

Safety Assessment of Alkyl Esters as Used in Cosmetics

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International Journal of Toxicology
2015, Vol. 34(Supplement 2) 5S-69S
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DOI: 10.1177/1091581815594027
ijt.sagepub.com



Abstract

The Cosmetic Ingredient Review Expert Panel (Panel) assessed the safety of 237 alkyl esters for use in cosmetics. The alkyl esters included in this assessment have a variety of reported functions in cosmetics, with skin-conditioning agent being the most common function. The Panel reviewed available animal and clinical data in making its determination of safety on these ingredients, and where there were data gaps, similarity in structure, properties, functions, and uses of these ingredients allowed for extrapolation of the available toxicological data to assess the safety of the entire group. The Panel concluded that these ingredients are safe in cosmetic formulations in the present practices of use and concentration when formulated to be nonirritating.

Keywords

alkyl esters, safety, cosmetics

Introduction

Cetyl esters is indicated in the *International Cosmetic Ingredient Dictionary and Handbook* as a synthetic wax composed of a mixture of esters of saturated fatty acids and fatty alcohols with carbon chain lengths between 14 and 18.¹ The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) reviewed this ingredient in 1997 and concluded that cetyl esters is safe as used in cosmetics.²

Cetyl esters is a constituent of a broader group of cosmetic ingredients, the alkyl esters, which consist of the reaction products of fatty acids and alcohols. The 237 alkyl esters being reviewed in this safety assessment are presented alphabetically in Table 1. Although 57 of these alkyl esters have been reviewed previously by the Panel, they are included because their structural and functional similarities allow for the grouping of all alkyl esters, thereby creating a complete family.

The conclusions reached for the previously reviewed ingredients (including cetyl esters), along with summaries of the data included in those existing safety assessments, are provided in Table 2.²⁻²² Only new data available for these alkyl esters are included in the text of this safety assessment to support the safety of this class of cosmetic ingredients.

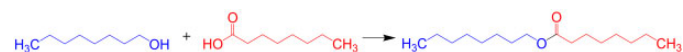
In addition, the Panel previously concluded that many of the individual constituents that make up the alkyl esters (ie, the alcohol and/or the acid), are safe as used in cosmetics. Because the safety of the individual constituents may be relevant to the safety of the ester, Table 3 indicates whether all, one, or none of the individual constituents of each alkyl esters have been found safe for use in cosmetics, and Table 4 provides the conclusions

previously reported for those individual components.^{4,8,9,11,12,17,23-35} Data on the individual constituents are available in the existing CIR safety assessments and are not summarized here; however, the reported maximum concentration of use is provided to reflect contextual constraints.

Chemistry

Definition and Structure

The ingredients in this review are alkyl esters. The core relationship between these ingredients is a carboxyl ester functional group flanked on both sides by extended alkyl chains. Some of these alkyl chains are saturated and some are unsaturated, and some of the chains are straight and some branched. Formal definitions for the ingredients included in this assessment are provided in Table 5.¹



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Table 1. Alkyl Esters Group (Presented Alphabetically).

Arachidyl behenate	Cetyl stearate ^a	Isobutyl myristate ^a	Lauryl isostearate
Arachidyl erucate	Cetyl tallowate	Isobutyl palmitate	Lauryl laurate
Arachidyl propionate ^a	Chimyl isostearate	Isobutyl perlargonate ^a	Lauryl myristate ^a
Batyl isostearate	Chimyl stearate	Isobutyl stearate ^a	Lauryl oleate
Batyl stearate	Coco-caprylate	Isobutyl tallowate	Lauryl palmitate
Behenyl beeswax	Coco-caprylate/caprinate	Isocetyl behenate	Lauryl stearate
Behenyl behenate	Coco-rapeseedate	Isocetyl isodecanoate	Lignoceryl erucate
Behenyl erucate	Decyl castorate	Isocetyl isostearate	Myristyl isostearate
Behenyl isostearate	Decyl cocoate ^a	Isocetyl laurate	Myristyl laurate
Behenyl olivate	Decyl isostearate	Isocetyl myristate	Myristyl myristate ^a
Behenyl/isostearyl beeswax	Decyl jojobate	Isocetyl palmitate	Myristyl neopentanoate
Butyl avocadate	Decyl laurate	Isocetyl stearate ^a	Myristyl stearate ^a
Butyl babassuate	Decyl myristate ^a	Isodecyl cocoate ^a	Octyldodecyl oleate
Butyl isostearate	Decyl oleate ^a	Isodecyl hydroxystearate	Octyldodecyl avocadate
Butyl myristate ^a	Decyl palmitate	Isodecyl isononanoate ^a	Octyldodecyl beeswax
Butyl oleate	Decyltetradecyl cetearate	Isodecyl laurate	Octyldodecyl behenate
Butyl stearate ^a	Erucyl arachidate	Isodecyl myristate ^a	Octyldodecyl cocoate ^a
Butyloctyl beeswax	Erucyl erucate	Isodecyl neopentanoate	Octyldodecyl erucate
Butyloctyl behenate	Erucyl oleate	Isodecyl oleate ^a	Octyldodecyl hydroxystearate
Butyloctyl candelillate	Ethylhexyl adipate/palmitate/ stearate	Isodecyl palmitate	Octyldodecyl isostearate
Butyloctyl cetearate	Ethylhexyl C10-40 isoalkyl acidate	Isodecyl stearate	Octyldodecyl meadowfoamate
Butyloctyl oleate	Ethylhexyl cocoate ^a	Isohexyl caprate	Octyldodecyl myristate ^a
Butyloctyl palmitate	Ethylhexyl hydroxystearate	Isohexyl laurate	Octyldodecyl neodecanoate
C10-40 isoalkyl acid octyldodecanol esters	Ethylhexyl isononanoate ^a	Isohexyl neopentanoate	Octyldodecyl neopentanoate
C14-30 alkyl beeswax	Ethylhexyl isopalmitate	Isohexyl palmitate	Octyldodecyl octyldodecanoate
C16-36 alkyl stearate	Ethylhexyl isostearate	Isolauryl behenate	Octyldodecyl oleate
C18-38 alkyl beeswax	Ethylhexyl laurate	Isononyl isononanoate ^a	Octyldodecyl olivate
C18-38 alkyl C24-54 acid ester	Ethylhexyl myristate ^a	Isooctyl caprylate/caprinate	Octyldodecyl ricinoleate ^a
C20-40 alkyl behenate	Ethylhexyl neopentanoate	Isooctyl tallate	Octyldodecyl safflowerate
C20-40 alkyl stearate	Ethylhexyl oleate	Isopropyl arachidate	Octyldodecyl stearate
C30-50 alkyl beeswax	Ethylhexyl olivate	Isopropyl avocadate	Oleyl arachidate
C30-50 alkyl stearate	Ethylhexyl palmitate ^a	Isopropyl babassuate	Oleyl erucate
C32-36 isoalkyl stearate	Ethylhexyl pelargonate ^a	Isopropyl behenate	Oleyl linoleate
C40-60 alkyl stearate	Ethylhexyl stearate ^a	Isopropyl hydroxystearate	Oleyl myristate ^a
C4-5 isoalkyl cocoate	Heptyl undecylenate	Isopropyl isostearate ^a	Oleyl oleate
Caprylyl butyrate	Heptylundecyl hydroxystearate	Isopropyl jojobate	Oleyl stearate
Caprylyl caprylate	Hexyl isostearate	Isopropyl laurate	Propylheptyl caprylate
Caprylyl eicosenoate	Hexyl laurate	Isopropyl linoleate	Stearyl beeswax
Cetearyl behenate	Hexyldecyl hexyldecanoate	Isopropyl myristate ^a	Stearyl caprylate ^a
Cetearyl candelillate	Hexyldecyl isostearate	Isopropyl oleate	Stearyl behenate ^a
Cetearyl isononanoate ^a	Hexyldecyl laurate	Isopropyl palmitate ^a	Stearyl erucate
Cetearyl nonanoate ^a	Hexyldecyl oleate	Isopropyl ricinoleate ^a	Stearyl heptanoate ^a
Cetearyl olivate	Hexyldecyl palmitate	Isopropyl stearate ^a	Stearyl linoleate
Cetearyl palmate	Hexyldecyl stearate	Isopropyl tallowate	Stearyl olivate ^a
Cetearyl palmitate	Hexyldodecyl/octyldodecyl hydroxystearate	Isostearyl avocadate	Stearyl palmitate ^a
Cetearyl rice branate	Hydrogenated castor oil behenyl esters	Isostearyl behenate	Stearyl stearate ^a
Cetearyl stearate	Hydrogenated castor oil cetyl esters	Isostearyl erucate	Tetradecyleicosyl stearate
Cetyl babassuate	Hydrogenated castor oil stearyl esters	Isostearyl hydroxystearate	Tetradecyloctadecyl stearate
Cetyl behenate	Hydrogenated ethylhexyl olivate	Isostearyl isononanoate ^a	Tetradecylpropionates
Cetyl caprate	Hydrogenated ethylhexyl sesamate	Isostearyl isostearate	Tridecyl cocoate ^a
Cetyl caprylate	Hydrogenated isocetyl olivate	Isostearyl laurate	Tridecyl behenate
Cetyl dimethyloctanoate	Hydrogenated isopropyl jojobate	Isostearyl linoleate	Tridecyl erucate
Cetyl esters	Hydroxycetyl isostearate	Isostearyl myristate ^a	Tridecyl isononanoate ^a
Cetyl isononanoate ^a	Hydroxyoctacosanyl hydroxystearate	Isostearyl neopentanoate ^a	Tridecyl laurate
Cetyl laurate	Isoamyl laurate	Isostearyl palmitate	Tridecyl myristate ^a
Cetyl myristate ^a		Isotridecyl isononanoate ^a	Tridecyl neopentanoate
Cetyl myristoleate		Isotridecyl laurate	Tetradecyloctadecyl behenate
Cetyl oleate		Isotridecyl myristate ^a	Tetradecyloctadecyl hexyldecanoate
Cetyl palmitate ^a		Isotridecyl stearate	Tetradecyloctadecyl myristate ^a
Cetyl ricinoleate ^a		Lauryl behenate	Tridecyl stearate
		Lauryl cocoate ^a	

Abbreviation: CIR, Cosmetic Ingredient Review.

^aThe ingredient was reviewed previously by the CIR.

Table 2. Conclusions (Year Issued) and Data Summaries of Previously Reviewed Alkyl Esters.

Alkyl ester	Conclusion (year)	Summary data	Reference
Final report on the safety assessment of arachidyl propionate			
Arachidyl propionate	Safe as used (1990; reaffirmed 2008)	<ul style="list-style-type: none"> – The acute oral LD₅₀ in rats was >20 g/kg; up to 2500 mg/kg at concentrations of 25% in corn oil was not toxic in a 90-day oral study – The acute dermal LD₅₀ in rabbits was > 2 g/kg – Not a primary irritant to rabbit skin when tested undiluted, a formulation containing 7% was not irritating in a 24-hour SIOPT, and a 10% solution was nonirritating and undiluted test article was slightly irritating in a cumulative irritation test; not a sensitizer when injected undiluted test material and was not comedogenic when tested undiluted – Undiluted test material and a formulation containing 7% were not irritating to rabbit eyes 	3,4
Final report on the amended safety assessment of myristic acid and its salts and esters as used in cosmetics (2010)			
Final report on the safety assessment of butyl myristate (1990)			
Butyl myristate	Safe as used (1990; 2010)	<ul style="list-style-type: none"> – <i>Discussion item:</i> data on myristic acid myristyl and isopropyl myristate were extrapolated and also used in the determination of safety (1990 report) – Was observed to enhance dermal penetration of some chemicals – The oral LD₅₀ in rats was >8 g/kg – A single application of 2 g/kg was nontoxic and nonirritating in rabbits – A 24-hour occlusive application of undiluted test material produced moderate irritation (PII = 2.88) in rabbits; a moderate irritant but not a sensitizer in guinea pigs when injected intradermally – Nonirritating to rabbit eyes 	5 5,22
Cetyl myristate	Safe as used (2010)	– No data were available	5
Decyl myristate	Safe as used (2010)	– No data were available	5
Ethylhexyl myristate	Safe as used (2010)	– No data were available	5
Isobutyl myristate	Safe as used (2010)	– No data were available	5
Isocetyl myristate	Safe as used (2010)	– No data were available	5
Isodecyl myristate	Safe as used (2010)	– No data were available	5
Isopropyl myristate	Safe as used (1982; 2010)	<ul style="list-style-type: none"> – In a study in which monkeys were exposed for 5 seconds to an aerosol antiperspirant containing an unspecified concentration of [¹⁴C]isopropyl myristate, the distribution in the exhaled air and in several tissues indicated only 0.25% of the sprayed dose was absorbed and about 10% of this reached the lower respiratory tract – The acute oral LD₅₀ was >16 mL/kg in rats and 49.7 mL/kg in mice – The acute dermal LD₅₀ in rabbits was 5 g/kg; dermal application of 2 g/kg a formulation containing 16%-20% in rabbits for 26 days (20 applications) did not produce signs of toxicity but did cause severe erythema and moderate edema and other dermal effects and microscopically marked to severe acanthosis and hyperkeratosis and mixed inflammatory cell infiltration; application of 2 mL/kg of a formulation containing 43%-47% in rabbits for 4 weeks (21 applications) produced erythema, edema, drying, cracking, and fissuring, but microscopic effects were only seen at the application site – 1-hour inhalation exposure to formulations containing 16%-20% (33-41 mg/L) and 4.7% (9.7 mg/L) did not produce any deaths or evidence of systemic toxicity in rats; in 13-week inhalation studies, a formulation containing 16%-20% was not toxic to guinea pigs (daily mean concentration of 63.3-224 mg/m³ air for three 1-hour exposures/d) but did produce coughing and wheezing in monkeys. Macrophage accumulations within the alveolar and bronchiolar walls were seen in the lungs in direct proportion to the dosage of the aerosol (5.3-37.0 mg/m³ in air) – A 50% solution in isopropyl alcohol significantly accelerated the carcinogenic activity of 0.15% benzo[a]pyrene on the skin of mice; no tumors were produced in mice by application of a 1% solution for 18 weeks; applications of 10%-100% to the backs of Swiss mice 2×/wk did not result in test article-related carcinogenic lesions – In Draize tests, undiluted test material and 15%-58% in formulations was at mostly minimally irritating to the skin of rabbits, however, application of undiluted test material for 3 days was moderately to severely irritating, produced comedogenic activity in rabbit ears 	5,6

(continued)

Table 2. (continued)

Alkyl ester	Conclusion (year)	Summary data	Reference
		<ul style="list-style-type: none"> – In human testing, undiluted test material was not irritating (15 subjects) and the highest PII with formulations containing 15%-58% was 0.1 (9%-50%) in primary irritation studies; in cumulative irritation studies, undiluted test material (25 subjects) and formulations containing 15%-58% (9-13 subjects) were minimally irritating; no sensitization was seen in maximization studies (20% in pet or –42.9% in formulation; 25 subjects) or RIPTs (15 and 52%-58%; 99 and 320 subjects); a formulation containing 42.9% was not phototoxic (10 subjects) or a photoallergen (25 subjects) – Undiluted material was minimally irritating to rabbit eyes and formulations containing 15%-58% were non- to mildly irritating – Not genotoxic in the <i>Salmonella</i>/microsome test 	
Isostearyl myristate	Safe as used (2010)	<ul style="list-style-type: none"> – Mixed results were seen regarding dermal penetration enhancement – In a study in which monkeys were exposed for 5 seconds to an aerosol antiperspirant containing test material, the distribution in the exhaled air and in several tissues indicated only 0.25% of the sprayed dose was absorbed and about 10% of this reached the lower respiratory tract – No other data were available 	5
Isotridecyl myristate	Safe as used (2010)	<ul style="list-style-type: none"> – No data were available 	5
Lauryl myristate	Safe as used (2010)	<ul style="list-style-type: none"> – No data were available 	5
Myristyl myristate	Safe as used (1982; 2010)	<ul style="list-style-type: none"> – The acute oral LD₅₀ in rats was >14.4 g/kg – The acute dermal LD₅₀ in rabbits was >2 g/kg – Undiluted test material was at most mildly irritating in rabbits, produced comedogenic activity in rabbit ears – In human studies, 8% in formulation was not an irritant (20 subjects) or sensitizer (196 subjects) – Undiluted material, 15%-50% in corn oil, and formulations containing 15%-58% were non- to minimally irritating in rabbit eyes 	5,6
Octyldodecyl myristate	Safe as used (2010)	<ul style="list-style-type: none"> – No data were available 	5
Oleyl myristate	Safe as used (2010)	<ul style="list-style-type: none"> – No data were available 	5
Tetradecyloctadecyl myristate	Safe as used (2010)	<ul style="list-style-type: none"> – No data were available 	5
Tridecyl myristate	Safe as used (2010)	<ul style="list-style-type: none"> – No data were available 	5
Final report on the safety assessment of butyl stearate, cetyl stearate, isobutyl stearate, isocetyl stearate, isopropyl stearate, myristyl stearate, and octyl stearate			
Butyl stearate	Safe as used (1985, reaffirmed 2005)	<ul style="list-style-type: none"> – The acute oral LD₅₀ in rats was >32 g/kg; in a 2-year feeding study in rats with up to 6000 mg/kg/d, no test article-related toxicity was observed – Dietary administration of 6.25% to male and female rats for 10 weeks prior to mating did not affect fertility, litter size, or neonate survival, but growth was decreased pre- and postweaning – Undiluted test material was at most moderately irritating (in one study) to rabbit skin (PIIs ranged from 0 to 2.75); 0.1% in physiological saline was not a sensitizer in 2 guinea pigs when tested using intracutaneous injections; 50% in mineral oil weakly comedogenic in rabbits in a 2-week study – In human testing, 24- and 48-hour occlusive patch testing with 2% in formulation resulted in PIIs of 0.03 and 0.11, respectively (number of subjects not specified); 50% in mineral oil was at most a mild irritant and was not a sensitizer in an RIPT (111 subjects); 10% in formulation was not an irritant, sensitizer, (54 subjects), or photosensitizer (10 subjects) – Undiluted test material was not irritating to rabbit eyes 	7,8
Cetyl stearate	Safe as used (1985, reaffirmed 2005)	<ul style="list-style-type: none"> – 50% in mineral oil was at most a mild irritant and was not a sensitizer in an RIPT (111 subjects), although sensitization was reported in 1 subject 	7,8
Ethylhexyl stearate (originally octyl stearate)	Safe as used (1985, reaffirmed 2005)	<ul style="list-style-type: none"> – The acute oral LD₅₀ in rats was >8 mL/kg – Undiluted test material was at most mildly irritating to rabbit skin (PIIs 0.0 and 1.42); in a 6-day cumulative skin irritation study, undiluted test material had a MIII of 0.67 and was poorly tolerated and a 10% aq solution had a MIII of 0.33 was relatively well tolerated 	7,8

(continued)

Table 2. (continued)

Alkyl ester	Conclusion (year)	Summary data	Reference
		<ul style="list-style-type: none"> – In human testing, a formulation containing 7.6% was not an irritant or sensitizer (56 subjects), not phototoxic (10 subjects), and not a photosensitizer (27 subjects), although some slight reactions were reported in the photosensitization study – Undiluted test material did not provoke any significant injury in rabbit eyes (max PII 4.67/100 at 1 hour) <p><i>Discussion item:</i> the Panel noted that the reproductive toxicity of 2-ethyl-1-hexanol was addressed in a fetotoxicity study (performed on diethylhexyl adipate); it was suggested that the fetotoxicity reported for mice in that study was actually due to a zinc deficiency and that given the extent of 2-ethyl-1-hexanol absorption and the load that would be expected to enter the hepatic circulation, the potential for 2-ethyl-1-hexanol-induced reproductive toxicity was not thought to be an issue</p>	
Isobutyl stearate	Safe as used (1985, reaffirmed 2005)	<ul style="list-style-type: none"> – Undiluted test material was mildly irritating to rabbit skin (PIIs = 0.62) in a 24-hour occlusive study – In human testing, a mild irritant and not a sensitizer when tested undiluted in an RIPT (149 subjects); 50% in mineral oil was not phototoxic or a photosensitizer (23 subjects) 	7.8
Isocetyl stearate	Safe as used (1985, reaffirmed 2005)	<ul style="list-style-type: none"> – No data were available 	7.8
Isopropyl stearate	Safe as used (1985, reaffirmed 2005)	<ul style="list-style-type: none"> – Maximum reported use concentration was up to 25% in a leave-on formulation – The acute oral LD₅₀ in rats was >8 mL/kg – Undiluted test material was moderately irritating to rabbit skin (PIIs 2.35 in 2 studies) – In human testing, 1.0% in formulation was non- (105 subjects) to slightly irritating (12 subjects) and produced no adverse reactions in a 4-week use test (40 subjects) – Undiluted test material was not irritating to rabbit eyes 	7.8
Myristyl stearate	Safe as used (1985, reaffirmed 2005)	<ul style="list-style-type: none"> – Maximum reported use concentration was up to 5% in a leave-on formulation – The acute oral LD₅₀ in mice was >10 g/kg with corn oil and >1 g/kg neat – Undiluted test material was not irritating to rabbit skin (PII = 0.0) – In human testing, formulations containing 2.35%-9.8% produced no skin reactions in open and closed patch tests 22-100 subjects/test) – Undiluted test material produced slight vessel injection involving only the conjunctivae at 24 hours and no irritation was observed on days 2-7 	7.8
Final report on the safety assessment of pelargonic acid (aka nonanoic acid) and the nonanoate esters			
		<p><i>Discussion items:</i> Because of the skin penetration enhancement property of pelargonic acid in the presence of <i>p</i>-aminobenzoic acid, care should be taken in formulating products containing this ingredient in combination with any ingredients whose safety was based on lack of dermal absorption or when dermal absorption was a concern; because animal sources have been reported, this ingredient must be free of detectable pathogenic viruses or infectious agents</p>	9
Cetearyl isononanoate	Safe as used (2010)	<ul style="list-style-type: none"> – The oral LD₅₀ in mice was >5 g/kg; in an oral study in which rats were dosed with 100, 300, or 1000 mg/kg, reversible fatty alterations were induced in the liver of female mid dose and male and female high-dose animals and the NOAEL was 100 mg/kg/d – Not a reproductive toxicant in a study in which 100-1000 mg/kg was administered orally to gravid rats on days 6-15 of gestation, and the NOAEL for maternal and embryo-/fetotoxicity was 100 mg/kg – Not mutagenic in an Ames test at doses up to 5000 µg/plate with or without metabolic activation – Slightly irritating to the skin of hairless mice and not irritating to rabbit skin; not a sensitizer in guinea pigs (25% injected intracutaneously at induction and challenge); 10%-100% was not comedogenic in rabbit ears 	9

(continued)

Table 2. (continued)

Alkyl ester	Conclusion (year)	Summary data	Reference
Cetearyl nonanoate	Safe as used (2010)	<ul style="list-style-type: none"> – In human testing, 20% active and undiluted test material had very good skin compatibility in a 24-hour SIOPT (21 subjects); a formulation containing 1.5% was not a contact allergen in a maximization test (25 subjects) and undiluted test material was not an irritant or sensitizer in a provocative RIPT (20 eczema patients) – 10% active was not irritating to rabbit eyes – The oral LD₅₀ in rats was 2 g/kg – The acute dermal LD₅₀ in rats was >2 g/kg, and there was no dermal irritation observed – Undiluted test material (97% pure) was nonirritating to rabbit skin; not a sensitizer in a GPMT (10% for intracutaneous induction, 50% for topical induction, 10% at challenge, sesame oil was the vehicle) – Not mutagenic in an Ames test at doses up to 5000 µg/plate with or without metabolic activation – In human testing, undiluted test material (97% pure) was not an irritant in a 48-hour SIOPT (52 subjects); undiluted test material was not an irritant or a sensitizer in an RIPT (106 subjects) – Undiluted test material was minimally irritating to rabbit eyes 	9
Cetyl isononanoate	Safe as used (2010)	<ul style="list-style-type: none"> – No data were available 	9
Ethylhexyl isononanoate	Safe as used (2010)	<ul style="list-style-type: none"> – Not mutagenic in an Ames test at doses up to 5000 µg/plate with or without metabolic activation – In human testing, undiluted test material did not indicate potential for allergic contact sensitization in an RIPT (10 subjects) 	9
Ethylhexyl pelargonate	Safe as used (2010)	<ul style="list-style-type: none"> – The acute oral LD₅₀ in rats was >5 g/kg – Undiluted test material was not irritating to rabbit skin (PII = 0.40) – Undiluted test material was not irritating to rabbit eyes 	9
Isobutyl pelargonate	Safe as used (2010)	<ul style="list-style-type: none"> – No data were available 	9
Isodecyl isononanoate	Safe as used (2010)	<ul style="list-style-type: none"> – In human testing, a formulation containing 51.35% was not an irritant or sensitizer in an RIPT (101 subjects) and a formulation containing 2.6% was not a contact allergen in a maximization test (26 subjects) 	9
Isononyl isononanoate	Safe as used (2010)	<ul style="list-style-type: none"> – The acute oral LD₅₀ in rats was >5 g/kg; 300 and 1000 mg/kg/d induced mortality and all doses (100-1000mg/kg/d) induced liver and kidney toxicity in a 4-week oral study in rats – 300 mg/kg/d (2 weeks) and 860 mg/kg/d (8 days) induced liver and adrenal gland toxicity in a dermal study in rats – Not embryotoxic or fetotoxic in rats dosed by gavage with 300 mg/kg/d on days 6-17 postcoitum – Not mutagenic in an Ames test at doses up to 5000 µg/plate with or without metabolic activation – Slightly irritating to rabbit skin (study details not provided) – In human testing, lipstick formulations containing 3.552% (53 subjects) and 3.128% (97 subjects) were not irritants or sensitizers in RIPTs and a formulation containing 24.66% was not a contact allergen in a maximization test (26 subjects) – Not irritating to rabbit eyes (concentration tested was not stated) 	9
Isostearyl isononanoate	Safe as used (2010)	<ul style="list-style-type: none"> – No data were available 	9
Isotridecyl isononanoate	Safe as used (2010)	<ul style="list-style-type: none"> – In human testing, a formulation containing 4.3% was not a contact allergen in a maximization test (28 subjects) 	9
Tridecyl isononanoate	Safe as used (2010)	<ul style="list-style-type: none"> – No data were available 	9
Final report on the safety assessment of cetyl esters			
Cetyl esters	Safe as used (1997)	<ul style="list-style-type: none"> – (Synonymous with synthetic spermaceti wax) a commercial cetyl esters preparation comprised of a mixture of one or more of the following esters: cetyl palmitate, myristyl myristate, cetyl stearate, myristyl stearate, cetyl myristate, and stearyl stearate – The oral LD₅₀ in mice of a formulation containing 60%-65% was >20 g/kg – A formulation containing 60%-65% was not irritating to rabbit skin in a 24-hour SIOPT 	2

(continued)

Table 2. (continued)

Alkyl ester	Conclusion (year)	Summary data	Reference
		<ul style="list-style-type: none"> – A formulation containing 60%-65% was not an irritant to rabbit eyes <p><i>Discussion item:</i> data from the safety assessments on cetyl palmitate, myristyl myristate, cetyl stearate, and myristyl stearate were extrapolated to determine safety</p>	
Final report on the safety assessment of octyl palmitate, cetyl palmitate, and isopropyl palmitate			
Cetyl palmitate	Safe as used (1982; reaffirmed in 2005)	<ul style="list-style-type: none"> – Was quantitatively excreted in the feces of male rats when fed at 20% in the diet – Acute oral LD₅₀ was > 14.4 g/kg in rats; not toxic in a 9-day dietary study in rats – No mortality was observed when a 50% slurry was applied to rabbit skin under an occlusive patch – Was at most mildly irritating in rabbits when applied undiluted or in formulation (2.5%-2.7%) under occlusion; a 1% suspension produced minimal irritation and was not sensitizing in the Landsteiner and Jacobs test in guinea pigs – In humans, a formulation containing 2.7% was not a primary irritant (10 subjects); in maximization studies, a formulation containing 2.5% was classified as a weak potential sensitizer that was unlikely to present a risk of contact sensitization under conditions of normal use (50 subjects) and one containing 2.7% was classified as a weak potential sensitizer of the lowest grade (25 subjects); a formulation containing 2.7% was not phototoxic (10 subjects) or photoallergenic (25 subjects); low irritation potential was observed in in-use studies (28-56 days; 30-100 subjects per study) – Minimally irritating to rabbit eyes; Oils ranged from 0.3 to 6.7 for undiluted test material and 0.0 for a 5% (w/w) dispersion 	8,10
Ethylhexyl palmitate (originally, octyl palmitate)	Safe as used (1982; reaffirmed in 2005)	<ul style="list-style-type: none"> – The acute oral LD₅₀ was >64 mL/kg in rats – The acute dermal LD₅₀ was >9.4 mL/kg in rabbits (only 2 rabbits in each group); dermal toxicity was not observed in a 6-week dermal study with undiluted material; undiluted test material was “poorly tolerated” in a 60-day study with “congestive dermatitis” in 2/3 rabbits – Was a mild irritant tested undiluted in an SIOPT in rabbits; 0.1% suspensions were not sensitizers in the Landsteiner and Jacobs test in guinea pigs – In human studies, 3 formulations containing 1%-5% and one containing 40%-50% tested in 48-hour occlusive tests with 100 subjects and 3 formulations containing 45.72%-46.52% tested in an 18-day occlusive RIPT with 20 subjects were not irritants, and in a 21-day occlusive RIPT, a formulations containing 42.25% resulted in signs of irritation in 7/24 subjects and the avg. cumulative irritation score was 2.58/84 – Oils for undiluted test material ranged from 0.33 to 4.17 in 3 Draize studies, indicating that it did not cause significant injury to rabbit eyes 	8,10
Isopropyl palmitate	Safe as used (1982; reaffirmed in 2005)	<ul style="list-style-type: none"> – The acute oral LD₅₀ was >64 mL/kg in rats – The dermal LD₅₀ was >2.0 mL/kg in rabbits – No inhalation toxicity in rats exposed to 200 mg/L for 1 hour – Undiluted test material was nonirritating to slightly irritating to rabbit skin – In human testing, in 3 studies with 24-hour occlusive patches with undiluted test material performed in a total of 160 subjects, there were 5 irritation scores of 0.5/4, and the remainder was 0/4 and in a 10-day primary irritation study, a formulation containing 45.6% was not irritating in 10 subjects; not a sensitizer when tested undiluted in an RIPT with 102 subjects or in formulation at 45.6% in a maximization test with 25 subjects; a formulation containing 45.6% was not phototoxic (10 subjects) or photoallergenic (25 subjects) – Oils ranged from 0.0 to 6.5 in 5 Draize studies, indicating that it did not cause significant injury to rabbit eyes 	8,10
Final report on the safety assessment of <i>Ricinus communis</i> (castor) seed oil, hydrogenated castor oil, glyceryl ricinoleate, glyceryl ricinoleate se, ricinoleic acid, potassium ricinoleate, sodium ricinoleate, zinc ricinoleate, cetyl ricinoleate, ethyl ricinoleate, glycol ricinoleate, isopropyl ricinoleate, methyl ricinoleate, and octyldodecyl ricinoleate			
<p><i>Discussion item:</i> safety test data on <i>Ricinus communis</i> (castor) seed oil, which contains ricinoleic acid (and for which data were included), were considered applicable for extrapolation to determine safety; retrospective study reports</p>			

(continued)

Table 2. (continued)

