003-0.067 ^c	NR	NR	NR	NR	NR	NR
Dermal Contact	163	0.000007-0.45	4	NR	5	NR	2	0.52
Deodorant (underarm)	NR	0.0045-0.07	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	41	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	12	0.000007-0.2	4	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	33	0.001-9	19	0.25-23
<i>Duration of Use</i>								
Leave-On	1	NR	2	NR	6	0.001-2	1	NR
Rinse Off	NR	NR	3	1.6-3	27	1.3-9	18	0.25-23
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR
<i>Exposure Type</i>								
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	2 ^a ; 1 ^b	NR	1 ^a	NR
Incidental Inhalation-Powder	NR	NR	2 ^b	NR	1 ^b	0.0018-2 ^c	NR	NR
Dermal Contact	1	NR	5	1.6-3	33	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	7	2-5.3	10	0.25-3
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR

Table 6. Frequency (2019) and concentration of use (2016) according to duration and type of exposure for fatty acids and fatty acid salts.^{2,39}

	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>
	Potassium Palmitate		Potassium Tallowate		Sodium Behenate		Sodium Castorate	
Totals[†]	25	0.26-21.1	3	0.2-12.9	14	NR	6	NR
<i>Duration of Use</i>								
Leave-On	6	0.26	NR	0.2	14	NR	NR	NR
Rinse Off	19	0.3-21.1	3	12.9	NR	NR	6	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR
<i>Exposure Type</i>								
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	6	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	6	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	104	0.005-14	NR	74.5-84.7	67	0.000002-3.7
<i>Duration of Use</i>								
Leave-On	8	NR	21	0.075-6	NR	74.5	62	0.000002-0.025
Rinse Off	3	3	83	0.005-14	NR	84.7	5	0.000025-3.7
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	0.35-0.38
<i>Exposure Type</i>								
Eye Area	2	NR	NR	NR	NR	NR	8	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	33 ^a ; 19 ^b	NR
Incidental Inhalation-Powder	4 ^b	NR	3 ^b	6 ^c	NR	NR	19 ^b	NR
Dermal Contact	11	3	91	0.005-14	NR	74.5-84.7	67	0.000002-3.7
Deodorant (underarm)	NR	NR	14 ^a	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	13	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	56	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 6. Frequency (2019) and concentration of use (2016) according to duration and type of exposure for fatty acids and fatty acid salts.^{2,39}

	# 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		Sodium Undecylenate		Trilinoleic Acid	
Totals†	119	0.06-55.8	121	5.1-80	1	NR	4	NR
Duration of Use								
Leave-On	30	0.06-4.1	4	NR	1	NR	3	NR
Rinse Off	87	1.3-55.8	117	5.1-80	NR	NR	1	NR
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	4 ^a ; 1 ^b	NR	1 ^b	NR	1 ^b	NR	3 ^a	NR
Incidental Inhalation-Powder	1 ^b	NR	1 ^b	NR	1 ^b	NR	NR	NR
Dermal Contact	119	0.06-55.8	121	5.1-80	NR	NR	NR	NR
Deodorant (underarm)	23 ^a	4.1	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR	4	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	62	5.9-55.8	102	9-80	NR	NR	NR	NR
Baby Products	1	0.06	2	NR	NR	NR	NR	NR

	Undecanoic Acid		Undecylenic Acid	
Totals‡	NR	0.0014-0.14	1	0.2-25
Duration of Use				
Leave-On	NR	0.0014-0.096	1	0.2-25
Rinse Off	NR	0.016-0.14	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR
Exposure Type				
Eye Area	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	0.0014	1 ^a	NR
Incidental Inhalation-Powder	NR	NR	NR	0.2
Dermal Contact	NR	0.0014-0.14	NR	0.2
Deodorant (underarm)	NR	0.0014-0.096	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR
Nail	NR	NR	NR	25
Mucous Membrane	NR	0.016-0.14	NR	NR
Baby Products	NR	NR	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 7. Current and historical frequency and concentration according to duration and type of exposure for previously reviewed fatty acids and fatty acid salts

	Aluminum Distearate				Aluminum Stearate			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2019 ³⁹	2001/2003 ³	2016 ²	2001/2003 ³	2019 ³⁹	2001/2003 ³	2016 ²	2001/2003 ³
Totals[†]	24	50	0.004-5.5	0.1-5	55	3	0.00014-3.4	0.3-8
Duration of Use								
Leave-On	21	46	0.004-5.5	0.1-5	54	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	7	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	15 ^a ; 15 ^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	15 ^b	1 ^b	3.1; 0.0099-1.3 ^c	4; 0.3-0.4 ^b
Dermal Contact	18	43	0.004-5.5	0.1-3	49	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				Ammonium Stearate			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2019 ³⁹	2001/2003 ³	2016 ²	2001/2003 ³	2019 ³⁹	2001/2003 ³	2016 ²	2001/2003 ³
Totals[†]	3	12	NR	NR	4	NR	NR	NR
Duration of Use								
Leave-On	3	11	NR	NR	4	NR	NR	NR
Rinse Off	NR	1	NR	NR	NR	NR	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure Type								
Eye Area	NR	4	NR	NR	4	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	2 ^a ; 1 ^b	5 ^a ; 1 ^b	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	1 ^b	1 ^b	NR	NR	NR	NR	NR	NR
Dermal Contact	3	3	NR	NR	1	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	5	NR	NR	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	NR	NR	NR	NR	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR

	Calcium Stearate				Hydroxystearic Acid			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2019 ³⁹	2001/2003 ³	2016 ²	2001/2003 ³	2019 ³⁹	1996 ⁵	2016 ²	1995 ⁵
Totals[†]	264	107	0.000098-5	0.02-23	125	2	0.00011-14	2.5-10
Duration of Use								
Leave-On	257	103	0.000098-5	0.02-23	123	2	0.005-14	2.5-10
Rinse Off	7	4	0.00089-2.4	0.1-2	2	NR	0.00011-2	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure Type								
Eye Area	211	72	0.01-4	0.2-20	15	NR	0.018-14	NR
Incidental Ingestion	4	3	0.1-2	1-23	63	NR	0.15-10	2.5
Incidental Inhalation-Spray	1; 3 ^b	1	0.000098-0.05; 0.005-0.025 ^a	3	2; 12 ^a ; 3 ^b	2 ^b	NR	NR
Incidental Inhalation-Powder	12; 3 ^b	12	0.1-5; 0.65-5 ^c	0.2-9	3 ^b	2 ^b	0.5; 0.001-2.6 ^c	NR
Dermal Contact	254	99	0.00089-5	0.02-20	53	2	0.005-14	5-10
Deodorant (underarm)	NR	NR	5	0.02 ^a	9 ^a	NR	NR	5-10 ^a
Hair - Non-Coloring	NR	NR	0.000098-0.03	NR	7	NR	0.8-4	NR
Hair-Coloring	5	4	0.09-2.4	1	NR	NR	NR	NR
Nail	1	1	0.03-5	0.09-4	1	NR	0.00011-0.038	NR
Mucous Membrane	5	3	0.1-2	1-23	63	NR	0.15-10	2.5
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR

Table 7. Current and historical frequency and concentration according to duration and type of exposure for previously reviewed fatty acids and fatty acid salts

	Isostearic Acid				Lauric Acid			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2019 ³⁹	2002/2005 ⁷	2016 ²	2002/2005 ⁷	2019 ³⁹	2006 ⁹	2016 ²	2006 ⁹
Totals[†]	271	119	0.004-20	0.003-26	563	121	0.0011-18	0.000004-11
Duration of Use								
Leave-On	233	113	0.012-16	0.003-16	37	11	0.0011-13	0.00002-3
Rinse Off	38	6	0.004-20	1-26	524	90	0.005-18	0.000004-8
Diluted for (Bath) Use	NR	NR	NR	NR	2	20	0.11	2-11
Exposure Type								
Eye Area	79	13	0.013-9.5	0.01-3	2	NR	0.0048-0.8	NR
Incidental Ingestion	10	6	0.025-0.29	10	3	1	0.0011	0.00003
Incidental Inhalation-Spray	4; 40 ^a ; 45 ^b	32 ^a ; 9 ^b	0.032; 0.02-3 ^a	0.5-3 ^a ; 0.3-2 ^b	4 ^a ; 12 ^b	7 ^a	0.2; 0.2 ^a	0.00002-0.001; 0.00003-1 ^a ; 0.00006 ^b
Incidental Inhalation-Powder	1 ^c ; 45 ^b	3; 9 ^b	0.012-0.3; 0.045-3.8 ^c	0.3-3; 0.3-2 ^b	12 ^b	NR	0.019-10 ^c	0.00006 ^b
Dermal Contact	182	96	0.01-9.6	0.003	361	70	0.0018-18	0.00002-11
Deodorant (underarm)	2 ^a	2 ^a	NR	NR	5 ^a	3 ^a	0.3	0.3 ^a
Hair - Non-Coloring	10	4	0.004-2	1	32	7	0.005-4.2	0.000004-4
Hair-Coloring	2	NR	0.75-20	18	165	43	0.01-1.5	NR
Nail	NR	2	3-16	2	1	NR	NR	NR
Mucous Membrane	28	6	0.025-0.29	2	133	40	0.0011-5	0.00003-11
Baby Products	1	NR	NR	NR	1	NR	0.0018-0.31	NR
	Lithium Stearate				Magnesium Stearate			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2019 ³⁹	2001/2003 ³	2016 ²	2001/2003 ³	2019 ³⁹	2001/2003 ³	2016 ²	2001/2003 ³
Totals[†]	85	17	0.1-4	2-3	890	96	0.012-10	0.02-8
Duration of Use								
Leave-On	85	17	0.1-4	2-3	835	92	0.012-10	0.02-8
Rinse Off	NR	NR	NR	NR	55	4	0.33-5	1
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure Type								
Eye Area	78	1	NR	2	457	49	0.5-10	1-5
Incidental Ingestion	4	1	NR	NR	5	NR	0.012	1
Incidental Inhalation-Spray	NR	NR	NR	3 ^a	3; 20 ^a ; 8 ^b	6 ^a ; 8 ^b	0.75; 0.15-0.6 ^a	0.02-3 ^a ; 0.1 ^b
Incidental Inhalation-Powder	NR	2	3	NR	127; 8 ^b	21; 8 ^b	1-7.2; 0.12-1 ^c	1-8; 0.1 ^b ; 2 ^c
Dermal Contact	81	16	0.1-4	2	826	95	0.03-10	0.02-8
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	3	10	NR	0.15-1	NR
Hair-Coloring	NR	NR	NR	NR	43	NR	0.33-5	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	4	1	NR	NR	11	5	0.012	1
Baby Products	NR	NR	NR	NR	NR	NR	NR	2
	Myristic Acid				Oleic Acid			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2019 ³⁹	2010 ¹⁰	2016 ²	2010 ¹⁰	2019 ³⁹	2006 ⁹	2016 ²	2006 ⁹
Totals[†]	404	207	0.0005-28.7	0.00002-20	1077	1131	0.0002-20.9	0.000004-20
Duration of Use								
Leave-On	174	61	0.0005-20.2	0.00002-20	307	106	0.0002-17	0.00005-20
Rinse Off	228	146	0.0031-28.7	0.00002-19	769	1014	0.0005-20.9	0.000004-19
Diluted for (Bath) Use	2	NR	1	2	1	11	0.0005-3	NR
Exposure Type								
Eye Area	29	3	0.011-1	0.5	70	49	0.01-5	0.1-5
Incidental Ingestion	2	5	NR	NR	89	5	0.0015-0.2	16
Incidental Inhalation-Spray	1; 36 ^a ; 71 ^b	11 ^a ; 14 ^b	2.5; 0.002-7 ^a	0.00002; 0.00002-2 ^a ; 0.8-20 ^b	78 ^a ; 28 ^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
Incidental Inhalation-Powder	6; 71 ^b	1; 14 ^b	0.1-0.66; 0.03-20.2 ^c	0.5; 0.8-20 ^b	1 ^c ; 28 ^b	1 ^c ; 2 ^b	0.24; 0.04-3.3 ^c	0.0001; 1 ^c ; 0.2-2 ^b
Dermal Contact	373	171	0.0005-28.7	0.005-20	178	102	0.0002-20.9	0.000004-15
Deodorant (underarm)	1 ^a	1 ^a	0.015	2 ^a	3 ^a	NR	0.64; 1.5 ^d	0.0007-0.6 ^a
Hair - Non-Coloring	15	29	0.002-7	0.00002-5	18	10	0.001-3.8	0.000007-20
Hair-Coloring	NR	NR	0.2-0.33	0.00002	731	974	1.4-17	19
Nail	2	NR	0.04	NR	7	2	0.0003-0.3	0.0008
Mucous Membrane	37	16	0.0031-1.35	0.1-19	93	40	0.0005-10	0.000004-16
Baby Products	NR	NR	0.05	NR	1	6	0.1-0.36	1-2