Alkyl ester	Conclusion (year)	Summary data	Reference
		of sensitization reactions to ricinoleic acid in patients with eczematous cheilitis were determined to be expected in that patient group but not the general population, and based on the Panel's expertise and experience, the incidence of positive reactions to ricinoleic acid was very low	
Cetyl ricinoleate	Safe as used (2007)	– The acute oral LD ₅₀ in mice was >2 g/kg – Not irritating to rabbit skin (test concentration not stated)	11
Isopropyl ricinoleate	Safe as used (2007)	– No specific safety data were available	11
Octyldodecyl ricinoleate	Safe as used (2007)	– No specific safety data were available	11
Final report on the safety assessment of <i>Cocos nucifera</i> (coconut) oil and related ingredients			
		<i>Discussion items:</i> because there is no reason to expect the toxicity to differ from that of coconut oil, coconut acid, hydrogenated coconut oil, and hydrogenated coconut acid and therefore the data available on these ingredients are supportive of safety; necessary procedures should be continued by the cosmetics industry to limit pesticide residues and heavy metals	
Decyl cocoate	Safe as used (2011)	– No data were available	12
Ethylhexyl cocoate	Safe as used (2011)	– No data were available	12
Isodecyl cocoate	Safe as used (2011)	– No data were available	12
Lauryl cocoate	Safe as used (2011)	– No data were available	12
Octyldodecyl cocoate	Safe as used (2011)	– No data were available	12
Tridecyl cocoate	Safe as used (2011)	– No data were available	12
Final report on the safety assessment of decyl and isodecyl oleates			
Decyl oleate	Safe as used (1982; reaffirmed in 2003)	– The acute oral LD ₅₀ was > 40 mL/kg and >5 g/kg in rats – In a primary dermal irritation study using rabbits, the PIs for a 10% solution in corn oil, 20% solution in mineral oil, and undiluted test material were 0.08, 0.05, and 0.28, respectively, and in a modified Draize test, a 15% solution in polyoxyethylene sorbitan stearate (3%), preservative (2%), and water and undiluted test material were nonirritating; in an 8-week study in rabbits, daily application of the 15% solution produced some papulae or vesicles but was generally well tolerated and the undiluted material resulted in skin thickening in 3 rabbits (total tested not stated) and vesicles in 1 rabbit and was poorly tolerated; a 15% solution in corn oil was not a sensitizer in the Landsteiner and Jacobs test in guinea pigs – In human testing, no sensitization was reported in an RIPT in 103 subjects with a formulation containing 1%-5% or in 402 subjects with 4 formulations containing 5.5%	13,14
Isodecyl oleate	Safe as used (1982; reaffirmed in 2003)	– At most, a very slight irritant to rabbit eyes when tested undiluted – The acute LD ₅₀ was > 40 mL/kg in rats – Undiluted test material had a PII of 1.0 in 3 rabbits, but subsequent testing reported a PII of 0.28 and additional studies with a 15% solution in polyoxyethylene sorbitan stearate (3%), preservative (2%), and water indicated the material was nonirritating (PII scores of 0.0 and 0.13 for the undiluted material and 0.0 for the 15% solution); in an 8-week study in rabbits, daily application of the 15% solution produced episodic macules, papulae, and vesicles but was relatively well tolerated and the undiluted material was poorly tolerated with congestive dermis effects; a 15% solution in corn oil was not a sensitizer in the Landsteiner and Jacobs test in guinea pigs – In humans, undiluted test material was not an irritant in an SIOPT in 19 subjects and in a 21-day cumulative irritancy test in 9 subjects with undiluted material, the irritation score was 1.0/756 – At most, a very slight irritant to rabbit eyes when tested undiluted	13,14
Final report on the safety assessment of isopropyl isostearate			
Isopropyl isostearate	Safe as used (1992, reaffirmed in 2011)	– Undiluted test material was a nonirritant (PII = 0.42) in rabbit skin 24 and 72 hours after application, and in an 8-week study, a 10% aq solution was relatively well tolerated (IIMM = 2.00) but the undiluted material was poorly	15,16

(continued)

Table 2. (continued)

Alkyl ester	Conclusion (year)	Summary data	Reference
		<p>tolerated (IIMM = 3.34) and discontinued after 5 weeks; undiluted test material induced severe comedones in rabbit ears</p> <p>– 10% aq and undiluted test material were slight ocular irritants in rabbit eyes</p> <p><i>Discussion item:</i> because limited toxicological data (dermal irritation, ocular irritation, and comedogenicity data) were available, the Panel used data on similar isopropyl esters that had already been reviewed and found safe to determine safety</p>	
Final report on the safety assessment of isopropyl linoleate			
Isopropyl linoleate	Insufficient to support safety (1992)	<p>– The oral LD₅₀ in rats of 10% in corn oil was >64 cm³/kg</p> <p>– 10% aq and undiluted test material were classified as slightly irritant and nonirritant, respectively, in primary irritation studies in rabbits; both 10% aq and undiluted test materials were slight irritants when the study was repeated with purer samples; in another primary skin irritation study, 10% in corn oil did not product any irritation reactions in albino rabbits</p> <p>– 10% aq and undiluted test material were slight ocular irritants, while 10% in corn oil was not irritating to rabbit eyes</p> <p><i>Discussion item:</i> human irritation and sensitization data and genotoxicity data were needed</p>	20
Final report on the safety assessment of isostearyl neopentanoate			
Isostearyl neopentanoate	Safe as used (1985, reaffirmed in 2006)	<p>– The acute oral LD₅₀ was >40 mL/kg in rats; in a 93 day study, oral administration of undiluted test material in rats was safe in terms of cumulative systemic toxicity</p> <p>– Undiluted test material applied under a 24-hour patch was not irritating to rabbit skin and formulations containing 1.2%-32% was a most mildly irritating in rabbits; not considered a sensitizer in a GPMT (observations were attributed to scratches) and not a sensitizer in the Landsteiner and Jacobs test in guinea pigs; a formulation containing 3% was a mild primary skin irritant but was not phototoxic; 50% in mineral oil was marginally comedogenic and undiluted was noncomedogenic in rabbit ears</p> <p>– In human testing, was nonirritating in a 48-hour SIOPT when tested undiluted or in formulations containing 3%-5% (10 or 100 subjects), 4% in formulation (20 subjects) was minimally irritating (PII = 0.08) and 1.2% in formulation was nonirritating (20 subjects) in a 24-hour SIOPT, a formulation containing 3% was mildly irritating in a 21-day study (15 subjects); undiluted test material and formulations containing 5%-32% were not sensitizers in RIPT studies (52-210 subjects per study), although some irritation was reported; a formulation containing 16.05% was not phototoxic or a photoallergen in 27 subjects</p> <p>– Undiluted test material was minimally irritating in rabbit eyes and formulations containing 1.2%-36% were at most minimally irritating</p> <p><i>Discussion items:</i> because of the skin penetration enhancement property of pelargonic acid in the presence of <i>p</i>-aminobenzoic acid, care should be taken in formulating products containing this ingredient in combination with any ingredients whose safety was based on lack of dermal absorption or when dermal absorption was a concern</p>	17,21
Final report on stearyl heptanoate and related stearyl alkanooates as used in cosmetics			
Final report on the safety assessment of stearyl heptanoate			
		<p><i>Discussion items:</i> data from the original review on stearyl heptanoate were applicable to determine safety, including extrapolated data on stearyl alcohol and heptanoic acid</p>	18
Stearyl behenate	Safe as used (2010)	– No data were available	18
Stearyl caprylate	Safe as used (2010)	– No data were available	18
Stearyl heptanoate	Safe as used (1995, reaffirmed 2010)	<p>– The oral LD₅₀ in rats was >16 mL/kg</p> <p>– A mixture that also contained stearyl caprylate was not mutagenic in an Ames test with or without metabolic activation and had no clastogenic effect in an in vivo micronucleus test in which mice were given a single oral dose of 500-1500 mg/kg in corn oil</p>	18,19

(continued)

Table 2. (continued)

Alkyl ester	Conclusion (year)	Summary data	Reference
		<ul style="list-style-type: none"> – Undiluted test material was mildly irritating to rabbit skin (PII = 1.21/8); a formulation containing 1.5% was not a sensitizer in guinea pigs; a formulation containing 1.5% produced slight to moderate comedogenicity in rabbit ears – In human testing, cosmetic formulations containing 0.7% (198 subjects) and 1.5% (156, 194, and 202 subjects) were not sensitizers in RIPTs – Undiluted test material was a category 3 ocular irritant in rabbit eyes and a formulation containing 1.5% was not a primary ocular irritant <p><i>Discussion items:</i> although irritation testing was performed at 100%, sensitization testing was only performed with a maximum concentration of 1.5%; however, there was no indication that this ingredient would be a sensitizer; mild reactions were observed in ocular irritation studies with undiluted material and no irritation with a formulation containing 1.5%, therefore the Panel was of the opinion that in formulation, this ingredient would not produce significant ocular irritation; because there was limited information available, data on stearyl alcohol and heptanoic acid were extrapolated to determine safety</p>	
Stearyl olivate	Safe as used (2010)	– No data were available	18
Stearyl palmitate	Safe as used (2010)	– No data were available	18
Stearyl stearate	Safe as used (2010)	– No data were available	18

Abbreviations: GPMT, guinea pig maximization test; IIMM, maximum irritation index; LD₅₀, median lethal dose; OII, ocular irritation index; PII, primary irritation index; RIPT, repeated insult patch test; SIOPT, single insult occlusive patch test; avg, average; aq, aqueous.

Table 3. Alkyl Esters Group.^a

Ingredients have been reviewed by the CIR and found safe ^b			
Arachidyl propionate	Ethylhexyl isononanoate	Isopropyl isostearate	Octyldodecyl cocoate
Butyl myristate	Ethylhexyl myristate	Isopropyl myristate	Octyldodecyl myristate
Butyl stearate	Ethylhexyl palmitate	Isopropyl palmitate	Octyldodecyl ricinoleate
Cetearyl isononanoate	Ethylhexyl pelargonate	Isopropyl ricinoleate	Oleyl myristate
Cetearyl nonanoate	Ethylhexyl stearate	Isopropyl stearate	Stearyl behenate
Cetyl esters	Isobutyl myristate	Isostearyl isononanoate	Stearyl caprylate
Cetyl isononanoate	Isobutyl perlargonate	Isostearyl myristate	Stearyl heptanoate
Cetyl myristate	Isobutyl stearate	Isostearyl neopentanoate	Stearyl olivate
Cetyl palmitate	Isocetyl myristate	Isotridecyl isononanoate	Stearyl palmitate
Cetyl ricinoleate	Isocetyl stearate	Isotridecyl myristate	Stearyl stearate
Cetyl stearate	Isodecyl cocoate	Lauryl cocoate	Tetradecyloctadecyl myristate
Decyl cocoate	Isodecyl isononanoate	Lauryl myristate	Tridecyl cocoate
Decyl myristate	Isodecyl myristate	Myristyl myristate	Tridecyl isononanoate
Decyl oleate	Isodecyl oleate	Myristyl stearate	Tridecyl myristate
Ethylhexyl cocoate	Isononyl isononanoate		
Both the acid and the alcohol have been found safe by the CIR			
Batyl isostearate	Cetearyl stearate	Isostearyl hydroxystearate	Myristyl isostearate
Batyl stearate	Cetyl laurate cetyl oleate	Isostearyl isostearate	Myristyl laurate
Behenyl isostearate	Chimyl isostearate	Isopropyl hydroxystearate	Octyldodecyl hydroxystearate
Behenyl olivate	Chimyl stearate	Isopropyl laurate	Octyldodecyl isostearate
Butyl isostearate	Hydrogenated castor oil behenyl esters	Isopropyl oleate	Octyldodecyl oleate
Butyl oleate		Isostearyl hydroxystearate	Octyldodecyl olivate
Cetearyl olivate	Hydrogenated castor oil cetyl esters	Isostearyl isostearate	Octyldodecyl stearate
Cetearyl palmate	Hydrogenated castor oil stearyl esters	Isostearyl laurate	Oleyl oleate
Cetearyl palmitate		Isostearyl palmitate	Oleyl stearate
Cetearyl rice branate	Isopropyl hydroxystearate		
	Isopropyl laurate		
	Isopropyl oleate		

(continued)

Table 3. (continued)

The acid or the alcohol (bolded) has been found safe by the CIR			
Behenyl beeswax	Coco -rapeseedate	Isoamyl laurate	Lauryl laurate
Behenyl behenate	Decyl isostearate	Isobutyl palmitate	Lauryl oleate
Behenyl erucate	Decyl laurate	Isocetyl isostearate	Lauryl palmitate
Behenyl/isostearyl beeswax	Decyl palmitate	Isocetyl laurate	Lauryl stearate
Butyl avocadate	Decyltetradecyl cetearate	Isocetyl palmitate	Myristyl neopentanoate
Butyl babassuate	Ethylhexyl adipate/palmitate/	Isodecyl hydroxystearate	Octyldecyl oleate
Butyloctyl cetearate ^c	stearate	Isodecyl laurate	Octyldecyl avocadate
Butyloctyl oleate	Ethylhexyl hydroxystearate	Isodecyl palmitate	Octyldecyl beeswax
Butyloctyl palmitate	Ethylhexyl isostearate	Isodecyl stearate	Octyldecyl behenate
C16-36 alkyl stearate	Ethylhexyl laurate	Isohexyl laurate	Octyldecyl erucate
C20-40 alkyl stearate	Ethylhexyl oleate	Isohexyl palmitate	Octyldecyl meadowfoamate
C30-50 alkyl stearate	Erucyl oleate	Isooctyl tallate	Octyldecyl neodecanoate
C40-60 alkyl stearate	Heptylundecyl hydroxystearate	Isopropyl arachidate	Octyldecyl neopentanoate
Cetearyl behenate	Hexyldecyl isostearate	Isopropyl avocadate	Octyldecyl
Cetearyl candelillate	Hexyldecyl laurate	Isopropyl babassuate	octyldecanoate
Cetyl babassuate	Hexyldecyl oleate	Isopropyl behenate	Octyldecyl safflowerate
Cetyl behenate	Hexyldecyl palmitate	Isopropyl jojobate	Oleyl arachidate
Cetyl caprate	Hexyldecyl stearate	Isopropyl tallowate	Oleyl erucate
Cetyl caprylate	Hexyldecyl stearate	Isostearyl avocadate	Oleyl linoleate
Cetyl dimethyloctanoate	Hexyldecyl stearate	Isostearyl behenate	Stearyl beeswax
Cetyl tallowate	Hexyldecyl stearate	Isostearyl erucate	Stearyl erucate
C10-40 isoalkyl acid octyldecanol	Hexyl isostearate	Isostearyl linoleate	Stearyl linoleate
esters	Hexyl laurate	Isotridecyl laurate	Tetradecyleicosyl stearate
C4-5 isoalkyl cocoate	Hydrogenated ethylhexyl olive	Isotridecyl stearate	Tetradecyloctadecyl stearate
C32-36 isoalkyl stearate	Hydrogenated ethylhexyl	Lauryl isostearate	Tridecyl laurate
Coco -caprylate	sesamate		Tridecyl stearate
Coco -caprylate/caprate	Hydrogenated isocetyl olive		
	Hydrogenated isopropyl jojobate		
	Hydroxycetyl isostearate		
	Hydroxyoctacosanyl		
	hydroxystearate		
CIR has not concluded on the safety of the acid or the alcohol			
Arachidyl behenate	Caprylyl butyrate	Erucyl erucate	Isooctyl caprylate/caprate
Arachidyl erucate	Caprylyl caprylate	Heptyldecyl undecylenate	Lauryl behenate
Butyloctyl beeswax	Caprylyl eicosenoate	Hexyldecyl hexyldecanoate	Lignoceryl erucate
Butyloctyl behenate	Decyl castorate	Isobutyl tallowate	Propylheptyl caprylate
Butyloctyl candelillate	Decyl jojobate	Isocetyl behenate	Tetradecyloctadecyl behenate
C14-30 alkyl beeswax	Ethylhexyl C10-40 isoalkyl acidate	Isocetyl isodecanoate	Tetradecyloctadecyl
C18-38 alkyl beeswax	Ethylhexyl isopalmitate	Isodecyl neopentanoate	hexyldecanoate
C30-50 alkyl beeswax	Ethylhexyl neopentanoate	Isohexyl caprylate	Tetradecylpropionates
C20-40 alkyl behenate	Ethylhexyl olive	Isohexyl neopentanoate	Tridecyl behenate
C18-38 alkyl c24-54 acid ester	Erucyl arachidate	Isolauryl behenate	Tridecyl erucate
			Tridecyl neopentanoate

Abbreviation: CIR, Cosmetic Ingredient Review.

^aGrouped by whether individual constituents have been reviewed.

^bIsopropyl linoleate was reviewed previously by the CIR, with a conclusion of insufficient data to support safety.

^cThe acid component is a mixture of fatty acids, containing predominantly palmitic and stearic acids, both of which have been reviewed.

Table 4. Constituent Alcohols and Acids With CIR Conclusions.

Constituent	Conclusion (year issued; maximum use concentration reported)	Reference
Alcohols		
Batyl alcohol	Safe as used (2011; 3% in leave-ons, 1% in rinse-offs)	23
Behenyl alcohol	Safe as used (1988; reaffirmed 2008; 50% in leave-ons; 10% in rinse-offs)	4,24
Butyl alcohol	Safe as used (2008; 15% in leave-ons; <0.1% in rinse-offs)	25
Cetearyl alcohol	Safe as used (1988; reaffirmed 2008; 25% in leave-ons; 25% in rinse-off)	4,24
Cetyl alcohol	Safe as used (1988; reaffirmed 2008; 50% in leave-ons; 25% in rinse-offs)	4,24
Cetyl glycol (hydroxycetyl alcohol)	Safe as used (2011; no reported use)	26
Chimyl alcohol	Safe as used (2011; 0.5% in leave-ons, 0.002% in rinse-offs)	23
Coconut alcohol	Safe as used (2011; 0.9% in leave-ons; 0.8% in rinse-offs)	12
Isopropyl alcohol	Safe as used (2012; 100% in leave-ons; 35% in rinse-offs)	27
Isostearyl alcohol	Safe as used (1988; reaffirmed 2008; 50% in leave-ons; 5% in rinse-offs)	4,24

(continued)

Table 4. (continued)

Constituent	Conclusion (year issued; maximum use concentration reported)	Reference
Jjoba alcohol	Safe as used (2008; 1% in leave-ons; 0.5% in rinse-offs)	28
Myristyl alcohol	Safe as used (1988; reaffirmed 2008; 12% in leave-ons; 7% in rinse-offs)	4,24
Octyldodecanol	Safe as used (1985, reaffirmed 2006; 85% in leave-ons; 30% in rinse-offs)	17,29
Oleyl alcohol	Safe as used (1985; reaffirmed 2006; >50% in leave-ons; 25% in rinse-offs)	17,29
Stearyl alcohol	Safe as used (1985; reaffirmed 2006; 56% in leave-ons; 25% in rinse-offs)	17,29
Acids		
Adipic acid	Safe as used (2012; 0.000001% in leave-on; 18% in rinse-off)	30
Babassu acid	Safe as used (2011; no reported use)	31
Coconut acid	Safe as used (2011; not reported in leave-ons; 14% in rinse-offs)	12,31
Hydroxystearic acid	Safe as used (1999; 10% in leave-ons; not reported for rinse-offs)	32
Isostearic acid	Safe as used (1983; reaffirmed in 2005; 16% in leave-ons, 26% in rinse-offs)	8,33
Lauric acid	Safe as used (1987; reaffirmed in 2006; 10% in leave-ons, 25% in rinse-offs)	17,34
Myristic acid	Safe as used (2010; 15% in leave-ons; 50% in rinse-offs)	5
Oleic acid	Safe as used (1987; reaffirmed in 2006; 25% in leave-ons; 50% in rinse-offs)	17,34
Olive acid	Safe as used (2011; no reported use)	31
Palm acid	Safe as used (2011; not reported in leave-ons; 17% in rinse-offs)	31
Palmitic acid	Safe as used (1987; reaffirmed in 2006; 25% in leave-ons, 25% in rinse-offs)	17,34
Pelargonic acid	Safe as used (2011; no reported use)	9
Rice bran acid	Safe as used (2011; no reported use)	31
Ricinoleic acid	Safe as used (2007; use concentration not reported)	11
Safflower acid	Safe as used (2011; no reported use)	31
Stearic acid	Safe as used (1987; reaffirmed in 2006; >50% in leave-ons; 50% in rinse-offs)	17,34
Tall oil acid	Safe as used (2009; not reported in leave-ons; 8% in rinse-offs)	35

Abbreviation: CIR, Cosmetic Ingredient Review.

Table 5. Definitions and Functions.

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Arachidyl behenate/42233-14-7	The ester of arachidyl alcohol and behenic acid. <i>The ester obtained from the reaction of arachidyl alcohol with behenic acid.</i>	Skin-cond agent—oc; visc incr agent—nonaq
Arachidyl erucate/86601-86-7	The ester of arachidyl alcohol and erucic acid. <i>The ester obtained from the reaction of arachidyl alcohol with erucic acid.</i>	Skin-cond agent—emol
Arachidyl propionate/65591-14-2	The ester of arachidyl alcohol and n-propionic acid. <i>The ester obtained from the reaction of arachidyl alcohol and n-propionic acid.</i>	Skin-cond agent—emol
Batyl isostearate/170754-20-8	An ester of batyl alcohol and isostearic acid. <i>The mixture of esters obtained from the reaction of batyl alcohol with branched-chain stearic acids.</i>	Skin-cond agent—oc
Batyl stearate/13232-26-3	An ester of batyl alcohol and stearic acid. <i>The ester obtained from the reaction of batyl alcohol with stearic acid.</i>	Skin-cond agent—oc
Behenyl beeswax	The ester of behenyl alcohol and beeswax acid. <i>The mixture of esters obtained from the reaction of behenyl alcohol with a mixture of straight-chain fatty acids, containing 24 to 36 carbons in alkyl chain length (beeswax acid).</i>	Skin-cond agent—oc
Behenyl behenate/17671-27-1	The ester of behenic acid and behenyl alcohol. <i>The ester obtained from the reaction of behenic acid with behenyl alcohol.</i>	Skin-cond agent—oc
Behenyl erucate/18312-32-8	The ester of behenyl alcohol and erucic acid. <i>The ester obtained from the reaction of behenyl alcohol with erucic acid.</i>	Skin-cond agent—oc

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Behenyl isostearate/181496-25-3	The ester of behenyl alcohol and isostearic acid that conforms to the formula. <i>The mixture of esters obtained from the reaction of behenyl alcohol with branched-chain stearic acids.</i>	Skin-cond agent—oc
Behenyl/isostearyl beeswax	The ester of a mixture of behenyl alcohol and isostearyl alcohol with beeswax acid. <i>The mixture of esters obtained from the reaction of behenyl alcohol and branched-chain stearyl alcohols with a mixture of straight-chain fatty acids, containing 24 to 36 carbons in alkyl chain length (beeswax acid).</i>	Skin-cond agent—oc
Behenyl olivate	The ester of behenyl alcohol and olive acid that conforms generally to the formula. <i>The mixture of esters obtained from the reaction of behenyl alcohol with the fatty acids derived from olive acid.</i>	Skin-cond agent—misc; emul stabilizer; film former; slip modifier; visc incr agent—nonaq
Butyl avocadate	The ester of butyl alcohol and the fatty acids derived from <i>Persea gratissima</i> (avocado) oil. <i>The mixture of esters obtained from the reaction of butyl alcohol with the fatty acids derived from Persea gratissima (avocado) oil.</i>	Skin-cond agent—misc
Butyl babassuate	The ester of butyl alcohol and the fatty acids derived from babassu oil. <i>The mixture of esters obtained from the reaction of butyl alcohol with the fatty acids derived from babassu oil.</i>	Disp agent—nonsurf; emul stab; skin-cond, agent—emol; surf—solub agent
Butyl isostearate	The ester of butyl alcohol and isostearic acid that conforms to the formula. <i>The mixture of esters obtained from the reaction of butyl alcohol with branched-chain stearic acids.</i>	Skin-cond, agent—emol
Butyl myristate/110-36-1	The ester of butyl alcohol and myristic acid. <i>The ester obtained from the reaction of butyl alcohol with myristic acid.</i>	Skin-cond, agent—emol
Butyl oleate/142-77-8	The ester of butyl alcohol and oleic acid. <i>The ester obtained from the reaction of butyl alcohol with oleic acid.</i>	Skin-cond, agent—emol; fragrance ingr
Butyl stearate/123-95-5	The ester of butyl alcohol and stearic acid. <i>The ester obtained from the reaction of butyl alcohol and stearic acid.</i>	Skin-cond, agent—emol; fragrance ingr
Butyloctyl beeswax/151661-98-2	The ester of butyloctanol and beeswax acid. <i>The mixture of esters obtained from the reaction of 2-butyloctanol with a mixture of straight-chain fatty acids, containing 24 to 36 carbons in alkyl chain length (beeswax acid).</i>	Skin-cond agent—oc
Butyloctyl behenate	The organic compound that conforms to the formula. <i>The ester obtained from the reaction of 2-butyloctanol with behenic acid.</i>	Skin-cond agent—emol
Butyloctyl candelillate/226994-03-2	The ester of 2-butyloctanol and the acids derived from <i>Euphorbia cerifera</i> (candelilla) wax. <i>The mixture of esters obtained from the reaction of 2-butyloctanol with the fatty acids derived from Euphorbia cerifera (candelilla) wax.</i>	Skin-cond agent—oc
Butyloctyl cetearate/101227-08-1	The ester of butyloctanol and a blend of fatty acids containing predominantly palmitic and stearic acid. <i>The mixture of esters obtained from the reaction of 2-butyloctanol with a mixture of fatty acids containing predominately palmitic acid and stearic acid.</i>	Skin-cond agent—emol
Butyloctyl oleate	The ester of butyloctanol and oleic acid. <i>The ester obtained from the reaction of 2 butyloctanol with oleic acid.</i>	Skin-cond agent—oc
Butyloctyl palmitate	The ester of butyloctanol and palmitic acid. <i>The ester obtained from the reaction of 2-butyloctanol with palmitic acid.</i>	Skin-cond agent—emol
C14-30 alkyl beeswax/209225-40-1	The ester of a mixture of fatty alcohols containing 14 to 30 carbons in the alkyl chain with beeswax acid. <i>The mixture of esters obtained from the reaction of a mixture</i>	Skin-cond agent—oc

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
C18-38 alkyl beeswax/223706-17-0	<p><i>of fatty alcohols, containing 14 to 30 carbons in the alkyl chain, with a mixture of straight-chain fatty acids, containing 24 to 36 carbons in alkyl chain (beeswax acid).</i></p> <p>The ester of a mixture of fatty alcohols containing 18 to 38 carbon atoms in the alkyl chain and beeswax acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 18 to 38 carbons in the alkyl chain, with a mixture of straight-chain fatty acids, containing 24 to 36 carbons in alkyl chain (beeswax acid).</i></p>	Skin-cond agent—oc
C30-50 alkyl beeswax/223707-19-5	<p>The ester of C30-50 alcohols and beeswax acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 30 to 50 carbons in the alkyl chain, with a mixture of straight-chain fatty acids, containing 24 to 36 carbons in alkyl chain (beeswax acid).</i></p>	Skin-cond agent—oc
C20-40 alkyl behenate	<p>The ester of C20-40 alcohols and behenic acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 20 to 40 carbons in the alkyl chain, with behenic acid.</i></p>	Skin-cond agent—oc
C18-38 alkyl C24-54 acid ester	<p>The ester of a mixture of fatty alcohols containing 18 to 38 carbon atoms and a mixture of fatty acids containing 24 to 54 carbon atoms. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 30 to 50 carbons in the alkyl chain, with a mixture of straight-chain fatty acids, containing 24 to 54 carbons in alkyl chain.</i></p>	Visc incr agent—nonaq
C16-36 alkyl stearate	<p>The ester of C16-36 alcohols and stearic acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 16 to 36 carbons in the alkyl chain, with stearic acid.</i></p>	Skin-cond agent—oc
C20-40 alkyl stearate	<p>The ester of C20-40 alcohols and stearic acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 20 to 40 carbons in the alkyl chain, with stearic acid.</i></p>	Skin-cond agent—oc; visc incr agent—aq
C30-50 alkyl stearate	<p>The ester of C30-50 alcohols and stearic acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 30 to 50 carbons in the alkyl chain, with stearic acid.</i></p>	Skin-cond agent—oc
C40-60 alkyl stearate	<p>The ester of C40-60 alcohols and stearic acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 40 to 60 carbons in the alkyl chain, with stearic acid.</i></p>	Skin-cond agent—oc
Caprylyl butyrate/110-39-4	<p>The ester of n-octanol with butyric acid that conforms to the formula. <i>The ester obtained from the reaction of n-octanol with butyric acid.</i></p>	Skin-cond agent—misc; fragrance ingredient
Caprylyl caprylate/2306-88-9	<p>The organic compound that conforms to the formula. <i>The ester obtained from the reaction of n-octanol with n-octanoic acid.</i></p>	Skin-cond agent—emol
Caprylyl eicosenoate	<p>The organic compound that conforms to the formula. <i>The ester obtained from the reaction of n-octanol with 11-eicosenoic acid.</i></p>	Skin-cond agent—misc
Cetearyl behenate	<p>The ester of cetearyl alcohol and behenic acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 16 to 18 carbons in the alkyl chain, with behenic acid.</i></p>	Skin-cond agent—oc
Cetearyl candelillate	<p>The ester of cetearyl alcohol and the fatty acids derived from <i>Euphorbia cerifera</i> (candelilla) wax. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 16 to 18 carbons in the alkyl chain, with the fatty acids derived from Euphorbia cerifera (Candelilla) Wax.</i></p>	Skin-cond agent—oc

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Cetearyl isononanoate	The ester of cetearyl alcohol and a branched chain nonanoic acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 16 to 18 carbons in the alkyl chain, with branched chain nonanoic acid.</i>	Skin-cond agent—emol; hair-cond agent
Cetearyl nonanoate/878027-13-5	The organic compound that conforms to the formula. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 16 to 18 carbons in the alkyl chain, with nonanoic acid.</i>	Skin-cond agent—emol
Cetearyl olivate	The ester of cetearyl alcohol and the fatty acids derived from olive oil. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 16-18 carbons in the alkyl chain, with the fatty acids derived from olive oil.</i>	Hair-cond agent
Cetearyl palmate	The ester of cetearyl alcohol and palm acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 16 to 18 carbons in the alkyl chain, with the fatty acids derived from palm acid.</i>	Skin-cond agent—emol; emul stab
Cetearyl palmitate/85341-79-3	The ester of cetearyl alcohol and palmitic acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 16 to 18 carbons in the alkyl chain, with palmitic acid.</i>	Skin-cond agent—emol; hair-cond agent
Cetearyl rice branate	The ester of cetearyl alcohol and rice bran acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 16 to 18 carbons in the alkyl chain, with the fatty acids derived from rice bran acid.</i>	Skin-cond agent—misc
Cetearyl stearate/93820-97-4	The ester of cetearyl alcohol and stearic acid. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 16 to 18 carbons in the alkyl chain, with stearic acid.</i>	Skin-cond agent—oc
Cetyl babassuate/613236-40-1	The ester of cetyl alcohol and the fatty acids derived from <i>Orbignya oleifera</i> (babassu) oil. <i>The mixture of esters obtained from the reaction of cetyl alcohol with the fatty acids derived from Orbignya oleifera (babassu) oil.</i>	Skin-cond agent—emol; visc incr agent—aq
Cetyl behenate/42233-11-4	The ester of that conforms to the formula. <i>The ester obtained from the reaction of cetyl alcohol with behenic acid.</i>	Skin-cond agent—oc
Cetyl caprate	The ester of cetyl alcohol and capric acid. <i>The ester obtained from the reaction of cetyl alcohol with capric acid.</i>	Skin-cond agent—emol
Cetyl caprylate/29710-31-4	The ester of cetyl alcohol and caprylic acid. <i>The ester obtained from the reaction of cetyl alcohol with caprylic acid.</i>	Skin-cond agent—emol
Cetyl dimethyloctanoate	The ester of cetyl alcohol and dimethyloctanoic acid. <i>The ester obtained from the reaction of cetyl alcohol with dimethyloctanoic acid.</i>	Skin-cond agent—emol
Cetyl esters	A synthetic wax intended to be indistinguishable from natural spermaceti wax with regard to composition and properties. It consists of a mixture of esters of 14 to 18 carbon fatty acids and alcohols. <i>The mixture of esters obtained from the reaction of a mixture of fatty alcohols, containing 14 to 18 carbons in the alkyl chain, with a mixture of straight-chain fatty acids, containing 14 to 18 carbons in the alkyl chain.</i>	Skin-cond agent—emol
Cetyl isononanoate/84878-33-1	The ester of cetyl alcohol with a branched chain nonanoic acid. <i>The mixture of esters obtained from the reaction of cetyl alcohol with branched-chain nonanoic acids.</i>	Skin-cond agent—emol

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Cetyl laurate/20834-06-4	The ester of cetyl alcohol and lauric acid that conforms to the formula. <i>The ester obtained from the reaction of cetyl alcohol with lauric acid.</i>	Skin-cond agent—emol
Cetyl myristate/2599-01-1	The ester of cetyl alcohol and myristic acid. <i>The ester obtained from the reaction of cetyl alcohol and myristic acid.</i>	Skin-cond agent—oc
Cetyl myristoleate	The ester of cetyl alcohol and myristoleic acid that conforms to the formula. <i>The ester obtained from the reaction of cetyl alcohol and myristoleic acid.</i>	Skin-cond agent—misc
Cetyl oleate/22393-86-8	The ester of cetyl alcohol and oleic acid. <i>The ester obtained from the reaction of cetyl alcohol with oleic acid.</i>	Skin-cond agent—emol
Cetyl palmitate/540-10-3	The ester of cetyl alcohol and palmitic acid. <i>The ester obtained from the reaction of cetyl alcohol with palmitic acid.</i>	Skin-cond, agent—oc; fragrance ingr
Cetyl ricinoleate/10401-55-5	The ester of cetyl alcohol and ricinoleic acid. <i>The ester obtained from the reaction of cetyl alcohol with ricinoleic acid.</i>	Skin-cond agent—oc
Cetyl stearate/1190-63-2	The ester of cetyl alcohol and stearic acid. <i>The ester obtained from the reaction of cetyl alcohol with stearic acid.</i>	Skin-cond agent—oc
Cetyl tallowate	The ester of cetyl alcohol and tallow acid. <i>The mixture of esters obtained from the reaction of cetyl alcohol with the fatty acids derived from tallow acid.</i>	Skin-cond agent—misc
Chimyl isostearate	The ester of chimyl alcohol and isostearic acid. <i>The mixture of esters obtained from the reaction of cetyl glyceryl ether with branched-chain stearic acids.</i>	Skin-cond agent—emol
Chimyl stearate/131932-18-8	The ester of chimyl alcohol and stearic acid. <i>The ester obtained from the reaction of cetyl glyceryl ether with stearic acid.</i>	Skin-cond agent—emol
C10-40 isoalkyl acid octyldodecanol esters	A mixture of esters of octyldodecanol with branched-chain alkyl acids containing 10 to 40 carbons. <i>The mixture of esters obtained from the reaction of 2-octyldodecanol with branched-chain fatty acids, containing 10 to 40 carbons in the alkyl chain.</i>	Skin-cond agent—misc; visc incr agent—nonaq
C4-5 isoalkyl cocoate	The ester of a branched, saturated fatty alcohol containing 4 to 5 carbons, with coconut acid. <i>The mixture of esters obtained from the reaction of branched-chain alcohols, containing 4 to 5 carbons, with the fatty acids derived from coconut acid.</i>	Skin-cond agent—emol
C32-36 isoalkyl stearate/68201-22-9	The ester of a branched, saturated fatty alcohol containing 32 to 36 carbons, with stearic acid. <i>The mixture of esters obtained from the reaction of branched-chain alcohols, containing 32 to 36 carbons, with stearic acid.</i>	Skin-cond agent—emol
Coco-caprylate	The organic compound that conforms to the formula. <i>The mixture of esters obtained from the reaction of the fatty alcohols derived from coconut alcohol with caprylic acid.</i>	Skin-cond agent—emol
Coco-caprylate/caprates	A mixture of esters of coconut alcohol with caprylic acid and capric acid. <i>The mixture of esters obtained from the reaction of the fatty alcohols derived from coconut alcohol with a mixture of caprylic acid and capric acid.</i>	Skin-cond agent—emol
Coco-rapeseedate	The ester of coconut alcohol and the fatty acids derived from <i>Brassica campestris</i> (rapeseed) oil. <i>The mixture of esters obtained from the reaction of the fatty alcohols derived from coconut alcohol with the fatty acids derived from Brassica campestris (rapeseed) oil.</i>	Skin-cond agent—emol

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Decyl castorate	The ester of decyl alcohol and the fatty acids derived from <i>Ricinus communis</i> (castor) oil. <i>The mixture of esters obtained from the reaction of decyl alcohol with the fatty acids derived from ricinus communis (castor) oil.</i>	Skin-cond agent—emol; emul stab
Decyl cocoate	The ester of decyl alcohol and the fatty acids derived from <i>Cocos nucifera</i> (coconut) oil. <i>The mixture of esters obtained from the reaction of decyl alcohol with the fatty acids derived from Cocos nucifera (coconut) oil.</i>	Skin-cond agent—oc
Decyl isostearate/84605-08-3	The ester of decyl alcohol and isostearic acid. <i>The mixture of esters obtained from the reaction of decyl alcohol with branched-chain stearic acids.</i>	Skin-cond agent—emol
Decyl jojobate	The ester of decyl alcohol and the fatty acids derived from <i>Simmondsia chinensis</i> (jojoba) oil. <i>The mixture of esters obtained from the reaction of decyl alcohol with the fatty acids derived from Simmondsia chinensis (jojoba) oil.</i>	Skin-cond agent—emol
Decyl laurate/36528-28-6	The organic compound that conforms to the formula. <i>The ester obtained from the reaction of decyl alcohol with lauric acid.</i>	Skin-cond agent—emol
Decyl myristate/41927-71-3	The ester of decyl alcohol and myristic acid that conforms to the formula. <i>The ester obtained from the reaction of decyl alcohol with myristic acid.</i>	Skin-cond agent—oc
Decyl oleate/3687-46-5	The ester of decyl alcohol and oleic acid. <i>The ester obtained from the reaction of decyl alcohol with oleic acid.</i>	Skin-cond agent—emol
Decyl olivate	The ester of decyl alcohol and the fatty acids derived from <i>Olea europaea</i> (olive) oil. <i>The mixture of esters obtained from the reaction of decyl alcohol with the fatty acids derived from Olea europaea (olive) oil.</i>	Skin-cond agent—oc
Decyl palmitate/42232-27-9	The ester of decyl alcohol and palmitic acid that conforms to the formula. <i>The ester obtained from the reaction of decyl alcohol with palmitic acid.</i>	Skin-cond agent—emol
Decyltetradecyl cetearate/97404-34-7	The ester of decyltetradecanol and a blend of fatty acids containing predominantly palmitic and stearic acid. <i>The mixture of esters obtained from the reaction of 2 decyltetradecanol with a mixture of fatty acids, containing predominantly palmitic acid and stearic acid.</i>	Skin-cond agent—emol
Ethylhexyl adipate/palmitate/stearate	A mixture of esters formed by the reaction of 2-ethylhexyl alcohol with adipic, palmitic, and stearic acids.	Skin-cond agent—emol
Ethylhexyl C10-40 isoalkyl acidate	The ester of C10-40 isoalkyl acid and 2-ethylhexyl alcohol. <i>The mixture of esters obtained from the reaction of 2 ethylhexyl alcohol with branched-chain acids, containing 10 to 40 carbons in the alkyl chain.</i>	Skin-cond agent—misc; visc incr agent—nonaq
Ethylhexyl cocoate/91052-62-9;92044-87-6	The ester of 2-ethylhexanol and coconut acid that conforms to the formula. <i>The mixture of esters obtained from the reaction of 2 ethylhexyl alcohol with the fatty acids derived from coconut acid.</i>	Skin-cond agent—emol
Ethylhexyl hydroxystearate/29383-26-4; 29710-25-6	The ester of 2-ethylhexyl alcohol and 12-hydroxystearic acid. <i>The ester obtained from the reaction of 2-ethylhexyl alcohol with 12 hydroxystearic acid.</i>	Skin-cond agent—emol
Ethylhexyl isononanoate/70969-70-9; 71566-49-9	The ester of 2-ethylhexyl alcohol and a branched chain nonanoic acid. <i>The mixture of esters obtained from the reaction of 2 ethylhexyl alcohol with branched-chain nonanoic acids.</i>	Skin-cond agent—emol
Ethylhexyl isopalmitate/93843-32-4	The ester of 2-ethylhexanol and a branched chain 16 carbon aliphatic acid. <i>The mixture of esters obtained from the reaction of 2-ethylhexanol with branched-chain palmitic acids.</i>	Skin-cond agent—emol

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Ethylhexyl isostearate/81897-25-8; 85186-76-1	The ester of 2-ethylhexyl alcohol and isostearic acid. <i>The mixture of esters obtained from the reaction of 2-ethylhexyl alcohol with branched-chain stearic acids.</i>	Skin-cond agent—emol
Ethylhexyl laurate/20292-08-4	The ester of 2-ethylhexyl alcohol and lauric acid. <i>The ester obtained from the reaction of 2-ethylhexyl alcohol with lauric acid.</i>	Skin-cond agent—emol
Ethylhexyl myristate/29806-75-5	The ester of 2-ethylhexyl alcohol and myristic acid. <i>The ester obtained from the reaction of 2-ethylhexyl alcohol with myristic acid.</i>	Skin-cond agent—emol
Ethylhexyl neopentanoate	Ester of 2-ethylhexanol and neopentanoic acid. <i>The ester obtained from the reaction of 2-ethylhexanol with neopentanoic acid.</i>	Skin-cond agent—emol
Ethylhexyl oleate/26399-02-0	The ester of oleic acid and 2-ethyl hexyl alcohol. <i>The ester obtained from the reaction of 2-ethylhexyl alcohol with oleic acid.</i>	Skin-cond agent—emol
Ethylhexyl olivate	The ester of ethylhexyl alcohol and the fatty acids derived from <i>Olea europaea</i> (olive) oil. <i>The mixture of esters obtained from the reaction of 2-ethylhexyl alcohol with the fatty acids derived from Olea europaea (olive) oil.</i>	Skin-cond agent—oc
Ethylhexyl palmitate/29806-73-3	The ester of 2-ethylhexyl alcohol and palmitic acid. <i>The ester obtained from the reaction of 2-ethylhexyl alcohol with palmitic acid.</i>	Skin-cond agent—emol; fragrance ingr
Ethylhexyl pelargonate/59587-44-9	The ester of 2-ethylhexyl alcohol and pelargonic acid. <i>The ester obtained from the reaction of 2-ethylhexyl alcohol with pelargonic acid.</i>	Skin-cond agent—emol
Ethylhexyl stearate/22047-49-0	The ester of 2-ethylhexyl alcohol and stearic acid. <i>The ester obtained from the reaction of 2-ethylhexyl alcohol with stearic acid.</i>	Skin-cond agent—emol
Erucyl arachidate	The ester of erucyl alcohol and arachidic acid. <i>The ester obtained from the reaction of erucyl alcohol with arachidic acid.</i>	Skin-cond agent—misc
Erucyl erucate/27640-89-7; 84605-12-9	The ester of erucyl alcohol and erucic acid. <i>The ester obtained from the reaction of erucyl alcohol with erucic acid.</i>	Skin-cond agent—misc
Erucyl oleate/85617-81-8	The ester of erucyl alcohol and oleic acid that conforms to the formula. <i>The ester obtained from the reaction of erucyl alcohol with oleic acid.</i>	Skin-cond agent—misc
Heptyl undecylenate/68141-27-5	The organic compound that conforms to the formula. <i>The ester obtained from the reaction of heptyl alcohol with 10-undecenoic acid.</i>	Skin-cond agent—emol
Heptylundecyl hydroxystearate/74659-69-1	The organic compound that conforms to the formula. <i>The ester obtained from the reaction of 2-heptylundecyl alcohol with 12-hydroxystearate.</i>	Skin-cond agent—emol
Hexyldecyl hexyldecanoate	The ester that conforms to the formula. <i>The ester obtained from the reaction of 2 hexyldecanol with 2 hexyldecanoic acid.</i>	Skin-cond agent—emol
Hexyldecyl isostearate/69247-84-3	The ester of hexyldecyl alcohol and isostearic acid. <i>The mixture of esters obtained from the reaction of 2-hexyldecyl alcohol with branched-chain stearic acids.</i>	Skin-cond agent—oc
Hexyldecyl laurate/34362-27-1; 227450-65-9	The ester of hexyldecanol and lauric acid. <i>The ester obtained from the reaction of 2 hexyldecanol with lauric acid.</i>	Skin-cond agent—emol; skin-cond agent—oc
Hexyldecyl oleate/94278-07-6	The ester of hexyldecanol and oleic acid. <i>The ester obtained from the reaction of 2 hexyldecanol with oleic acid.</i>	Skin-cond agent—oc
Hexyldecyl palmitate/69275-02-1	The ester of hexyldecanol and palmitic acid that conforms to the formula. <i>The ester obtained from the reaction of 2-hexyldecanol with palmitic acid.</i>	Skin-cond agent—oc

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Hexyldeacyl stearate/17618-45-0	The ester of stearic acid and hexyldecanol. <i>The ester obtained from the reaction of 2 hexyldecanol with stearic acid.</i>	Skin-cond agent—emol; skin-cond agent—oc
Hexyldodecyl/octyldeacyl hydroxystearate	The product formed by the reaction of hexyldodecanol and octyldecanol with hydroxystearic acid. <i>The mixture of esters obtained from the reaction of a mixture of 2 hexyldodecanol and 2-octyldecanol with 12-hydroxystearic acid.</i>	skin-cond agent—emol
Hexyl isostearate/94247-25-3	The ester of hexyl alcohol and isostearic acid that conforms to the formula. <i>The mixture of esters obtained from the reaction of hexyl alcohol with branched-chain stearic acids.</i>	Skin-cond agent—emol
hexyl laurate/34316-64-8	The ester of hexyl alcohol and lauric acid. <i>The ester obtained from the reaction of hexyl alcohol with lauric acid.</i>	Skin-cond agent—emol
Hydrogenated castor oil behenyl esters	The hydrogenation product of the esters formed by the reaction of castor oil and behenyl alcohol. <i>The hydrogenation product of the mixture of esters obtained from the reaction of behenyl alcohol with castor oil.</i>	Hair-cond agent; binder; emul stab
Hydrogenated castor oil cetyl esters	The hydrogenation product of the esters formed by the reaction of castor oil with cetyl alcohol. <i>The hydrogenation product of the mixture of esters obtained from the reaction of cetyl alcohol with castor oil.</i>	Skin-cond agent—misc; hair-cond agent; binder; emul stab
Hydrogenated castor oil stearyl esters	The hydrogenation product of the esters formed by the reaction of castor oil and stearyl alcohol. <i>The hydrogenation product of the mixture of esters obtained from the reaction of stearyl alcohol with castor oil.</i>	Skin-cond agent—misc; hair-cond agent; binder; emul stab
Hydrogenated ethylhexyl olivate	A mixture of esters produced by the reaction of ethylhexanol and hydrogenated olive oil. <i>The mixture of esters obtained from the reaction of 2 ethylhexyl alcohol with hydrogenated olive oil.</i>	Skin-cond agent—emol
Hydrogenated ethylhexyl sesamate	The product of the transesterification of 2-ethylhexyl alcohol and sesame seed oil that has been hydrogenated. <i>The mixture of esters obtained from the reaction of 2 ethylhexyl alcohol with hydrogenated sesame seed oil.</i>	Skin-cond agent—emol; binder
Hydrogenated isocetyl olivate	The end-product of the controlled hydrogenation of the mixture of esters formed by the reaction of isocetyl alcohol with olive acid. <i>The hydrogenation product of the mixture of esters obtained from the reaction of branched-chain cetyl alcohols with the fatty acids derived from olive acid.</i>	Skin-cond agent—misc; binder; disp agent; humectant
Hydrogenated isopropyl jojobate	The end-product of the controlled hydrogenation of isopropyl jojobate. <i>The hydrogenation product of the mixture of esters obtained from the reaction of isopropyl alcohol with the fatty acids derived from Simmondsia chinensis (jojoba) oil.</i>	Skin-cond agent—oc
Hydroxycetyl isostearate	The ester of hydroxycetyl alcohol and isostearic acid. <i>The mixture of esters obtained from the reaction of cetyl glycol with branched-chain stearic acids.</i>	Skin-cond agent—emol
Hydroxyoctacosanyl hydroxystearate/93840-71-2	The ester of hydroxyoctacosanyl alcohol and hydroxystearic acid. <i>The ester obtained from the reaction of 2 hydroxyoctacosanyl alcohol with 12-hydroxystearic acid.</i>	Skin-cond agent—emol; visc incr agent
Isoamyl laurate/6309-51-9	The ester of isoamyl alcohol and lauric acid. <i>The ester obtained from the reaction of isoamyl alcohol with lauric acid.</i>	Skin-cond agent—emol; fragrance ingr
Isobutyl myristate/25263-97-2	The ester of isobutyl alcohol and myristic acid. <i>The ester obtained from the reaction of isobutyl alcohol with myristic acid.</i>	Skin-cond agent—emol

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Isobutyl palmitate/110-34-9	The ester of isobutyl alcohol and palmitic acid. <i>The ester obtained from the reaction of isobutyl alcohol with palmitic acid.</i>	Skin-cond agent—emol; fragrance ingr
Isobutyl pelargonate/30982-03-7	The ester of isobutyl alcohol and pelargonic acid. <i>The ester obtained from the reaction of isobutyl alcohol with nonanoic acid.</i>	Skin-cond agent—emol; fragrance ingr
Isobutyl stearate/646-13-9	The ester of isobutyl alcohol and stearic acid. <i>The ester obtained from the reaction of isobutyl alcohol with stearic acid</i>	Skin-cond agent—emol
Isobutyl tallowate/68526-50-1	The ester of isobutyl alcohol and tallow acid. <i>The mixture of esters obtained from the reaction of isobutyl alcohol with the fatty acids derived from tallow acid.</i>	Skin-cond agent—emol
Isocetyl behenate/94247-28-6	The ester of isocetyl alcohol and behenic acid. <i>The mixture of esters obtained from the reaction of branched-chain cetyl alcohols with behenic acid.</i>	Skin-cond agent—oc
Isocetyl isodecanoate/129588-05-2	The mixture of esters obtained from the reaction of isocetyl alcohol with a branched, fatty acid containing 10 carbons in the alkyl chain. <i>The mixture of esters obtained from the reaction of branched-chain cetyl alcohols with branched-chain decanoic acids.</i>	Skin-cond agent—emol
Isocetyl isostearate/52006-45-8	The ester of isocetyl alcohol and isostearic acid. <i>The mixtures of esters obtained from the reaction of branched-chain cetyl alcohols with branched-chain stearic acids.</i>	Skin-cond agent—emol
Isocetyl laurate/89527-28-6	The ester of isocetyl alcohol and lauric acid. <i>The mixture of esters obtained from the reaction of branched-chain cetyl alcohols with lauric acid.</i>	Skin-cond agent—emol
Isocetyl myristate/83708-66-1	The ester of isocetyl alcohol and myristic acid. <i>The mixture of esters obtained from the reaction of branched-chain cetyl alcohols with myristic acid.</i>	Skin-cond agent—oc
Isocetyl palmitate/127770-27-8	The ester of isocetyl alcohol and palmitic acid. <i>The mixture of esters obtained from the reaction of branched-chain cetyl alcohols with palmitic acid.</i>	Skin-cond agent—emol
Isocetyl stearate/25339-09-7	The ester of isocetyl alcohol and stearic acid. <i>The mixture of esters obtained from the reaction of branched-chain cetyl alcohols with stearic acid.</i>	Skin-cond agent—emol
Isodecyl cocoate	The ester of branched chain decyl alcohols and coconut acid. <i>The mixture of esters obtained from the reaction of branched-chain decyl alcohols with the fatty acids derived from coconut acid.</i>	Skin-cond agent—emol
Isodecyl hydroxystearate/29383-27-5; 59231-36-6	The ester of branched chain decyl alcohols and 12-hydroxystearic acid. <i>The mixture of esters obtained from the reaction of branched-chain decyl alcohols with 12 hydroxystearic acid.</i>	Skin-cond agent—emol
Isodecyl isononanoate/41395-89-5; 59231-35-5	The ester of branched chain decyl alcohols and a branched chain nonanoic acid. <i>The mixture of esters obtained from the reaction of branched-chain decyl alcohols with branched-chain nonanoic acids.</i>	Skin-cond agent—emol
Isodecyl laurate/14779-93-2; 94247-10-6	The ester of branched chain decyl alcohols and lauric acid. <i>The mixture of esters obtained from the reaction of branched-chain decyl alcohols with lauric acid.</i>	Skin-cond agent—emol
Isodecyl myristate/17670-91-6; 51473-24-6	The ester of branched chain decyl alcohols and myristic acid. <i>The mixture of esters obtained from the reaction of branched-chain decyl alcohols with myristic acid.</i>	Skin-cond agent—emol
Isodecyl neopentanoate/60209-82-7	The ester of branched chain decyl alcohols and neopentanoic acid. <i>The mixture of esters obtained from</i>	Skin-cond agent—emol

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Isodecyl oleate/59231-34-4	<i>the reaction of branched-chain decyl alcohols with neopentanoic acid.</i> The ester of branched chain decyl alcohols and oleic acid. <i>The mixture of esters obtained from the reaction of branched-chain decyl alcohols with oleic acid.</i>	Skin-cond agent—emol
Isodecyl palmitate/14779-95-4; 59231-33-3	The ester of branched chain decyl alcohols and palmitic acid. <i>The mixture of esters obtained from the reaction of branched-chain decyl alcohols with palmitic acid.</i>	Skin-cond agent—emol
Isodecyl stearate/31565-38-5	The ester of branched decyl alcohols and stearic acid. <i>The mixture of esters obtained from the reaction of branched-chain decyl alcohols with stearic acid.</i>	Skin-cond agent—emol
Isohexyl caprate	The ester of capric acid and a branched chain, 6-carbon alcohol. <i>The mixture of esters obtained from the reaction of branched-chain hexyl alcohols with capric acid.</i>	Skin-cond agent—emol
Isohexyl laurate/59219-73-7	The ester of a branched chain hexyl alcohol and lauric acid. <i>The mixture of esters obtained from the reaction of branched-chain hexyl alcohols with lauric acid.</i>	Skin-cond agent—emol
Isohexyl neopentanoate/131141-70-3; 150588-62-8	The ester of isohexyl alcohol and neopentanoic acid that conforms to the formula. <i>The mixture of esters obtained from the reaction of branched-chain hexyl alcohols with neopentanoic acid.</i>	Skin-cond agent—emol
Isohexyl palmitate/55194-91-7; 59219-72-6	The ester of branched chain hexyl alcohols and palmitic acid. <i>The mixture of esters obtained from the reaction of branched-chain hexyl alcohols with palmitic acid.</i>	Skin-cond agent—emol
Isolauryl behenate	The ester of branched chain dodecyl alcohols and behenic acid. <i>The mixture of esters obtained from the reaction of branched-chain lauryl alcohols with behenic acid.</i>	Skin-cond agent—oc
Isononyl isononanoate/42131-25-9; 59219-71-5	The ester of branched chain nonyl alcohols with a branched chain nonanoic acid. <i>The mixture of esters obtained from the reaction of branched-chain nonyl alcohols with branched-chain nonanoic acids.</i>	Skin-cond agent—emol
Isooctyl caprylate/caprate	The ester of branched chain octyl alcohols with a mixture of caprylic and capric acids. <i>The mixture of esters obtained from the reaction of branched-chain octyl alcohols with a mixture of caprylic and capric acids.</i>	Skin-cond agent—emol; antioxidant
Isooctyl tallate	The organic compound that conforms to the formula. <i>The mixture of esters obtained from the reaction of branched-chain octyl alcohols with the fatty acids derived from tall oil.</i>	Skin-cond agent—emol; plasticizer; solvent
Isopropyl arachidate/26718-90-1	The ester of isopropyl alcohol and arachidic acid that conforms to the formula. <i>The ester obtained from the reaction of isopropyl alcohol with arachidic acid.</i>	Skin-cond agent—emol
Isopropyl avocadate/90990-05-9	The ester of isopropyl alcohol and the fatty acids derived from avocado oil. <i>The mixture of esters obtained from the reaction of isopropyl alcohol with the fatty acids derived from avocado oil.</i>	Skin-cond agent—emol
Isopropyl babassuate	The ester of isopropyl alcohol and the fatty acids derived from <i>Orbignya oleifera</i> (Babassu) oil. <i>The mixture of esters obtained from the reaction of isopropyl alcohol with the fatty acids derived from Orbignya Oleifera (Babassu) Oil.</i>	Skin-cond agent—emol; binder; disp agent—nonsurf; emul stab
Isopropyl behenate/26718-95-6	The ester of isopropyl alcohol and behenic acid. <i>The ester obtained from the reaction of isopropyl alcohol with behenic acid.</i>	Skin-cond agent—emol
Isopropyl hydroxystearate	The ester of isopropyl alcohol and 12-hydroxystearic acid. <i>The ester obtained from the reaction of isopropyl alcohol with 12 hydroxystearic acid.</i>	Skin-cond agent—emol

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Isopropyl isostearate/31478-84-9; 68171-33-5	The ester of isopropyl alcohol and isostearic acid. <i>The mixture of esters obtained from the reaction of isopropyl alcohol with branched-chain stearic acids.</i>	Skin-cond agent—emol; binder
Isopropyl jojobate	The ester of isopropyl alcohol and the acids derived from <i>Simmondsia chinensis</i> (jojoba) oil. <i>The mixture of esters obtained from the reaction of isopropyl alcohol with the fatty acids derived from Simmondsia chinensis (jojoba) oil.</i>	Skin-cond agent—emol
Isopropyl laurate/10233-13-3	The ester of isopropyl alcohol and lauric acid. <i>The ester obtained from the reaction of isopropyl alcohol with lauric acid.</i>	Skin-cond agent—emol; binder; fragrance ingr
Isopropyl linoleate/22882-95-7	The ester of isopropyl alcohol and linoleic acid. <i>The ester obtained from the reaction of isopropyl alcohol with linoleic acid.</i>	Skin-cond agent—emol
Isopropyl myristate/110-27-0	The ester of isopropyl alcohol and myristic acid. <i>The ester obtained from the reaction of isopropyl alcohol with myristic acid.</i>	Skin-cond agent—emol; binder; fragrance ingr
Isopropyl oleate/112-11-8; 17364-07-7	The ester of isopropyl alcohol and oleic acid. <i>The ester obtained from the reaction of isopropyl alcohol with oleic acid.</i>	Skin-cond agent—emol; binder
Isopropyl palmitate/142-91-6	The ester of isopropyl alcohol and palmitic acid. <i>The ester obtained from the reaction of isopropyl alcohol with myristic acid.</i>	Skin-cond agent—emol; binder; fragrance ingr
Isopropyl ricinoleate/71685-99-9	The ester of isopropyl alcohol and ricinoleic acid. <i>The ester obtained from the reaction of isopropyl alcohol with ricinoleic acid.</i>	Skin-cond agent—emol
Isopropyl stearate/112-10-7	The ester of isopropyl alcohol and stearic acid. <i>The ester obtained from the reaction of isopropyl alcohol with stearic acid.</i>	Skin-cond agent—emol; binder
Isopropyl tallowate	The ester of isopropyl alcohol and tallow acid. <i>The mixture of esters obtained from the reaction of isopropyl alcohol with the fatty acids derived from tallow acid.</i>	Skin-cond agent—emol; binder
Isostearyl avocadate/90990-06-0	The ester of isostearyl alcohol and the acids derived from avocado oil. <i>The mixture of esters obtained from the reaction of branched-chain stearic alcohols with the fatty acids derived from avocado oil.</i>	Skin-cond agent—emol
Isostearyl behenate/125804-16-2	The ester of isostearyl alcohol and behenic acid. <i>The mixture of esters obtained from the reaction of branched-chain stearic alcohols with behenic acid.</i>	Skin-cond agent—oc
Isostearyl erucate/84605-10-7	The ester of isostearyl alcohol and erucic acid. <i>The mixture of esters obtained from the reaction of branched-chain stearyl alcohols with erucic acid.</i>	Skin-cond agent—oc
Isostearyl hydroxystearate/162888-05-3; 338450-67-2	The ester of isostearyl alcohol and hydroxystearic acid. <i>The mixture of esters obtained from the reaction of branched-chain stearyl alcohols with 12-hydroxystearic acid.</i>	Skin-cond agent—emol
Isostearyl isononanoate/90967-66-1; 163564-45-2	The ester of isostearyl alcohol and isononanoic acid. <i>The mixture of esters obtained from the reaction of branched-chain stearyl alcohols with branched-chain nonanoic acids.</i>	Skin-cond agent—emol
Isostearyl isostearate/41669-30-1	The ester of isostearyl alcohol and isostearic acid. <i>The mixture of esters obtained from the reaction of branched-chain stearyl alcohols with branched-chain stearic acids.</i>	Skin-cond agent—emol; binder
Isostearyl laurate	The ester of isostearyl alcohol and lauric acid. <i>The mixture of esters obtained from the reaction of branched-chain stearyl alcohols with lauric acid</i>	Skin-cond agent—emol
Isostearyl linoleate/127358-80-9	The ester of isostearyl alcohol and linoleic acid. <i>The mixture of esters obtained from the reaction of branched-chain stearyl alcohols with linoleic acid.</i>	Skin-cond agent—emol

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Isostearyl myristate/72576-81-9	The ester of isostearyl alcohol and myristic acid. <i>The mixture of esters obtained from the reaction of branched-chain stearyl alcohols with myristic acid.</i>	Skin-cond agent—emol; binder
Isostearyl neopentanoate/58958-60-4	The ester of isostearyl alcohol and neopentanoic acid. <i>The mixture of esters obtained from the reaction of branched-chain stearyl alcohols with neopentanoic acid.</i>	Skin-cond agent—emol; binder
Isostearyl palmitate/69247-83-2; 72576-80-8	The ester of isostearyl alcohol and palmitic acid. <i>The mixture of esters obtained from the reaction of branched-chain stearyl alcohols with palmitic acid.</i>	Skin-cond agent—emol; binder
Isotridecyl isononanoate/42131-27-1; 59231-37-7	The ester of isotridecyl alcohol and isononanoic acid. <i>The mixture of esters obtained from the reaction of branched-chain tridecyl alcohols with branched-chain nonanoic acids.</i>	Skin-cond agent—emol
Isotridecyl laurate/94134-83-5	The ester of isotridecyl alcohol and lauric acid that conforms generally to the formula. <i>The mixture of esters obtained from the reaction of branched-chain tridecyl alcohols with lauric acid.</i>	Skin-cond agent—oc; hair-cond agent
Isotridecyl myristate/96518-24-0	The ester of myristic acid and isotridecyl alcohol. <i>The mixture of esters obtained from the reaction of branched-chain tridecyl alcohols with myristic acid.</i>	Skin-cond agent—oc; hair-cond agent
Isotridecyl stearate/31565-37-4	The monoester of isotridecyl alcohol and stearic acid that conforms to the formula. <i>The mixture of esters obtained from the reaction of branched-chain tridecyl alcohols with stearic acid.</i>	Skin-cond agent—emol
Lauryl behenate/42233-07-8	The ester of lauryl alcohol and behenic acid. <i>The ester obtained from the reaction of lauryl alcohol with behenic acid.</i>	Skin-cond agent—oc
Lauryl cocoate	The ester of lauryl alcohol and the fatty acids derived from coconut oil. <i>The mixture of esters obtained from the reaction of lauryl alcohol with the fatty acids derived from coconut oil.</i>	Skin-cond agent—emol; skin-cond agent—oc
Lauryl isostearate/93803-85-1	The ester of lauryl alcohol and isostearic acid. <i>The mixture of esters obtained from the reaction of lauryl alcohol with branched-chain stearic acids.</i>	Skin-cond agent—emol
Lauryl laurate/13945-76-1	The ester of lauryl alcohol and lauric acid. <i>The ester obtained from the reaction of lauryl alcohol with lauric acid.</i>	Skin-cond agent—misc; binder; emul stab; hair-cond agent; opacifying agent
Lauryl myristate/2040-64-4	The ester of lauryl alcohol and myristic acid. <i>The ester obtained from the reaction of lauryl alcohol with myristic acid.</i>	Skin-cond agent—oc; hair-cond agent
Lauryl oleate/36078-10-1	Ester of lauryl alcohol and oleic acid that conforms to the formula. <i>The ester obtained from the reaction of lauryl alcohol with oleic acid.</i>	Skin-cond agent—oc
Lauryl palmitate/42232-29-1	The ester of lauryl alcohol and palmitic acid. <i>The ester obtained from the reaction of lauryl alcohol with palmitic acid.</i>	Skin-cond agent—oc
Lauryl stearate/5303-25-3	The ester of lauryl alcohol and stearic acid. <i>The ester obtained from the reaction of lauryl alcohol with stearic acid.</i>	Skin-cond agent—oc
Lignoceryl erucate	The ester of lignoceryl alcohol and erucic acid. <i>The ester obtained from the reaction of lignoceryl alcohol with erucic acid.</i>	Skin-cond agent—emol
Myristyl isostearate/94247-26-4	The ester of myristyl alcohol and isostearic acid. <i>The mixture of esters obtained from the reaction of myristyl alcohol with branched-chain stearic acids.</i>	Skin-cond agent—emol
Myristyl laurate/22412-97-1	The ester of myristyl alcohol and lauric acid. <i>The ester obtained from the reaction of myristyl alcohol with lauric acid.</i>	Surf—emulsifying agent