Table 7. Current and historical frequency and concentration according to duration and type of exposure for previously reviewed fatty acids and fatty acid salts

	Palmitic Acid				Potassium Stearate			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2019 ³⁹	2006 ⁹	2016 ²	2006 ⁹	2019 ³⁹	2001/2003 ³	2016 ²	2001/2003 ³
Totals[†]	1532	132	0.000000001-21	0.000006-20	157	NR	0.0083-45	0.05-12
Duration of Use								
Leave-On	1184	47	0.000000001-21	0.00003-16	72	NR	0.0083-7.5	0.05
Rinse Off	342	74	0.00082-21	0.00002-20	85	NR	0.0097-45	12
Diluted for (Bath) Use	6	11	NR	0.000006-2	NR	NR	NR	NR
Exposure Type								
Eye Area	233	3	0.011-5.3	0.003-4	5	NR	0.033-0.8	NR
Incidental Ingestion	101	1	0.00033-1	0.2-16	NR	NR	NR	NR
Incidental Inhalation-Spray	4; 422 ^a ; 248 ^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	29 ^a ; 22 ^b	NR	0.2-7.5 ^a	NR
Incidental Inhalation-Powder	16; 3 ^c ; 248 ^b	1; 5 ^b	0.12; 0.03-8.6 ^c	0.01-1; 0.5-7 ^b	3; 1 ^c ; 22 ^b	NR	0.0083; 0.18-1.8 ^c	NR
Dermal Contact	1167	99	0.000005-21	0.000006-20	124	NR	0.0083-45	0.05-12
Deodorant (underarm)	38 ^a	1 ^a	0.06-3.5; 0.0021 ^d	0.09-3 ^a	NR	NR	NR	NR
Hair - Non-Coloring	45	30	0.000000001-8	0.00002-3	15	NR	0.0097-7.5	NR
Hair-Coloring	61	1	0.005-2	NR	16	NR	3.1	NR
Nail	5	NR	0.0042-7.5	0.02-0.03	1	NR	NR	NR
Mucous Membrane	175	22	0.00033-9.7	0.000006-16	20	NR	0.59-3	NR
Baby Products	3	NR	0.98-1.7	NR	1	NR	NR	NR

	Potassium Tallowate				Sodium Stearate			
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	2019 ³⁹	2009 ¹¹	2016 ²	2009 ¹¹	2019 ³⁹	2001/2003 ³	2016 ²	2001/2003 ³
Totals[†]	NR	9	NR	NR	566	184	0.000075-84	0.0001-25
Duration of Use								
Leave-On	NR	NR	NR	NR	355	132	0.000075-84	0.0001-25
Rinse Off	NR	9	NR	NR	211	51	0.000075-84	0.3-18
Diluted for (Bath) Use	NR	NR	NR	NR	NR	1	NR	NR
Exposure Type								
Eye Area	NR	NR	NR	NR	14	4	0.09-8.4	0.7-8
Incidental Ingestion	NR	NR	NR	NR	1	NR	7	0.1
Incidental Inhalation-Spray	NR	NR	NR	NR	33 ^a ; 32 ^b	6; 5 ^a ; 11 ^b	0.13 ^a	5-8; 7 ^a
Incidental Inhalation-Powder	NR	NR	NR	NR	1; 32 ^b	2 ^c ; 11 ^b	0.1-6 ^c	NR
Dermal Contact	NR	9	NR	NR	526	170	0.000075-84	0.0001-25
Deodorant (underarm)	NR	NR	NR	NR	230 ^a	101 ^a	3.5-10	5-25 ^a
Hair - Non-Coloring	NR	NR	NR	NR	4	NR	0.00075-0.1	NR
Hair-Coloring	NR	NR	NR	NR	34	14	0.4-5.5	10-12
Nail	NR	NR	NR	NR	NR	NR	7.5	NR
Mucous Membrane	NR	9	NR	NR	121	32	0.001-34.3	0.1-18
Baby Products	NR	NR	NR	NR	NR	2	0.033	NR

	Stearic Acid			
	# of Uses		Max Conc of Use (%)	
	2019 ³⁹	2006 ⁹	2016 ²	2006 ⁹
Totals[†]	6265	2133	0.00006-37.4	0.000002-43
Duration of Use				
Leave-On	5098	1580	0.0001-21	0.00005-22
Rinse Off	1160	539	0.00006-37.4	0.000002-43
Diluted for (Bath) Use	7	14	0.02-1	0.000007-7
Exposure Type				
Eye Area	773	224	0.002-21	0.009-22
Incidental Ingestion	102	40	0.0013-12	0.02-9
Incidental Inhalation-Spray	4; 2335 ^a ; 1251 ^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	26; 29 ^c ; 1251 ^b	6; 11 ^c ; 409 ^b	0.36-2.1; 0.05-20 ^c ; 2.3-5.5 ^b	0.1-1; 2-3 ^c ; 0.1-16 ^b
Dermal Contact	5300	1819	0.0001-37.4	0.000007-43
Deodorant (underarm)	60 ^a	21 ^a	0.05-4.1	0.2-9 ^a
Hair - Non-Coloring	142	29	0.00006-20	0.000002-7
Hair-Coloring	255	137	0.08-5	NR
Nail	9	13	0.021-9.1	0.04-5
Mucous Membrane	336	101	0.0013-37.4	0.000007-19
Baby Products	31	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 8. Ingredients not reported in use.

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

Table 9. FDA and EPA regulations applicable to fatty acids and fatty acid salts**Direct and Indirect Food Substances Affirmed as GRAS**

(21CFR §184.1025, §184.1065, §184.1090, §184.1229, §184.1440, §186.1770, and §186.1771)

Calcium Stearate	Magnesium Stearate	Sodium Palmitate
Caprylic Acid	Sodium Oleate	Stearic Acid
Linoleic Acid		

GRAS as Substance Migrating from Packaging

(21CFR §182.70 and §182.90)

Oleic Acid

Approved Direct Food Additives

(21CFR §172.515, §172.615, §172.860, §172.862, and §172.863)

Aluminum Distearate	Caprylic Acid	Palmitic Acid	Sodium Laurate
Aluminum Stearate	Lauric Acid	Potassium Caprate	Sodium Oleate
Aluminum Stearates	Magnesium Palmitate	Potassium Laurate	Sodium Palmitate
Aluminum Tristearate	Magnesium Stearate	Potassium Oleate	Sodium Stearate
Calcium Laurate	Myristic Acid	Potassium Palmitate	Stearic Acid
Calcium Stearate	Oleic Acid (including that derived	Potassium Stearate	Undecylenic Acid
Capric Acid	from tall oil fatty acids)	Sodium Caprate	
Caproic Acid			

Approved Secondary Direct Food Additives

(21CFR §173.315 and §173.340)

Aluminum Distearate	Capric Acid	Magnesium Stearate	Palmitic Acid
Aluminum Stearate	Caproic Acid	Myristic Acid	Potassium Stearate
Aluminum Tristearate	Caprylic Acid	Oleic Acid	Stearic Acid
Calcium Stearate	Lauric Acid		

Approved Indirect Food Additives

(21CFR §175.105, §175.210, §175.300, §175.320, §176.170, §176.200, §176.210, §177.1010, §177.1200, §177.2260, §177.2600, §177.2800, §178.1010, §178.2010, §178.3297, §178.3570, §178.3910)

Aluminum Dilinoleate	Calcium Stearate	Myristic Acid	Sodium Caprate
Aluminum Distearate	Capric Acid	Oleic Acid	Sodium Caprylate
Aluminum Isostearates/Palmitates	Caproic Acid	Palmitic Acid	Sodium Castorate
Aluminum Isostearates/Stearates	Caprylic Acid	Potassium Behenate	Sodium Dilinoleate
Aluminum Isostearates/Laurates/Palmitates	Dilinoleic Acid	Potassium Caprate	Sodium Isostearate
Aluminum Isostearates/Laurates/Stearates	Erucic Acid	Potassium Castorate	Sodium Lanolate
Aluminum Lanolate	Hydroxystearic Acid	Potassium Isostearate	Sodium Lardate
Aluminum Stearate	Isostearic Acid	Potassium Lanolate	Sodium Laurate
Aluminum Stearates	Lauric Acid	Potassium Laurate	Sodium Linoleate
Aluminum Tristearate	Linoleic Acid	Potassium Linoleate	Sodium Oleate
Aluminum Isostearate	Linolenic Acid	Potassium Oleate	Sodium Palmitate
Ammonium Oleate	Lithium Stearate	Potassium Palmitate	Sodium Stearate
Ammonium Stearate	Magnesium Lanolate	Potassium Stearate	Sodium Tallowate
Behenic Acid	Magnesium Palmitate	Potassium Tallate	Stearic Acid
Calcium Behenate	Magnesium Stearate	Potassium Tallowate	Trilinoleic Acid
Calcium Laurate	Magnesium Tallowate	Sodium Behenate	

Active ingredients in over-the-counter (OTC) drug products for certain uses which currently have inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses

(21CFR §310.545)

Calcium Undecylenate (dandruff/seborrheic dermatitis/psoriasis drug products)
Sodium Caprylate (topical antifungal drug products for diaper rash drug products)
Sodium Oleate (laxative drug products)
Undecylenic Acid (dandruff/seborrheic dermatitis/psoriasis drug products)

Approved Over-the-Counter Drug Use

(21CFR §333.210)

Calcium Undecylenate and Undecylenic Acid (topical antifungal: total undecylenate concentration of 10%-15%)

GRAS for Animals

(21CFR §582.5065)

Linoleic Acid

Approved for Animal Drugs or Feed

(21 CFR §522.1610 and §573.280)

Calcium Stearate
Sodium Oleate
Sodium Stearate

Tolerances and Exemptions for Pesticide Chemical Residues in Food

(40CFR §180.940 and §180.1068)

Calcium Stearate (no limit)	Potassium Oleate
Capric Acid (end-use concentration not to exceed 100 ppm)	Potassium Palmitate
Caprylic Acid (end-use concentration not to exceed 52 ppm)	Potassium Stearate
Potassium Laurate	

Table 10. Non-cosmetic uses of fatty acid and fatty acid salts^{80,81,87}

Ingredient	Use
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; flattening 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; flattening 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
Isomerized Safflower Acid	Dietary supplement for weight loss
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; flattening 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; flattening agent; stabilizer and lubricant for plastics; dietary supplement; in medicines
Myristic Acid	In lubricants; in coatings for anodized aluminum; antifoaming agent in pharmaceutical 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 pharmaceutical 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
Sodium Palmitate	Polymerization catalyst for synthetic rubbers; laundry soap; detergents; pharmaceuticals; printing inks; emulsifier
Sodium Stearate	Industrial and household soap; emulsifying and stiffening agent in pharmaceutical 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 11. Acute toxicity studies

Concentration/Vehicle	Dose/Study Protocol	Results	LD ₅₀	Reference
<i>Dermal</i>				
Capric Acid in PEG 300	Acute dermal toxicity study in 5 male and 5 female HanRcc:WIST (SPF) rats; performed in accordance with OECD TG 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 1 st 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	²³
Lithium Stearate; no vehicle used	Acute dermal toxicity study in 5 male and 5 female Wistar rats; performed in accordance with OECD TG 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	²⁸
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 eschar formation was also noted in some animals during the 1 st 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	³⁰
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 TG 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	³²
<i>Oral</i>				
Ammonium Oleate; concentration not reported, no vehicle used	Gavage study in male and female rats (strain not reported); performed in accordance with OECD TG 401; 4, 8, 16, 32, 48, or 64 ml/kg; 5 animals per dose	Rats in the 16 mg/kg dose groups and greater experienced 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	²⁰
Behenic Acid; 20% in corn oil	Gavage study in 5 male and 5 female Sprague-Dawley rats; performed in accordance with OECD TG 401; 2000 mg/kg bw	No adverse effects observed	> 2000 mg/kg bw	²²
Behenic Acid; 50% in DMSO	Gavage study in 5 male and 5 female Wistar rats; performed in accordance with OECD TG 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	²²
Calcium Stearate in corn oil	Gavage study in 3 female Sprague-Dawley rats; 2000 mg/kg bw; study performed with a 2 nd confirmatory experiment (6 rats total)	Soiled perineal region, inanimation, prone position; no unscheduled deaths; no adverse effects at necropsy	> 2000 mg/kg bw	³⁵
Capric Acid; concentration not reported; no vehicle used	Gavage study in 5 male and 5 female Wistar rats; performed in accordance with OECD TG 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	²³