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Myristyl myristate/3234-85-3	The ester of myristyl alcohol and myristic acid. <i>The ester obtained from the reaction of myristyl alcohol with myristic acid</i>	Skin-cond agent—oc
Myristyl neopentanoate/144610-93-5	The ester of myristyl alcohol and neopentanoic acid. <i>The ester obtained from the reaction of myristyl alcohol with neopentanoic acid.</i>	Skin-cond agent—emol
Myristyl stearate/17661-50-6	The ester of myristyl alcohol and stearic acid. <i>The ester obtained from the reaction of myristyl alcohol and stearic acid.</i>	Skin-cond agent—oc
Octyldecyl oleate	The ester of octyldecanol and oleic acid. <i>The ester obtained from the reaction of 2-octyldecanol with oleic acid.</i>	Skin-cond agent-emol
Octyldodecyl avocadoate	The ester of octyldodecanol and the fatty acids derived from avocado oil. <i>The mixture of esters obtained from the reaction of 2-octyldodecanol with the fatty acids derived from avocado oil.</i>	Skin-cond agent—emol
Octyldodecyl beeswax	The ester of octyldodecanol and beeswax acid. <i>The mixture of esters obtained from the reaction of 2-octyldodecanol with a mixture of straight-chain fatty acids, containing 24 to 36 carbons in alkyl chain length (beeswax acid).</i>	Skin-cond agent—emol
Octyldodecyl behenate/125804-08-2	The ester of octyldodecanol and behenic acid that conforms to the formula. <i>The ester obtained from the reaction of 2-octyldodecanol with behenic acid.</i>	Skin-cond agent—oc
Octyldodecyl cocoate	The ester of octyldodecanol and coconut acid. <i>The mixture of esters obtained from the reaction of 2-octyldodecanol and the fatty-acids derived from coconut acid.</i>	Skin-cond agent—emol
Octyldodecyl erucate/88103-59-7	The ester of octyldodecanol and erucic acid. <i>The ester obtained from the reaction of 2-octyldodecanol with erucic acid.</i>	Skin-cond agent—oc
Octyldodecyl hydroxystearate/308122-33-0	The ester of octyldodecanol and 12-hydroxystearic acid. <i>The ester obtained from the reaction of 2-octyldodecanol and 12 hydroxystearic acid.</i>	Skin-cond agent—oc
Octyldodecyl isostearate/93803-87-3	The ester of octyldodecanol and isostearic acid. <i>The mixture of esters obtained from the reaction of 2-octyldodecanol WITH isostearic acid.</i>	Skin-cond agent—oc
Octyldodecyl meadowfoamate	The ester of octyldodecanol and the fatty acids derived from <i>Limnanthes alba</i> (meadowfoam) seed oil. <i>The mixture of esters obtained from the reaction of 2 octyldodecanol with the fatty acids derived from Limnanthes alba (meadowfoam) seed oil.</i>	Skin-cond agent—oc
Octyldodecyl myristate/22766-83-2; 83826-43-1	The ester of octyldodecanol and myristic acid. <i>The ester obtained from the reaction of 2 octyldodecanol with myristic acid.</i>	Skin-cond agent—oc
Octyldodecyl neodecanoate/1004272-41-6	The ester of octyldodecanol and neodecanoic acid. <i>The ester obtained from the reaction of 2-octyldodecanol with neodecanoic acid.</i>	Skin-cond agent—emol
Octyldodecyl neopentanoate/158567-66-9	The ester of octyldodecanol and neopentanoic acid. <i>The ester obtained from the reaction of 2-octyldodecanol with neopentanoic acid.</i>	Skin-cond agent—emol
Octyldodecyl octyldodecanoate	The ester of octyldecanol and octyldodecanoic acid. <i>The ester obtained from the reaction of 2-octyldecanol with 2 octyldodecanoic acid.</i>	Skin-cond agent—oc
Octyldodecyl oleate/22801-45-2	The ester of octyldodecanol and oleic acid. <i>The ester obtained from the reaction of 2-octyldodecanol with oleic acid.</i>	Skin-cond agent—oc

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Octyldodecyl olivate/22801-45-2	The ester of octyldodecanol and the fatty acids derived from <i>Olea europaea</i> (olive) oil. <i>The ester obtained from the reaction of 2-octyldodecanol with the fatty acids derived from Olea europaea (olive) oil.</i>	Skin-cond agent—emol; skin-cond agent—oc; binder; film former; hair-cond agent; slip modifier
Octyldodecyl ricinoleate/79490-62-3; 125093-27-8	The ester of octyldodecanol and ricinoleic acid. <i>The ester obtained from the reaction of 2-octyldodecanol with ricinoleic acid.</i>	Hair-cond agent; shampoo
Octyldodecyl safflowerate	The ester of octyldodecanol and the fatty acids derived from <i>Carthamus tinctorius</i> (safflower) oil. <i>The ester obtained from the reaction of 2-octyldodecanol with the fatty acids derived from Carthamus tinctorius (safflower) oil.</i>	Skin-cond agent—emol
Octyldodecyl stearate/22766-82-1	The ester of octyldodecanol and stearic acid. <i>The ester obtained from the reaction of 2-octyldodecanol with stearic acid.</i>	Skin-cond agent—oc
Oleyl arachidate/22393-96-0; 156952-79-3	The ester of oleyl alcohol and arachidic acid. <i>The ester obtained from the reaction of oleyl alcohol with arachidic acid.</i>	Skin-cond agent—oc
Oleyl erucate/17673-56-2; 143485-69-2	The ester of oleyl alcohol and erucic acid. <i>The ester obtained from the reaction of oleyl alcohol with erucic acid.</i>	Skin-cond agent—oc
Oleyl linoleate/17673-59-5	The ester of oleyl alcohol and linoleic acid. <i>The ester obtained from the reaction of oleyl alcohol with linoleic acid.</i>	Skin-cond agent—oc; hair-cond agent
Oleyl myristate/22393-93-7	The ester of oleyl alcohol and myristic acid. <i>The ester obtained from the reaction of oleyl alcohol with myristic acid.</i>	Skin-cond agent—oc; hair-cond agent
Oleyl oleate/3687-45-4; 17363-94-9	The ester of oleyl alcohol and oleic acid. <i>The ester obtained from the reaction of oleyl alcohol with oleic acid.</i>	Skin-cond agent—emol; skin-cond agent-emol
Oleyl stearate/33057-39-5; 17673-50-6	The ester of oleyl alcohol and stearic acid. <i>The ester obtained from the reaction of oleyl alcohol with stearic acid.</i>	Skin-cond agent—oc; hair-cond agent
Propylheptyl caprylate/868839-23-0	The organic compound that conforms to the formula. <i>The ester obtained from the reaction of 2-propylheptanol with caprylic acid.</i>	Skin-cond agent—emol
Stearyl beeswax/42233-11-4	The ester of stearyl alcohol and beeswax acid. <i>The mixture of esters obtained from the reaction of stearyl alcohol with a mixture of straight-chain fatty acids, containing 24 to 36 carbons in alkyl chain length (beeswax acid).</i>	Skin-cond agent—oc
Stearyl behenate/24271-12-3	The ester of stearyl alcohol and behenic acid. <i>The ester obtained from the reaction of stearyl alcohol with behenic acid.</i>	Skin-cond agent—oc
Stearyl caprylate/18312-31-7	The ester of stearyl alcohol and caprylic acid. <i>The ester obtained from the reaction of stearyl alcohol with caprylic acid.</i>	Skin-cond agent—oc
Stearyl erucate/86601-84-5; 96810-34-3	The ester of stearyl alcohol and erucic acid. <i>The ester obtained from the reaction of stearyl alcohol with erucic acid.</i>	Visc incr agent—nonaq
Stearyl heptanoate/66009-41-4	The ester of stearyl alcohol and heptanoic acid. <i>The ester obtained from the reaction of stearyl alcohol with heptanoic acid.</i>	Skin-cond agent—oc
Stearyl Linoleate/17673-53-9	The ester of stearyl alcohol and linoleic acid that conforms to the formula. <i>The ester obtained from the reaction of stearyl alcohol with linoleic acid.</i>	Skin-cond agent—oc; visc incr agent—nonaq
Stearyl olivate	The ester of stearyl alcohol and the fatty acids derived from <i>Olea europaea</i> (olive) oil. <i>The ester obtained from</i>	Skin-cond agent—emol; surf—emulsifying agent

(continued)

Table 5. (continued)

Ingredient/CAS no.	Definition (italicized text generated by CIR)	Function
Stearyl palmitate/2598-99-4	<i>the reaction of stearyl alcohol with the fatty acids derived from Olea europaea (olive) oil.</i> The ester of stearyl alcohol and palmitic acid. <i>The ester obtained from the reaction of stearyl alcohol with palmitic acid.</i>	Skin-cond agent—misc; hair-cond agent; binder; emul stab; humectant; film former; opacifying agent
Stearyl stearate/2778-96-3	The ester of stearyl alcohol and stearic acid. <i>The ester obtained from the reaction of stearyl alcohol with stearic acid.</i>	Skin-cond agent—oc; visc incr agent—nonaq
Tetradecyleicosyl stearate	The ester of myristyleicosanol and stearic acid. <i>The ester obtained from the reaction of myristyleicosanol with stearic acid.</i>	Skin-cond agent—oc
Tetradecyloctadecyl behenate	The ester of tetradecyloctadecanol and behenic acid. <i>The ester obtained from the reaction of tetradecyloctadecanol with behenic acid.</i>	Skin-cond agent—oc; binder; emul stab; film former; opacifying agent
Tetradecyloctadecyl hexyldecanoate/ 93982-00-4	The organic compound that conforms to the formula. <i>The ester obtained from the reaction of 2 tetradecyloctyldecanol with 2-hexyldecanoic acid.</i>	Skin-cond agent—emol
Tetradecyloctadecyl myristate	The ester of tetradecyloctadecanol and myristic acid. <i>The ester obtained from the reaction of 2 tetradecyloctyldecanol with myristic acid.</i>	Skin-cond agent—oc; binder; emul stab; film former; opacifying agent
Tetradecyloctadecyl stearate	The ester of tetradecyloctadecanol and stearic acid. <i>The ester obtained from the reaction of 2-tetradecyloctadecanol with stearic acid.</i>	Skin-cond agent—oc; binder; emul stab; film former; opacifying agent
Tetradecylpropionates	An isomeric mixture of esters consisting chiefly of 2 tetradecylpropionate, 3-tetradecylpropionate, and 4-tetradecylpropionate. <i>The mixture of esters obtained from the reaction of a mixture of 2-, 3-, and 4-tetradecanols with propionic acid.</i>	Skin-cond agent—emol; solvent
Tridecyl behenate/42233-08-9	The ester of tridecyl alcohol and behenic acid. <i>The ester obtained from the reaction of tridecyl alcohol with behenic acid.</i>	Skin-cond agent—oc
Tridecyl cocoate	The ester of tridecyl alcohol and coconut acid. <i>The mixture of esters obtained from the reaction of tridecyl alcohol with the fatty acids derived from coconut acid.</i>	Skin-cond agent—oc
Tridecyl erucate/131154-74-0; 221048-36-8	The ester of tridecyl alcohol and erucic acid. <i>The ester obtained from the reaction of tridecyl alcohol with erucic acid.</i>	Skin-cond agent—oc
Tridecyl isononanoate/125804-18-4	The ester of tridecyl alcohol and isononanoic acid that conforms to the formula. <i>The ester of tridecyl alcohol and branched-chain nonanoic acids.</i>	Skin-cond agent—emol
Tridecyl laurate/36665-67-5	The ester of tridecyl alcohol and lauric acid that conforms to the formula. <i>The ester obtained from the reaction of tridecyl alcohol with lauric acid.</i>	Skin-cond agent—oc
Tridecyl myristate/36617-27-3	The ester of tridecyl alcohol and myristic acid. <i>The ester obtained from the reaction of tridecyl alcohol with myristic acid.</i>	Skin-cond agent—oc
Tridecyl neopentanoate/106436-39-9; 105859-93-6	The ester of tridecyl alcohol and neopentanoic acid. <i>The ester obtained from the reaction of tridecyl alcohol with neopentanoic acid.</i>	Skin-cond agent—emol
Tridecyl stearate/31556-45-3	The ester of tridecyl alcohol and stearic acid. <i>The ester obtained from the reaction of tridecyl alcohol with stearic acid.</i>	Skin-cond agent—emol

Abbreviations: cond, conditioning; disp, dispersing; emol, emollient; emul, emulsion; incr, increasing; ingr, ingredient; misc, miscellaneous; nonaq, nonaqueous; nonsurf, nonsurfactant; oc, occlusive; solub, solubilizing; stab, stabilizer; surf, surfactant; visc, viscosity.

Table 6. Methods of Manufacture.

Ingredient	Method of manufacture	Reference
Arachidyl propionate	Manufactured as a mixture of the esters of the C ₁₈ –C ₂₈ fatty alcohols, of which C ₂₀ fatty alcohol ester is the major constituent	3
Butyl oleate	Reaction of butanol and oleic acid in the presence of dihydrogen phosphate prepared from <i>n</i> -butanol and oleic acid by heating, with sulfuric acid as a catalyst	36
	Esterification of oleic acid with butyl alcohol in <i>n</i> -hexane in the presence of the macroporous sulfonic resin K241 I	37,38
	Synthesized with <i>Candida antarctica</i> lipase catalyst or using a sodium alcoholate catalyst	39
	Esterification of oleic acid with butanol in the presence of <i>p</i> -toluene sulfonic acid	40
	Lipase-catalyzed oleic acid esterification by <i>n</i> -butyl alcohol in almost nonaqueous media without an organic solvent	41
Butyl myristate	Derived from the esterification of myristic acid and butyl alcohol in the presence of an acid catalyst	22
Butyl stearate	The esterification of stearic acid with butyl alcohol; the reaction products are refined by catalyst neutralization, vacuum distillation, or various decolorization-deodorization techniques to remove traces of alcohol	7
Cetyl behenate	Esterification of behenic acid with cetyl alcohol using <i>n</i> -butyl benzene as the solvent and tetra <i>n</i> -butyl titanate as the catalyst	42
Cetyl oleate	Cetyl alcohol and oleic acid were dissolved in benzene and heated, using sulfuric acid as a catalyst; the mixture was then washed, the benzene filtered and removed by vacuum distillation, and the ester separated twice by distillation esterification of oleic acid with cetyl alcohol in <i>n</i> -hexane in the presence of <i>p</i> -toluene sulfonic acid	43
	Lipase-catalyzed oleic acid esterification by cetyl alcohol in almost nonaqueous media without an organic solvent	39
		44
Cetyl stearate	The esterification of stearic acid with cetyl alcohol; the reaction products are refined by catalyst neutralization, vacuum distillation, or various decolorization–deodorization techniques to remove traces of alcohol	7
Ethylhexyl laurate	Coproduced by the lipase-catalyzed acylation of racemic alcohol and vinyl laurate in the production of (R)-2-ethylhexanol	45
Ethylhexyl oleate	Synthesized with <i>Candida antarctica</i> lipase catalyst or using a sodium alcoholate catalyst	40
Ethylhexyl stearate	The esterification of stearic acid with octyl alcohol; the reaction products are refined by catalyst neutralization, vacuum distillation, or various decolorization–deodorization techniques to remove traces of alcohol	7
Isobutyl stearate	The esterification of stearic acid with isobutyl alcohol; the reaction products are refined by catalyst neutralization, vacuum distillation, or various decolorization–deodorization techniques to remove traces of alcohol	7
Isocetyl myristate	The esterification of isocetyl alcohol and myristic acid	5
Isocetyl stearate	The esterification of stearic acid with isocetyl alcohol; the reaction products are refined by catalyst neutralization, vacuum distillation, or various decolorization–deodorization techniques to remove traces of alcohol can be made by heating with or without acid catalyst	7
Isopropyl arachidate	Arachidic acid was treated with isopropyl alcohol in large molar excess, <i>p</i> -toluene sulfonic acid was the catalyst	46
Isopropyl laurate	Lauric acid was treated with isopropyl alcohol in large molar excess, <i>p</i> -toluene sulfonic acid was the catalyst	46
Isopropyl myristate	Commercially produced by distillation, which is preceded by the esterification of myristic acid and isopropanol, in the presence of an acid catalyst	6
Isopropyl oleate	Esterification of oleic acid with isopropyl alcohol in <i>n</i> -hexane in the presence of K241 I	39
	Synthesized with <i>Candida antarctica</i> lipase catalyst or using a sodium alcoholate catalyst	40
Isopropyl stearate	The esterification of stearic acid with isopropyl alcohol; the reaction products are refined by catalyst neutralization, vacuum distillation, or various decolorization–deodorization techniques to remove traces of alcohol	7
Isostearyl neopentanoate	Prepared by esterifying isoostearyl alcohol with neopentanoic acid in the presence of a catalyst	21
Lauryl behenate	Esterification of behenic acid with lauryl alcohol using <i>n</i> -butyl benzene as the solvent and tetra <i>n</i> -butyl titanate as the catalyst	42
Lauryl oleate	Esterification of oleic acid with lauryl alcohol in <i>n</i> -hexane in the presence of <i>p</i> -toluene sulfonic acid	39
	Synthesized with <i>Candida antarctica</i> lipase catalyst or using a sodium alcoholate catalyst	
Lauryl palmitate	Lipase-catalyzed esterification of palmitic acid and lauryl alcohol using Novozym 435 as the biocatalyst	49
Myristyl laurate	The fatty acid chloride was reacted with myristic acid in the presence of pyridine, using diethyl ether as the solvent	47
Myristyl myristate	Produced by the esterification of myristic acid and myristyl alcohol in the presence of an acid catalyst	6

(continued)

Table 6. (continued)

Ingredient	Method of manufacture	Reference
Myristyl stearate	The esterification of stearic acid with myristyl alcohol; the reaction products are refined by catalyst neutralization, vacuum distillation, or various decolorization–deodorization techniques to remove traces of alcohol	7
Octyldodecyl myristate	The esterification of myristic acid with 2-octyl dodecanol, manufactured from vegetable sources	5
Oleyl arachidate	The fatty acid chloride was reacted with oleic acid in the presence of pyridine, using diethyl ether as the solvent	47
Oleyl oleate	The fatty acid chloride was reacted with oleic acid in the presence of pyridine, using diethyl ether as the solvent	47 44
	Lipase-catalyzed oleic acid esterification by oleyl alcohol in almost nonaqueous media without an organic solvent	40
	Synthesized with <i>Candida antarctica</i> lipase catalyst or using a sodium alcoholate catalyst	
Oleyl stearate	The fatty acid chloride was reacted with oleic acid in the presence of pyridine, using diethyl ether as the solvent	47

Methods of Manufacture

Most of these alkyl esters are produced synthetically via classical Fischer type esterification methods (ie, reaction of a carboxylic acid with an alcohol to produce a carboxylic ester; Table 1), although the reaction may be promoted by acid or base catalysis, or by the use of an acid chloride.

Some of the natural source ingredients in this review may be produced by transesterification (ie, exchange of alcohol moieties to create a different ester product). For example, the triglycerides (ie, glyceryl triesters) in natural oils can be reacted with alcohols to produce new monoesters (and diglycerides, monoglycerides, and glycerin, depending on reaction stoichiometry). Available methods of manufacture are summarized in Table 6.^{3,5-7,21,22,36-51}

Physical and Chemical Properties

Alkyl esters are hydrophobic materials that range from oils, at the lowest molecular weights/shortest chain lengths, to waxy solids, at the highest molecular weights/longest chain lengths. Physical and chemical properties data are provided in Table 7.^{3,5-7,9,10,12,13,15,21,22,36,40-43,45-48,50,52-63}

Impurities

One published reference stated that in the synthesis of oleate esters using sodium alcoholates (base catalyst), methyl oleate was the major impurity.⁴⁰ (The safety assessment of decyl and isodecyl oleate includes and took into account toxicity data on methyl oleate.¹³)

Use

Cosmetic

The alkyl esters are reported to function in cosmetics mostly as skin-conditioning agents.¹ Some of the alkyl esters are reported to have additional functions; for example, isoocetyl

tallate is reported to also function as a plasticizer and solvent, and tetradecylpropionates is reported to function as a solvent (Table 5).

The Food and Drug Administration (FDA) collects information from manufacturers on the use of individual ingredients in cosmetic formulations as a function of cosmetic product category in its Voluntary Cosmetic Registration Program (VCRP). The VCRP data obtained from the FDA⁶⁴ in 2013 and data received in response to a survey of the maximum reported use concentration by category conducted by the Personal Care Products Council (Council)⁶⁵⁻⁶⁸ indicate that 112 of the 237 alkyl esters named in this safety assessment are currently used in cosmetic formulations. Ethylhexyl palmitate has the most reported uses, 1525, followed by isopropyl myristate, 1182 reported uses, and isopropyl palmitate, 1125 reported uses (cetyl esters is reported to be used in 476 cosmetic formulations). Many of the alkyl esters are used at high concentrations in cosmetic formulations. Ethylhexyl palmitate had the highest reported use concentration, 78% in body and hand preparations, followed by isopropyl myristate, which is used at 77.3% in other hair grooming aids and 76.6% in aerosol hair spray formulations.

The frequency and concentration of use data and the historical data of previously reviewed ingredients are summarized in Table 8. The ingredients not in use according to the VCRP and industry survey are listed in Table 9.⁶⁵⁻⁶⁷

In quite a few cases, reports of uses were received in the VCRP, but no concentration of use data are available. For example, caprylyl caprylate is reported to be used in 11 cosmetic formulations, but no use concentration data were reported. Additionally, there were quite a few instances in which no reported uses were received in the VCRP, but a use concentration was provided in the industry survey. For example, oleyl linoleate was not reported in the VCRP to be in use, but the industry survey indicated that it is used in leave-on formulations at up to 11%. It should be presumed in these cases that there is at least one use in every category for which a concentration is reported.

Table 7. Chemical and Physical Properties.

Property	Description	Reference
Arachidyl behenate		
Molecular weight	621.12	48
Boiling point	648.7°C (760 Torr; calculated)	48
Density	0.856 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	20.146 (25°C; calculated)	48
Arachidyl erucate		
Molecular weight	619.10	48
Boiling point	608.3°C (760 Torr; calculated)	48
Density	0.898 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	16.353 (25°C; calculated)	48
Arachidyl propionate		
Characteristics	Soft, waxy, amber-colored solid with a slight characteristic odor	3
Melting point	36-38°C	3
Boiling point	224°C	3
Specific gravity	0.83	3
Solubility	Soluble in mineral oil and insoluble in water	3
Batyl stearate		
Molecular weight	611.03	48
Boiling point	656.9°C (760 Torr; calculated)	48
Density	0.856 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	20.146 (25°C; calculated)	48
pKa	14.08 (most acidic temperature: 25°C; calculated)	48
Behenyl behenate		
Molecular weight	649.18	52
Behenyl erucate		
Molecular weight	647.15	48
Boiling point	669.1°C (760 Torr; calculated)	48
Density	0.860 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	20.755 (25°C; calculated)	48
Butyl myristate		
Form	Colorless oily liquid	22
Boiling point	167°C-197°C (5 mm Hg)	22
Specific gravity	0.850-0.858 (25°C)	22
Solubility	Soluble in acetone, castor oil, chloroform, methanol, mineral oil, and toluene; insoluble in water	22
Butyl oleate		
Appearance and form	Mobile, yellow, oily liquid	
Molecular weight	338.57	36
Melting point	-31.7°C	40
	-35.5°C	41
Boiling point	235°C-45°C	36
Density	0.870 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	9.547 (25°C; calculated)	48
Butyl stearate		
Characteristics	Stable, colorless, oily liquid	7
Molecular weight	340.57	7
Melting point	16°C-20.5°C	7

(continued)

Table 7. (continued)

Property	Description	Reference
Boiling point	212°C-216°C	7
Specific gravity	0.851-0.861 (20°/20°C)	7
Refractive index	1.441 (25°C)	7
Saponification value	146-177	7
Solubility	Soluble in acetone, chloroform, ether, alcohol, ketones, ethyl acetate, aromatic and aliphatic hydrocarbons, fats, waxes, mineral oils, and many plasticizers; and insoluble in water	7
Caprylyl butyrate		
Molecular weight	200.32	48,52
Melting point	-55.6°C	53
Boiling point	244.1°C	53
Water solubility	5.81 mg/L (25°C; estimated)	53
Density	0.870 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	4.861 (25°C; calculated)	48
Caprylyl caprylate		
Molecular weight	256.42	48,52
Melting point	-18.1°C	53
Boiling point	306.8°C	53
Water solubility	0.112 mg/L (25°C; estimated)	53
Density	0.865 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	6.899 (25°C; calculated)	48
Cetearyl isononanoate		
Form	Yellowish liquid	9
Melting point	<15°C	9
Refractive index	1.445-1.450	9
Density	0.854-8.858 g/mL	9
Saponification value	140-146	9
Solubility	Insoluble in water	9
Cetyl behenate		
Molecular weight	565.01	48
Melting point	65°C	42
Boiling point	569.4°C (760 Torr; calculated)	48
Density	0.857 g/cm ³ (20°C; 760 Torr; calculated)	48
Specific gravity	0.8178-0.804 (70°C-100°C, respectively)	42
Refractive index	1.441-1.433 (70°C-90°C, respectively)	42
Log P	18.108 (25°C; calculated)	48
Cetyl caprylate		
Form	Liquid	79
Molecular weight	368.64	48,52
Boiling point	414.2°C (760 Torr; calculated)	48
Density	0.860 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	10.975 (25°C; calculated)	48
Cetyl esters		
Characteristics	White to off-white, somewhat translucent solid with a crystalline structure and a faint odor	54
Melting range	43°C-47°C	54

(continued)

Table 7. (continued)

Property	Description	Reference
Specific gravity	0.820-0.840 (50°C)	54
Saponification value	109-120	54
Solubility	Soluble in boiling alcohol, ether, chloroform, and fixed oils; insoluble in water and cold alcohol	54
Composition	Mixture consisting of esters of primarily saturated fatty alcohols (C ₁₄ to C ₁₈) and saturated fatty acids (C ₁₄ to C ₁₈)	54
Cetyl isononanoate		
Molecular weight	382.66	9
Log P	0.28 (calculated)	9
Cetyl laurate		
Molecular weight	424.74	48
Melting point	40-41°C	55
Boiling point	462.2°C (760 Torr; calculated)	48
Density	0.860 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	113.013 (25°C; calculated)	48
Cetyl myristoleate		
Molecular weight	450.78	48
Boiling point	519.6°C (calculated)	48
Log P	14.005 (25°C; calculated)	48
Cetyl oleate		
Molecular weight	506.89	52
Melting point	25.5°C	62
Saponification value	110.7	43
Cetyl palmitate		
Molecular weight	481	10
Characteristics	White, crystalline, wax-like substance	10
Melting point	46°C-54°C	10
Specific gravity	0.832 (25°C)	10
Refractive index	1.4398 (n _D 70)	10
Solubility	Soluble in alcohol and ether; insoluble in water	10
C32-36 isoalkyl stearate		
Molecular weight	761.38	52
Decyl cocoate		
Characteristics	Almost odorless light yellow liquid	12
Specific gravity	0.85 g/cm ³ (25°C)	12
Saponification value	155-170	12
Decyl laurate		
Molecular weight	340.58	52
Boiling point	388.9°C (760 Torr; calculated)	48
Log P	9.956 (25°C; calculated)	48
Decyl oleate		
Characteristics	Light yellow liquid	13
Molecular weight	422	13
Specific gravity	0.855-0.865	13
Saponification value	103-142	13
Solubility	Soluble in alcohol and insoluble in water	13
Decyl palmitate		
Molecular weight	396.69	48,52

(continued)

Table 7. (continued)

Property	Description	Reference
Melting point	30°C	63
Boiling point	438.7°C (760 Torr; calculated)	48
Density	0.860 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	11.994 (25°C; calculated)	48
Ethylhexyl hydroxystearate		
Characteristics	Clear to slightly opalescent, yellow, oily liquid with a slight fatty odor	54
Boiling point	490.6°C (760 Torr; calculated)	48
Specific gravity	0.889-0.895 (25°/25°C)	54
Saponification value	140-160	54
Solubility	Soluble in ethyl alcohol and corn oil Insoluble in water and propylene glycol	54
Log P	9.776 (25°C; calculated)	48
Ethylhexyl isononanoate		
Molecular weight	270.45	9
Log P	5.91 (calculated)	9
Ethylhexyl isopalmitate		
Form	liquid	79
Ethylhexyl laurate		
Molecular weight	312.53	48,52
Melting point	-30°C	56
Boiling point	>250°C (1013 hPa) 124°C-126°C (0.1 mm Hg)	56 45
Water solubility	1 mg/L (20°C)	56
Density	0.86 g/cm ³ (20°C)	56
Log P	8.781 (25°C; calculated)	48
Ethylhexyl oleate		
Molecular weight	394.67	48
Melting point	-2.9°C	40
Boiling point	465.8°C (760 Torr; calculated)	48
Density	0.867 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	11.429 (25°C; calculated)	48
Ethylhexyl palmitate		
Molecular weight	388	10
Characteristics	Clear, colorless, practically odorless liquid	10
Specific gravity	0.850-0.865 (25°C)	10
Refractive index	1.445-1.4465 (25°C)	10
Solubility	Soluble in acetone, castor oil, corn oil, chloroform, ethanol, and mineral oil; insoluble in water, glycerin, and propylene glycol	10
Ethylhexyl pelargonate		
Molecular weight	270.45	9
Density	0.864 ± 0.06 g/cm ³ (20°C)	9
Log P	7.432 (calculated)	9
Ethylhexyl stearate		
Molecular weight	396	7
Erucyl erucate		
Molecular weight	645.14	48
Boiling point	668.1°C (760 Torr; calculated)	48

(continued)

Table 7. (continued)

Property	Description	Reference
Density	0.865 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	20.346 (25°C; calculated)	48
Erucyl oleate		48
Molecular weight	589.03	48
Boiling point	631.3	48
Density	0.866 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	18.308 (25°C; calculated)	48
Heptyl undecylenate		48,52
Molecular weight	282.46	48
Boiling point	351.0°C (760 Torr; calculated)	48
Density	0.871 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	7.510 (25°C; calculated)	48
Heptylundecyl hydroxystearate		48
Molecular weight	552.96	48
Boiling point	607.3°C (760 Torr; calculated)	48
Density	0.885 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	14.870 (25°C; calculated)	48
pKa	15.40 (most acidic temp: 25°C)	48
Hexyldeacyl laurate		52
Molecular weight	424.74	52
Hexyldeacyl oleate		48,52
Molecular weight	506.89	48,52
Boiling point	563.6°C (760 Torr; calculated)	48
Density	0.863 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	15.505 (25°C; calculated)	48
Hexyldeacyl palmitate		52
Molecular weight	480.85	52
Hexyl laurate		48,52
Molecular weight	284.48	48,52
Melting point	-3.4°C	57
Boiling point	130°C	57
Density	0.864 g/cm ³ (20°C; 760 Torr; calculated)	48
Refractive index	1.4382	57
Log P	7.918 (25°C; calculated)	48
Hydroxyoctacosanyl hydroxystearate		48,52
Molecular weight	709.22	48,52
Boiling point	311.8°C (760 Torr; calculated)	48
Density	0.864 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	7.253 (25°C; calculated)	48
Isoamyl laurate		48,52
Molecular weight	270.45	48,52
Boiling point	631.3	48
Density	0.866 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	18.308 (25°C; calculated)	48
Isobutyl palmitate		48,52
Molecular weight	312.53	48,52
Boiling point	354.6°C (760 Torr; calculated)	48
Density	0.862 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	8.781 (25°C; calculated)	48

(continued)

Table 7. (continued)

Property	Description	Reference
Isobutyl pelargonate		9
Molecular weight	214.34	9
Density	0.867 ± 0.06 g/cm ³ (20°C)	9
Log P	5.307 (calculated)	9
Isobutyl stearate		7
Characteristics	A paraffin-like crystal substance a low temperature; a liquid at room temperature	7
Molecular weight	340.57	7
Melting point	20°C	7
Saponification value	170-180	7
Isocetyl myristate		5
Characteristics	Oily liquid with practically no odor	5
Density	0.862	5
Solubility	Soluble in most organic solvents; insoluble in water	5
Isocetyl isostearate		79
Form	Liquid	79
Molecular weight	508.9	52
Isocetyl palmitate		79
Form	Liquid	79
Isocetyl stearate		7
Characteristics	An oily, colorless, or yellow liquid with practically no odor	7
Molecular weight	508	7
Specific gravity	0.8520-0.858 (25°/25°C)	7
Refractive index	1.451-1.453 (25°C)	7
Saponification value	110-118	7
Solubility	Soluble in ethanol, isopropanol, mineral oil, castor oil, acetone, and ethyl acetate; insoluble in water, glycerin, and propylene glycol	7
Isodecyl isononanoate		9
Molecular weight	298.5	9
Refractive index	1.437-1.439 (25°C)	9
Specific gravity	0.852-0.858 (25°/25°C)	9
Saponification value	175-192	9
Log P	6.68 (calculated)	9
Isodecyl laurate		58
Form	Colorless or pale yellow liquid	58
Molecular weight	340.58	48
Boiling point	374.2°C (760 Torr; calculated)	48
Density	0.860 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	9.644 (25°C; calculated)	48
Isodecyl neopentanoate		52
Molecular weight	242.40	52
Isodecyl oleate		13
Molecular weight	422	13
Saponification value	130-145	13
Isodecyl palmitate		48,52
Molecular weight	396.69	48,52
Boiling point	425.2°C (760 Torr; calculated)	48
Density	0.858 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	11.682 (25°C; calculated)	48