Table 11. Acute toxicity studies

Concentration/Vehicle	Dose/Study Protocol	Results	LD ₅₀	Reference
Capric Acid in water; concentration not reported	Gavage study in 5 male and 5 female Wistar rats; performed in accordance with OECD TG 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	²³
Caprylic Acid; concentration not reported; no vehicle used	Gavage study in 5 male and 5 female Wistar rats; performed in accordance with OECD TG 401; 2000 mg/kg bw	Firm and/or small white/greyish irregular patches in the forestomach observed in all animals	> 2000 mg/kg bw	²⁵
Caprylic Acid; 25% in water	Gavage study in 5 male and 5 female Wistar rats; performed in accordance with OECD TG 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	²⁵
Isomerized Linoleic Acid; concentration not reported; in propylene glycol	Gavage study in 5 male and 5 female Wistar rats; performed in accordance with OECD TG 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	²⁶
Lauric Acid; concentration not reported; in water	Gavage study in 5 male and 5 female Wistar rats; performed in accordance with OECD TG 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	²⁷
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	²⁷
Lithium Stearate; concentration not reported, in water	Gavage fixed dose study in Wistar rats; 1 female at 300 mg/kg bw and 5 females at 2000 mg/kg bw; performed in accordance with OECD TG 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	²⁸
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	²⁸
Palmitic Acid; concentration not reported, in DMSO	Gavage study in 5 male and 5 female Wistar rats; performed in accordance with OECD TG 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	²⁹
Stearic Acid; concentration not reported, in DMSO	Gavage study in 5 male and 5 female Wistar rats; performed in accordance with OECD TG 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	³⁰
Stearic Acid; 20%, vehicle not reported	Gavage study in 5 male and 5 female Wistar rats; performed in accordance with OECD TG 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	³⁰
Stearic Acid; 20% w/v aqueous solution	Gavage study in 5 male and 5 female Sprague-Dawley rats; performed in accordance with OECD TG 401; 6000 mg/kg bw	No clinical signs of toxicity or abnormalities at necropsy were observed	> 6000 mg/kg bw	³⁰
Undecylenic Acid; concentration not reported, in corn oil	Gavage study in 5 male and 5 female Sprague-Dawley rats; performed in accordance with OECD TG 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	³²
Undecylenic Acid; concentration not reported, in sesame oil	Gavage study in 3-12 Carworth CF1 mice per dose group (number per sex not stated); 0.034-0.29 g per mouse	Hyperirritability, spasmodical jumping, shock-like collapse prior to death	8150 mg/kg bw	^{32,37}

Abbreviations: DMSO – dimethyl sulfoxide; OECD – Organization for Economic Co-operation and Development; TG – test guideline

Table 12. Repeated dose toxicity studies

Concentration/Dose/Vehicle	Species	Study Protocol/Duration	Results	Reference
<i>Dermal</i>				
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 TG 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	²⁸
<i>Oral</i>				
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 TG 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
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	³⁵
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 TG 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	²³
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 TG 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	²³
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 TG 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	²³
Isomerized Safflower Acid; 7% to 15% in control feed and a proprietary blend	20 male and 20 female Wistar outbred rats per dose group with an additional 10 per sex for low and high dose recovery examinations	Dietary study for 90 days; animals received test material in feed as either standard fat content with safflower oil or in modified feed with a proprietary blend with safflower oil	NOAEL was 2433 mg/kg/day for male and 2728 mg/kg/day for female rats; no clinical signs of toxicity or effects on mortality observed during treatment; feed consumption and body weight gains were significantly lower in the high-dose males and females of the proprietary blend initially; female in high dose propriety group had hepatocellular hypertrophy that was likely an adaptive response to the high concentration of the proprietary blend in the diet and was reversible after ceasing ingestion of the test material; an increase in plasma insulin levels were also observed in the high dose proprietary blend females but there was no effect on plasma glucose levels.	⁶²

Table 12. 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 TG 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 forestomachs due to epithelial cell hyperplasia/hyperkeratosis in high dose group	³²
Sodium Undecylenate; 0, 20, 60, or 180/360 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 TG 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	³²
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	⁵⁷

Abbreviations: LOAEL – lowest observed adverse effect level; NOAEL – no observed adverse effect level; OECD – Organization for Economic Co-operation and Development; TG – test guideline

Table 13. DART studies

Concentration/Dose/Vehicle	Species	Study Protocol/Duration	Results	Reference
<i>Dermal</i>				
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 TG 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	²⁸
<i>Oral</i>				
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 TG 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	²²
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	³⁵
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 TG 421 (male rats were not treated or assessed); 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	²³
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 TG 414; dams received test material on gestation days 6 to 15	Maternal and fetal NOAEL \geq 1500 mg/kg bw/day; no treatment-related adverse effects observed in parental animals or offspring	²³
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 TG 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	²⁵
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	⁶⁰
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 TG 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	³²

Table 13. 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 TG 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	³²
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 TG 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	³²

Abbreviations: LOAEL – lowest observed adverse effect level; NOAEL – no observed adverse effect level; NOEL – no observed effect level; OECD – Organization for Economic Co-operation and Development; TG – test guideline

Table 14. Genotoxicity studies

Concentration/Dose	Species/Strain/Cell	Method	Results	Reference
<i>In Vitro</i>				
Ammonium Oleate; 0.1 to 333 µg/plate with and without metabolic activation	<i>Salmonella typhimurium</i> strains TA98, TA100, TA1535, and TA1537	Ames test	Not genotoxic	20
Behenic Acid; 156 to 5000 µg/plate with and without metabolic activation in DMSO	<i>S. typhimurium</i> strains TA98, TA100, TA1535, and TA1537 and <i>Escherichia coli</i> strain WP2 uvr A	Ames test	Not genotoxic	22
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	22
Calcium Stearate; up to 312.5 µg/plate with and without metabolic activation in tetrahydrofuran	<i>S. typhimurium</i> strains TA98, TA100, TA1535, and TA1537 and <i>E. coli</i> strain WP2 uvr A	Ames test	Not genotoxic	35
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	35
Capric Acid; 500 to 5000 µg/plate with and without metabolic activation in DMSO	<i>S. typhimurium</i> strains TA98 and TA100, <i>E. coli</i> strain WP2 uvr A pKM 101, and <i>E. coli</i> strain – not specified	Ames test	Not genotoxic	23
Capric Acid; 1000 to 10,000 µg/plate with and without metabolic activation in DMSO	<i>S. typhimurium</i> strains TA98 and TA100 and <i>E. coli</i> strain WP2 uvr A pKM 101	Ames test	Not genotoxic	23
Capric Acid; concentration and vehicle not reported; with and without metabolic activation	<i>S. typhimurium</i> strains TA97, TA98, TA100, TA1535, and TA1537	Ames test	Not genotoxic	61
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	23
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	23
Capric Acid; 5 to 20 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	23
Caproic Acid; 3.1 to 5000 µg/plate with and without metabolic activation in Tween 80/double distilled water	<i>S. typhimurium</i> strains TA98, TA100, TA1535, TA1537, and TA1538	Ames test	Not genotoxic	24
Caproic Acid; 1000 to 10,000 µg/plate with and without metabolic activation in DMSO	<i>S. typhimurium</i> strains TA98 and TA100 and <i>E. coli</i> strain WP2 uvr A pKM 101	Ames test	Not genotoxic	24
Caproic Acid; 10 to 1000 µg/plate with and without metabolic activation in DMSO	<i>S. typhimurium</i> strains TA97 and TA102	Ames test	Not genotoxic	24
Caprylic Acid; 10 to 3333 µg/plate with and without metabolic activation in DMSO	<i>S. typhimurium</i> strains TA97, TA98, TA100, TA1535, and TA1537	Ames test	Not genotoxic	25
Caprylic Acid; 4 to 2500 µg/plate with and without metabolic activation in Tween 80/double distilled water	<i>S. typhimurium</i> strains TA98, TA100, TA1535, TA1537, and TA1538	Ames test	Not genotoxic	25
Caprylic Acid; concentration and vehicle not reported; with and without metabolic activation	<i>S. typhimurium</i> strains TA97, TA98, TA100, TA1535, and TA1537	Ames test	Not genotoxic	61
Isomerized Linoleic Acid; up to 2500 µg/plate with and without metabolic activation in water/Tween 80	<i>S. typhimurium</i> strains TA98, TA100, TA1535, TA1537, and TA1538	Ames test	Not genotoxic	26
Isomerized Safflower Acid as a proprietary blend; up to 5000 µg/plate with and without metabolic activation	<i>S. typhimurium</i> strains TA98, TA100, TA102, TA1535, and TA1537	Ames test	Not genotoxic	62
Isomerized Safflower Acid as a proprietary blend; up to 300 µg/ml with and without metabolic activation	Human peripheral blood lymphocytes	Chromosome aberration assay	Not genotoxic	62
Lauric Acid; 4 to 2500 µg/plate with and without metabolic activation in DMSO	<i>S. typhimurium</i> strains TA98, TA100, TA1535, TA1537, and TA1538	Ames test	Not genotoxic	27
Lauric Acid; concentration and vehicle not reported; with and without metabolic activation	<i>S. typhimurium</i> strains TA97, TA98, TA100, TA1535, and TA1537	Ames test	Not genotoxic	61
Linoleic Acid; concentrations and vehicle not reported, with and without metabolic activation	<i>S. typhimurium</i> strains TA98, TA100, TA1535, TA1537; may have included TA97	Ames test	Not genotoxic	63

Table 14. Genotoxicity studies

Concentration/Dose	Species/Strain/Cell	Method	Results	Reference
Lithium Stearate; 5 to 5000 µg/plate with and without metabolic activation in acetone	<i>S. typhimurium</i> strains TA98, TA100, TA1535, and TA1537 and <i>E. coli</i> strain WP2 uvr A	Ames test	Not genotoxic	²⁸
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	²⁸
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	²⁸
Magnesium Stearate; 156 to 5000 µg/plate with and without metabolic activation; in DMSO	<i>S. typhimurium</i> strains TA98, TA100, TA1535, and TA1537 and <i>E. coli</i> strain WP2 uvr A	Ames test	Not genotoxic	⁶⁴
Magnesium Stearate; up to 1000 µg/ml with and without metabolic activation; in 0.5% sodium carboxymethyl cellulose	CHL/IU Chinese hamster lung fibroblast cells	Mammalian chromosome aberration test	Not genotoxic	⁶⁴
Myristic Acid; concentration and vehicle not reported; with and without metabolic activation	<i>S. typhimurium</i> strains TA97, TA98, TA100, TA1535, and TA1537	Ames test	Not genotoxic	⁶¹
Undecylenic Acid; up to 750 µg/ml with and without metabolic activation; in DMSO	<i>S. typhimurium</i> strains TA98, TA100, TA1535, TA1537, and TA1538	Ames test	Not genotoxic	³²
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	³²
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	³²
Undecylenic Acid; up to 500 µg/ml with and without metabolic activation; in DMSO	Human lymphocytes	Mammalian chromosome aberration test	Not genotoxic	³²
<i>In Vivo</i>				
Magnesium Stearate; 0, 500, 1000, or 2000 mg/kg in 0.5% sodium carboxymethyl cellulose	6 male CD-1 mice per dose group	Micronucleus assay; test material administered via gavage in a single treatment	Not genotoxic	⁶⁴
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	³²

Abbreviations: DMSO – dimethyl sulfoxide; TK – thymidine kinase

Table 15. Dermal irritation and sensitization studies

Concentration/Dose/Vehicle	Test System/Population	Method	Results	Reference
<i>Irritation – In Vitro</i>				
Aluminum Tristearate; undiluted	Human epidermis	Mat Tek EpiDerm™ model	Predicted to be not irritating	21
Capric Acid; at least 99% pure	Full-thickness Wistar rat dorsal and flank tissue	In vitro corrosivity test	Predicted to be not corrosive	67
Capric Acid; at least 99% pure	Full-thickness human mammary tissue; subcutaneous tissue removed	In vitro corrosivity test	Predicted to be not corrosive	67
Capric Acid; concentration and vehicle not reported	RHE	SkinEthic™ RHE 42 bis skin irritation model (validation study)	Predicted to be irritating	70
Caproic Acid; at least 99% pure	Full-thickness Wistar rat dorsal and flank tissue	In vitro corrosivity test	Predicted to be corrosive	67
Caproic Acid; at least 99% pure	Full-thickness human mammary tissue; subcutaneous tissue removed	In vitro corrosivity test	Predicted to be corrosive	67
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%	24
Caproic Acid; 100%	Human epidermis	Episkin™ test	Predicted to be corrosive	24
Caproic Acid; 100%	Wistar rat skin disks prepared from dorsal skin with excess fat tissue removed	TER test	Predicted to be corrosive	24
Caproic Acid; 100%	Reconstituted collagen matrix	CORROSITEX™ assay	Predicted to be corrosive in 1 out of 3 laboratories	24
Caproic Acid; 100%	Intact human skin equivalent	Skin 2TM ZK1350 assay	Predicted to be corrosive in 2 out of 3 laboratories	24
Caprylic Acid; concentration not reported, no vehicle used	Wistar rat disks prepared from dorsal and flank skin	TER test	Predicted to be corrosive	25
Caprylic Acid; at least 99% pure	Full-thickness Wistar rat dorsal and flank tissue	In vitro corrosivity test	Predicted to be corrosive	67
Caprylic Acid; at least 99% pure	Full-thickness human mammary tissue; subcutaneous tissue removed	In vitro corrosivity test	Predicted to be not corrosive	67
Caprylic Acid; 99% pure	RHE	SkinEthic™ RHE skin corrosion test	Predicted to be corrosive	68
Caprylic Acid; concentration not reported	Human skin keratinocytes	Modified EpiSkin™ full thickness skin model	Predicted to be corrosive	69
Caprylic Acid; concentration not reported	Human skin fibroblasts	Modified SkinEthic™ RHE skin model	Predicted to be corrosive	69
Isostearic Acid; 99% pure	RHE	SkinEthic™ RHE skin corrosion test	Predicted to be not corrosive	68
Lauric Acid; at least 99% pure	Full-thickness Wistar rat dorsal and flank tissue	In vitro corrosivity test	Predicted to be not corrosive	67
Lauric Acid; at least 99% pure	Full-thickness human mammary tissue; subcutaneous tissue removed	In vitro corrosivity test	Predicted to be not corrosive	67
Lauric Acid; concentration and vehicle not reported	RHE	SkinEthic™ RHE 42 bis skin irritation model (validation study)	Predicted to be not irritating	70
Lithium Stearate; concentration not reported, no vehicle used	Human epidermis	Episkin test	Predicted to be not corrosive	28
Lithium Stearate; concentration not reported, no vehicle used	Human epidermis	Episkin test	Predicted to be not irritating	28
Undecylenic Acid; concentration and vehicle not reported	RHE	SkinEthic™ RHE 42 bis skin irritation model (validation study)	Predicted to be irritating	70
<i>Irritation – Animal</i>				
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 TG 404; test sites occluded, with and without abrasion; 4 h exposure on 1.5 in ² site followed by washing with solvent	PII = 0.04; mean erythema score = 0.04 with effects fully reversed at 48 h; mean edema score = 0	20
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 TG 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	24

Table 15. Dermal irritation and sensitization studies

Concentration/Dose/Vehicle	Test System/Population	Method	Results	Reference
Caprylic Acid; 100%	3 New Zealand White rabbits; sex not reported	Acute dermal irritation study in accordance with OECD TG 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	²⁵
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 ≥ 3.3 and 3.2, respectively; non-irritating at 30% through 70%	²⁵
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%	²⁵
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 2 animals at 65% and 80%	²⁵
Caprylic Acid; 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD TG 404; 4 h exposure	Necrosis and eschar observed at day 2 and 3; PII = 4.44	⁶⁶
Caprylic Acid/Capric Acid mix (55:45); 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD TG 404; 4 h exposure	Necrosis and eschar observed at day 2 and 3; PII = 5.11	⁶⁶
Caprylic Acid/ Capric Acid mix (60:40); 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD TG 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	⁶⁶
Caprylic Acid/ Capric Acid mix (65:35); 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD TG 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	⁶⁶
Caprylic Acid/ Capric Acid mix (65:35); 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD TG 404; 4 h exposure	Reactions observed outside of test site in all animals starting 4.5 h; PII = 5.33	⁶⁶
Isostearic Acid; 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD TG 404; 4 h exposure	Reactions outside of test site in all animals starting on day 1; PII = 4.33	⁶⁶
Lauric Acid; concentration not reported; in water	3 New Zealand White rabbits; sex not reported	Acute dermal irritation study in accordance with OECD TG 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	²⁷
Lauric Acid; concentration not reported; no vehicle used	4 Kleinrussen rabbits; sex not reported	Acute dermal irritation study in accordance with OECD TG 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	²⁷
Lauric Acid; 100%	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD TG 404; 4 h exposure	PII = 0.44	⁶⁶
Oleic Acid; 10% in a formulation with a pharmaceutical	2 groups of 3 rabbits; sex and strain not reported	Primary and cumulative skin irritation; 100 mg test material applied to shaved dorsa that were divided into four quadrants of about 4 cm ² each and occluded; two quadrants were scarified; one group received test material for only 4 h and the other received test material for 24 h for 5 consecutive days	No primary or cumulative dermal irritation observed	⁵²
Palmitic Acid; concentration not reported; no vehicle used	4 Kleinrussen rabbits; sex not reported	Acute dermal irritation study in accordance with OECD TG 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	²⁹
Sodium Undecylenate; 33% aq	3 rabbits; details not provided	Acute dermal irritation study in accordance with OECD TG 404; 4 h exposure	PII = 1.67	⁶⁶
Trilinoleic Acid; concentration not reported; 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	³¹
Undecylenic Acid; 100%	4 rabbits; details not provided	Acute dermal irritation study in accordance with OECD TG404; 4 h exposure	PII = 2.42	⁶⁶

Table 15. Dermal irritation and sensitization studies

Concentration/Dose/Vehicle	Test System/Population	Method	Results	Reference
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	²⁷
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	²⁷
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	²⁹
Sensitization – In Chemico				
Linoleic Acid (99% pure); 100 mM in acetonitrile (9:1)	Heptapeptides containing cysteine or lysine	DPRA in accordance with OECD TG 442C	Positive	⁷¹
Linolenic Acid (99% pure); 100 mM in isopropyl alcohol (9:1)	Heptapeptides containing cysteine or lysine	DPRA in accordance with OECD TG 442C	Positive	⁷¹
Oleic Acid (97% pure); 100 mM in acetonitrile (9:1)	Heptapeptides containing cysteine or lysine	DPRA in accordance with OECD TG 442C	Negative	⁷¹
Undecylenic Acid (98% pure); 100 mM in acetonitrile (9:1)	Heptapeptides containing cysteine or lysine	DPRA in accordance with OECD TG 442C	Negative	⁷¹
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.	²⁰
Ammonium Oleate; 10%, 25%, or 50% in acetone/olive oil (4:1 v/v)	5 female CBA/Ca mice/dose group	LLNA	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%	²⁰
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	²³
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	²³
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%	³³
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	³³

Table 15. Dermal irritation and sensitization studies

Concentration/Dose/Vehicle	Test System/Population	Method	Results	Reference
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, 1 st challenge with 0.5% in corn oil and 2 nd 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 2 nd 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	³³
Lauric Acid; induction and challenge with 2.5% in ethanol	20 Pirbright white guinea pigs; sex not reported	Maximization test; occlusive	Not sensitizing	²⁷
Linoleic Acid (99% pure); 5.0%, 10.0%, 25.0%, and 50% in dose-finding study; 25% in primary study; in acetone:olive oil (4:1, v/v)	Groups of 5 female CBA/J mice	LLNA:DAE	Weak skin sensitizer	⁷¹
Linolenic Acid (99% pure); 5.0%, 10.0%, 25.0%, and 50% in dose-finding study; 25% in primary study; in acetone:olive oil (4:1, v/v)	Groups of 5 female CBA/J mice	LLNA:DAE	Weak skin sensitizer	⁷¹
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	²⁸
Oleic Acid (97% pure); 5.0%, 10.0%, 25.0%, and 50% in dose-finding study; 10% in primary study; in acetone:olive oil (4:1, v/v)	Groups of 5 female CBA/J mice	LLNA:DAE	Weak skin sensitizer	⁷¹
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	³²
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	³¹
Undecylenic Acid (98% pure); 5.0%, 10.0%, 25.0%, and 50% in dose-finding study; 25% in primary study; in acetone:olive oil (4:1, v/v)	Groups of 5 female CBA/J mice	LLNA:DAE	Weak skin sensitizer	⁷¹
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	³²

Abbreviations: DPRA -direct peptide reactivity assay; EC3 – estimated concentration of a substance expected to produce an SI of 3; LLNA – local lymph node assay; LLNA:DAE – modified local lymph node assay with an elicitation phase; OECD – Organization for Economic Co-operation and Development; PII – primary dermal irritation index; RHE – reconstructed human epidermis; SI – stimulation index; TER – transcutaneous electrical resistance; TG – test guideline;

Table 16. Ocular irritation studies

Concentration/Dose	Test System/Population	Method	Results	Reference
In Vitro				
Caproic Acid; 50% in sesame oil	Bovine corneas	Bovine Corneal Opacity and Permeability test in accordance with OECD TG 437; tissues treated with 750 µl of the test material for 10 min	Corrosive	²⁴
Lithium Stearate; concentration not reported, no vehicle used	Corneal epithelial tissue reconstruct	Reconstructed Human Corneal model; tissues treated with 30 mg of the test material for 10 min	Predicted to be non-irritating	²⁸
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	²³
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	²⁵
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	²⁵
Lauric Acid; concentration not reported, no vehicle used	3 New Zealand White rabbits; sex not reported	Ocular irritation study in accordance with OECD TG 405; details not provided	Ocular irritant; lacrimation and corneal epithelial damage in all animals; no corrosion observed	²⁷
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	²⁷
Lauric Acid; concentration not reported, no vehicle used	1 Kleinrussen rabbit; sex not reported	Ocular irritation study in accordance with OECD TG 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	²⁷
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	⁷⁴
Lithium Stearate; concentration not reported, no vehicle used	2 New Zealand White rabbits; sex not reported	Ocular irritation study in accordance with OECD TG 405; 0.1 ml instilled; eyes were not rinsed;	Mild ocular irritant; moderate conjunctival irritation observed	²⁸
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	⁷⁵
Palmitic Acid; concentration not reported, no vehicle used	4 Kleinrussen rabbits; sex not reported	Ocular irritation study in accordance with OECD TG 405; 0.1 ml instilled; eyes were not rinsed	Not irritating	²⁹
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	⁷⁴
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	⁷⁴
Undecylenic Acid; concentration not reported, no vehicle used	3 male New Zealand White rabbits	Ocular irritation study in accordance with OECD TG 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	³²

OECD = Organization for Economic Co-operation and Development; TG – test guideline

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2019 FDA VCRP RAW DATA

03B - Eyeliner	300925	ALUMINUM DISTEARATE	2
03C - Eye Shadow	300925	ALUMINUM DISTEARATE	1
03F - Mascara	300925	ALUMINUM DISTEARATE	2
03G - Other Eye Makeup Preparations	300925	ALUMINUM DISTEARATE	2
06G - Hair Bleaches	300925	ALUMINUM DISTEARATE	3
07A - Blushers (all types)	300925	ALUMINUM DISTEARATE	1
07B - Face Powders	300925	ALUMINUM DISTEARATE	4
07C - Foundations	300925	ALUMINUM DISTEARATE	2
07E - Lipstick	300925	ALUMINUM DISTEARATE	1
07F - Makeup Bases	300925	ALUMINUM DISTEARATE	2
07H - Makeup Fixatives	300925	ALUMINUM DISTEARATE	1
07I - Other Makeup Preparations	300925	ALUMINUM DISTEARATE	1
12C - Face and Neck (exc shave)	300925	ALUMINUM DISTEARATE	1
12F - Moisturizing	300925	ALUMINUM DISTEARATE	1
03B - Eyeliner	7047849	ALUMINUM STEARATE	1
03C - Eye Shadow	7047849	ALUMINUM STEARATE	2
03D - Eye Lotion	7047849	ALUMINUM STEARATE	1
03F - Mascara	7047849	ALUMINUM STEARATE	2
05G - Tonics, Dressings, and Other Hair Grooming Aids	7047849	ALUMINUM STEARATE	2
06G - Hair Bleaches	7047849	ALUMINUM STEARATE	1
07C - Foundations	7047849	ALUMINUM STEARATE	6
07F - Makeup Bases	7047849	ALUMINUM STEARATE	8
08C - Nail Creams and Lotions	7047849	ALUMINUM STEARATE	1
12C - Face and Neck (exc shave)	7047849	ALUMINUM STEARATE	14
12D - Body and Hand (exc shave)	7047849	ALUMINUM STEARATE	1
12F - Moisturizing	7047849	ALUMINUM STEARATE	9
12G - Night	7047849	ALUMINUM STEARATE	2
12J - Other Skin Care Preps	7047849	ALUMINUM STEARATE	3
13A - Suntan Gels, Creams, and Liquids	7047849	ALUMINUM STEARATE	2
03F - Mascara	977165766	ALUMINUM STEARATES	1
12F - Moisturizing	977165766	ALUMINUM STEARATES	1
12G - Night	977165766	ALUMINUM STEARATES	1
12C - Face and Neck (exc shave)	637127	ALUMINUM TRISTEARATE	1
12F - Moisturizing	637127	ALUMINUM TRISTEARATE	1
12G - Night	637127	ALUMINUM	1