(continued)

Table 7. (continued)

Property	Description	Reference
Isodecyl stearate		
Molecular weight	424.74	52
Isohexyl caprate		
Molecular weight	256.42	48
Boiling point	296.8°C (760 Torr; calculated)	48
Density	0.864 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	6.743 (25°C; calculated)	48
Isohexyl laurate		
Characteristics	Pale yellow liquid with a coconut-like odor	54
Molecular weight	284.48	48
Boiling point	326.5°C (760 Torr; calculated)	48
Refractive index	1.439-1.442 (20°C)	54
Specific gravity	0.843-0.853 (25°/25°C)	54
Saponification value	130-145	54
Solubility	Soluble in most organic solvents Insoluble in water	54
Free fatty acid content	0.1% (max; as lauric acid)	54
Log P	7.762 (25°C; calculated)	48
Isohexyl neopentanoate		
Molecular weight	186.29	48
Boiling point	193.2°C (760 Torr; calculated)	48
Density	0.870 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	3.941 (25°C; calculated)	48
Isohexyl palmitate		
Characteristics	Light yellow liquid with a fatty-type odor	54
Molecular weight	340.58	48
Boiling point	381.5°C (760 Torr; calculated)	48
Refractive index	1.4433-1.4443 (20°C)	54
Specific gravity	0.850-0.860 (25°/25°C)	54
Saponification value	165-171	54
Solubility	Soluble in alcohol and mineral oil; insoluble in water and lower glycols and glycerin	54
Log P	9.800 (25°C; calculated)	48
Isononyl isononanoate		
Molecular weight	284.48	9
Refractive index	1.430-1.436 (25°C)	9
Specific gravity	0.849-0.855 (25°/25°C)	9
Saponification value	192-202	9
Log P	6.27 (calculated)	9
Isopropyl arachidate		
Form	White crystal	46
Molecular weight	354.61	48
Melting point	53°C-55°C	46
Boiling point	394.4°C (760 Torr; calculated)	48
Density	0.860 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	10.310 (25°C; calculated)	48
Isopropyl behenate		
Molecular weight	382.66	48
Boiling point	419.6°C (760 Torr; calculated)	48
Density	0.859 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	11.329 (25°C; calculated)	48

(continued)

Table 7. (continued)

Property	Description	Reference
Isopropyl isostearate		
Form	Liquid	15
Specific gravity	0.853-0.859 (25°C)	15
Solubility	Soluble in acetone, ethyl acetate, isopropyl alcohol, and mineral oil	15
Isopropyl laurate		
Form	Yellow oil	46
Molecular weight	242.40	48
Boiling point	196°C	53
Specific gravity	0.851-0.857	59
Refractive index	1.427-1.433 (20°C)	59
Solubility	Insoluble in water; solubility in 95% ethanol, 1 mL in 1 mL	59
Log P	6.234 (25°C; calculated)	48
Isopropyl linoleate		
Molecular weight	322.53	48
Boiling point	399.0°C (760 Torr; calculated)	48
Density	0.880 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	8.478 (25°C; calculated)	48
Isopropyl myristate		
Characteristics	Colorless, almost odorless liquid with a bland taste	6
Boiling point	192.6°C (20 mm Hg)	6
Specific gravity	0.847-0.853 (25°C)	6
Refractive index	1.432-1.430 (25°C)	6
Solubility	Soluble in acetone, castor oil, chloroform, cottonseed oil, ethanol, ethyl acetate, mineral oil, and toluene; insoluble in water, glycerol, sorbitan, and propylene glycol	6
Isopropyl oleate		
Molecular weight	324.54	52
Melting point	-33.4°C	40
Boiling point	369.8°C (760 Torr; calculated)	48
Density	0.870 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	8.881 (25°C; calculated)	48
Isopropyl palmitate		
Molecular weight	318	10
Characteristics	Colorless, almost odorless, mobile liquid mixture of isopropyl esters consisting of a minimum of 60% isopropyl palmitate	10
Melting point	11°C	10
Specific gravity	0.850-0.855 (25°C)	10
Refractive index	1.4355-1.4375 (25°C)	10
Solubility	Soluble in acetone, castor oil, chloroform, cottonseed oil, ethyl acetate, ethanol, and mineral oil Insoluble in water, glycerin, and propylene glycol	10
Isopropyl stearate		
Form	Liquid at room temperature	7
Molecular weight	326	7

(continued)

Table 7. (continued)

Property	Description	Reference
Isostearyl hydroxystearate		
Molecular weight	552.96	48
Boiling point	607.3°C (760 Torr; calculated)	48
Density	0.885 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	14.870 (25°C; calculated)	48
Isostearyl isononanoate		
Molecular weight	410.72	9
Log P	10.02 (calculated)	9
Isostearyl isostearate		
Molecular weight	536.96	52
Log P	17.399 (calculated)	60
Isostearyl neopentanoate		
Form	Clear, slightly yellow liquid	21
Molecular weight	348-390	21
Refractive index	1.4485-1.4515 (25°C)	21
Specific gravity	0.858-0.870 (25°C)	21
Saponification value	144-161	21
Solubility	Soluble in mineral oil, 95% ethanol, propylene glycol, isopropyl myristate, oleyl alcohol, peanut oil; insoluble in water, 80% ethanol,	21
Isotridecyl isononanoate		
Molecular weight	340.58	9
Refractive index	1.433-1.445 (25°C)	9
Specific gravity	0.859-0.861 (25°C/25°C)	9
Saponification value	155-162	9
Log P	7.94 (calculated)	9
Isotridecyl laurate		
Molecular weight	382.66	48
Boiling point	419.6°C (760 Torr; calculated)	48
Density	0.859 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	11.329 (25°C; calculated)	48
Isotridecyl stearate		
Molecular weight	466.82	52
Lauryl behenate		
Molecular weight	508.90	48
Melting point	53°C	42
Boiling point	528.4°C (760 Torr; calculated)	48
Specific gravity	0.8295-0.8137 (60°C-90°C, respectively)	42
Refractive index	1.443-1.433 (60°C-80°C, respectively)	42
Log P	16.070 (25°C; calculated)	48
Lauryl laurate		
Molecular weight	368.64	48
Melting point	27°C	61
Boiling point	226°C	61
Density	0.860 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	10.975 (25°C; calculated)	48
Lauryl oleate		
Molecular weight	485.75	48
Melting point	14.5°C	62
	18.4°C	40
Boiling point	519.6°C (760 Torr; calculated)	48

(continued)

Table 7. (continued)

Property	Description	Reference
Density	0.865g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	13.623 (25°C; calculated)	48
Lauryl palmitate		
Molecular weight	424.74	48
Boiling point	462.2°C (760 Torr; calculated)	48
Density	0.859 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	13.013 (25°C; calculated)	48
Lauryl stearate		
Molecular weight	452.08	48
Boiling point	484.9°C (760 Torr; calculated)	48
Density	0.858 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	14.032 (25°C; calculated)	48
Myristyl laurate		
Molecular weight	396.69	48
Boiling point	438.7°C (760 Torr; calculated)	48
Density	0.860 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	11.994 (25°C; calculated)	48
Myristyl myristate		
Melting point	37°C-39°C	6
Saponification value	119-129	6
Myristyl neopentanoate		
Molecular weight	298.50	48
Boiling point	332.3°C (760 Torr; calculated)	48
Density	0.863 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	8.173 (25°C; calculated)	48
Myristyl laurate		
Melting point	40°C-40.4°C	47
Myristyl stearate		
Molecular weight	480.85	48
Form	Waxy solid at room temperature	7
Octyldodecyl behenate		
Molecular weight	621.12	48
Boiling point	603.0°C (760 Torr; calculated)	48
Density	0.855 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	19.990 (25°C; calculated)	48
Octyldodecyl erucate		
Molecular weight	619.10	48
Boiling point	646.0°C (760 Torr; calculated)	48
Density	0.860 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	19.581 (25°C; calculated)	48
Octyldodecyl myristate		
Characteristics	Colorless odorless liquid	5
Saponification value	105-111	5
Octyldodecyl neopentanoate		
Molecular weight	382.66	48
Boiling point	405.6°C (760 Torr; calculated)	48
Density	0.859 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	11.074 (25°C; calculated)	48
Octyldodecyl oleate		
Molecular weight	562.99	48

(continued)

Table 7. (continued)

Property	Description	Reference
Boiling point	608.2°C (760 Torr; calculated)	48
Density	0.861 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	17.543 (25°C; calculated)	48
Octyldodecyl stearate		48
Molecular weight	565.01	48
Boiling point	563.8°C (760 Torr; calculated)	48
Density	0.856 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	17.952 (25°C; calculated)	48
Oleyl arachidate		48
Molecular weight	562.99	47
Melting point	39.5°C-40°C	48
Boiling point	617.5°C (760 Torr; calculated)	48
Density	0.862 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	17.699 (25°C; calculated)	48
Oleyl erucate		48
Molecular weight	589.03	48
Boiling point	637.7°C (760 Torr; calculated)	48
Density	0.866 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	18.308 (25°C; calculated)	48
Oleyl linoleate		48
Molecular weight	530.91	48
Boiling point	595.5°C (760 Torr; calculated)	48
Density	0.874 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	15.867 (25°C; calculated)	48
Oleyl oleate		48
Molecular weight	532.92	47
Melting point	-4.0°C to -3.5°C -1.5°C	40
Boiling point	596.5°C (760 Torr; calculated)	48
Density	0.868 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	16.270 (25°C; calculated)	48
Oleyl stearate		48
Molecular weight	534.94	47
Melting point	34.0°C-34.5°C	48
Boiling point	595.8°C (760 Torr; calculated)	48
Density	0.862 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	16.680 (25°C; calculated)	48
Propylheptyl caprylate		48
Molecular weight	284.48	50
Purity	>80%	50
Melting point	-38.9°C	50
Boiling point	319.0°C (101.3 kPa)	50

(continued)

Table 7. (continued)

Property	Description	Reference
Water solubility	<0.01 mg/L (20°C)	50
Density	0.863 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	7.963 (25°C; calculated)	48
Stearyl erucate		48
Molecular weight	591.05	48
Boiling point	627.8°C (760 Torr; calculated)	48
Density	0.861 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	18.718 (25°C; calculated)	48
Stearyl linoleate		48
Molecular weight	532.92	48
Boiling point	590.8°C (760 Torr; calculated)	48
Density	0.868 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	16.276 (25°C; calculated)	48
Tetradecyloctadecyl hexyldecanoate		48
Molecular weight	705.27	48
Boiling point	653.7°C (760 Torr; calculated)	48
Density	0.854 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	22.891 (25°C; calculated)	48
Tridecyl behenate		48
Molecular weight	522.93	48
Boiling point	538.8°C (760 Torr; calculated)	48
Density	0.857 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	16.579 (25°C; calculated)	48
Tridecyl erucate		48
Molecular weight	520.91	48
Boiling point	573.1°C (760 Torr; calculated)	48
Density	0.863 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	16.170 (25°C; calculated)	48
Tridecyl laurate		48
Molecular weight	382.66	48
Boiling point	426.6°C (760 Torr; calculated)	48
Density	0.860 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	11.485 (25°C; calculated)	48
Tridecyl isononanoate		9
Molecular weight	340.58	9
Log P	8.02 (calculated)	9
Tridecyl stearate		48
Molecular weight	466.82	48
Boiling point	496.0°C (760 Torr; calculated)	48
Density	0.858 g/cm ³ (20°C; 760 Torr; calculated)	48
Log P	14.541 (25°C; calculated)	48

Some alkyl esters are reported to be used in baby skin products, to be used in products applied to the eye area or mucous membranes, or in products that could possibly be ingested. Additionally, some of the alkyl esters are used in cosmetic sprays and could possibly be inhaled. Examples of sprays at the highest concentrations of use are 76.6% isopropyl myristate

in hair sprays, 45% ethylhexyl palmitate in indoor tanning preparations, and 23% isopropyl myristate in deodorant formulations. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 µm, with propellant sprays yielding a greater fraction of droplets/particles <10 µm compared with pump

Table 8. Frequency and Concentration of Use (Historical and Current) According to Duration and Type of Exposure.

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %																								
	Arachidyl behenate				Arachidyl propionate				Behenyl beeswax																										
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2005 ⁴	2012 ⁶⁵	1987 ³ /2006 ⁴	2013 ⁶⁴	2012 ⁶⁵																											
Totals ^a	20	0.3-4	48	47	0.0003-14.2	≤10	1	0.4																											
Duration of use																																			
Leave-on	20	0.3-4	40	44	0.002-14.2	≤10	1	0.4																											
Rinse-off	NR	NR	8	3	0.0003-14.1	0.002	NR	NR																											
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR																											
Exposure type																																			
Eye area	5	3	3	NR	3-14	5	1	0.4																											
Incidental ingestion	2	3-4	6	8	8-15	≤10	NR	NR																											
Incidental inhalation—spray ^b	NR	NR	NR	1 ^c	14 ^d	≤5 ^c	NR	NR																											
	0.0002 (spray)																																		
Incidental inhalation—powder	NR	NR	NR	NR	14	NR	NR	NR																											
Dermal contact	18	0.3-3	37	35	0.002-14.2	≤5	NR	0.4																											
Deodorant (underarm)	NR	NR	NR	NR	14.1 (not a spray)	NR	NR	NR																											
Hair—noncoloring	NR	NR	5	4	0.0003-0.003	NR	NR	NR																											
Hair—coloring	NR	NR	NR	NR	NR	NR	NR	NR																											
Nail	NR	NR	NR	NR	0.05-0.09	0.04	NR	NR																											
Mucous membrane	2	3-4	7	8	8-15	≤10	NR	NR																											
Baby products	NR	NR	NR	NR	NR	NR	NR	NR																											
<table border="0" style="width: 100%; text-align: center;"> <tr> <td></td> <td colspan="2">Behenyl behenate</td> <td colspan="4">Behenyl erucate</td> <td colspan="2">Behenyl olivate</td> <td colspan="2"></td> </tr> <tr> <td></td> <td>2013⁶⁴</td> <td>2012⁶⁵</td> <td>2013⁶⁴</td> <td>2012⁶⁵</td> <td>2013⁶⁴</td> <td>2012⁶⁵</td> <td>2013⁶⁴</td> <td>2012⁶⁵</td> <td colspan="3"></td> </tr> </table>														Behenyl behenate		Behenyl erucate				Behenyl olivate					2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵			
	Behenyl behenate		Behenyl erucate				Behenyl olivate																												
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵																											
Totals ^a	6	0.4-5	9	0.5	NR	0.5	NR	0.5																											
Duration of use																																			
Leave-on	6	0.4-5	9	0.5	NR	0.5	NR	0.5																											
Rinse-off	NR	NR	NR	NR	NR	NR	NR	NR																											
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR																											
Exposure type																																			
Eye area	3	0.6-5	NR	NR	NR	NR	NR	NR																											
Incidental ingestion	NR	4	9	0.5	NR	0.5	NR	NR																											
Incidental inhalation—spray	NR	NR	NR	NR	NR	NR	NR	NR																											
Incidental inhalation—powder	NR	NR	NR	NR	NR	NR	NR	NR																											
Dermal contact	5	0.4-2	NR	NR	NR	NR	NR	0.5																											
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR																											
Hair—noncoloring	NR	NR	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	4	9	0.5	NR	0.5	NR	NR																											
Baby products	NR	NR	NR	NR	NR	NR	NR	NR																											
<table border="0" style="width: 100%; text-align: center;"> <tr> <td></td> <td colspan="2">Butyl avocadate</td> <td colspan="4">Butyl myristate</td> <td colspan="4">Butyl stearate</td> </tr> <tr> <td></td> <td>2013⁶⁴</td> <td>2012⁶⁵</td> <td>2013⁶⁴</td> <td>2007⁵</td> <td>2012⁶⁵</td> <td>2008⁵</td> <td>2013⁶⁴</td> <td>2002⁸</td> <td>2012⁶⁵</td> <td>1985⁷/2003⁸</td> <td colspan="1"></td> </tr> </table>														Butyl avocadate		Butyl myristate				Butyl stearate					2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2007 ⁵	2012 ⁶⁵	2008 ⁵	2013 ⁶⁴	2002 ⁸	2012 ⁶⁵	1985 ⁷ /2003 ⁸	
	Butyl avocadate		Butyl myristate				Butyl stearate																												
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2007 ⁵	2012 ⁶⁵	2008 ⁵	2013 ⁶⁴	2002 ⁸	2012 ⁶⁵	1985 ⁷ /2003 ⁸																									
Totals ^a	11	1	4	26	5	NR	55	78	0.0008-12	0.002-43																									
Duration of use																																			
Leave-on	7	1	4	26	5	NR	10	73	0.002-12	0.002-25																									
Rinse-off	4	NR	NR	NR	NR	NR	NR	5	0.0008-2	0.001-10																									
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR	NR	43																									
Exposure type																																			
Eye area	NR	NR	NR	NR	NR	NR	5	23	0.4-9	0.2-25																									
Incidental ingestion	NR	NR	NR	16	NR	NR	2	34	0.1-12	0.02-25																									
Incidental inhalation—spray	1 ^d	NR	NR	NR	NR	NR	NR	NR	0.6 ^d -5	NR																									
Incidental inhalation—powder	NR	NR	NR	NR	NR	NR	NR	NR	0.5-2	NR																									
Dermal contact	7	1	4	10	NR	NR	8	44	0.0008-9	0.02-43																									
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	1	0.6 (not a spray)	>1-5 ^c																									

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %	
	Butyl avocadate				Butyl myristate				Butyl stearate			
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2007 ⁵	2012 ⁶⁵	2008 ⁵	2013 ⁶⁴	2002 ⁸	2012 ⁶⁵	1985 ⁷ /2003 ⁸		
Totals ^a	11	1	4	26	5	NR	55	78	0.0008-12	0.002-43		
Hair—noncoloring	4	NR	NR	NR	5	NR	NR	NR	NR	0.01-10		
Hair—coloring	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		
Nail	NR	NR	NR	NR	NR	NR	NR	NR	NR	>0.1-5		
Mucous membrane	NR	NR	NR	16	NR	NR	2	39	0.1-12	0.1-43		
Baby products	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		
	C20-40 alkyl stearate		Caprylyl caprylate		Caprylyl eicosenoate							
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵						
	Totals ^a	11	NR	11	NR	2	0.3					
Duration of use												
Leave-on	11	NR	11	NR	2	0.3						
Rinse-off	NR	NR	NR	NR	NR	NR						
Diluted for (bath) use	NR	NR	NR	NR	NR	NR						
Exposure type												
Eye area	NR	NR	1	NR	NR	NR						
Incidental ingestion	8	NR	NR	NR	NR	NR						
Incidental inhalation—spray	NR	NR	NR	NR	NR	NR						
Incidental inhalation—powder	NR	NR	NR	NR	NR	0.3						
Dermal contact	NR	NR	11	NR	2	0.3						
Deodorant (underarm)	NR	NR	NR	NR	NR	NR						
Hair—Noncoloring	3	NR	NR	NR	NR	NR						
Hair—coloring	NR	NR	NR	NR	NR	NR						
Nail	NR	NR	NR	NR	NR	NR						
Mucous membrane	8	NR	NR	NR	NR	NR						
Baby products	NR	NR	NR	NR	NR	NR						
	Cetearyl behenate		Cetearyl candelillate		Cetearyl isononanoate							
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2009 ⁹	2012 ⁶⁵	2009 ⁹				
	Totals ^a	3	7-15	2	6	168	123	0.2-40	0.05-50			
Duration of use												
Leave-on	3	7-15	2	6	145	108	0.2-40	0.05-50				
Rinse-off	NR	NR	NR	NR	23	15	1-4	2-3				
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR				
Exposure type												
Eye area	1	NR	NR	NR	22	15	NR	0.05				
Incidental ingestion	NR	7	1	6	1	1	5	NR				
Incidental inhalation—spray	NR	NR	1 ^d	NR	7 ^d	7 ^{c,d}	40 (spray) 6 (pump spray)	27-50 ^c				
Incidental inhalation—powder	NR	NR	NR	NR	1	2	NR	0.05-11				
Dermal contact	3	14-15	1	NR	163	120	0.2-40	0.05-50				
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR				
Hair—noncoloring	NR	NR	NR	NR	3	NR	NR	NR				
Hair—coloring	NR	NR	NR	NR	NR	NR	NR	NR				
Nail	NR	NR	NR	NR	1	2	NR	NR				
Mucous membrane	NR	7	1	6	3	3	5	NR				
Baby products	NR	NR	NR	NR	NR	NR	NR	NR				
	Cetearyl nonanoate		Cetearyl olivate		Cetearyl stearate							
	2013 ⁶⁴	2009 ⁹	2012 ⁶⁵	2009 ⁹	2013 ⁶⁴	2012 ⁶⁶						
	Totals ^a	NR	NR	NR	3	152	0.3-3	3	NR			
Duration of use												
Leave-on	NR	NR	NR	3	118	0.3-3	3	NR				
Rinse-off	NR	NR	NR	NR	34	0.4-2	NR	NR				
Diluted for (bath) use	NR	NR	NR	NR	NR	2 ^d	NR	NR				

(continued)

Table 8 (continued)

	# of uses				Max conc of use, %				# of uses				Max conc of use, %			
	Cetearyl nonanoate				Cetearyl olivate				Cetearyl stearate							
	2013 ⁶⁴	2009 ⁹	2012 ⁶⁵	2009 ⁹	2013 ⁶⁴	2012 ⁶⁶			2013 ⁶⁴	2012 ⁶⁶						
Totals ^a	NR	NR	NR	3	152	0.3-3			3	NR						
Exposure type																
Eye area	NR	NR	NR	NR	15	1-3			NR	NR						
Incidental ingestion	NR	NR	NR	NR	NR	NR			NR	NR						
Incidental inhalation—spray	NR	NR	NR	NR	2 ^d	2 ^d			NR	NR						
Incidental inhalation—powder	NR	NR	NR	NR	1	NR			NR	NR						
Dermal contact	NR	NR	NR	3	147	0.3-3			3	NR						
Deodorant (underarm)	NR	NR	NR	NR	3 ^c	NR			NR	NR						
Hair—noncoloring	NR	NR	NR	NR	3	2			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	3	NR			NR	NR						
Baby products	NR	NR	NR	NR	1	NR			NR	NR						
Cetyl babassuate																
Cetyl caprate																
Cetyl caprylate																
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵					
Totals ^a	2		NR		NR		0.5		14		2-4					
Duration of use																
Leave-on	2		NR		NR		0.5		12		2-4					
Rinse-off	NR		NR		NR		NR		2		NR					
Diluted for (bath) use	NR		NR		NR		NR		NR		NR					
Exposure type																
Eye area	NR		NR		NR		NR		1		NR					
Incidental ingestion	NR		NR		NR		0.5		NR		NR					
Incidental inhalation—spray	NR		NR		NR		NR		NR		NR					
Incidental inhalation—powder	NR		NR		NR		NR		2		NR					
Dermal contact	2		NR		NR		NR		14		2-4					
Deodorant (underarm)	NR		NR		NR		NR		NR		NR					
Hair—noncoloring	NR		NR		NR		NR		NR		NR					
Hair—coloring	NR		NR		NR		NR		NR		NR					
Nail	NR		NR		NR		NR		NR		NR					
Mucous membrane	NR		NR		NR		0.5		NR		NR					
Baby products	NR		NR		NR		NR		2		NR					
Cetyl esters																
Cetyl isononanoate																
Cetyl laurate																
	2013 ⁶⁴	1995 ²	2012 ⁶⁶	1995 ²	2013 ⁶⁴	2009 ⁹	2012 ⁶⁵	2009 ⁹	2013 ⁶⁴	2012 ⁶⁵						
Totals ^a	476	210	0.7-30	7	NR	NR	NR	1-5	1	NR						
Duration of use																
Leave-on	240	168	0.8-30	7	NR	NR	NR	1-5	1	NR						
Rinse-off	236	42	0.7-5	7	NR	NR	NR	NR	NR	NR						
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR						
Exposure type																
Eye area	24	9	3-4	NS	NR	NR	NR	1	NR	NR						
Incidental ingestion	8	26	3-11.5	NS	NR	NR	NR	NR	NR	NR						
Incidental inhalation—spray	5 ^d	6 ^d	NR	NS	NR	NR	NR	NR	NR	NR						
Incidental inhalation—powder	1	NR	NR	NS	NR	NR	NR	NR	NR	NR						
Dermal contact	183	156	0.8-5	NS	NR	NR	NR	1-5	1	NR						
Deodorant (underarm)	1 ^c	5 ^c	NR	NS	NR	NR	NR	NR	NR	NR						
Hair—noncoloring	282	11	0.7-5	NS	NR	NR	NR	1	NR	NR						
Hair—coloring	3	15	NR	NS	NR	NR	NR	NR	NR	NR						
Nail	NR	1	NR	NS	NR	NR	NR	NR	NR	NR						
Mucous membrane	11	30	NR	NS	NR	NR	NR	NR	NR	NR						
Baby products	1	NR	NR	NS	NR	NR	NR	NR	NR	NR						

(continued)

Table 8 (continued)

	# of uses				Max conc of use, %				# of uses				Max conc of use, %			
	Cetyl myristate				Cetyl palmitate				Cetyl ricinoleate							
	2013 ⁶⁴	2007 ⁵	2012 ⁶⁵	2008 ⁵	2013 ⁶⁴	2001 ⁸	2012 ⁶⁵	1976 ¹⁰ /2001 ⁸	2013 ⁶⁴	2002 ¹¹	2012 ⁶⁵	2004 ¹¹				
Totals ^a	4	7	NR	6	511	236	0.002-11	0.01-11	137	55	0.3-16	0.1-10				
Duration of use																
Leave-on	4	7	NR	6	469	208	0.002-11	0.0-11	127	50	0.3-15.2	0.1-10				
Rinse-off	NR	NR	NR	NR	42	28	0.006-5	0.02-1	10	5	0.3	0.1-0.5				
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR				
Exposure type																
Eye area	1	1	NR	NR	51	54	3-11	0.2-11	14	NR	0.3-5	NR				
Incidental ingestion	NR	NR	NR	NR	22	10	2-7	10	31	26	2-15.2	0.5-10				
Incidental inhalation—spray	NR	NR	NR	NR	16 ^d	13 ^{c,d}	0.4 ^d ;6;	2 ^d	1 ^d	1 ^d	NR	NR				
Incidental inhalation—powder	NR	NR	NR	NR	NR	NR	0.8	NR	4	NR	NR	NR				
Dermal contact	4	7	NR	6	442	213	0.002-11	0.02-11	106	29	0.3-6	0.1-4				
Deodorant (underarm)	NR	NR	NR	NR	2 ^c	NR	NR	0.3 ^c	NR	NR	NR	NR				
Hair—noncoloring	NR	NR	NR	NR	9	12	2	1	NR	NR	NR	NR				
Hair—coloring	NR	NR	NR	NR	NR	NR	0.8	0.2	NR	NR	NR	NR				
Nail	NR	NR	NR	NR	2	NR	2-7	NR	NR	NR	NR	NR				
Mucous membrane	NR	NR	NR	NR	26	10	0.006-7	0.02-10	31	26	2-15.2	0.5-10				
Baby products	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR				
Cetyl stearate																
Cetyl tallowate																
Coco-caprylate																
	2013 ⁶⁴	2002 ⁸	2012 ⁶⁵	1985 ⁷ / 2003 ⁸	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵				
Totals	5	2	1-4	0.3-15	1	NR	8	NR	8	NR	NR	NR				
Duration of use																
Leave-on	5	2	4	0.3-15	1	NR	6	NR	6	NR	NR	NR				
Rinse-off	NR	NR	1	0.6-3	NR	NR	2	NR	2	NR	NR	NR				
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR				
Exposure type																
Eye area	2	NR	NR	0.6-10	NR	NR	1	NR	1	NR	NR	NR				
Incidental ingestion	NR	2	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR				
Incidental inhalation—spray	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR				
Incidental inhalation—powder	NR	NR	NR	>1-5	NR	NR	NR	NR	NR	NR	NR	NR				
Dermal contact	5	NR	NR	0.3-15	1	NR	5	NR	5	NR	NR	NR				
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR				
Hair—Noncoloring	NR	NR	1-4	2-3	NR	NR	3	NR	3	NR	NR	NR				
Hair—coloring	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR				
Nail	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR				
Mucous membrane	NR	2	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR				
Baby products	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR				
Coco-caprylate/caprinate																
Decyl cocoate																
Decyl oleate																
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2007 ¹²	2012 ⁶⁵	2008 ¹²	2013 ⁶⁴	2001 ¹⁴	2012 ⁶⁵	1976 ¹³ /2001 ¹⁴	2013 ⁶⁴	2012 ⁶⁵				
Totals	261	0.5-62	5	NR	NR	NR	227	147	0.5-20	≤0.1-88	NR	NR				
Duration of use																
Leave-on	232	0.5-35	3	NR	NR	NR	214	121	0.5-4	0.5-88	NR	NR				
Rinse-off	23	1-62	2	NR	NR	NR	13	25	2-20	≤0.1-25	NR	NR				
Diluted for (bath) use	6	NR	NR	NR	NR	NR	NR	1	NR	>5-25	NR	NR				
Exposure type																
Eye area	43	0.7-35	NR	NR	NR	NR	5	NR	20	>1->50	NR	NR				
Incidental ingestion	8	0.5-9	NR	NR	NR	NR	NR	1	NR	8	NR	NR				
Incidental inhalation—spray	14 ^d	2-6 ^d	NR	NR	NR	NR	NR	3	2	>0.1-1	NR	NR				
Incidental inhalation—powder	2	4-16	NR	NR	NR	NR	NR	1	NR	>1-88 ^{c,d}	NR	NR				

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %	
	Coco-caprylate/caprates				Decyl cocoate				Decyl oleate			
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2007 ¹²	2012 ⁶⁵	2008 ¹²	2013 ⁶⁴	2001 ¹⁴	2012 ⁶⁵	1976 ¹³ /2001 ¹⁴		
Totals	261	0.5-62	5	NR	NR	NR	227	147	0.5-20	≤0.1-88		
Duration of use												
Dermal contact	252	0.5-62	5	NR	NR	NR	218	137	0.5-20	≤0.1-88		
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	1 ^c	1 ^c	NR	NR		
Hair—noncoloring	1	30	NR	NR	NR	NR	9	6	2-3	>0.1-1		
Hair—coloring	NR	NR	NR	NR	NR	NR	NR	NR	2	3		
Nail	NR	NR	NR	NR	NR	NR	1	3	NR	>5-10		
Mucous membrane	9	0.5-9	NR	NR	NR	NR	NR	1	NR	>5-88		
Baby products	NR	NR	NR	NR	NR	NR	NR	NR	NR	>1-5		
	Decyl olivate		Ethylhexyl cocoate				Ethylhexyl hydroxystearate					
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2007 ¹²	2012 ⁶⁵	2008 ¹²	2013 ⁶⁴	2012 ⁶⁵				
	Totals ^a	1	NR	94	18	0.0006-41	0.01-41	270	0.09-18			
Duration of use												
Leave-on	1	NR	81	17	0.0006-41	0.01-41	243	0.1-18				
Rinse-off	NR	NR	13	1	5-9	3-5	27	0.09-3				
Diluted for (bath) use	NR	NR	NR	NR	6	6	NR	3				
Exposure type												
Eye area	NR	NR	9	5	12	0.02-2	18	2-8				
Incidental ingestion	NR	NR	4	NR	8	0.01-19	81	2-18				
Incidental inhalation—spray	NR	NR	11 ^d	1	NR	4-10 ^d	3 ^d	NR				
Incidental inhalation—powder	NR	NR	NR	NR	NR	NR	1	NR				
Dermal contact	1	NR	85	16	2-41	0.02-41	186	0.1-9				
Deodorant (underarm)	NR	NR	NR	NR	NR	5 ^c	NR	NR				
Hair—noncoloring	NR	NR	2	2	NR	NR	4	0.09-2				
Hair—coloring	NR	NR	NR	NR	NR	NR	NR	NR				
Nail	NR	NR	3	NR	0.0006	NR	NR	NR				
Mucous membrane	NR	NR	5	NR	8	0.01-19	94	0.2-18				
Baby products	NR	NR	NR	NR	NR	5	NR	NR				
	Ethylhexyl isononanoate				Ethylhexyl isopalmitate		Ethylhexyl isostearate					
	2013 ⁶⁴	2009 ⁹	2012 ⁶⁵	2009 ⁹	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵				
	Totals ^a	144	116	0.02-75	0.02-74	7	NR	9	27-40			
Duration of use												
Leave-on	141	112	0.02-75	0.02-74	7	NR	9	27-40				
Rinse-off	3	4	0.3-20	0.8-1	NR	NR	NR	NR				
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR				
Exposure type												
Eye area	10		0.8-20	0.8-65	1	NR	9	27-40				
Incidental ingestion	NR	9	2	NR	NR	NR	NR	NR				
Incidental inhalation—spray	27 ^d	27 ^{c,d}	0.02-0.1 ^d ; 2; 4 (pump spray)	18	1 ^d	NR	NR	NR				
Incidental inhalation—powder	3	NR	NR	3	NR	NR	NR	NR				
Dermal contact	139	102	0.02-75	0.02-74	7	NR	9	27-40				
Deodorant (underarm)	NR	NR	3 (not spray)	NR	NR	NR	NR	NR				
Hair—noncoloring	5	4	8	0.8-8	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	1	10	2	NR	NR	NR	NR	NR				
Baby products	NR	NR	NR	NR	NR	NR	NR	NR				