		TRISTEARATE	
03A - Eyebrow Pencil	1002897	AMMONIUM STEARATE	1
03F - Mascara	1002897	AMMONIUM STEARATE	3
03F - Mascara	506309	ARACHIDIC ACID	6
08E - Nail Polish and Enamel	506309	ARACHIDIC ACID	1
12A - Cleansing	506309	ARACHIDIC ACID	3
12C - Face and Neck (exc shave)	506309	ARACHIDIC ACID	1
12D - Body and Hand (exc shave)	506309	ARACHIDIC ACID	1
01B - Baby Lotions, Oils, Powders, and Creams	112856	BEHENIC ACID	2
03A - Eyebrow Pencil	112856	BEHENIC ACID	5
03C - Eye Shadow	112856	BEHENIC ACID	26
03D - Eye Lotion	112856	BEHENIC ACID	1
03F - Mascara	112856	BEHENIC ACID	12
04B - Perfumes	112856	BEHENIC ACID	1
04E - Other Fragrance Preparation	112856	BEHENIC ACID	1
05A - Hair Conditioner	112856	BEHENIC ACID	3
05E - Rinses (non-coloring)	112856	BEHENIC ACID	1
05F - Shampoos (non-coloring)	112856	BEHENIC ACID	2
05G - Tonics, Dressings, and Other Hair Grooming Aids	112856	BEHENIC ACID	2
05I - Other Hair Preparations	112856	BEHENIC ACID	3
06D - Hair Shampoos (coloring)	112856	BEHENIC ACID	1
07A - Blushers (all types)	112856	BEHENIC ACID	1
07C - Foundations	112856	BEHENIC ACID	5
07E - Lipstick	112856	BEHENIC ACID	3
07F - Makeup Bases	112856	BEHENIC ACID	3
07G - Rouges	112856	BEHENIC ACID	2
07I - Other Makeup Preparations	112856	BEHENIC ACID	3
10A - Bath Soaps and Detergents	112856	BEHENIC ACID	4
10B - Deodorants (underarm)	112856	BEHENIC ACID	29
11A - Aftershave Lotion	112856	BEHENIC ACID	1
12A - Cleansing	112856	BEHENIC ACID	24
12C - Face and Neck (exc shave)	112856	BEHENIC ACID	7
12D - Body and Hand (exc shave)	112856	BEHENIC ACID	3
12F - Moisturizing	112856	BEHENIC ACID	7
12G - Night	112856	BEHENIC ACID	2
12H - Paste Masks (mud packs)	112856	BEHENIC ACID	1
12J - Other Skin Care Preps	112856	BEHENIC ACID	3

05A - Hair Conditioner	999004013	C14-28 ALKYL ACID	13
05F - Shampoos (non-coloring)	999004013	C14-28 ALKYL ACID	11
05I - Other Hair Preparations	999004013	C14-28 ALKYL ACID	2
06C - Hair Rinses (coloring)	999004013	C14-28 ALKYL ACID	1
06D - Hair Shampoos (coloring)	999004013	C14-28 ALKYL ACID	1
12F - Moisturizing	999004013	C14-28 ALKYL ACID	1
05A - Hair Conditioner	999004012	C14-28 ISOALKYL ACID	13
05F - Shampoos (non-coloring)	999004012	C14-28 ISOALKYL ACID	11
05I - Other Hair Preparations	999004012	C14-28 ISOALKYL ACID	2
06C - Hair Rinses (coloring)	999004012	C14-28 ISOALKYL ACID	1
06D - Hair Shampoos (coloring)	999004012	C14-28 ISOALKYL ACID	1
05B - Hair Spray (aerosol fixatives)	3578721	CALCIUM BEHENATE	1
03B - Eyeliner	1592230	CALCIUM STEARATE	3
03C - Eye Shadow	1592230	CALCIUM STEARATE	208
04E - Other Fragrance Preparation	1592230	CALCIUM STEARATE	1
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	1592230	CALCIUM STEARATE	1
06G - Hair Bleaches	1592230	CALCIUM STEARATE	4
07A - Blushers (all types)	1592230	CALCIUM STEARATE	13
07B - Face Powders	1592230	CALCIUM STEARATE	12
07C - Foundations	1592230	CALCIUM STEARATE	5
07E - Lipstick	1592230	CALCIUM STEARATE	4
07F - Makeup Bases	1592230	CALCIUM STEARATE	2
07G - Rouges	1592230	CALCIUM STEARATE	4
07I - Other Makeup Preparations	1592230	CALCIUM STEARATE	1
08G - Other Manicuring Preparations	1592230	CALCIUM STEARATE	1
10E - Other Personal Cleanliness Products	1592230	CALCIUM STEARATE	1
12A - Cleansing	1592230	CALCIUM STEARATE	1
12D - Body and Hand (exc shave)	1592230	CALCIUM STEARATE	2
12E - Foot Powders and Sprays	1592230	CALCIUM STEARATE	1
04E - Other Fragrance Preparation	334485	CAPRIC ACID	1
12A - Cleansing	334485	CAPRIC ACID	5

05G - Tonics, Dressings, and Other Hair Grooming Aids	124072	CAPRYLIC ACID	1
07A - Blushers (all types)	124072	CAPRYLIC ACID	1
07E - Lipstick	124072	CAPRYLIC ACID	2
12D - Body and Hand (exc shave)	124072	CAPRYLIC ACID	1
12F - Moisturizing	124072	CAPRYLIC ACID	2
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	6144281	DILINOLEIC ACID	71
12J - Other Skin Care Preps	5393817	HYDROXYCAPRIC ACID	1
12C - Face and Neck (exc shave)	92348624	HYDROXYCAPRYLIC ACID	2
12F - Moisturizing	92348624	HYDROXYCAPRYLIC ACID	1
12J - Other Skin Care Preps	92348624	HYDROXYCAPRYLIC ACID	1
07H - Makeup Fixatives	1679534	10-HYDROXYDECANOIC ACID	1
12A - Cleansing	1679534	10-HYDROXYDECANOIC ACID	2
12C - Face and Neck (exc shave)	1679534	10-HYDROXYDECANOIC ACID	1
12D - Body and Hand (exc shave)	1679534	10-HYDROXYDECANOIC ACID	1
12F - Moisturizing	1679534	10-HYDROXYDECANOIC ACID	2
12G - Night	1679534	10-HYDROXYDECANOIC ACID	1
12J - Other Skin Care Preps	1679534	10-HYDROXYDECANOIC ACID	1
03A - Eyebrow Pencil	1330707	HYDROXYSTEARIC ACID	5
03B - Eyeliner	1330707	HYDROXYSTEARIC ACID	3
03C - Eye Shadow	1330707	HYDROXYSTEARIC ACID	3
03D - Eye Lotion	1330707	HYDROXYSTEARIC ACID	1
03F - Mascara	1330707	HYDROXYSTEARIC ACID	1
03G - Other Eye Makeup Preparations	1330707	HYDROXYSTEARIC ACID	2
04B - Perfumes	1330707	HYDROXYSTEARIC ACID	2
05G - Tonics, Dressings, and Other Hair Grooming Aids	1330707	HYDROXYSTEARIC ACID	7
07A - Blushers (all types)	1330707	HYDROXYSTEARIC ACID	3
07C - Foundations	1330707	HYDROXYSTEARIC ACID	1
07D - Leg and Body Paints	1330707	HYDROXYSTEARIC ACID	1

07E - Lipstick	1330707	HYDROXYSTEARIC ACID	63
07I - Other Makeup Preparations	1330707	HYDROXYSTEARIC ACID	11
08G - Other Manicuring Preparations	1330707	HYDROXYSTEARIC ACID	1
10B - Deodorants (underarm)	1330707	HYDROXYSTEARIC ACID	9
12A - Cleansing	1330707	HYDROXYSTEARIC ACID	2
12C - Face and Neck (exc shave)	1330707	HYDROXYSTEARIC ACID	3
12F - Moisturizing	1330707	HYDROXYSTEARIC ACID	4
12G - Night	1330707	HYDROXYSTEARIC ACID	1
12J - Other Skin Care Preps	1330707	HYDROXYSTEARIC ACID	2
03D - Eye Lotion	999001992	ISOMERIZED LINOLEIC ACID	7
07A - Blushers (all types)	999001992	ISOMERIZED LINOLEIC ACID	1
10E - Other Personal Cleanliness Products	999001992	ISOMERIZED LINOLEIC ACID	1
12D - Body and Hand (exc shave)	999001992	ISOMERIZED LINOLEIC ACID	5
12F - Moisturizing	999001992	ISOMERIZED LINOLEIC ACID	4
12G - Night	999001992	ISOMERIZED LINOLEIC ACID	2
12H - Paste Masks (mud packs)	999001992	ISOMERIZED LINOLEIC ACID	2
12J - Other Skin Care Preps	999001992	ISOMERIZED LINOLEIC ACID	1
01B - Baby Lotions, Oils, Powders, and Creams	30399849	ISOSTEARIC ACID	1
03A - Eyebrow Pencil	30399849	ISOSTEARIC ACID	1
03B - Eyeliner	30399849	ISOSTEARIC ACID	2
03C - Eye Shadow	30399849	ISOSTEARIC ACID	4
03D - Eye Lotion	30399849	ISOSTEARIC ACID	2
03F - Mascara	30399849	ISOSTEARIC ACID	67
03G - Other Eye Makeup Preparations	30399849	ISOSTEARIC ACID	3
05A - Hair Conditioner	30399849	ISOSTEARIC ACID	1
05B - Hair Spray (aerosol fixatives)	30399849	ISOSTEARIC ACID	4
05F - Shampoos (non-coloring)	30399849	ISOSTEARIC ACID	2
05G - Tonics, Dressings, and Other Hair Grooming Aids	30399849	ISOSTEARIC ACID	3
06B - Hair Tints	30399849	ISOSTEARIC ACID	1
06D - Hair Shampoos (coloring)	30399849	ISOSTEARIC ACID	1

07A - Blushers (all types)	30399849	ISOSTEARIC ACID	3
07C - Foundations	30399849	ISOSTEARIC ACID	29
07E - Lipstick	30399849	ISOSTEARIC ACID	10
07F - Makeup Bases	30399849	ISOSTEARIC ACID	7
07H - Makeup Fixatives	30399849	ISOSTEARIC ACID	3
07I - Other Makeup Preparations	30399849	ISOSTEARIC ACID	3
10A - Bath Soaps and Detergents	30399849	ISOSTEARIC ACID	5
10B - Deodorants (underarm)	30399849	ISOSTEARIC ACID	2
10E - Other Personal Cleanliness Products	30399849	ISOSTEARIC ACID	13
11E - Shaving Cream	30399849	ISOSTEARIC ACID	1
12A - Cleansing	30399849	ISOSTEARIC ACID	13
12C - Face and Neck (exc shave)	30399849	ISOSTEARIC ACID	32
12D - Body and Hand (exc shave)	30399849	ISOSTEARIC ACID	13
12F - Moisturizing	30399849	ISOSTEARIC ACID	27
12G - Night	30399849	ISOSTEARIC ACID	5
12H - Paste Masks (mud packs)	30399849	ISOSTEARIC ACID	1
12I - Skin Fresheners	30399849	ISOSTEARIC ACID	1
12J - Other Skin Care Preps	30399849	ISOSTEARIC ACID	7
13B - Indoor Tanning Preparations	30399849	ISOSTEARIC ACID	2
13C - Other Suntan Preparations	30399849	ISOSTEARIC ACID	2
01C - Other Baby Products	143077	LAURIC ACID	1
02B - Bubble Baths	143077	LAURIC ACID	2
03E - Eye Makeup Remover	143077	LAURIC ACID	1
03F - Mascara	143077	LAURIC ACID	1
05A - Hair Conditioner	143077	LAURIC ACID	1
05F - Shampoos (non-coloring)	143077	LAURIC ACID	25
05G - Tonics, Dressings, and Other Hair Grooming Aids	143077	LAURIC ACID	4
05I - Other Hair Preparations	143077	LAURIC ACID	2
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	143077	LAURIC ACID	159
06D - Hair Shampoos (coloring)	143077	LAURIC ACID	1
06G - Hair Bleaches	143077	LAURIC ACID	4
06H - Other Hair Coloring Preparation	143077	LAURIC ACID	1
07E - Lipstick	143077	LAURIC ACID	3
08B - Cuticle Softeners	143077	LAURIC ACID	1
10A - Bath Soaps and Detergents	143077	LAURIC ACID	71
10B - Deodorants (underarm)	143077	LAURIC ACID	5
10E - Other Personal Cleanliness	143077	LAURIC ACID	57

Products			
11E - Shaving Cream	143077	LAURIC ACID	12
11F - Shaving Soap	143077	LAURIC ACID	3
11G - Other Shaving Preparation Products	143077	LAURIC ACID	4
12A - Cleansing	143077	LAURIC ACID	184
12C - Face and Neck (exc shave)	143077	LAURIC ACID	8
12D - Body and Hand (exc shave)	143077	LAURIC ACID	4
12H - Paste Masks (mud packs)	143077	LAURIC ACID	1
12J - Other Skin Care Preps	143077	LAURIC ACID	8
03C - Eye Shadow	60333	LINOLEIC ACID	7
03D - Eye Lotion	60333	LINOLEIC ACID	48
03F - Mascara	60333	LINOLEIC ACID	3
03G - Other Eye Makeup Preparations	60333	LINOLEIC ACID	13
05A - Hair Conditioner	60333	LINOLEIC ACID	23
05C - Hair Straighteners	60333	LINOLEIC ACID	3
05F - Shampoos (non-coloring)	60333	LINOLEIC ACID	12
05G - Tonics, Dressings, and Other Hair Grooming Aids	60333	LINOLEIC ACID	17
05I - Other Hair Preparations	60333	LINOLEIC ACID	6
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	60333	LINOLEIC ACID	3
06C - Hair Rinses (coloring)	60333	LINOLEIC ACID	1
07A - Blushers (all types)	60333	LINOLEIC ACID	2
07B - Face Powders	60333	LINOLEIC ACID	8
07C - Foundations	60333	LINOLEIC ACID	14
07E - Lipstick	60333	LINOLEIC ACID	118
07F - Makeup Bases	60333	LINOLEIC ACID	4
07G - Rouges	60333	LINOLEIC ACID	1
07I - Other Makeup Preparations	60333	LINOLEIC ACID	5
08B - Cuticle Softeners	60333	LINOLEIC ACID	1
08E - Nail Polish and Enamel	60333	LINOLEIC ACID	1
10A - Bath Soaps and Detergents	60333	LINOLEIC ACID	6
10E - Other Personal Cleanliness Products	60333	LINOLEIC ACID	1
11A - Aftershave Lotion	60333	LINOLEIC ACID	6
12A - Cleansing	60333	LINOLEIC ACID	25
12C - Face and Neck (exc shave)	60333	LINOLEIC ACID	71
12D - Body and Hand (exc shave)	60333	LINOLEIC ACID	39
12F - Moisturizing	60333	LINOLEIC ACID	154
12G - Night	60333	LINOLEIC ACID	38

12H - Paste Masks (mud packs)	60333	LINOLEIC ACID	7
12I - Skin Fresheners	60333	LINOLEIC ACID	1
12J - Other Skin Care Preps	60333	LINOLEIC ACID	28
13A - Suntan Gels, Creams, and Liquids	60333	LINOLEIC ACID	6
13B - Indoor Tanning Preparations	60333	LINOLEIC ACID	7
13C - Other Suntan Preparations	60333	LINOLEIC ACID	2
03C - Eye Shadow	463401	LINOLENIC ACID	1
03D - Eye Lotion	463401	LINOLENIC ACID	13
03G - Other Eye Makeup Preparations	463401	LINOLENIC ACID	4
05A - Hair Conditioner	463401	LINOLENIC ACID	14
05C - Hair Straighteners	463401	LINOLENIC ACID	3
05F - Shampoos (non-coloring)	463401	LINOLENIC ACID	10
05G - Tonics, Dressings, and Other Hair Grooming Aids	463401	LINOLENIC ACID	7
05I - Other Hair Preparations	463401	LINOLENIC ACID	7
06C - Hair Rinses (coloring)	463401	LINOLENIC ACID	1
07B - Face Powders	463401	LINOLENIC ACID	1
07C - Foundations	463401	LINOLENIC ACID	4
07E - Lipstick	463401	LINOLENIC ACID	8
08E - Nail Polish and Enamel	463401	LINOLENIC ACID	1
10A - Bath Soaps and Detergents	463401	LINOLENIC ACID	4
11A - Aftershave Lotion	463401	LINOLENIC ACID	4
12A - Cleansing	463401	LINOLENIC ACID	5
12C - Face and Neck (exc shave)	463401	LINOLENIC ACID	26
12D - Body and Hand (exc shave)	463401	LINOLENIC ACID	8
12F - Moisturizing	463401	LINOLENIC ACID	53
12G - Night	463401	LINOLENIC ACID	15
12H - Paste Masks (mud packs)	463401	LINOLENIC ACID	1
12I - Skin Fresheners	463401	LINOLENIC ACID	1
12J - Other Skin Care Preps	463401	LINOLENIC ACID	14
13A - Suntan Gels, Creams, and Liquids	463401	LINOLENIC ACID	6
13B - Indoor Tanning Preparations	463401	LINOLENIC ACID	3
03C - Eye Shadow	4485125	LITHIUM STEARATE	77
03G - Other Eye Makeup Preparations	4485125	LITHIUM STEARATE	1
07A - Blushers (all types)	4485125	LITHIUM STEARATE	2
07C - Foundations	4485125	LITHIUM STEARATE	1

07E - Lipstick	4485125	LITHIUM STEARATE	4
10A - Bath Soaps and Detergents	4040486	MAGNESIUM LAURATE	4
03A - Eyebrow Pencil	557040	MAGNESIUM STEARATE	1
03B - Eyeliner	557040	MAGNESIUM STEARATE	2
03C - Eye Shadow	557040	MAGNESIUM STEARATE	416
03D - Eye Lotion	557040	MAGNESIUM STEARATE	1
03F - Mascara	557040	MAGNESIUM STEARATE	6
03G - Other Eye Makeup Preparations	557040	MAGNESIUM STEARATE	31
04C - Powders (dusting and talcum, excluding aftershave talc)	557040	MAGNESIUM STEARATE	5
05B - Hair Spray (aerosol fixatives)	557040	MAGNESIUM STEARATE	2
05F - Shampoos (non-coloring)	557040	MAGNESIUM STEARATE	5
05I - Other Hair Preparations	557040	MAGNESIUM STEARATE	3
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	557040	MAGNESIUM STEARATE	1
06E - Hair Color Sprays (aerosol)	557040	MAGNESIUM STEARATE	1
06G - Hair Bleaches	557040	MAGNESIUM STEARATE	9
06H - Other Hair Coloring Preparation	557040	MAGNESIUM STEARATE	32
07A - Blushers (all types)	557040	MAGNESIUM STEARATE	119
07B - Face Powders	557040	MAGNESIUM STEARATE	121
07C - Foundations	557040	MAGNESIUM STEARATE	45
07E - Lipstick	557040	MAGNESIUM STEARATE	4
07F - Makeup Bases	557040	MAGNESIUM STEARATE	3
07G - Rouges	557040	MAGNESIUM STEARATE	7
07H - Makeup Fixatives	557040	MAGNESIUM STEARATE	1
07I - Other Makeup Preparations	557040	MAGNESIUM STEARATE	37
09C - Other Oral Hygiene Products	557040	MAGNESIUM STEARATE	1
10A - Bath Soaps and Detergents	557040	MAGNESIUM STEARATE	4
10D - Feminine Deodorants	557040	MAGNESIUM STEARATE	2
12C - Face and Neck (exc shave)	557040	MAGNESIUM STEARATE	4
12D - Body and Hand (exc shave)	557040	MAGNESIUM STEARATE	2
12F - Moisturizing	557040	MAGNESIUM STEARATE	11
12G - Night	557040	MAGNESIUM STEARATE	2
12H - Paste Masks (mud packs)	557040	MAGNESIUM STEARATE	3
12J - Other Skin Care Preps	557040	MAGNESIUM STEARATE	1
13A - Suntan Gels, Creams, and Liquids	557040	MAGNESIUM STEARATE	1

13B - Indoor Tanning Preparations	557040	MAGNESIUM STEARATE	6
11C - Mens Talcum	557040	MAGNESIUM STEARATE	1
02B - Bubble Baths	544638	MYRISTIC ACID	2
03A - Eyebrow Pencil	544638	MYRISTIC ACID	1
03B - Eyeliner	544638	MYRISTIC ACID	2
03C - Eye Shadow	544638	MYRISTIC ACID	4
03D - Eye Lotion	544638	MYRISTIC ACID	6
03F - Mascara	544638	MYRISTIC ACID	12
03G - Other Eye Makeup Preparations	544638	MYRISTIC ACID	4
05A - Hair Conditioner	544638	MYRISTIC ACID	1
05B - Hair Spray (aerosol fixatives)	544638	MYRISTIC ACID	1
05F - Shampoos (non-coloring)	544638	MYRISTIC ACID	1
05G - Tonics, Dressings, and Other Hair Grooming Aids	544638	MYRISTIC ACID	9
05I - Other Hair Preparations	544638	MYRISTIC ACID	3
07B - Face Powders	544638	MYRISTIC ACID	6
07C - Foundations	544638	MYRISTIC ACID	2
07D - Leg and Body Paints	544638	MYRISTIC ACID	2
07E - Lipstick	544638	MYRISTIC ACID	2
07I - Other Makeup Preparations	544638	MYRISTIC ACID	1
08C - Nail Creams and Lotions	544638	MYRISTIC ACID	1
08G - Other Manicuring Preparations	544638	MYRISTIC ACID	1
10A - Bath Soaps and Detergents	544638	MYRISTIC ACID	23
10B - Deodorants (underarm)	544638	MYRISTIC ACID	1
10E - Other Personal Cleanliness Products	544638	MYRISTIC ACID	10
11A - Aftershave Lotion	544638	MYRISTIC ACID	1
11E - Shaving Cream	544638	MYRISTIC ACID	28
11F - Shaving Soap	544638	MYRISTIC ACID	4
11G - Other Shaving Preparation Products	544638	MYRISTIC ACID	4
12A - Cleansing	544638	MYRISTIC ACID	155
12C - Face and Neck (exc shave)	544638	MYRISTIC ACID	22
12D - Body and Hand (exc shave)	544638	MYRISTIC ACID	49
12F - Moisturizing	544638	MYRISTIC ACID	23
12G - Night	544638	MYRISTIC ACID	2
12H - Paste Masks (mud packs)	544638	MYRISTIC ACID	2
12J - Other Skin Care Preps	544638	MYRISTIC ACID	17
13A - Suntan Gels, Creams, and	544638	MYRISTIC ACID	2

Liquids			
01B - Baby Lotions, Oils, Powders, and Creams	112801	OLEIC ACID	1
02D - Other Bath Preparations	112801	OLEIC ACID	1
03A - Eyebrow Pencil	112801	OLEIC ACID	1
03B - Eyeliner	112801	OLEIC ACID	3
03C - Eye Shadow	112801	OLEIC ACID	1
03D - Eye Lotion	112801	OLEIC ACID	5
03F - Mascara	112801	OLEIC ACID	54
03G - Other Eye Makeup Preparations	112801	OLEIC ACID	6
05A - Hair Conditioner	112801	OLEIC ACID	6
05E - Rinses (non-coloring)	112801	OLEIC ACID	1
05F - Shampoos (non-coloring)	112801	OLEIC ACID	6
05G - Tonics, Dressings, and Other Hair Grooming Aids	112801	OLEIC ACID	3
05I - Other Hair Preparations	112801	OLEIC ACID	2
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	112801	OLEIC ACID	714
06B - Hair Tints	112801	OLEIC ACID	2
06G - Hair Bleaches	112801	OLEIC ACID	3
06H - Other Hair Coloring Preparation	112801	OLEIC ACID	12
07A - Blushers (all types)	112801	OLEIC ACID	1
07C - Foundations	112801	OLEIC ACID	11
07E - Lipstick	112801	OLEIC ACID	89
07F - Makeup Bases	112801	OLEIC ACID	1
07G - Rouges	112801	OLEIC ACID	1
07I - Other Makeup Preparations	112801	OLEIC ACID	4
08B - Cuticle Softeners	112801	OLEIC ACID	3
08C - Nail Creams and Lotions	112801	OLEIC ACID	1
08F - Nail Polish and Enamel Removers	112801	OLEIC ACID	1
08G - Other Manicuring Preparations	112801	OLEIC ACID	2
10A - Bath Soaps and Detergents	112801	OLEIC ACID	3
10B - Deodorants (underarm)	112801	OLEIC ACID	3
11E - Shaving Cream	112801	OLEIC ACID	2
11G - Other Shaving Preparation Products	112801	OLEIC ACID	2
12A - Cleansing	112801	OLEIC ACID	16
12C - Face and Neck (exc shave)	112801	OLEIC ACID	21