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %	
	Ethylhexyl laurate				Ethylhexyl myristate				Ethylhexyl olivate			
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2007 ⁵	2012 ⁶⁵	2008 ⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵
Totals ^a	1	NR	2	NR	NR	NR	2	NR				
Duration of use												
Leave-on	1	NR	1	NR	NR	NR	2	NR				
Rinse-off	NR	NR	1	NR	NR	NR	NR	NR				
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR				
Exposure type												
Eye area	NR	NR	NR	NR	NR	NR	1	NR				
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR				
Incidental inhalation—spray	NR	NR	NR	NR	NR	NR	NR	NR				
Incidental inhalation—powder	NR	NR	NR	NR	NR	NR	NR	NR				
Dermal contact	1	NR	2	NR	NR	NR	2	NR				
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR				
Hair—noncoloring	NR	NR	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				
	Ethylhexyl palmitate				Ethylhexyl pelargonate				Ethylhexyl stearate			
	2013 ⁶⁴	2001 ⁸	2012 ⁶⁵	1976 ¹⁰ / 2001 ⁸	2013 ⁶⁴	2009 ⁹	2012 ⁶⁵	2009 ⁹	2013 ⁶⁴	2002 ⁸	2012 ⁶⁵	1985 ⁷ /2003 ⁸
Totals	1525	417	0.0003-78	0.1->50	14	3	2-4	2-25	335	31	0.0004-38	>0.1-25
Duration of use												
Leave-on	1475	407	0.0003-78	0.1->50	2	2	2	3-25	305	27	0.0004-38	>0.1-25
Rinse-off	48	10	0.05-50	2-21	12	1	3-4	2-5	25	2	0.1-29	NR
Diluted for (bath) use	2	NR	10	6-23	NR	NR	NR	NR	5	2	NR	>0.1-5
Exposure type												
Eye area	424	141	0.01-50	0.2->50	NR	NR	NR	2	38	5	0.003-38	0.8-11
Incidental ingestion	221	100	NR	4-42	NR	NR	NR	NR	7	1	19-27.1	NR
Incidental inhalation—spray	53 ^d	2 ^c	3-16; 4-45 (aerosol); 0.4 (pump spray)	21 (spray) 0.5- >50 ^{c,d}	NR	NR	NR	NR	16 ^d	5 ^{c,d}	2-10 ^d	NR
Incidental inhalation—powder	80	13	0.3-10	0.3-22	NR	NR	NR	NR	10	2	6	0.5
Dermal contact	1276	314	0.003-78	0.1->50	3	3	2	2-25	327	31	0.0004-38	>0.1-25
Deodorant (underarm)	8 ^c	1	1 (aerosol)	2 ^c	NR	NR	NR	NR	NR	NR	NR	NR
Hair—noncoloring	18	NR	2-4	2-17	NR	NR	NR	NR	8	NR	5	NR
Hair—coloring	NR	NR	NR	NR	11	NR	3-4	5	NR	NR	29	NR
Nail	15	3	5-50	5-28	NR	NR	NR	NR	NR	NR	NR	NR
Mucous membrane	228	100	1-10	4-42	NR	NR	NR	NR	14	3	5-27.1	>0.1-5
Baby products	2	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Heptyl undecylenate				Heptylundecyl hydroxystearate				Hexyl isostearate			
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵				
Totals ^a	10	0.01-26	10	20	NR	0.008-0.04						
Duration of use												
Leave-on	9	0.01-26	10	20	NR	0.008-0.04						
Rinse-off	1	0.01-0.1	NR	NR	NR	NR						
Diluted for (bath) use	NR	NR	NR	NR	NR	NR						
Exposure type												
Eye area	3	26	8	NR	NR	NR						
Incidental ingestion	3	NR	2	20	NR	NR						
Incidental inhalation—spray	NR	0.01 (pump spray)	NR	NR	NR	NR						
Incidental inhalation—powder	NR	NR	NR	NR	NR	NR						

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %	
	Heptyl undecylenate				Heptylundecyl hydroxystearate				Hexyl isostearate			
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵	
Totals ^a	10		0.01-26		10		20		NR		0.008-0.04	
Dermal contact	5		10-26		8		NR		NR		0.008	
Deodorant (underarm)	NR		NR		NR		NR		NR		NR	
Hair—noncoloring	1		0.01-0.1		NR		NR		NR		NR	
Hair—coloring	NR		NR		NR		NR		NR		NR	
Nail	NR		NR		NR		NR		NR		0.04	
Mucous membrane	3		NR		2		20		NR		NR	
Baby products	NR		NR		NR		NR		NR		NR	
	Hexyl laurate		Hexyldeacyl isostearate		Hexyldeacyl laurate							
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵	
	Totals ^a	213		0.07-3		NR		0.2-2		41		1-2
Duration of use												
Leave-on	210		0.07-3		NR		2		35		2	
Rinse-off	3		2		NR		0.2-7		6		2	
Diluted for (bath) use	NR		NR		NR		NR		NR		NR	
Exposure type												
Eye area	19		0.3-3		NR		NR		2		NR	
Incidental ingestion	28		0.1-2		NR		NR		NR		NR	
Incidental inhalation—spray	11 ^d		0.07-0.1		NR		NR		NR		NR	
Incidental inhalation—powder	7		2		NR		NR		NR		NR	
Dermal contact	178		0.07-3		NR		0.2-2		40		1-2	
Deodorant (underarm)	NR		NR		NR		NR		NR		NR	
Hair—noncoloring	2		2-3		NR		0.7-2		1		2	
Hair—coloring	NR		NR		NR		NR		NR		NR	
Nail	1		2		NR		NR		NR		NR	
Mucous membrane	28		0.1-2		NR		NR		NR		NR	
Baby products	3		NR		NR		NR		NR		NR	
	Hexyldeacyl stearate		Hydrogenated ethylhexyl olivate		Hydroxyoctacosanyl hydroxystearate							
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵	
	Totals	34		0.5-13		8		0.05-15.5		5		NR
Duration of use												
Leave-on	45		0.5-13		7		4-15.5		5		NR	
Rinse-off	9		3		1		0.05		NR		NR	
Diluted for (bath) use	NR		NR		NR		NR		NR		NR	
Exposure type												
Eye area	2		3		2		4		1		NR	
Incidental ingestion	NR		0.9		NR		NR		NR		NR	
Incidental inhalation—spray	NR		NR		NR		15.5 (pump spray)		NR		NR	
Incidental inhalation—powder	NR		NR		NR		NR		NR		NR	
Dermal contact	34		0.5-13		6		4-7		5		NR	
Deodorant (underarm)	NR		NR		NR		NR		NR		NR	
Hair—noncoloring	NR		NR		2		0.05-15.5		NR		NR	
Hair—coloring	NR		NR		NR		NR		NR		NR	
Nail	NR		NR		NR		NR		NR		NR	
Mucous membrane	NR		NR		NR		NR		NR		NR	
Baby products	NR		NR		NR		NR		NR		NR	
	Isoamyl laurate		Isobutyl myristate		Isobutyl stearate							
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴ 2007 ⁵		2012 ⁶⁵ 2008 ⁵		2013 ⁶⁴ 2002 ⁸		2012 ⁶⁵ 2003 ⁸	
	Totals	NR		1-2		NR	NR	NR	3-30	NR	3	NR
Duration of use												
Leave-on	NR		1		NR	NR	NR	3-30	NR	2	NR	7
Rinse-off	NR		2		NR	NR	NR	10	NR	1	NR	NR
Diluted for (bath) use	NR		NR		NR	NR	NR	NR	NR	NR	NR	NR

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %			
	Isoamyl laurate		Isobutyl myristate		Isobutyl myristate		Isobutyl stearate		Isobutyl stearate		Isobutyl stearate			
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2007 ⁵	2012 ⁶⁵	2008 ⁵	2013 ⁶⁴	2002 ⁸	2012 ⁶⁵	2003 ⁸	2013 ⁶⁴	2002 ⁸	2012 ⁶⁵	2003 ⁸
Totals	NR	1-2	NR	NR	NR	3-30	NR	3	NR	NR	NR	NR	7	
Exposure type														
Eye area	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Incidental inhalation—spray	NR	NR	NR	NR	NR	3 ^d	NR	NR	NR	NR	NR	NR	NR	
Incidental inhalation—powder	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Dermal contact	NR	NR	NR	NR	NR	3-30	NR	3	NR	NR	NR	NR	7	
Deodorant (underarm)	NR	1-2	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Hair—noncoloring	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Hair—coloring	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Nail	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	1	NR	NR	NR	NR	NR	
Baby products	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Isocetyl behenate														
Isocetyl myristate														
Isocetyl palmitate														
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2007 ⁵	2012 ⁶⁵	2008 ⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵
Totals	1	NR	11	6	0.4-37	NR	5	NR	5	NR	5	NR	5	NR
Duration of use														
Leave-on	1	NR	10	NR	0.4-36.5	NR	5	NR	5	NR	5	NR	5	NR
Rinse-off	NR	NR	1	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type														
Eye area	NR	NR	3	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation—spray	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation—powder	NR	NR	1	NR	0.4-2	NR	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	1	NR	11	NR	0.4-36.5	NR	5	NR	5	NR	5	NR	5	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Hair—noncoloring	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Hair—coloring	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Isocetyl stearate														
Isodecyl cocoate														
Isodecyl isononanoate														
	2013 ⁶⁴	2002 ⁸	2012 ⁶⁵	1985 ⁷ / 2003 ⁸	2013 ⁶⁴	2007 ¹²	2012 ⁶⁵	2008 ¹²	2013 ⁶⁴	2009 ⁹	2012 ⁶⁵	2009 ⁹	2013 ⁶⁴	2009 ⁹
Totals ^a	230	84	0.1-34	0.02-30	NR	NR	2	NR	38	26	1-43.5	0.05-59	38	26
Duration of use														
Leave-on	216	77	0.1-34	0.1-30	NR	NR	2	NR	35	24	1-43.5	0.05-59	35	24
Rinse-off	14	7	0.6-5	0.02-30	NR	NR	NR	NR	3	2	10	2-10	3	2
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type														
Eye area	3	2	0.1-16	30	NR	NR	NR	NR	7	2	1-40	6-21	7	2
Incidental ingestion	22	4	0.3-24	0.1-24	NR	NR	NR	NR	4	NR	40-43.5	0.05-18	4	NR
Incidental inhalation—spray	3 ^d	NR	0.6 ^d	10	NR	NR	NR	NR	2 ^d	2 ^d	NR	5 ^d	2 ^d	2 ^d
Incidental inhalation—powder	3	NR	NR	>1-25	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	200	79	0.1-34	0.02-30	NR	NR	2	NR	34	25	1-40	2-59	34	25
Deodorant (underarm)	NR	NR	NR	3	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Hair—noncoloring	8	NR	0.5-1	NR	NR	NR	NR	NR	NR	1	NR	2	NR	NR
Hair—coloring	NR	NR	0.6	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	1	NR	>1-5	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Mucous membrane	22	4	0.3-24	0.1-30	NR	NR	NR	NR	4	NR	40-43.5	0.05-18	4	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %																																																																																																																																																																																																																																																																																																																																																																																																													
	Isodecyl laurate				Isodecyl myristate				Isodecyl neopentanoate																																																																																																																																																																																																																																																																																																																																																																																																															
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2007 ⁵		2012 ⁶⁵		2008 ⁵		2013 ⁶⁴		2012 ⁶⁵																																																																																																																																																																																																																																																																																																																																																																																																									
Totals ^a	4		NR		1		1		NR		NR		137		0.05-17																																																																																																																																																																																																																																																																																																																																																																																																									
Duration of use																																																																																																																																																																																																																																																																																																																																																																																																																								
Leave-on	2		NR		1		1		NR		NR		131		0.05-17																																																																																																																																																																																																																																																																																																																																																																																																									
Rinse-off	2		NR		NR		NR		NR		NR		6		0.1-2																																																																																																																																																																																																																																																																																																																																																																																																									
Diluted for (bath) use	NR		NR		NR		NR		NR		NR		NR		NR																																																																																																																																																																																																																																																																																																																																																																																																									
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Eye area	2		NR		1		NR		NR		NR		29		1-17																																																																																																																																																																																																																																																																																																																																																																																																									
Incidental ingestion	NR		NR		NR		NR		NR		NR		7		0.6-5																																																																																																																																																																																																																																																																																																																																																																																																									
Incidental inhalation—spray	NR		NR		NR		NR		NR		NR		7 ^d		3 0.5 (aerosol) 0.3 (pump spray)																																																																																																																																																																																																																																																																																																																																																																																																									
Incidental inhalation—powder	NR		NR		NR		NR		NR		NR		4		2																																																																																																																																																																																																																																																																																																																																																																																																									
Dermal contact	4		NR		1		1		NR		NR		126		0.05-17																																																																																																																																																																																																																																																																																																																																																																																																									
Deodorant (underarm)	NR		NR		NR		NR		NR		NR		NR		NR																																																																																																																																																																																																																																																																																																																																																																																																									
Hair—noncoloring	NR		NR		NR		NR		NR		NR		1		0.3-2																																																																																																																																																																																																																																																																																																																																																																																																									
Hair—coloring	NR		NR		NR		NR		NR		NR		NR		NR																																																																																																																																																																																																																																																																																																																																																																																																									
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Mucous membrane	NR		NR		NR		NR		NR		NR		7		0.6-5																																																																																																																																																																																																																																																																																																																																																																																																									
Baby products	NR		NR		NR		NR		NR		NR		NR		3																																																																																																																																																																																																																																																																																																																																																																																																									
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2"></th> <th colspan="4">Isodecyl oleate</th> <th colspan="4">Isohexyl caprate</th> <th colspan="4">Isononyl isononanoate</th> </tr> <tr> <th colspan="2">2013⁶⁴</th> <th colspan="2">2001¹⁴</th> <th colspan="2">2012⁶⁵</th> <th colspan="2">1976¹³/ 2001¹⁴</th> <th colspan="2">2013⁶⁴</th> <th colspan="2">2012⁶⁵</th> <th colspan="2">2013⁶⁴</th> <th colspan="2">2009⁹</th> <th colspan="2">2012⁶⁵</th> <th colspan="2">2009⁹</th> </tr> </thead> <tbody> <tr> <td>Totals^a</td> <td colspan="2">15</td> <td colspan="2">44</td> <td colspan="2">0.07-4</td> <td colspan="2">>0.1-25</td> <td colspan="2">3</td> <td colspan="2">NR</td> <td colspan="2">687</td> <td colspan="2">343</td> <td colspan="2">0.07-53</td> <td colspan="2">0.03-64</td> </tr> <tr> <td colspan="22">Duration of use</td> </tr> <tr> <td>Leave-on</td> <td colspan="2">14</td> <td colspan="2">37</td> <td colspan="2">0.07-4</td> <td colspan="2">>1-25</td> <td colspan="2">3</td> <td colspan="2">NR</td> <td colspan="2">663</td> <td colspan="2">328</td> <td colspan="2">0.07-53</td> <td colspan="2">0.04-64</td> </tr> <tr> <td>Rinse-off</td> <td colspan="2">1</td> <td colspan="2">7</td> <td colspan="2">2-3</td> <td colspan="2">>1-25</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">25</td> <td colspan="2">15</td> <td colspan="2">0.3-25</td> <td colspan="2">0.03</td> </tr> <tr> <td>Diluted for (bath) use</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">>0.1-10</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">15</td> <td colspan="2">15</td> </tr> <tr> <td colspan="22">Exposure type</td> </tr> <tr> <td>Eye area</td> <td colspan="2">NR</td> <td colspan="2">1</td> <td colspan="2">2</td> <td colspan="2">>1-5</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">95</td> <td colspan="2">47</td> <td colspan="2">0.8-53</td> <td colspan="2">2-26</td> </tr> <tr> <td>Incidental ingestion</td> <td colspan="2">NR</td> <td colspan="2">22</td> <td colspan="2">0.07</td> <td colspan="2">4-8</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">100</td> <td colspan="2">28</td> <td colspan="2">5-47</td> <td colspan="2">8-50</td> </tr> <tr> <td>Incidental inhalation—spray</td> <td colspan="2">3</td> <td colspan="2">1</td> <td colspan="2">4 (aerosol) 2 (pump spray)</td> <td colspan="2">3^d</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">32^d</td> <td colspan="2">20^{c,d}</td> <td colspan="2">0.1-6^d; 26-45 0.4 (pump spray)</td> <td colspan="2">0.4-6; 0.08- 21^d; 21-46^c</td> </tr> <tr> <td>Incidental inhalation—powder</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">29</td> <td colspan="2">12</td> <td colspan="2">4-9</td> <td colspan="2">2-15</td> </tr> <tr> <td>Dermal contact</td> <td colspan="2">4</td> <td colspan="2">17</td> <td colspan="2">2-3</td> <td colspan="2">>0.1-25</td> <td colspan="2">3</td> <td colspan="2">NR</td> <td colspan="2">582</td> <td colspan="2">314</td> <td colspan="2">0.07-53</td> <td colspan="2">0.04-64</td> </tr> <tr> <td>Deodorant (underarm)</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">>1-5</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">1^c</td> <td colspan="2">1^c</td> <td colspan="2">7 (not spray) 7 (aerosol)</td> <td colspan="2">3^c</td> </tr> <tr> <td>Hair—noncoloring</td> <td colspan="2">10</td> <td colspan="2">4</td> <td colspan="2">2-4</td> <td colspan="2">2</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">3</td> <td colspan="2">1</td> <td colspan="2">0.4-1</td> <td colspan="2">0.08-7</td> </tr> <tr> <td>Hair—coloring</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">33</td> </tr> <tr> <td>Nail</td> <td colspan="2">1</td> <td colspan="2">1</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">2</td> <td colspan="2">NR</td> <td colspan="2">6</td> <td colspan="2">0.4-5</td> </tr> <tr> <td>Mucous membrane</td> <td colspan="2">NR</td> <td colspan="2">22</td> <td colspan="2">0.07</td> <td colspan="2">>0.1-10</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">101</td> <td colspan="2">29</td> <td colspan="2">5-47</td> <td colspan="2">8-50</td> </tr> <tr> <td>Baby products</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">3</td> <td colspan="2">NR</td> </tr> </tbody> </table>																		Isodecyl oleate				Isohexyl caprate				Isononyl isononanoate				2013 ⁶⁴		2001 ¹⁴		2012 ⁶⁵		1976 ¹³ / 2001 ¹⁴		2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2009 ⁹		2012 ⁶⁵		2009 ⁹		Totals ^a	15		44		0.07-4		>0.1-25		3		NR		687		343		0.07-53		0.03-64		Duration of use																						Leave-on	14		37		0.07-4		>1-25		3		NR		663		328		0.07-53		0.04-64		Rinse-off	1		7		2-3		>1-25		NR		NR		25		15		0.3-25		0.03		Diluted for (bath) use	NR		NR		NR		>0.1-10		NR		NR		NR		NR		15		15		Exposure type																						Eye area	NR		1		2		>1-5		NR		NR		95		47		0.8-53		2-26		Incidental ingestion	NR		22		0.07		4-8		NR		NR		100		28		5-47		8-50		Incidental inhalation—spray	3		1		4 (aerosol) 2 (pump spray)		3 ^d		NR		NR		32 ^d		20 ^{c,d}		0.1-6 ^d ; 26-45 0.4 (pump spray)		0.4-6; 0.08- 21 ^d ; 21-46 ^c		Incidental inhalation—powder	NR		NR		NR		NR		NR		NR		29		12		4-9		2-15		Dermal contact	4		17		2-3		>0.1-25		3		NR		582		314		0.07-53		0.04-64		Deodorant (underarm)	NR		NR		NR		>1-5		NR		NR		1 ^c		1 ^c		7 (not spray) 7 (aerosol)		3 ^c		Hair—noncoloring	10		4		2-4		2		NR		NR		3		1		0.4-1		0.08-7		Hair—coloring	NR		NR		NR		NR		NR		NR		NR		NR		NR		33		Nail	1		1		NR		NR		NR		NR		2		NR		6		0.4-5		Mucous membrane	NR		22		0.07		>0.1-10		NR		NR		101		29		5-47		8-50		Baby products	NR		NR		NR		NR		NR		NR		NR		NR		3		NR	
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Totals ^a	15		44		0.07-4		>0.1-25		3		NR		687		343		0.07-53		0.03-64																																																																																																																																																																																																																																																																																																																																																																																																					
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Rinse-off	1		7		2-3		>1-25		NR		NR		25		15		0.3-25		0.03																																																																																																																																																																																																																																																																																																																																																																																																					
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Deodorant (underarm)	NR		NR		NR		>1-5		NR		NR		1 ^c		1 ^c		7 (not spray) 7 (aerosol)		3 ^c																																																																																																																																																																																																																																																																																																																																																																																																					
Hair—noncoloring	10		4		2-4		2		NR		NR		3		1		0.4-1		0.08-7																																																																																																																																																																																																																																																																																																																																																																																																					
Hair—coloring	NR		NR		NR		NR		NR		NR		NR		NR		NR		33																																																																																																																																																																																																																																																																																																																																																																																																					
Nail	1		1		NR		NR		NR		NR		2		NR		6		0.4-5																																																																																																																																																																																																																																																																																																																																																																																																					
Mucous membrane	NR		22		0.07		>0.1-10		NR		NR		101		29		5-47		8-50																																																																																																																																																																																																																																																																																																																																																																																																					
Baby products	NR		NR		NR		NR		NR		NR		NR		NR		3		NR																																																																																																																																																																																																																																																																																																																																																																																																					
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2"></th> <th colspan="2">Isopropyl hydroxystearate</th> <th colspan="4">Isopropyl isostearate</th> <th colspan="2">Isopropyl jojobate</th> </tr> <tr> <th colspan="2">2013⁶⁴</th> <th colspan="2">2012⁶⁵</th> <th colspan="2">2013⁶⁴</th> <th colspan="2">2005¹⁶</th> <th colspan="2">2012⁶⁵</th> <th colspan="2">1989¹⁵/ 2007¹⁶</th> <th colspan="2">2013⁶⁴</th> <th colspan="2">2012⁶⁵</th> </tr> </thead> <tbody> <tr> <td>Totals</td> <td colspan="2">NR</td> <td colspan="2">8</td> <td colspan="2">412</td> <td colspan="2">69</td> <td colspan="2">0.5-19</td> <td colspan="2">≤0.1-65</td> <td colspan="2">23</td> <td colspan="2">0.3-6</td> </tr> <tr> <td colspan="17">Duration of use</td> </tr> <tr> <td>Leave-on</td> <td colspan="2">NR</td> <td colspan="2">8</td> <td colspan="2">400</td> <td colspan="2">63</td> <td colspan="2">0.5-19</td> <td colspan="2">≤0.1-30</td> <td colspan="2">23</td> <td colspan="2">0.3-6</td> </tr> <tr> <td>Rinse-off</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">12</td> <td colspan="2">6</td> <td colspan="2">0.7-6</td> <td colspan="2">2-65</td> <td colspan="2">NR</td> <td colspan="2">NR</td> </tr> <tr> <td>Diluted for (bath) use</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">NR</td> </tr> <tr> <td colspan="17">Exposure type</td> </tr> <tr> <td>Eye area</td> <td colspan="2">NR</td> <td colspan="2">8</td> <td colspan="2">233</td> <td colspan="2">9</td> <td colspan="2">0.8-10</td> <td colspan="2">0.6-8</td> <td colspan="2">4</td> <td colspan="2">0.7</td> </tr> <tr> <td>Incidental ingestion</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">24</td> <td colspan="2">NR</td> <td colspan="2">15-17</td> <td colspan="2">12-24</td> <td colspan="2">3</td> <td colspan="2">NR</td> </tr> <tr> <td>Incidental inhalation—spray</td> <td colspan="2">NR</td> <td colspan="2">NR</td> <td colspan="2">7^d</td> <td colspan="2">NR</td> <td colspan="2">0.6 (pump spray)</td> <td colspan="2">NR</td> <td colspan="2">1^d</td> <td colspan="2">NR</td> </tr> </tbody> </table>																		Isopropyl hydroxystearate		Isopropyl isostearate				Isopropyl jojobate		2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2005 ¹⁶		2012 ⁶⁵		1989 ¹⁵ / 2007 ¹⁶		2013 ⁶⁴		2012 ⁶⁵		Totals	NR		8		412		69		0.5-19		≤0.1-65		23		0.3-6		Duration of use																	Leave-on	NR		8		400		63		0.5-19		≤0.1-30		23		0.3-6		Rinse-off	NR		NR		12		6		0.7-6		2-65		NR		NR		Diluted for (bath) use	NR		NR		NR		NR		NR		NR		NR		NR		Exposure type																	Eye area	NR		8		233		9		0.8-10		0.6-8		4		0.7		Incidental ingestion	NR		NR		24		NR		15-17		12-24		3		NR		Incidental inhalation—spray	NR		NR		7 ^d		NR		0.6 (pump spray)		NR		1 ^d		NR																																																																																																																																																																																																																							
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Rinse-off	NR		NR		12		6		0.7-6		2-65		NR		NR																																																																																																																																																																																																																																																																																																																																																																																																									
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Eye area	NR		8		233		9		0.8-10		0.6-8		4		0.7																																																																																																																																																																																																																																																																																																																																																																																																									
Incidental ingestion	NR		NR		24		NR		15-17		12-24		3		NR																																																																																																																																																																																																																																																																																																																																																																																																									
Incidental inhalation—spray	NR		NR		7 ^d		NR		0.6 (pump spray)		NR		1 ^d		NR																																																																																																																																																																																																																																																																																																																																																																																																									

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %		
	Isopropyl hydroxystearate				Isopropyl isostearate				Isopropyl jojobate				
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴	2005 ¹⁶	2012 ⁶⁵	1989 ¹⁵ / 2007 ¹⁶		2013 ⁶⁴		2012 ⁶⁵	
Totals	NR		8		412	69	0.5-19	≤0.1-65		23		0.3-6	
Incidental inhalation—powder	NR		NR		18	2	2-19	0.6-30		NR		NR	
Dermal contact	NR		8		383	68	0.5-19	≤0.1-30		20		0.7-6	
Deodorant (underarm)	NR		NR		NR	NR	NR	5		NR		NR	
Hair—noncoloring	NR		NR		5	1	0.5-0.8	65		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		25	NR	15-17	12-24		3		NR	
Baby products	NR		NR		2	2	NR	NR		NR		NR	
	Isopropyl linoleate				Isopropyl myristate				Isopropyl palmitate				
	2013 ⁶⁴	1988 ²⁰	2012 ⁶⁵	1988 ²⁰	2013 ⁶⁴	2007 ⁵	2012 ⁶⁵	2008 ⁵	2013 ⁶⁴	2001 ⁸	2012 ⁶⁵	1976 ¹⁰ /2001 ⁸	
Totals	NR	21 ^c	0.1	>0.1-10 ^c	1182	1057	0.000005-77.3	0.001-82		1125	535	0.0001-60	0.000002->50
Duration of use													
Leave-on	NR	NS	0.1	NS	959	874	0.0002-77.3	0.001-82		995	434	0.0001-60	0.00001->50
Rinse-off	NR	NS	0.1	NS	208	160	0.000005-67	0.4-60		104	81	0.0003-31	0.000002-11
Diluted for (bath) use	NR	NS	NR	NS	15	23	1-22	2-23		26	20	0.001-60	0.3-60
Exposure type													
Eye area	NR	NS	NR	NS	131	99	0.9-31	0.04-20		81	19	0.1-34	0.25-10
Incidental ingestion	NR	NS	NR	NS	57	49	2-18	1-26		107	80	1-34	5-25
Incidental inhalation—spray	NR	NS	NR	NS	82 ^d	55	0.6-36 ^d 0.02-76.6 (aerosol)	0.02-10 1-58 ^c		51 ^d	43 ^{c,d}	0.4-5 ^d ; 9-60 ^c 0.8-17 (aerosol); 3-20 (pump spray)	0.2-60 ^{c,d}
Incidental inhalation—powder	NR	NS	0.1	NS	29	19	0.7-3	0.3-4		37	12	3-18	0.00001-14
Dermal contact	NR	NS	0.1	NS	942	893	0.0003-60	0.001-82		946	415	0.0001-60	0.000002->50
Deodorant (underarm)	NR	NS	NR	NS	23 ^c	10	0.0003-23 (not spray) 0.03-23 (aerosol) 8 (pump spray)	0.08-51		16 ^c	1 ^c	0.5-17 (not spray) 3-5 (aerosol)	0.0023-17 ^c
Hair—noncoloring	NR	NS	0.1	NS	151	107	0.000005-77.3	0.02-48		58	17	0.0003-20	0.00005-12
Hair—coloring	NR	NS	NR	NS	22	5	30-68	22-30 (11-22 after dilution)		NR	16	44	>0.1-1
Nail	NR	NS	NR	NS	10	7	0.05-38	3-38		14	6	0.5-12	0.06-10
Mucous membrane	NR	NS	NR	NS	114	91	1-22	1-60		153	91	0.05-34	0.00001-60
Baby products	NR	NS	NR	NS	6	4	17	3		4	4	2-11	5
	Isopropyl ricinoleate				Isopropyl stearate				Isostearyl avocadate				
	2013 ⁶⁴	2002 ¹¹	2012 ⁶⁵	2004 ¹¹	2013 ⁶⁴	2002 ⁸	2012 ⁶⁵	1985 ⁷ /2003 ⁸		2013 ⁶⁴		2012 ⁶⁵	
Totals ^a	NR	NR	2	NR	10	16	0.9-16	0.5-87		1		NR	
Duration of use													
Leave-on	NR	NR	2	NR	9	12	1-16	0.5-50		1		NR	
Rinse-off	NR	NR	NR	NR	1	4	0.9-9	6-87		NR		NR	
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	7	>5-10		NR		NR	
Exposure type													
Eye area	NR	NR	NR	NR	1	3	2	5-76		NR		NR	
Incidental ingestion	NR	NR	2	NR	NR	NR	16	87		NR		NR	
Incidental inhalation—spray	NR	NR	NR	NR	NR	NR	NR	>25-50 ^c		NR		NR	
Incidental inhalation—powder	NR	NR	NR	NR	NR	NR	NR	NR		NR		NR	
Dermal contact	NR	NR	NR	NR	10	16	1-9	0.5-76		1		NR	
Deodorant (underarm)	NR	NR	NR	NR	1 ^c	NR	NR	3		NR		NR	
Hair—noncoloring	NR	NR	NR	NR	NR	NR	NR	6-8		NR		NR	
Hair—coloring	NR	NR	NR	NR	NR	NR	NR	NR		NR		NR	
Nail	NR	NR	NR	NR	NR	NR	0.9	10		NR		NR	