12D - Body and Hand (exc shave)	112801	OLEIC ACID	7
12F - Moisturizing	112801	OLEIC ACID	54
12G - Night	112801	OLEIC ACID	9
12H - Paste Masks (mud packs)	112801	OLEIC ACID	1
12I - Skin Fresheners	112801	OLEIC ACID	1
12J - Other Skin Care Preps	112801	OLEIC ACID	12
13A - Suntan Gels, Creams, and Liquids	112801	OLEIC ACID	6
13B - Indoor Tanning Preparations	112801	OLEIC ACID	2
13C - Other Suntan Preparations	112801	OLEIC ACID	3
01B - Baby Lotions, Oils, Powders, and Creams	57103	PALMITIC ACID	3
02A - Bath Oils, Tablets, and Salts	57103	PALMITIC ACID	4
02D - Other Bath Preparations	57103	PALMITIC ACID	2
03A - Eyebrow Pencil	57103	PALMITIC ACID	2
03B - Eyeliner	57103	PALMITIC ACID	11
03C - Eye Shadow	57103	PALMITIC ACID	17
03D - Eye Lotion	57103	PALMITIC ACID	32
03F - Mascara	57103	PALMITIC ACID	153
03G - Other Eye Makeup Preparations	57103	PALMITIC ACID	18
05A - Hair Conditioner	57103	PALMITIC ACID	8
05B - Hair Spray (aerosol fixatives)	57103	PALMITIC ACID	1
05E - Rinses (non-coloring)	57103	PALMITIC ACID	1
05F - Shampoos (non-coloring)	57103	PALMITIC ACID	7
05G - Tonics, Dressings, and Other Hair Grooming Aids	57103	PALMITIC ACID	23
05I - Other Hair Preparations	57103	PALMITIC ACID	5
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	57103	PALMITIC ACID	34
06B - Hair Tints	57103	PALMITIC ACID	22
06E - Hair Color Sprays (aerosol)	57103	PALMITIC ACID	3
06G - Hair Bleaches	57103	PALMITIC ACID	2
07A - Blushers (all types)	57103	PALMITIC ACID	17
07B - Face Powders	57103	PALMITIC ACID	16
07C - Foundations	57103	PALMITIC ACID	11
07D - Leg and Body Paints	57103	PALMITIC ACID	2
07E - Lipstick	57103	PALMITIC ACID	101
07F - Makeup Bases	57103	PALMITIC ACID	5
07G - Rouges	57103	PALMITIC ACID	1

07I - Other Makeup Preparations	57103	PALMITIC ACID	22
08C - Nail Creams and Lotions	57103	PALMITIC ACID	1
08E - Nail Polish and Enamel	57103	PALMITIC ACID	3
08G - Other Manicuring Preparations	57103	PALMITIC ACID	1
10A - Bath Soaps and Detergents	57103	PALMITIC ACID	53
10B - Deodorants (underarm)	57103	PALMITIC ACID	38
10E - Other Personal Cleanliness Products	57103	PALMITIC ACID	15
11A - Aftershave Lotion	57103	PALMITIC ACID	5
11E - Shaving Cream	57103	PALMITIC ACID	39
11G - Other Shaving Preparation Products	57103	PALMITIC ACID	44
12A - Cleansing	57103	PALMITIC ACID	100
12B - Depilatories	57103	PALMITIC ACID	2
12C - Face and Neck (exc shave)	57103	PALMITIC ACID	103
12D - Body and Hand (exc shave)	57103	PALMITIC ACID	145
12F - Moisturizing	57103	PALMITIC ACID	363
12G - Night	57103	PALMITIC ACID	25
12H - Paste Masks (mud packs)	57103	PALMITIC ACID	15
12I - Skin Fresheners	57103	PALMITIC ACID	1
12J - Other Skin Care Preps	57103	PALMITIC ACID	46
13A - Suntan Gels, Creams, and Liquids	57103	PALMITIC ACID	8
13B - Indoor Tanning Preparations	57103	PALMITIC ACID	2
10A - Bath Soaps and Detergents	7211532	POTASSIUM BEHENATE	1
10E - Other Personal Cleanliness Products	7211532	POTASSIUM BEHENATE	1
12A - Cleansing	7211532	POTASSIUM BEHENATE	3
10A - Bath Soaps and Detergents	64366241	POTASSIUM CASTORATE	2
12G - Night	999003682	POTASSIUM HYDROGENATED TALLOWATE	1
10A - Bath Soaps and Detergents	68413467	POTASSIUM ISOSTEARATE	3
12D - Body and Hand (exc shave)	68413467	POTASSIUM ISOSTEARATE	2
07I - Other Makeup Preparations	10124659	POTASSIUM LAURATE	3
10A - Bath Soaps and Detergents	10124659	POTASSIUM LAURATE	5

10E - Other Personal Cleanliness Products	10124659	POTASSIUM LAURATE	2
12A - Cleansing	10124659	POTASSIUM LAURATE	20
12C - Face and Neck (exc shave)	10124659	POTASSIUM LAURATE	1
12F - Moisturizing	10124659	POTASSIUM LAURATE	2
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	143180	POTASSIUM OLEATE	2
10A - Bath Soaps and Detergents	143180	POTASSIUM OLEATE	4
10E - Other Personal Cleanliness Products	143180	POTASSIUM OLEATE	6
12A - Cleansing	143180	POTASSIUM OLEATE	6
12I - Skin Fresheners	143180	POTASSIUM OLEATE	1
03C - Eye Shadow	2624319	POTASSIUM PALMITATE	3
03G - Other Eye Makeup Preparations	2624319	POTASSIUM PALMITATE	1
10A - Bath Soaps and Detergents	2624319	POTASSIUM PALMITATE	4
10E - Other Personal Cleanliness Products	2624319	POTASSIUM PALMITATE	1
11F - Shaving Soap	2624319	POTASSIUM PALMITATE	4
12A - Cleansing	2624319	POTASSIUM PALMITATE	10
12D - Body and Hand (exc shave)	2624319	POTASSIUM PALMITATE	2
01B - Baby Lotions, Oils, Powders, and Creams	593293	POTASSIUM STEARATE	1
03D - Eye Lotion	593293	POTASSIUM STEARATE	3
03F - Mascara	593293	POTASSIUM STEARATE	1
03G - Other Eye Makeup Preparations	593293	POTASSIUM STEARATE	1
05A - Hair Conditioner	593293	POTASSIUM STEARATE	4
05C - Hair Straighteners	593293	POTASSIUM STEARATE	2
05F - Shampoos (non-coloring)	593293	POTASSIUM STEARATE	3
05G - Tonics, Dressings, and Other Hair Grooming Aids	593293	POTASSIUM STEARATE	5
05I - Other Hair Preparations	593293	POTASSIUM STEARATE	1
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	593293	POTASSIUM STEARATE	16
07A - Blushers (all types)	593293	POTASSIUM STEARATE	1
07B - Face Powders	593293	POTASSIUM STEARATE	3
07C - Foundations	593293	POTASSIUM STEARATE	2
07I - Other Makeup Preparations	593293	POTASSIUM STEARATE	1
08C - Nail Creams and Lotions	593293	POTASSIUM STEARATE	1

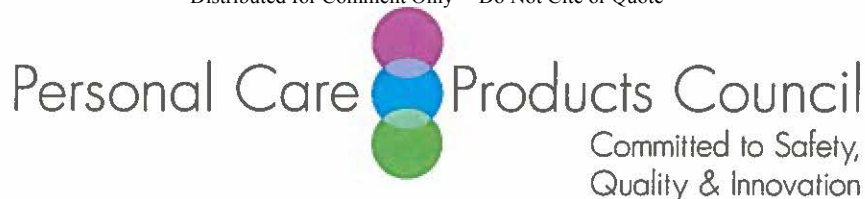
10A - Bath Soaps and Detergents	593293	POTASSIUM STEARATE	13
10E - Other Personal Cleanliness Products	593293	POTASSIUM STEARATE	7
11A - Aftershave Lotion	593293	POTASSIUM STEARATE	3
11E - Shaving Cream	593293	POTASSIUM STEARATE	4
11F - Shaving Soap	593293	POTASSIUM STEARATE	12
11G - Other Shaving Preparation Products	593293	POTASSIUM STEARATE	1
12A - Cleansing	593293	POTASSIUM STEARATE	20
12C - Face and Neck (exc shave)	593293	POTASSIUM STEARATE	3
12D - Body and Hand (exc shave)	593293	POTASSIUM STEARATE	18
12E - Foot Powders and Sprays	593293	POTASSIUM STEARATE	1
12F - Moisturizing	593293	POTASSIUM STEARATE	18
12G - Night	593293	POTASSIUM STEARATE	2
12H - Paste Masks (mud packs)	593293	POTASSIUM STEARATE	3
12J - Other Skin Care Preps	593293	POTASSIUM STEARATE	3
13A - Suntan Gels, Creams, and Liquids	593293	POTASSIUM STEARATE	1
13B - Indoor Tanning Preparations	593293	POTASSIUM STEARATE	3
11F - Shaving Soap	61790327	POTASSIUM TALLOWATE	3
10B - Deodorants (underarm)	5331771	SODIUM BEHENATE	14
10A - Bath Soaps and Detergents	8013067	SODIUM CASTORATE	6
03D - Eye Lotion	36111087	SODIUM ISOSTEARATE	1
03G - Other Eye Makeup Preparations	36111087	SODIUM ISOSTEARATE	1
10A - Bath Soaps and Detergents	36111087	SODIUM ISOSTEARATE	3
12C - Face and Neck (exc shave)	36111087	SODIUM ISOSTEARATE	4
12F - Moisturizing	36111087	SODIUM ISOSTEARATE	1
12G - Night	36111087	SODIUM ISOSTEARATE	1
05F - Shampoos (non-coloring)	629254	SODIUM LAURATE	13
07F - Makeup Bases	629254	SODIUM LAURATE	1
10A - Bath Soaps and Detergents	629254	SODIUM LAURATE	47
10B - Deodorants (underarm)	629254	SODIUM LAURATE	14
10E - Other Personal Cleanliness Products	629254	SODIUM LAURATE	9
12A - Cleansing	629254	SODIUM LAURATE	14
12D - Body and Hand (exc shave)	629254	SODIUM LAURATE	3
12F - Moisturizing	629254	SODIUM LAURATE	2

12J - Other Skin Care Preps	629254	SODIUM LAURATE	1
03D - Eye Lotion	143191	SODIUM OLEATE	6
03G - Other Eye Makeup Preparations	143191	SODIUM OLEATE	2
07I - Other Makeup Preparations	143191	SODIUM OLEATE	1
10A - Bath Soaps and Detergents	143191	SODIUM OLEATE	2
12A - Cleansing	143191	SODIUM OLEATE	3
12C - Face and Neck (exc shave)	143191	SODIUM OLEATE	18
12D - Body and Hand (exc shave)	143191	SODIUM OLEATE	1
12F - Moisturizing	143191	SODIUM OLEATE	21
12G - Night	143191	SODIUM OLEATE	11
12I - Skin Fresheners	143191	SODIUM OLEATE	1
12J - Other Skin Care Preps	143191	SODIUM OLEATE	1
01C - Other Baby Products	408355	SODIUM PALMITATE	1
02D - Other Bath Preparations	408355	SODIUM PALMITATE	2
10A - Bath Soaps and Detergents	408355	SODIUM PALMITATE	50
10B - Deodorants (underarm)	408355	SODIUM PALMITATE	23
10D - Feminine Deodorants	408355	SODIUM PALMITATE	1
10E - Other Personal Cleanliness Products	408355	SODIUM PALMITATE	9
11E - Shaving Cream	408355	SODIUM PALMITATE	4
11F - Shaving Soap	408355	SODIUM PALMITATE	4
12A - Cleansing	408355	SODIUM PALMITATE	20
12F - Moisturizing	408355	SODIUM PALMITATE	4
12J - Other Skin Care Preps	408355	SODIUM PALMITATE	1
03B - Eyeliner	822162	SODIUM STEARATE	1
03C - Eye Shadow	822162	SODIUM STEARATE	3
03D - Eye Lotion	822162	SODIUM STEARATE	3
03F - Mascara	822162	SODIUM STEARATE	1
03G - Other Eye Makeup Preparations	822162	SODIUM STEARATE	6
05F - Shampoos (non-coloring)	822162	SODIUM STEARATE	1
05G - Tonics, Dressings, and Other Hair Grooming Aids	822162	SODIUM STEARATE	1
05I - Other Hair Preparations	822162	SODIUM STEARATE	2
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	822162	SODIUM STEARATE	11
06F - Hair Lighteners with Color	822162	SODIUM STEARATE	5
06G - Hair Bleaches	822162	SODIUM STEARATE	16
06H - Other Hair Coloring	822162	SODIUM STEARATE	2

Preparation			
07B - Face Powders	822162	SODIUM STEARATE	1
07C - Foundations	822162	SODIUM STEARATE	12
07D - Leg and Body Paints	822162	SODIUM STEARATE	6
07E - Lipstick	822162	SODIUM STEARATE	1
07I - Other Makeup Preparations	822162	SODIUM STEARATE	6
10A - Bath Soaps and Detergents	822162	SODIUM STEARATE	104
10B - Deodorants (underarm)	822162	SODIUM STEARATE	230
10E - Other Personal Cleanliness Products	822162	SODIUM STEARATE	16
11E - Shaving Cream	822162	SODIUM STEARATE	4
11F - Shaving Soap	822162	SODIUM STEARATE	12
11G - Other Shaving Preparation Products	822162	SODIUM STEARATE	2
12A - Cleansing	822162	SODIUM STEARATE	33
12C - Face and Neck (exc shave)	822162	SODIUM STEARATE	23
12D - Body and Hand (exc shave)	822162	SODIUM STEARATE	9
12F - Moisturizing	822162	SODIUM STEARATE	25
12G - Night	822162	SODIUM STEARATE	4
12H - Paste Masks (mud packs)	822162	SODIUM STEARATE	5
12J - Other Skin Care Preps	822162	SODIUM STEARATE	18
13A - Suntan Gels, Creams, and Liquids	822162	SODIUM STEARATE	1
13B - Indoor Tanning Preparations	822162	SODIUM STEARATE	2
01C - Other Baby Products	8052480	SODIUM TALLOWATE	2
10A - Bath Soaps and Detergents	8052480	SODIUM TALLOWATE	92
10E - Other Personal Cleanliness Products	8052480	SODIUM TALLOWATE	10
11A - Aftershave Lotion	8052480	SODIUM TALLOWATE	1
11E - Shaving Cream	8052480	SODIUM TALLOWATE	2
11F - Shaving Soap	8052480	SODIUM TALLOWATE	2
11G - Other Shaving Preparation Products	8052480	SODIUM TALLOWATE	1
12A - Cleansing	8052480	SODIUM TALLOWATE	10
12C - Face and Neck (exc shave)	8052480	SODIUM TALLOWATE	1
12D - Body and Hand (exc shave)	3398332	SODIUM UNDECYLENATE	1
01B - Baby Lotions, Oils, Powders, and Creams	57114	STEARIC ACID	29
01C - Other Baby Products	57114	STEARIC ACID	2
02A - Bath Oils, Tablets, and Salts	57114	STEARIC ACID	4

02B - Bubble Baths	57114	STEARIC ACID	2
02D - Other Bath Preparations	57114	STEARIC ACID	1
03A - Eyebrow Pencil	57114	STEARIC ACID	40
03B - Eyeliner	57114	STEARIC ACID	83
03C - Eye Shadow	57114	STEARIC ACID	47
03D - Eye Lotion	57114	STEARIC ACID	87
03F - Mascara	57114	STEARIC ACID	457
03G - Other Eye Makeup Preparations	57114	STEARIC ACID	59
04A - Cologne and Toilet waters	57114	STEARIC ACID	1
04E - Other Fragrance Preparation	57114	STEARIC ACID	3
05A - Hair Conditioner	57114	STEARIC ACID	33
05C - Hair Straighteners	57114	STEARIC ACID	4
05E - Rinses (non-coloring)	57114	STEARIC ACID	1
05F - Shampoos (non-coloring)	57114	STEARIC ACID	30
05G - Tonics, Dressings, and Other Hair Grooming Aids	57114	STEARIC ACID	54
05I - Other Hair Preparations	57114	STEARIC ACID	20
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	57114	STEARIC ACID	105
06B - Hair Tints	57114	STEARIC ACID	131
06C - Hair Rinses (coloring)	57114	STEARIC ACID	1
06D - Hair Shampoos (coloring)	57114	STEARIC ACID	4
06F - Hair Lighteners with Color	57114	STEARIC ACID	1
06G - Hair Bleaches	57114	STEARIC ACID	2
06H - Other Hair Coloring Preparation	57114	STEARIC ACID	11
07A - Blushers (all types)	57114	STEARIC ACID	14
07B - Face Powders	57114	STEARIC ACID	26
07C - Foundations	57114	STEARIC ACID	142
07D - Leg and Body Paints	57114	STEARIC ACID	14
07E - Lipstick	57114	STEARIC ACID	102
07F - Makeup Bases	57114	STEARIC ACID	25
07G - Rouges	57114	STEARIC ACID	1
07H - Makeup Fixatives	57114	STEARIC ACID	4
07I - Other Makeup Preparations	57114	STEARIC ACID	37
08B - Cuticle Softeners	57114	STEARIC ACID	4
08C - Nail Creams and Lotions	57114	STEARIC ACID	4
08G - Other Manicuring Preparations	57114	STEARIC ACID	1
10A - Bath Soaps and Detergents	57114	STEARIC ACID	137
10B - Deodorants (underarm)	57114	STEARIC ACID	60

10E - Other Personal Cleanliness Products	57114	STEARIC ACID	90
11A - Aftershave Lotion	57114	STEARIC ACID	45
11D - Preshave Lotions (all types)	57114	STEARIC ACID	1
11E - Shaving Cream	57114	STEARIC ACID	94
11F - Shaving Soap	57114	STEARIC ACID	11
11G - Other Shaving Preparation Products	57114	STEARIC ACID	45
12A - Cleansing	57114	STEARIC ACID	375
12B - Depilatories	57114	STEARIC ACID	2
12C - Face and Neck (exc shave)	57114	STEARIC ACID	393
12D - Body and Hand (exc shave)	57114	STEARIC ACID	851
12E - Foot Powders and Sprays	57114	STEARIC ACID	7
12F - Moisturizing	57114	STEARIC ACID	2125
12G - Night	57114	STEARIC ACID	114
12H - Paste Masks (mud packs)	57114	STEARIC ACID	82
12I - Skin Fresheners	57114	STEARIC ACID	4
12J - Other Skin Care Preps	57114	STEARIC ACID	205
13A - Suntan Gels, Creams, and Liquids	57114	STEARIC ACID	11
13B - Indoor Tanning Preparations	57114	STEARIC ACID	20
13C - Other Suntan Preparations	57114	STEARIC ACID	7
05A - Hair Conditioner	999001624	TRILINOLEIC ACID	1
05G - Tonics, Dressings, and Other Hair Grooming Aids	999001624	TRILINOLEIC ACID	3
12F - Moisturizing	112389	UNDECYLENIC ACID	1



Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review (CIR)

FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: November 26, 2018

SUBJECT: Draft Report: Safety Assessment of Fatty Acids and Salts as Used in Cosmetics
(draft prepared for the December 3-4, 2018 CIR Expert Panel Meeting)

The Council respectfully submits the following comments on the draft report, Safety Assessment of Fatty Acids and Salts as Used in Cosmetics.

Key Issue

The Introduction of the report incorrectly states that the conclusion for Arachidonic Acid has "changed". Section 46 of the CIR procedures is titled "Classification of Ingredients Determined to Have Insufficient Data or Information". The CIR Expert Panel conclusion of insufficient data for Arachidonic Acid has not changed. According to CIR procedures, after 2 years the insufficient data conclusion was "classified" as "Use Not Supported by the Data and Information Submitted to CIR." Please use language consistent with the CIR procedures.

Additional Considerations

Method of Manufacturing - Including the information that Linoleic Acid is essential in mammalian skin in the Method of Manufacture section is not appropriate. Linoleic Acid is considered to be "essential" to mammals because it is not synthesized in mammals and must be obtained in the diet.

Method of Manufacturing, Oleic Acid old report summary - The word "oil" needs to be added after "olive".

Cosmetic Use - The NICNAS hazard assessment does not belong in the Cosmetic Use section.

Penetration Enhancement - Please state the concentration/dose of Oleic Acid and Sodium Caprate that were used in the penetration enhancement studies.

Short-Term and Subchronic; Summary - Please correct the spelling of "forestomaches" (last e should be deleted)

DART, Hydroxystearic Acid old report summary - Please state the gestation days of treatment used in the dermal teratogenicity studies of the two antiperspirant prototype formulations.

Genotoxicity, Magnesium Stearate old report summary - Please include the concentrations tested.
Other Relevant Studies, old report summaries - Please include the concentrations tested (Oleic Acid and Hydroxystearic Acid).

Dermal Irritation and Sensitization; Summary - Please correct "corrosive human epidermis models"

Dermal Irritation and Sensitization, Lauric Acid et al., old report summary - 35-65% should be called "concentrations" not "doses"

Dermal Irritation and Sensitization, Aluminum Distearate et al., old report summary - To be consistent with the other old report summaries, a reference needs to be added to this summary.

Dermal Irritation and Sensitization, Isostearic Acid, old report summary - What were the concentrations of Isostearic Acid in the formulations that were tested?

Phototoxicity and Photosensitization, old report summaries - References need to be added to these summaries.

Ocular Irritation, Aluminum Distearate et al., old report summary - A reference needs to be added to this summary.

Summary - Please correct: "fatty acids ingredients"

Table 3 - The meaning of "as lipid number" in the heading of the second column is not clear.
The second number represents the number of double bonds.



Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review (CIR)

FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: January 22, 2019

SUBJECT: Tentative Report: Safety Assessment of Fatty Acids & Fatty Acid Salts as Used in Cosmetics (release date: January 4, 2019)

The Council respectfully submits the following comments on the tentative report, Safety Assessment of Fatty Acids & Fatty Acid Salts as Used in Cosmetics.

Key Issues

Although it is currently stated in the Short-Term and Subchronic Toxicity section, it should be made clear throughout the report that conjugated linoleic acid (CLA) is a technical name for Isomerized Safflower Acid. Perhaps this information can be added to Table 1. In addition, it should be stated in the non-cosmetic use section that CLA is a dietary supplement and that according to this article from the University of Wisconsin, <https://news.wisc.edu/cla-approved-as-food-ingredient/> CLA received a GRAS determination from FDA in 2008.

Short-Term and Subchronic - The duration of the study on conjugated linoleic acid (INCI: Isomerized Safflower Oil) is not stated in the Short-Term and Subchronic Toxicity section. Table 11 indicates that this study is an 18-month dietary study. Based on the CIR report outline at <https://www.cir-safety.org/sites/default/files/CIR%20Report%20Format%20Outline.pdf> chronic studies are considered to be ≥ 6 months in duration. Therefore, this study should be moved to the Chronic section.

Additional Considerations

Non-Cosmetic Use - Fatty acids should be called components of dietary fats, rather than dietary fats. The NICNAS determinations do not describe how the ingredients are used. They do not belong in the Non-Cosmetic Use section.

Penetration Enhancement - What were the results of the study of Oleic Acid as a penetration enhancer?

DART - Which 9 days of gestation were rats treated with Caprylic Acid?

Dermal Irritation and Sensitization, Summary - The concentrations at which these ingredients are non-irritating are more important than knowing that they were irritating or corrosive at concentrations "up to 100%". For example, one *in vitro* study found Caproic Acid to be non-corrosive at 50% and 60%, while it was corrosive at 70%. If available, the EC₃ values for the LLNAs should be included in the text.

Dermal Irritation and Sensitization, Lauric Acid et al. old report summary - What species was used in the short-term repeated patch tests of Oleic and Myristic Acids?

Summary - As reported in the Acute section and Table 10, the dermal LD₅₀ values should be reported as "greater than 2000 mg/kg bw" rather than "200 mg/kg/bw", as stated in the Summary.

The 18-month study of conjugated linoleic acid (INCI: Isomerized Safflower Acid) should be added to the Summary.

Some indication of the doses used in the developmental and reproductive toxicity studies should be included in the Summary.

Table 1, Trilinoleic Acid - Please correct "tirmerization"

Table 8 - This table would be easier to read if it was presented in two columns: Ingredients and CFR Citations.

Table 9 - Please add column headings to this table. Isomerized Safflower Acid as conjugated linoleic acid (CLA) should be added to this table for use in dietary supplements (see <https://ods.od.nih.gov/factsheets/WeightLoss-Consumer/>).

Table 10 - Please review the last study (on Undecylenic Acid) in this table. The ECHA summary indicates that there were 3-12 mice (number per sex not stated) per dose group (not 3-12 male and 3-12 females as stated in Table 10). Please make it clear that the 0.034-0.29 g doses were the doses per mouse. Rather than dose/mouse the LD₅₀ is stated as mg/kg bw.

Table 11 - It should be made clear in the table that conjugated linoleic acid corresponds to the INCI name Isomerized Safflower Acid.

Table 14 - What is "Wistar rat disks"? If this is skin, was it full-thickness?

Rather than "mammary tissue" reference 62 likely studied skin from breast reduction surgery as the title of reference 62 is "Skin corrosivity potential of fatty acids...". If they actually studied "mammary tissue" the study does not belong in a table concerning dermal irritation and sensitization.

Please correct: "2aniamls" (reference 25) and "concentration not reports" (reference 31)

Table 15 - If available, please include more details about methods used in the *in vitro* studies, e.g., OECD TG number or dose volume and duration.