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %									
	Isopropyl hydroxystearate				Isopropyl isostearate				Isopropyl jojobate											
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2005 ¹⁶		2012 ⁶⁵		1989 ¹⁵ / 2007 ¹⁶		2013 ⁶⁴		2012 ⁶⁵					
Totals	NR		8		412		69		0.5-19		≤0.1-65		23		0.3-6					
Mucous membrane	NR	NR	2	NR	NR	NR	16	87	NR	NR	NR	NR	NR	NR	NR	NR				
Baby products	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR				
	Isostearyl behenate				Isostearyl hydroxystearate				Isostearyl isononanoate											
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2009 ⁹		2012 ⁶⁵		2009 ⁹					
	7		4		22		0.01-3		4		NR		NR		NR					
Duration of use																				
Leave-on	7		4						3		NR		NR		NR					
Rinse-off	NR		NR		22		0.01-3		1		NR		NR		NR					
Diluted for (bath) use	NR		NR		NR		NR		NR		NR		NR		NR					
Exposure type																				
Eye area	NR		NR				NR		NR		NR		NR		NR					
Incidental ingestion	NR		NR		8		3		NR		NR		NR		NR					
Incidental inhalation—spray	NR		NR		7		NR		NR		NR		NR		NR					
Incidental inhalation—powder	NR		NR		NR		NR		NR		NR		NR		NR					
Dermal contact	7		4		3		0.01		NR		NR		NR		NR					
Deodorant (underarm)	NR		NR		15		0.01-3		NR		NR		NR		NR					
Hair—Noncoloring	NR		NR		NR		NR		NR		NR		NR		NR					
Hair—coloring	NR		NR		NR		NR		NR		NR		NR		NR					
Nail	NR		NR		NR		NR		4		NR		NR		NR					
Mucous membrane	NR		NR		NR		NR		NR		NR		NR		NR					
Baby products	NR		NR		7		NR		NR		NR		NR		NR					
	Isostearyl isostearate				Isostearyl laurate				NR											
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵		2012 ⁶⁵							
	207		1-31		NR		0.4		2		2-3		2-3							
Duration of use																				
Leave-on	193		1-31		NR		NR		2		2-3		2-3							
Rinse-off	13		NR		NR		0.4		NR		NR		NR							
Diluted for (bath) use	1		NR		NR		NR		NR		NR		NR							
Exposure type																				
Eye area	5		4		NR		NR		NR		NR		NR							
Incidental ingestion	115		4-31		NR		NR		NR		NR		2							
Incidental inhalation—spray	1		NR		NR		NR		NR		NR		NR							
Incidental inhalation—powder	NR		NR		NR		NR		1		NR		NR							
Dermal contact	92		1-30		NR		0.4		2		2-3		2-3							
Deodorant (underarm)	NR		NR		NR		NR		NR		NR		NR							
Hair—noncoloring	NR		NR		NR		NR		NR		NR		NR							
Hair—coloring	NR		NR		NR		NR		NR		NR		NR							
Nail	NR		NR		NR		NR		NR		NR		NR							
Mucous membrane	115		4-31		NR		NR		NR		NR		2							
Baby products	NR		NR		NR		NR		NR		NR		NR							
	Isostearyl myristate				Isostearyl neopentanoate				Isostearyl palmitate											
	2013 ⁶⁴		2007 ⁵		2012 ⁶⁸		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵		2012 ⁶⁵							
	1		NR		2		NR		223		71		0.5-46		0.2-50		54		0.2-17	
Duration of use																				
Leave-on	1		NR		2		NR		208		66		0.5-46		0.2-50		46		0.2-17	
Rinse-off	NR		NR		NR		NR		15		4		5-16		>5-25		8		0.5-8	
Diluted for (bath) use	NR		NR		NR		NR		NR		NR		NR		NR		NR		NR	

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %					
	Isopropyl hydroxystearate				Isopropyl isostearate				Isopropyl jojobate							
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2005 ¹⁶		2012 ⁶⁵		1989 ¹⁵ / 2007 ¹⁶		2013 ⁶⁴		2012 ⁶⁵	
Totals	NR		8		412		69		0.5-19		≤0.1-65		23		0.3-6	
Exposure type																
Eye area	NR	NR	NR	NR	78	7	3-30	1-25	7			0.2-5				
Incidental ingestion	NR	NR	NR	NR	8	3	4-19	9-14	4			5-8				
Incidental inhalation—spray	NR	NR	NR	NR	4 ^d	6 ^{c,d}	0.5 (pump spray)		2-4 ^d	4 ^d		NR				
Incidental inhalation—powder	NR	NR	NR	NR	31	3	1-16		3-6	9		1-16				
Dermal contact	1	NR	2	NR	201	68	0.5-46		0.2-50	42		0.2-17				
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR		NR	NR		NR				
Hair—noncoloring	NR	NR	NR	NR	13	NR	16		NR	8		NR				
Hair—coloring	NR	NR	NR	NR	NR	NR	NR		NR	NR		NR				
Nail	NR	NR	NR	NR	1	NR	NR		NR	NR		1				
Mucous membrane	NR	NR	NR	NR	8	3	4-19		9-14	4		0.5-8				
Baby products	NR	NR	NR	NR	NR	NR	NR		NR	NR		NR				
Isotridecyl isononanoate													Isotridecyl stearate		Lauryl laurate	
2013 ⁶⁴		2009 ⁹		2012 ⁶⁵		2009 ⁹		2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵		
Totals ^a	81		62		1-21		0.7-51		1		NR		35		0.1-16	
Duration of use																
Leave-on	81		62		1-21		0.7-51		1		NR		35		0.1-16	
Rinse-off	NR		NR		3-4		NR		NR		NR		NR		NR	
Diluted for (bath) use	NR		NR		NR		NR		NR		NR		NR		NR	
Exposure type																
Eye area	4	NR	2-21	0.7	1		NR		2		0.8-16					
Incidental ingestion	18	19	2	10	NR		NR		2		NR					
Incidental inhalation—spray	3 ^d	NR	NR	0.8 ^d	NR		NR		3		NR					
Incidental inhalation—powder	6	6	2	10	NR		NR		NR		0.1					
Dermal contact	63	43	1-21	0.7-51	1		NR		32		0.1-16					
Deodorant (underarm)	NR	NR	NR	NR	NR		NR		NR		NR					
Hair—noncoloring	NR	NR	3	3	NR		NR		1		NR					
Hair—coloring	NR	NR	NR	NR	NR		NR		NR		NR					
Nail	NR	NR	NR	NR	NR		NR		1		NR					
Mucous membrane	18	19	2	10	NR		NR		2		NR					
Baby products	NR	NR	NR	NR	NR		NR		NR		NR					
Lauryl palmitate			Myristyl laurate			Myristyl myristate										
2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2007 ⁵		2012 ⁶⁵		2008 ⁵		
Totals ^a	2		NR		13		0.1-2		426		304		0.5-17		0.3-17	
Duration of use																
Leave-on	1		NR		12		0.2-2		385		271		0.5-17		0.4-17	
Rinse-off	1		NR		1		0.1-0.7		37		28		0.5-4		0.3-2	
Diluted for (bath) use	NR		NR		NR		NR		4		5		1-2		NR	
Exposure type																
Eye area	NR		NR		2		0.4-2		62		34		1-12		0.4-13	
Incidental ingestion	NR		NR		1		2		30		18		1-12		6-9	
Incidental inhalation—spray	NR		NR		NR		0.2 ^d		15 ^d		9 ^{c,d}		0.5-0.8 ^d ; 2-17		2-17 ^{c,d}	
Incidental inhalation—powder	NR		NR		NR		NR		4		NR		2-5		NR	
Dermal contact	1		NR		12		0.1-2		377		269		0.5-17		0.3-17	
Deodorant (underarm)	NR		NR		NR		NR		14 ^c		6 ^c		2 (not a spray)		2 ^c	
Hair—noncoloring	1		NR		NR		0.4-0.5		18		13		0.5-8		2	
Hair—coloring	NR		NR		NR		NR		NR		NR		1		NR	
Nail	NR		NR		NR		NR		1		4		1-7		2-3	
Mucous membrane	NR		NR		1		2		35		23		1-12		3-9	
Baby products	NR		NR		NR		NR		2		15		2-3		1-2	

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %	
	Myristyl neopentanoate		Myristyl stearate				Octyldodecyl erucate					
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2002 ⁸	2012 ⁶⁵	1985 ⁷ /2003 ⁸	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵		
Totals ^a	NR	2	2	NR	NR	>1-5	1			0.01-10		
Duration of use												
Leave-on	NR	2	2	NR	NR	>1-5	1			0.01-10		
Rinse-off	NR	NR	NR	NR	NR	NR	NR			0.01-0.1		
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR			NR		
Exposure type												
Eye area	NR	2	NR	NR	NR	NR	NR			0.01-0.2		
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR			10		
Incidental inhalation—spray	NR	NR	NR	NR	NR	NR	NR			NR		
Incidental inhalation—powder	NR	NR	NR	NR	NR	NR	NR			0.1		
Dermal contact	NR	2	2	NR	NR	>1-5	1			0.1-1		
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR			NR		
Hair—noncoloring	NR	NR	NR	NR	NR	NR	NR			NR		
Hair—coloring	NR	NR	NR	NR	NR	NR	NR			NR		
Nail	NR	NR	NR	NR	NR	4	NR			0.01		
Mucous membrane	NR	NR	NR	NR	NR	NR	NR			10		
Baby products	NR	NR	NR	NR	NR	NR	NR			NR		
Octyldodecyl hydroxystearate												
Octyldodecyl isostearate												
Octyldodecyl myristate												
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2007 ⁵	2012 ⁶⁵	2008 ⁵				
Totals ^a	1	NR	NR	2	160	95	0.05-32	0.007-21				
Duration of use												
Leave-on			NR	2	148	88	0.05-32	0.07-21				
Rinse-off	1	NR	NR	NR	12	7	0.4-3	NR				
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR				
Exposure type												
Eye area	NR	NR	NR	2	14	7	0.05-2	0.3-2				
Incidental ingestion	1	NR	NR	NR	19	10	0.08-21	0.07-21				
Incidental inhalation—spray	NR	NR	NR	NR	13 ^d	7 ^d	NR	1 ^d				
Incidental inhalation—powder	NR	NR	NR	NR	3	2	NR	NR				
Dermal contact	NR	NR	NR	2	137	83	0.05-32	0.007-12				
Deodorant (underarm)	1	NR	NR	NR	NR	NR	NR	NR				
Hair—noncoloring	NR	NR	NR	NR	2	1	3	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	19	10	0.08-21	0.07-21				
Baby products	NR	NR	NR	NR	2	2	NR	NR				
Octyldodecyl neopentanoate												
Octyldodecyl octyldodecanoate												
Octyldodecyl olivate												
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2012 ⁶⁵						
Totals	124	0.5-20	1	4	11	2						
Duration of use												
Leave-on	114	0.5-20	1	4	11	2						
Rinse-off	10	3	NR	NR	NR	NR						
Diluted for (bath) use	NR	NR	NR	NR	NR	NR						
Exposure type												
Eye area	20	1-9	NR	NR	2	NR						
Incidental ingestion	30	0.7-12	NR	NR	NR	NR						
Incidental inhalation—spray	7 ^d	7 ^d	NR	NR	NR	NR						
		20 (pump spray)										
Incidental inhalation—powder	2	2-4	NR	NR	NR	NR						
Dermal contact	84	0.8-20	1	4	11	2						
Deodorant (underarm)	NR	NR	NR	NR	NR	NR						

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %	
	Octyldodecyl neopentanoate				Octyldodecyl octyldodecanoate				Octyldodecyl olivate			
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵	
Totals	124		0.5-20		1		4		11		2	
Hair—noncoloring	10		0.5		NR		NR		NR		NR	
Hair—coloring	NR		NR		NR		NR		NR		NR	
Nail	NR		NR		NR		NR		NR		NR	
Mucous membrane	30		0.7-12		NR		NR		NR		NR	
Baby products	NR		NR		NR		NR		NR		NR	
	Octyldodecyl ricinoleate				Octyldodecyl stearate				Oleyl erucate			
	2013 ⁶⁴		2002 ¹¹		2012 ⁶⁵		2004 ¹¹		2013 ⁶⁴		2012 ⁶⁵	
	10		NR		0.9-3		3-5		42		3-19	
Totals	10		NR		0.9-3		3-5		42		3-19	
Duration of use												
Leave-on	5		NR		0.9-3		3-5		42		3-19	
Rinse-off	5		NR		NR		NR		NR		NR	
Diluted for (bath) use	NR		NR		NR		NR		NR		NR	
Exposure type												
Eye area	NR		NR		NR		NR		32		4-19	
Incidental ingestion	NR		NR		0.9-3		3-5		2		9	
Incidental inhalation—spray	NR		NR		NR		3 ^d		NR		NR	
Incidental inhalation—powder	NR		NR		NR		NR		1		NR	
Dermal contact	2		NR		3		3		40		3-19	
Deodorant (underarm)	NR		NR		NR		NR		NR		NR	
Hair—noncoloring	8		NR		NR		NR		NR		NR	
Hair—coloring	NR		NR		NR		NR		NR		NR	
Nail	NR		NR		NR		NR		NR		NR	
Mucous membrane	NR		NR		0.9-3		3-5		2		9	
Baby products	NR		NR		NR		NR		NR		NR	
	Oleyl linoleate				Oleyl oleate				Propylheptyl caprylate			
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2012 ⁶⁵	
	NR		10-11		10		0.4-9		47		1-13	
Totals	NR		10-11		10		0.4-9		47		1-13	
Duration of use												
Leave-on	NR		10-11		9		0.4-9		46		2-13	
Rinse-off	NR		10		1		1		1		1	
Diluted for (bath) use	NR		NR		NR		NR		NR		NR	
Exposure type												
Eye area	NR		NR		3		NR		16		NR	
Incidental ingestion	NR		10		3		9		13		13	
Incidental inhalation—spray	NR		NR		NR		NR		2 ^d		5	
Incidental inhalation—powder	NR		NR		3		NR		NR		NR	
Dermal contact	NR		10		7		0.4-3		33		2-6	
Deodorant (underarm)	NR		NR		NR		NR		NR		NR	
Hair—noncoloring	NR		NR		NR		NR		1		1	
Hair—coloring	NR		NR		NR		NR		NR		NR	
Nail	NR		NR		NR		NR		NR		NR	
Mucous membrane	NR		11		3		9		13		13	
Baby products	NR		NR		NR		NR		NR		NR	
	Stearyl beeswax				Stearyl behenate				Stearyl caprylate			
	2013 ⁶⁴		2012 ⁶⁵		2013 ⁶⁴		2010 ¹⁸		2012 ⁶⁵		2010 ¹⁸	
	10		0.4		NR		NR		NR		0.02	
Totals	10		0.4		NR		NR		NR		0.02	
Duration of use												
Leave-on	9		0.4		NR		NR		NR		0.02	
Rinse-off	1		NR		NR		NR		NR		NR	
Diluted for (bath) use	NR		NR		NR		NR		NR		NR	
Leave-on	28		19		0.3-5		0.3-1		29		20	
Rinse-off	1		1		NR		0.1-0.6		1		1	
Diluted for (bath) use	NR		NR		NR		NR		NR		NR	

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %		# of uses		Max conc of use, %		# of uses		Max conc of use, %	
	Stearyl beeswax				Stearyl behenate				Stearyl caprylate			
	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2010 ¹⁸	2012 ⁶⁵	2010 ¹⁸	2013 ⁶⁴	2010 ¹⁸	2012 ⁶⁵	2010 ¹⁸		
Totals	10	0.4	NR	NR	NR	0.02	29	20	0.3-5	0.1-1		
Exposure type												
Eye area	NR	0.4	NR	NR	NR	0.02	5	2	0.3-1	≤1		
Incidental ingestion	NR	NR	NR	NR	NR	NR	2	2	0.5	NR		
Incidental inhalation—spray	NR	NR	NR	NR	NR	NR	NR	NR	0.5 ^d	NR		
Incidental inhalation—powder	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		
Dermal contact	10	0.4	NR	NR	NR	NR	27	20	0.3-5	≤1		
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		
Hair—noncoloring	NR	NR	NR	NR	NR	NR	NR	NR	3	NR		
Hair—coloring	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		
Nail	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		
Mucous membrane	NR	NR	NR	NR	NR	NR	3	3	0.5	NR		
Baby products	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		
	Stearyl heptanoate				Stearyl olivate				Stearyl palmitate			
	2013 ⁶⁴	2010 ¹⁸	2012 ⁶⁵	1993 ¹⁹ / 2010 ¹⁸	2013 ⁶⁴	2010 ¹⁸	2012 ⁶⁵	2010 ¹⁸	2013 ⁶⁴	2010 ¹⁸	2012 ⁶⁵	2010 ¹⁸
Totals	99	102	0.6-11	0.07-25	3	1	NR	NR	NR	NR	0.02-0.6	3
Duration of use												
Leave-on	95	99	0.6-11	0.07-25	1	NR	NR	NR	NR	NR	0.02-0.6	3
Rinse-off	4	3	2-7	0.7-3	2	1	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type												
Eye area	19	NR	0.6-11	0.5-8	NR	NR	NR	NR	NR	NR	0.02-0.6	3
Incidental ingestion	11	8	2-11	5-25	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation—spray	1	1	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation—powder	NR	NR	2	NR	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	86	92	0.6-11	0.07-25	3	1	NR	NR	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	0.07 ^c	NR	NR	NR	NR	NR	NR	NR	NR
Hair—noncoloring	2	2	2-3	NR	NR	NR	NR	NR	NR	NR	NR	NR
Hair—coloring	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Mucous membrane	14	8	2-11	5-25	1	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Stearyl stearate				Tetradecyloctadecyl stearate				Tridecyl isononanoate			
	2013 ⁶⁴	2010 ¹⁸	2012 ⁶⁵	2010 ¹⁸	2013 ⁶⁴	2012 ⁶⁵	2013 ⁶⁴	2009 ⁹	2012 ⁶⁵	2009 ⁹		
Totals	27	22	0.02-3	0.02-4	2	NR	1	1	NR	9		
Duration of use												
Leave-on	25	20	0.02-3	0.02-4	2	NR	1	1	NR	9		
Rinse-off	2	2	2	2	NR	NR	NR	NR	NR	NR		
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		
Exposure type												
Eye area	6	5	0.2	≤1	NR	NR	NR	NR	NR	NR		
Incidental ingestion	5	5	0.3-0.9	≤1	NR	NR	NR	NR	NR	NR		
Incidental inhalation—spray	2	1	NR	NR	NR	NR	NR	NR	NR	NR		
Incidental inhalation—powder	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		
Dermal contact	15	16	0.02-2	≤4	2	NR	1	1	NR	9		
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		
Hair—noncoloring	2	1	3	3	NR	NR	NR	NR	NR	NR		
Hair—coloring	NR	NR	2	NR	NR	NR	NR	NR	NR	NR		
Nail	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		
Mucous membrane	7	7	0.3-2	≤2	NR	NR	NR	NR	NR	NR		
Baby products	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		

(continued)

Table 8 (continued)

	# of uses		Max conc of use, %			# of uses		Max conc of use, %		
	Tridecyl neopentanoate					Tridecyl stearate				
	2013 ⁶⁴		2012 ⁶⁵			2013 ⁶⁴		2012 ⁶⁵		
Totals	16		2-41		88		0.2-18			
Duration of use										
Leave-on	15		2-41		74		0.2-16			
Rinse-off	1		5		13		2-18			
Diluted for (bath) use	NR		NR		1		NR			
Exposure type										
Eye area	10		5-41		NR		0.3			
Incidental ingestion	1		2.5		11		3-16			
Incidental inhalation—spray	NR		NR		1 ^d		2			
							0.4 (pump spray)			
Incidental inhalation—powder	NR		5		1		NR			
Dermal contact	15		2-41		69		0.2-18			
Deodorant (underarm)	NR		NR		NR		NR			
Hair—noncoloring	NR		NR		87		0.4-7			
Hair—coloring	NR		NR		NR		NR			
Nail	NR		NR		NR		NR			
Mucous membrane	1		2-5		11		3-16			
Baby products	NR		NR		1		NR			

Abbreviations: NR, no reported uses; NS, not specified.

^aBecause 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.

^bPrior to 2012, concentration of use surveys did not request specific information about whether or not products are sprays.

^cIt is not known whether or not the product is a spray.

^dIncludes suntan products, and it is not known whether the reported product is a spray.

^eProduct categories generic, giving no indication of duration of use or exposure type.

sprays.^{69,70} Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable (ie, they would not enter the lungs) to any appreciable amount.^{71,72} 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.⁷² 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.

All of the alkyl esters named in this report, with the exception of behenyl olivate and hexyldodecyl/octyldodecyl hydroxystearate, are listed in the European Union inventory of cosmetic ingredients.⁷³

Noncosmetic

Isoamyl laurate and butyl stearate are approved as direct food additives for use as a flavor substance adjuvant (21CFR172.515). Many of the alkyl esters are approved as indirect food additives, as listed in the Code of Federal Regulations Title 21. Examples of noncosmetic uses of some of the alkyl esters are provided (Table 10).^{42,45,74}

Toxicokinetics

Absorption, Distribution, Metabolism, and Excretion

Cetyl myristoleate. Rats were fed chow containing 2% cetyl myristoleate or untreated feed for 2 hours.⁵¹ Hydrolysis was evaluated by the presence of cetyl alcohol, and no cetyl alcohol was found in the stomach, intestinal content, or intestinal mucosa in either group. Additional details were not provided.

Cetyl oleate. Groups of 5 male albino rats were fed a diet containing 20% cetyl oleate for 9 days; control groups were fed a fat-free diet or a diet containing 20% cottonseed oil.⁴³ The animals were given 12 g of diet per day. The absorption of cetyl oleate was reported to be 75.3%. By day 2 of the study, the animals fed cetyl oleate developed seborrhea, which progressively increased with feeding. The animals were killed after the termination of dosing, and microscopic examination reported thickening and hyperemia of the intestinal wall. The exuded lipid was identified as cetyl oleate. The researchers stated that the absorbability and seborrhea suggested that cetyl oleate was not hydrolyzed in the gut.

The researchers then dosed groups of 6 male rats with 2 g of cetyl oleate or an equal mixture of cetyl oleate + tributyrin by gavage, and the animals were fed a fat-free diet. Control

Table 9. Ingredients Not Reported to be in Current Use.⁶⁴⁻⁶⁷

Arachidyl erucate	Decyl myristate	Isopropyl behenate
Batyl isostearate	Decyl palmitate	Isopropyl laurate
Batyl stearate	Decyltetradecyl cetearate	Isopropyl oleate
Behenyl isostearate	Ethylhexyl adipate/palmitate/stearate	Isopropyl tallowate
Behenyl/isostearyl beeswax	Ethylhexyl C10-40 isoalkyl acidate	Isostearyl erucate
Butyl babassuate	Ethylhexyl neopentanoate	Isotridecyl laurate
Butyl isostearate	Ethylhexyl oleate	Isotridecyl myristate
Butyl oleate	Erucyl arachidate	Lauryl behenate
Butyloctyl beeswax	Erucyl erucate	Lauryl cocoate
Butyloctyl behenate	Erucyl oleate	Lauryl isostearate
Butyloctyl candelillate	Hexyldecyl hexyldecanoate	Lauryl myristate
Butyloctyl cetearate	Hexyldecyl oleate	Lauryl oleate
Butyloctyl oleate	Hexyldecyl palmitate	Lauryl stearate
Butyloctyl palmitate	Hexyldodecyl/octyldecyl hydroxystearate	Lignoceryl erucate
C14-30 alkyl beeswax	Hydrogenated castor oil behenyl esters	Myristyl isostearate
C18-38 alkyl beeswax	Hydrogenated castor oil cetyl esters	Octyldecyl oleate
C30-50 alkyl beeswax	Hydrogenated castor oil stearyl esters	Octyldodecyl avocaoate
C20-40 alkyl behenate	Hydrogenated ethylhexyl sesamate	Octyldodecyl beeswax
C18-38 alkyl C24-54 acid ester	Hydrogenated isocetyl olivate	Octyldodecyl behenate
C16-36 alkyl stearate	Hydrogenated isopropyl jojobate	Octyldodecyl cocoate
C30-50 alkyl stearate	Hydroxycetyl isostearate	Octyldodecyl hydroxystearate
C40-60 alkyl stearate	Isobutyl myristate	Octyldodecyl meadowfoamate
Caprylyl butyrate	Isobutyl palmitate	Octyldodecyl neodecanoate
Cetearyl nonanoate	Isobutyl pelargonate	Octyldodecyl oleate
Cetearyl palmate	Isobutyl stearate	Octyldodecyl safflowerate
Cetearyl palmitate	Isobutyl tallowate	Oleyl arachidate
Cetearyl rice branate	Isocetyl isodecanoate	Oleyl myristate
Cetyl behenate	Isocetyl isostearate	Oleyl stearate
Cetyl dimethyloctanoate	Isocetyl laurate	Stearyl behenate
Cetyl isononanoate	Isodecyl hydroxystearate	Stearyl erucate
Cetyl myristoleate	Isodecyl palmitate	Stearyl linoleate
Cetyl oleate	Isodecyl stearate	Tetradecyleicosyl stearate
Chimyl isostearate	Isohexyl laurate	Tetradecyloctadecyl behenate
Chimyl stearate	Isohexyl neopentanoate	Tetradecyloctadecyl hexyldecanoate
C10-40 isoalkyl acid octyldodecanol esters	Isohexyl palmitate	Tetradecyloctadecyl myristate
C4-5 isoalkyl cocoate	Isolauryl behenate	Tetradecylpropionates
C32-36 isoalkyl stearate	Isooctyl caprylate/caprinate	Tridecyl behenate
Coco-rapeseedate	Isooctyl tallate	Tridecyl cocoate
Decyl castorate	Isopropyl arachidate	Tridecyl erucate
Decyl isostearate	Isopropyl Avocadoate	Tridecyl laurate
Decyl jojobate	Isopropyl babassuate	Tridecyl myristate
Decyl laurate		

animals were dosed with sucrose. The animals were fasted overnight on day 10 of dosing, and 2 animals were then killed. Two of the remaining animals were killed 1 hour and 2 were killed 3 hours after a final dose. Seborrhea was observed in both test groups; only cetyl oleate was recovered from the exuded lipid in both test groups. Intestinal weight was markedly increased in the cetyl oleate + tributyrin group. The free fatty acid content of the stomach 3 hours after dosing and of the small intestine 1 and 3 hours after dosing was increased in the group dosed with cetyl oleate (only) when compared to controls. In the cetyl oleate + butyrin group, the free fatty acid content of the stomach was increased at both 1 and 3 hours, and in the small intestine it was increased after 1 hour.

Dermal Penetration

Isopropyl myristate. Isopropyl myristate, as a nonpolar penetration enhancer, is largely retained in the stratum corneum.⁷⁵ It was not detected in the receptor fluid of flow-through diffusion cells in in vitro skin permeation experiments using human epidermis (stratum corneum and viable epidermis) and dermis (varying thickness).

Isostearyl isostearate. Predeuterated isostearyl isostearate, 7 $\mu\text{L}/\text{cm}^2$, was applied neat to a $2 \times 8 \text{ cm}^2$ site on the ventral forearm of 14 humans for 3 hours under nonocclusive conditions.⁷⁶ The test site was tape-stripped 3 hours after application, and

Table 10. Examples of Noncosmetic Uses

Ingredient	Noncosmetic use	Reference
Behenyl behenate	Used in mold releasing agents in methyl acrylamide polymer	42
Butyl oleate	Indirect food additive as a plasticizer in rubber articles; biodiesel additive; polyvinylchloride plasticizer; water-resisting agent; in hydraulic fluids	21CFR177.2600 74
Ethylhexyl laurate	Lubricant for friction and in paper industry; activity enhancer for pesticides	45
Isoamyl laurate	Direct food additive as a synthetic flavoring substance and adjuvant	21CFR172.515
Isobutyl palmitate	Indirect food additive used in fiber finishing or in textile fibers	21CFR177.2260; 21CFR177.2800
Isooctyl tallate	Indirect food additive as a plasticizer in rubber articles	21CFR177.2600
Isopropyl laurate	Indirect food additive as a lubricant in the manufacture of metallic articles; use level not to exceed 10% by weight	21CFR178.3910
Isopropyl oleate	Indirect food additive as a lubricant in the manufacture of metallic articles or in mineral oil lubricants with incidental food contact	21CFR178.3910; 21CFR178.3570

attenuated total reflectance-Fourier transform infrared spectra measurements were determined. The researchers stated the most of the isostearyl isostearate was located at the surface of the stratum corneum. The percentage recovery of the amount applied was not specified.

Penetration Enhancement

Isopropyl myristate is a nonpolar penetration enhancer in pharmaceutical and cosmetic preparations. A 50:50 isopropanol–isopropyl myristate binary enhancer synergistically increased the transport of estradiol across a 2-layer human epidermis *in vitro*.⁷⁵ The average thicknesses (2 donors) of the stratum corneum and viable epidermis were 14 and 60 μm , respectively. Saturated estradiol solutions of the binary enhancer were used in the donor and the receiver. The isopropanol–isopropyl myristate binary volume ratio varied from 0:100, 25:75, 50:50, 75:25, and 100:0 isopropanol–isopropyl myristate. The permeability coefficient was lowest for neat isopropyl myristate, increased with increasing isopropanol until a 50:50 ratio was reached, and then was relatively constant as the percentage of isopropanol increased.

Isopropyl palmitate is reported to be used in topical formulations as a lipid layer penetration enhancer.⁷⁷ The skin penetration of 3 lipophilic compounds (partition coefficient order: gliclazide > nimesulfide > oxaprozin) and 1 hydrophilic compound (ribavirin) across excised rat abdominal skin after 2-hour pretreatment with 5% to 20% (w/w) isopropyl palmitate in ethanol was determined.⁷⁸ All pretreatment solutions produced a significant increase in the flux and permeation of all 4 compounds; the effectiveness was concentration dependent.

Skin penetration enhancement with isostearyl isostearate was evaluated *in vitro* using excised human abdominal skin by measuring the permeation of 5-fluorouracil through the skin after 6 hours.⁶⁰ Both isostearyl isostearate and the buffer control increased the rate of penetration of 5-fluorouracil, but isostearyl isostearate was not a penetration enhancer.

The effect of alkyl esters on the penetration of indomethacin *in vitro* through excised hairless rat skin was examined.⁷⁹ The permeation of 1% indomethacin from suspensions and from

hydrogenated phospholipid gels containing cetyl caprylate, ethylhexyl palmitate, isocetyl palmitate, isocetyl isostearate, or isocetyl stearate was determined. The permeation rate of indomethacin from the esters increases with increased solubility of the drug in the ester. The solubility of indomethacin in liquid paraffin is very low, and there was no permeation of indomethacin from liquid paraffin after 10 hours. Permeation from the isocetyl isostearate suspension was 3.8 $\mu\text{g}/\text{cm}^2$ after 10 hours, and isocetyl isostearate was the alkyl ester that indomethacin was least soluble in, but in comparison to liquid paraffin, solubility was increased 60-fold. (Of the esters studied, indomethacin had the highest solubility in and permeation from ethylhexyl isononanoate, an alkyl ester previously reviewed by the CIR, with approximately 23 $\mu\text{g}/\text{cm}^2$ permeating in 10 hours.) Permeation rates (and solubility) were higher in gels formed by a hydrogenated phospholipid than from suspensions. In all cases, a linear relationship existed between the cumulative amounts of indomethacin that permeated from any ester from 4 to 10 hours. In another study, the permeation rate of ketoprofen from an alkyl ester suspension through excised hairless rat skin was also proportional to its solubility in the suspension.⁸⁰

Animal Toxicology

Single-Dose (Acute) Toxicity

Dermal

Butyl oleate. The acute dermal toxicity of butyl oleate was determined in rabbits.⁸¹ A single dose of 5 g/kg body weight (bw) butyl oleate was applied to the skin of 10 rabbits. Slight erythema was observed in 3 rabbits and moderate erythema in 7, and slight edema was observed in 6 rabbits and moderate edema in 3. None of the animals died, and the dermal median lethal dose (LD_{50}) of butyl oleate in rabbits was >5 g/kg bw. Additional details were not provided.

Propylheptyl caprylate. Groups of 5 male and 5 female Wistar rats were dosed dermally with a single semioclusive application of 0 or 2000 mg/kg bw propylheptyl caprylate, applied neat.⁵⁰ No irritation or treatment-related signs of toxicity were

reported, and the dermal LD₅₀ of propylheptyl caprylate was >2 g/kg bw.

Ethylhexyl laurate. The dermal LD₅₀ of ethylhexyl laurate in rats was >3 g/kg bw.⁵⁶ Additional details were not provided.

Oral

Butyl oleate. A group of 10 rats were dosed orally with 5 g/kg bw butyl oleate.⁸¹ None of the animals died. The oral LD₅₀ of butyl oleate in rats was >5 g/kg bw.

Cetyl myristoleate. Five male and five female white rats were dosed orally with 5 g/kg bw cetyl myristoleate.⁵¹ There was no mortality, and the LD₅₀ was >5 g/kg bw.

Propylheptyl caprylate. Six female Wistar rats were dosed orally with 2 g/kg bw propylheptyl caprylate in corn oil.⁵⁰ All animals had hunched posture and piloerection for 6 hours after dosing, but none of the animals died during the study. The oral LD₅₀ of propylheptyl caprylate was >2 mg/kg bw.

Ethylhexyl laurate. The oral LD₅₀ of ethylhexyl laurate in rats was >2 g/kg bw.⁵⁶ (Details were not provided.)

Isodecyl laurate. The oral LD₅₀ of isodecyl laurate in Wistar rats was >13 g/kg bw (>15 mL/kg bw).⁵⁸ Additional details were not provided.

Inhalation

Ethylhexyl laurate. The inhalation median lethal concentration (LC₅₀) of ethylhexyl laurate in rats was >230 ppm.⁵⁶ Additional details were not provided.

Repeated-Dose Toxicity

Oral

Propylheptyl caprylate. Groups of 10 male and 10 female CD/Crl:CD(SD) rats were dosed daily by gavage with 0, 100, 300, or 1000 mg/kg bw/d propylheptyl caprylate in soybean oil for 90 days.⁵⁰ No test article-related deaths occurred. No test article-related clinical signs of toxicity or changes in bws or feed consumption, changes in the estrous cycle, or effects on sperm were observed, and there were no effects on any clinical chemistry or hematology parameters. A statistically significant decrease in the urinary pH values in males and females of the 300 and 1000 mg/kg bw/d groups was considered to be related to treatment. Absolute and relative liver weights were statistically significantly increased in animals of the high-dose group. The change in urinary pH was attributed to the possibility of an acidic metabolite being eliminated in large doses, and the changes in liver weight were considered a nonspecific adaptive change to the liver workload at the high doses, therefore, the no-observable adverse-effect level (NOAEL) was established as ≥1000 mg/mg bw/d propylheptyl caprylate.

Ethylhexyl laurate. Male and female Sprague-Dawley rats, number per group not specified, were dosed with 0, 100, 300, or 1000 mg/kg bw ethylhexyl laurate once daily, 5 days/wk, by

gavage for 28 days.⁵⁶ The NOAEL was 1000 mg/kg bw. No additional details were provided.

Isodecyl laurate. Male Wistar rats, number per group not specified, were dosed orally with 500, 1500, or 4500 mg/kg/d isodecyl laurate, 6 days/wk, for 4 weeks.⁵⁸ No treatment-related changes were observed at any dose level. No additional details were provided.

Genotoxicity

In Vitro

Propylheptyl caprylate. The mutagenic potential of 0.31, 0.62, 1.25, 2.5, and 5.0 μL/plate propylheptyl caprylate was evaluated in an Ames test, with and without metabolic activation, using *Salmonella typhimurium* strains TA1535, TA1573, TA98, TA100, and TA102.⁵⁰ Dimethyl sulfoxide served as the vehicle. Propylheptyl caprylate was not mutagenic with or without metabolic activation.

An in vitro mammalian chromosomal aberration assay was performed in Chinese hamster V79 lung fibroblasts with 22.4 to 2480 μg/mL propylheptyl caprylate.⁵⁰ The exposure time was 4 hours with metabolic activation and ranged from 4 to 28 hours without metabolic activation. Propylheptyl caprylate was not clastogenic to Chinese hamster V79 lung fibroblasts.

Ethylhexyl laurate. Ethylhexyl laurate, tested at doses 8, 40, 200, 1000, and 5000 μg/plate, was not mutagenic in an Ames test performed in *S typhimurium* (strains not specified) with and without metabolic activation.⁵⁶

Isodecyl laurate. An Ames test was performed with 312 to 5000 μg/plate isodecyl laurate.⁵⁸ Isodecyl laurate was not mutagenic toward *S typhimurium* strains TA97, TA98, TA100, and TA102. No additional details were provided.

In Vivo

Ethylhexyl laurate. A mouse micronucleus test was performed in which male and female mice were dosed by gavage with 0, 1.25, 2.5, and 5.0 mL/kg ethylhexyl laurate.⁵⁶ The animals were killed after 4, 48, or 72 hours. Ethylhexyl laurate was not genotoxic in this assay.

Carcinogenicity

Published carcinogenicity data were not found and unpublished data were not provided.

Irritation and Sensitization

Mixed results were reported in irritation testing in both nonhuman and human testing with some alkyl esters (Table 11). In rabbits, propylheptyl caprylate was moderately irritating⁵⁰ and ethylhexyl laurate was not irritating.⁵⁶ A formulation containing 10% isopropyl palmitate was moderately irritating in male hairless guinea pigs.⁷⁷ In one study in which it was unclear

Table 11. Irritation and Sensitization Studies.

Test article	Concentration/dose	Test population	Procedure	Results	Reference
			Dermal irritation		
			Nonhuman		
			Propylheptyl caprylate		
Propylheptyl caprylate	Applied neat; amount applied was not specified	SPF albino rabbits, 3 females	4-H semiocclusive patch; mean scores were calculated on the bases of 24, 48, and 72-hour scores, with a maximum value of 3	Moderately irritating Erythema: scores were 2, 2, and 2.33 Edema: scores were 0.33, 1, and 0	50
			Isopropyl palmitate		
Cream formulation consisting of 10% isopropyl palmitate, carbomers, sorbitan oleate, paraffin liquid, propylene glycol, trometamol, and purified water	5 mg cream/cm ² applied 2×/d	Hairless guinea pigs, 15 males	Tolerance test; open applications were made on each side of the dorsal trunk for 4 days; test sites were scored immediately prior to each application and at the end of the study on scale of 0-4 for erythema and 0-3 for both scaling and fissures for a total possible score of 10 Cream without isopropyl palmitate served as the negative vehicle control; cream consisting of glyceryl stearate, PEG-100 stearate, cetostearyl alcohol, paraffin oil, propylene glycol, citric acid monohydrate, sodium citrate was used as a positive vehicle control	Cream with 10% isopropyl palmitate, but not without it, caused a moderate degree of irritation The clinical scores as assessed by the AUC (given as the mean; study days were plotted on the x-axis and average clinical score on the y-axis) were 1.10, 7.25, and 9.10 for the negative control, the cream containing isopropyl palmitate, and the positive control, respectively	77
			Ethylhexyl laurate		
Ethylhexyl laurate	0.5 g	Rabbits, number not specified	OECD Guideline 404 for "acute dermal irritation/corrosion" testing; a semiocclusive patch is applied to an approximately 6 cm ² area for 4 hours; erythema and edema are each scored on a scale of 0-4	Slightly irritating using OECD guidelines Nonirritating according to the EC classification	56
			Isodecyl laurate		
Isodecyl laurate	30 in liquid paraffin 500 mg/dose	Unclear whether rats or rabbits were used	Applications were made to two 4 × 4 cm ² intact and abraded test sites; details were not provided	Not irritating	58
			Human		
			Propylheptyl caprylate		
Propylheptyl caprylate	Undiluted and 10, 25, or 50% in mineral oil 47.6 mg/cm ²	22 subjects	Single 48-hour occlusive application; approximately 0.2 mL of each test material was applied using a 1.9 × 1.9 cm ² patch	No dermal effects at any concentration	50

(continued)

Table 11. (continued)

Test article	Concentration/dose	Test population	Procedure	Results	Reference
Isopropyl myristate	Not specified	244 subjects with contact dermatitis	Isopropyl myristate Patch testing occurred over a 3-year period with a series of test materials (details were not provided)	Three positive responses to isopropyl myristate	82
Cream containing 10% isopropyl palmitate (described earlier)	0.1 mL	20 subjects	Isopropyl palmitate Human chamber scarification test; occlusive 23-hour patch; test material was applied to the abraded skin of the volar forearm daily for 3 days Paraffin oil was applied as the negative control and 0.5% aq SLS was used as the positive control; positive and negative vehicle control creams (described previously) were also tested Irritation was scored on a scale of 0-4 immediately prior to patch application and 1 hour after removal of the final patch	The test material was well-tolerated Clinical scores for the test material (2.71), the positive vehicle control (2.51), and the negative vehicle control (2.39) as assessed by AUC (given as the geometric mean; study days were plotted on the x-axis and average clinical score on the y-axis) were greater than that of the negative control (2.17), but the differences were not statistically significant Clinical score of the positive control was 5.29	77
2-Ethylhexyl esters of C8-14 fatty acids	50% and undiluted	10 subjects	Ethylhexyl laurate Open epicutaneous test; test substance was applied for 60 minutes (additional details were not provided)	Not irritating at either concentration	56
2-Ethylhexyl esters of C8-14 fatty acids	25%, 50%, and 100%	20 subjects	Closed epicutaneous test; applied for 24 hours under an occlusive patch (additional details were not provided)	25% and 50%: no reactions observed 100%: slight erythema, 3 incidences of moderate edema, and 1 of slight edema were observed	56
Dermal sensitization					
Nonhuman					
Propylheptyl caprylate	0%, 2%, 10%, and 50% in corn oil	Mouse	Propylheptyl caprylate LLNA	Not a sensitizer A lymphocyte proliferative response was not induced	50

(continued)

Table 11. (continued)

Test article	Concentration/dose	Test population	Procedure	Results	Reference
Ethylhexyl laurate	Intradermal induction: 0.5% Topical induction: 40% Challenge: 20%	Guinea pigs	Ethylhexyl laurate GPMT (details were not provided)	Not a sensitizer	56
Isodecyl laurate	Not specified	Guinea pigs	Isodecyl laurate GPMT (details were not provided)	Not a sensitizer	58
Butyl oleate	Not specified	25 subjects; 9 males and 16 females	Human Butyl oleate Maximization study; an occlusive patch was applied to the volar forearm of all subjects for 5 alternate-day 48-hour periods An occlusive patch with 5% SLS was applied prior to patching Sites were scored upon patch removal and 24 hours later	Not a sensitizer All challenge scores were 0	83
Body oil containing 77.9% ethylhexyl palmitate	Applied neat	104 subjects	Ethylhexyl palmitate Modified HR IPT; 24-hour semiocclusive patches with 150 μ L of test material Induction: 2 \times 2 cm ² Webril pad was applied for 24-hour, 3 \times /wk for 3 weeks; sites were graded 24 or 48 hours after patch removal Challenge: after a 1-week nontreatment period, 2 concurrent 24-hour challenge patches were applied, one to the induction site and one to a previously untreated area on the back; these sites were graded immediately upon and 24 hours after patch removal	Not an irritant or a sensitizer No reactions were observed during induction or challenge	84
Lip gloss formulation containing 25.9% ethylhexyl stearate	Applied neat	104 subjects	Ethylhexyl stearate Modified HR IPT; 24-hour semiocclusive patches with 150 mg of test material	Not an irritant or a sensitizer No reactions were observed during induction or challenge	85

(continued)

Table 11. (continued)

Test article	Concentration/dose	Test population	Procedure	Results	Reference
Eyebrow pencil formulation containing 38.8% ethylhexyl stearate	Applied neat	642 subjects	<p><i>Induction:</i> 2 × 2 cm² Webril pad was applied for 24-hour, 3 × /wk for 3 weeks; sites were graded 24 or 48 hours after patch removal</p> <p><i>Challenge:</i> after a 1-wk nontreatment period, 2 concurrent 24-hour challenge patches were applied, one to the induction site and one to a previously untreated area on the back; these sites were graded immediately upon and 24 hours after patch removal</p> <p>HRIPT; 24-hour semiocclusive patches</p> <p><i>Induction:</i> patches applied 3 × /wk for 3 weeks; sites were graded for irritation 24 or 48 hours after patch removal</p> <p><i>Challenge:</i> after a 2-wk nontreatment period, a 24-hour challenge patch was applied to a previously untreated area on the back; this site was graded upon patch removal and at 48 and 72 hours</p>	Not an irritant or a sensitizer No reactions were observed during induction or challenge	86
Concealer formulation containing 29.5% isocetyl myristate	Applied neat	104 subjects	<p>isocetyl myristate</p> <p>HRIPT; 24-hour semiocclusive patches; 0.2 g test material</p> <p><i>Induction:</i> 1 × 1 in² absorbent pad with clear adhesive dressing was applied 3 × /wk for 3 weeks; sites were graded for irritation 24 or 48 hours after patch removal</p> <p><i>Challenge:</i> after a 2-wk nontreatment period, a 24-hour challenge patch was applied to a previously untreated area on the back; this site was graded upon patch removal and at 72 hours</p>	Not an irritant or a sensitizer No reactions were observed during induction or challenge	87
Lipstick formulation containing 15.2% cetyl ricinoleate	Applied neat	621 subjects	<p>Cetyl ricinoleate</p> <p>HRIPT; 24-hour semiocclusive patches</p> <p><i>Induction:</i> patches applied 3 × /wk for 3 weeks; sites were graded for irritation 24 or 48 hours after patch removal</p> <p><i>Challenge:</i> after a 2-wk nontreatment period, a 24-hour challenge patch was applied to a previously untreated area on the back; this site was graded upon patch removal and at 48 and 72 hours</p>	Not an irritant or a sensitizer No reactions were observed during induction or challenge	88

Abbreviations: AUC, area under the curve; EC, European Commission; GPMT, guinea pig maximization test; HRIPT, human repeated insult patch test; LLNA, local lymph node assay; OECD, Organization for Economic Cooperation and Development; SLS, sodium lauryl sulfate.

whether the testing was done in rats or in rabbits, 30% isodecyl laurate in liquid paraffin was not a dermal irritant.⁵⁸ Propylheptyl caprylate, which was moderately irritating in rabbit skin, was not irritating to human skin when applied for 48 hours using an occlusive patch.⁵⁰ In other clinical tests, patch testing with isopropyl myristate resulted in 3/244 positive reactions in subjects with suspected contact dermatitis⁸² and a formulation containing 10% isopropyl palmitate, which was moderately irritating to guinea pig skin, was well tolerated in a human chamber scarification test.⁷⁷ Undiluted and 50% 2-ethylhexyl esters of C8-14 fatty acids applied openly for 60 minutes, and 25% and 50% applied with an occlusive 24-hour patch were not irritating, but undiluted 2-ethylhexyl esters of C8-14 fatty acids produced slight erythema and moderate edema when applied with an occlusive 24-hour patch.⁵⁶

The alkyl esters were not sensitizers in nonhuman or human studies. In a mouse local lymph node assay, propylheptyl caprylate did not induce a lymphocyte proliferative response, indicating that it is not a sensitizer.⁵⁰ Ethylhexyl laurate⁵⁶ and isodecyl laurate⁵⁸ were not sensitizers in a guinea pig maximization test. In clinical testing, butyl oleate was not a sensitizer in a maximization study⁸³ and a body oil containing 77.9% ethylhexyl palmitate,⁸⁴ a lip gloss containing 25.9% ethylhexyl stearate,⁸⁵ an eyebrow pencil formulation containing 38.8% ethylhexyl stearate,⁸⁶ a concealer containing 29.5% isocetyl myristate,⁸⁷ and a lipstick formulation containing 15.2% cetyl ricinoleate⁸⁸ were not sensitizers in human repeat insult patch tests (HRIPTs).

Ocular Irritation

Propylheptyl caprylate. The ocular irritation potential of propylheptyl caprylate was evaluated in 3 female rabbits.⁵⁰ Slight conjunctival irritation was observed in all animals 1 hour after instillation, and the irritation had increased to a more diffuse response in 1 animal at 24 hours after instillation. All effects subsided within 72 hours for 2 of the animals and by 7 days in the third animal. Propylheptyl caprylate was considered slightly irritating to rabbit eyes.

Ethylhexyl laurate. Ethylhexyl laurate was not irritating to rabbit eyes.⁵⁶ Additional details not provided.

Isodecyl laurate. A study was conducted in New Zealand white rabbits to determine the ocular irritation potential of 10% isodecyl laurate in liquid paraffin.⁵⁸ No significant treatment-related ocular lesions were observed. No additional details were provided.

Miscellaneous Effects

Dermal Effects

Isostearyl isostearate. In a clinical study, a determination of skin surface water loss, measured using a plastic occlusion stress test, indicated that isostearyl isostearate (2 mg/cm², applied neat) improved the stratum corneum water permeability barrier

function.⁸⁹ The researchers hypothesize that the improvement was due to effects on stratum corneum lipid phase behavior.

Summary

In 1997, the Expert Panel concluded that cetyl esters was safe as used in cosmetics. Because cetyl esters is a member of a broader group of 237 cosmetic ingredients having structural and functional similarities, that is, the alkyl esters, all of these ingredients are included in this rereview. Although 57 of the alkyl esters have been reviewed previously by the CIR, they are included so that a complete family has been formed. The alkyl esters consist of the reaction products of fatty acids and alcohols, and the core relationship between these ingredients is a carboxyl ester functional group flanked on both sides by alkyl chains. Some of these alkyl chains are straight and some are branched. Ingredients included in the safety assessment are primarily reported to function in cosmetics as skin-conditioning agents.

Most of these alkyl esters are produced synthetically via classical Fischer type esterification methods. However, some of the natural source ingredients in this review may be produced by transesterification. Alkyl esters are hydrophobic materials that range from oils at the lowest molecular weights/shortest chain lengths to waxy solids at the highest molecular weights/longest chain lengths.

The VCRP data obtained from the FDA in 2013 and data received in response to a survey of the maximum reported use concentration by category conducted by the Council indicate that 112 of the 237 alkyl esters named in this safety assessment are used in cosmetic formulations. Ethylhexyl palmitate has the most reported uses, 1525, followed by isopropyl myristate, 1182 reported uses, and isopropyl palmitate, 1125 reported uses. Ethylhexyl palmitate had the highest reported use concentration at 78% in body and hand preparations, followed by isopropyl myristate, which is used at 77.3% in other hair grooming aids and 76.6% in aerosol hair spray formulations. Isoamyl laurate and butyl stearate are approved as a direct food additives and a number of the alkyl esters are approved as indirect food additives.

In rats fed a diet containing 20% cetyl oleate, absorption of cetyl oleate was reported to be 75.3%. All the animals developed seborrhea. The absorbability and seborrhea suggested that cetyl oleate was not hydrolyzed in the gut.

Isopropyl myristate is a nonpolar penetration enhancer in pharmaceutical and cosmetic preparations. Isopropyl palmitate is reported to be used in topical formulations as a lipid layer penetration enhancer. Isostearyl isostearate increased the rate of penetration of fluorouracil through excised human abdominal skin, but it was not a penetration enhancer. Alkyl esters tended to increase the permeation rate of indomethacin and ketoprofen, the increase occurred due to increased solubility.

The dermal LD₅₀ of butyl oleate in rabbits was >5 g/kg, and the dermal LD₅₀ in rats of propylheptyl caprylate and ethylhexyl laurate was >2 and >3 g/kg/bw, respectively. The oral

LD₅₀ in rats was >5 g/kg for butyl oleate and for cetyl myristoleate, >2 g/kg for propylheptyl caprylate and ethylhexyl laurate, >13 g/kg for isodecyl oleate, and >64 cm³/kg for isopropyl linoleate. The inhalation LC₅₀ of ethylhexyl laurate in rats was >230 ppm. In repeated dose studies in rats, toxic effects were not observed with oral administration of up to 1000 mg/kg ethylhexyl laurate or 4500 mg/kg/d isodecyl laurate for 4 weeks or with up to 1000 mg/kg bw/d propylheptyl caprylate for 90 days.

Propylheptyl caprylate was not mutagenic in an Ames assay (≤ 5.0 μ L/plate) or clastogenic in an in vitro mammalian chromosomal aberration assay (≤ 2480 μ g/mL). Ethylhexyl laurate and isodecyl laurate were not mutagenic toward *S typhimurium* in an Ames assay at doses of ≤ 5000 μ g/plate, and ethylhexyl laurate, ≤ 5.0 mL/kg, was not genotoxic in a mouse micronucleus test.

Mixed results were reported in nonhuman irritation testing using some alkyl esters. In rabbits, propylheptyl caprylate was moderately irritating and ethylhexyl laurate was not irritating. A formulation containing 10% isopropyl palmitate was moderately irritating in male hairless guinea pigs. In one study in which it was unclear from the report whether the testing was done in rats or in rabbits, isodecyl laurate was not irritating to the skin. In a mouse local lymph node assay, propylheptyl caprylate did not induce a lymphocyte proliferative response, indicating that it is not a sensitizer. Ethylhexyl laurate and isodecyl laurate were not sensitizers in a guinea pig maximization test.

Mixed irritation results were also observed in human studies. Propylheptyl caprylate, which was moderately irritating in rabbit skin, was not irritating to human skin when applied for 48 hours using an occlusive patch. Patch testing with isopropyl myristate resulted in 3/244 positive reactions in subjects with suspected contact dermatitis. A formulation containing 10% isopropyl palmitate, which was moderately irritating to guinea pig skin, was well tolerated in a human chamber scarification test. Undiluted and 50% 2-ethylhexyl esters of C8-14 fatty acids applied openly for 60 minutes and 25% and 50% applied with an occlusive 24-hour patch were not irritating, but undiluted 2-ethylhexyl esters of C8-14 fatty acids produced slight erythema and moderate edema when applied with an occlusive 24-hour patch. No sensitization reactions were observed in human studies. Butyl oleate was not a sensitizer in a maximization study and a body oil containing 77.9% ethylhexyl palmitate, a lip gloss containing 25.9% ethylhexyl stearate, an eyebrow pencil formulation containing 38.8% ethylhexyl stearate, a concealer containing 29.5% isocetyl myristate, and a lipstick formulation containing 15.2% cetyl ricinoleate were not sensitizers in HRIPTs.

Ocular irritation studies were performed using rabbits. Cetyl esters, 60% to 65%, ethylhexyl laurate, 10% isodecyl laurate in liquid paraffin, and 10% isopropyl laurate in corn oil were not irritating to rabbit eyes and undiluted and 10% aqueous isopropyl linoleate and propylheptyl caprylate was slightly irritating to rabbit eyes.

Discussion

This CIR Expert Panel expanded its earlier safety assessment of cetyl esters to include all alkyl esters currently described as cosmetic ingredients based on similarities in molecular structures, physical and chemical properties, and usage in cosmetics. These ingredients consist of the reaction products of fatty acids and alcohols.

Although there are data gaps for individual ingredients, there are adequate data on many of the ingredients, and the relatedness of molecular structures, physicochemical properties, and functions and concentrations in cosmetics noted above allowed grouping these ingredients together and extending the available toxicological data to support the safety of the entire group. For example, dermal absorption and metabolism data for certain long-chain, branched alkyl esters were lacking. The consensus of the Panel was that earlier safety assessments had determined that dermal penetration of long-chain alcohols is predicted to be low, so the Panel extended that information to suggest that dermal penetration for alkyl esters is likely to be even lower. The Panel recognized that some of the alkyl esters can enhance the penetration of other ingredients through the skin. The Panel cautioned that care should be taken in formulating cosmetic products that may contain these ingredients in combination with any ingredients whose safety was based on their lack of dermal absorption data or when dermal absorption was a concern.

The Panel acknowledged that some of the alkyl esters may be formed from plant-derived or animal-derived acid or alcohol 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 dangers 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 agreed with determinations by the US FDA that tallow derivatives are not risk materials for transmission of infectious agents.

The Panel was also concerned that the potential exists for dermal irritation with the use of products formulated using some of the alkyl esters. The Panel thus specified that products must be formulated to be nonirritating.

Although a previous CIR safety assessment on isopropyl linoleate determined that the data were insufficient to determine safety for use in cosmetics and that human irritation and sensitization data and genotoxicity data were needed, the Panel reexamined that finding. Because it is now stated that products containing alkyl esters must be formulated to be nonirritating, irritation data are no longer needed for isopropyl linoleate. Sensitization data were available for other alkyl esters,

suggesting that sensitization would not be a concern for isopropyl linoleate. Likewise, the Panel concluded that the genotoxicity data were available on a number of structurally analogous compounds, suggesting an absence of genotoxicity for isopropyl linoleate.

The Panel also noted that although no carcinogenicity data were available, the negative genotoxicity data coupled with the fact that dermal penetration is expected to be low supports the Panel's view that carcinogenicity would not be a concern with cosmetic use of alkyl esters.

The Panel discussed the issue of incidental inhalation exposure to alkyl esters from powders and products that may be aerosolized. Some of the alkyl esters are reportedly used at up to 19% in products that may become airborne (ie, in face powders), and at quite high concentrations in cosmetic products that may be aerosolized (eg, 77% isopropyl myristate in hair sprays, 45% ethylhexyl palmitate in indoor tanning preparations, and 23% isopropyl myristate in deodorant formulations). There were no repeated-dose inhalation toxicity data available for the alkyl esters; however, the actual exposure in the breathing zone is small and given 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. Also, these ingredients are large molecules and most are quite insoluble in water, which supports the view that they are unlikely to be absorbed or cause local effects in the respiratory tract. The Panel also considered the data available to characterize the potential for alkyl esters to cause systemic toxicity, irritation, sensitization, or other effects, and concluded that ingredients of this family tend not to produce systemic toxicity at high doses in single-dose oral, dermal, or inhalation studies and not to produce significant systemic toxicity in oral repeated-dose studies. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products that may be aerosolized is available at <http://www.cir-safety.org/cir-findings>.

Conclusion

The CIR Expert Panel concluded that the alkyl esters, listed subsequently, are safe in the present practices of use and concentration described in this safety assessment when formulated to be nonirritating.

Arachidyl behenate,
 arachidyl erucate,*
 arachidyl propionate,
 batyl isostearate,*
 batyl stearate,*
 behenyl beeswax,
 behenyl behenate,
 behenyl erucate,
 behenyl isostearate,*
 behenyl olivate,
 behenyl/isostearyl beeswax,*

butyl avocadate,
 butyl babassuate,*
 butyl isostearate,*
 butyl myristate,
 butyl oleate,*
 butyl stearate,
 butyloctyl beeswax,*
 butyloctyl behenate,*
 butyloctyl candelillate,*
 butyloctyl cetearate,*
 butyloctyl oleate,*
 butyloctyl palmitate,*
 C10-40 isoalkyl acid octyldodecanol esters,*
 C14-30 alkyl beeswax,*
 C16-36 alkyl stearate,*
 C18-38 alkyl beeswax,*
 C18-38 alkyl C24-54 acid ester,*
 C20-40 alkyl behenate,*
 C20-40 alkyl stearate,
 C30-50 alkyl beeswax,*
 C30-50 alkyl stearate,*
 C32-36 isoalkyl stearate,*
 C40-60 alkyl stearate,*
 C4-5 isoalkyl cocoate,*
 caprylyl butyrate,*
 caprylyl caprylate,
 caprylyl eicosenoate,
 cetearyl behenate,
 cetearyl candelillate,
 cetearyl isononanoate,
 cetearyl nonanoate,*
 cetearyl olivate,
 cetearyl palmate,*
 cetearyl palmitate,*
 cetearyl rice branate,*
 cetearyl stearate,
 cetyl babassuate,
 cetyl behenate,*
 cetyl caprate,
 cetyl caprylate,
 cetyl dimethyloctanoate,*
 cetyl esters,
 cetyl isononanoate,*
 cetyl laurate,
 cetyl myristate,
 cetyl myristoleate,*
 cetyl oleate,*
 cetyl palmitate,
 cetyl ricinoleate,
 cetyl stearate,
 cetyl tallowate,
 chimyl isostearate,*
 chimyl stearate,*
 coco-caprylate,
 coco-caprylate/caprate,
 coco-rapeseedate,*

decyl castorate,*
decyl cocoate,
decyl isostearate,*
decyl jojobate,*
decyl laurate,*
decyl myristate,*
decyl oleate,
decyl olivate,
decyl palmitate,*
decyltetradecyl cetearate,*
erucyl arachidate,*
erucyl erucate,*
erucyl oleate,*
ethylhexyl adipate/palmitate/stearate,*
ethylhexyl C10-40 isoalkyl acidate,*
ethylhexyl cocoate,
ethylhexyl hydroxystearate,
ethylhexyl isononanoate,
ethylhexyl isopalmitate,
ethylhexyl isostearate,
ethylhexyl laurate,
ethylhexyl myristate,
ethylhexyl neopentanoate,*
ethylhexyl oleate,*
ethylhexyl olivate,
ethylhexyl palmitate,
ethylhexyl pelargonate,
ethylhexyl stearate,
heptyl undecylenate,
heptylundecyl hydroxystearate,
hexyl isostearate,
hexyl laurate,
hexyldecyl hexyldecanoate,*
hexyldecyl isostearate,
hexyldecyl laurate,
hexyldecyl oleate,*
hexyldecyl palmitate,*
hexyldecyl stearate,
hexyldodecyl/octyldecyl hydroxystearate,*
hydrogenated castor oil behenyl esters,*
hydrogenated castor oil cetyl esters,*
hydrogenated castor oil stearyl esters,*
hydrogenated ethylhexyl olivate,
hydrogenated ethylhexyl sesamate,*
hydrogenated isocetyl olivate,*
hydrogenated isopropyl jojobate,*
hydroxycetyl isostearate,*
hydroxyoctacosanyl hydroxystearate,
isoamyl laurate,
isobutyl myristate,*
isobutyl palmitate,*
isobutyl perlargonate,*
isobutyl stearate,*
isobutyl tallowate,*
isocetyl behenate,
isocetyl isodecanoate,*
isocetyl isostearate,*
isocetyl laurate,*
isocetyl myristate,
isocetyl palmitate,
isocetyl stearate,
isodecyl cocoate,
isodecyl hydroxystearate,*
isodecyl isononanoate,
isodecyl laurate,
isodecyl myristate,
isodecyl neopentanoate,
isodecyl oleate,
isodecyl palmitate,*
isodecyl stearate,*
isohexyl caprate,
isohexyl laurate,*
isohexyl neopentanoate,*
isohexyl palmitate,*
isolauryl behenate,*
isononyl isononanoate,
isooctyl caprylate/caprinate,*
isooctyl tallate,*
isopropyl arachidate,*
isopropyl avocadate,*
isopropyl babassuate,*
isopropyl behenate,*
isopropyl hydroxystearate,
isopropyl isostearate,
isopropyl jojobate,
isopropyl laurate,*
isopropyl linoleate,
isopropyl myristate,
isopropyl oleate,*
isopropyl palmitate,
isopropyl ricinoleate,
isopropyl stearate,
isopropyl tallowate,*
isostearyl avocadate,
isostearyl behenate,
isostearyl erucate,*
isostearyl hydroxystearate,
isostearyl isononanoate,
isostearyl isostearate,
isostearyl laurate,
isostearyl linoleate,
isostearyl myristate,
isostearyl neopentanoate,
isostearyl palmitate,
isotridecyl isononanoate,
isotridecyl laurate,*
isotridecyl myristate,*
isotridecyl stearate,
lauryl behenate,*
lauryl cocoate,*
lauryl isostearate,*
lauryl laurate,

lauryl myristate,*
 lauryl oleate,
 lauryl palmitate,
 lauryl stearate,
 lignoceryl erucate,*
 myristyl isostearate,*
 myristyl laurate,
 myristyl myristate,
 myristyl neopentanoate,
 myristyl stearate,
 octyldecyl oleate,*
 octyldodecyl avocadoate,*
 octyldodecyl beeswax,*
 octyldodecyl behenate,*
 octyldodecyl cocoate,*
 octyldodecyl erucate,
 octyldodecyl hydroxystearate,*
 octyldodecyl isostearate,
 octyldodecyl meadowfoamate,*
 octyldodecyl myristate,
 octyldodecyl neodecanoate,*
 octyldodecyl neopentanoate,
 octyldodecyl octyldodecanoate,
 octyldodecyl oleate,*
 octyldodecyl olivate,
 octyldodecyl ricinoleate,
 octyldodecyl safflowerate,*
 octyldodecyl stearate,
 oleyl arachidate,*
 oleyl erucate,
 oleyl linoleate,
 oleyl myristate,*
 oleyl oleate,
 oleyl stearate,*
 propylheptyl caprylate,
 stearyl beeswax,
 stearyl behenate,*
 stearyl caprylate,
 stearyl erucate,*
 stearyl heptanoate,
 stearyl linoleate,*
 stearyl olivate,
 stearyl palmitate,
 stearyl stearate,
 tetradecyleicosyl stearate,*
 tetradecyloctadecyl behenate,*
 tetradecyloctadecyl hexyldecanoate,*
 tetradecyloctadecyl myristate,*
 tetradecyloctadecyl stearate,
 tetradecylpropionates,*
 tridecyl behenate,*
 tridecyl cocoate,*
 tridecyl erucate,*
 tridecyl isononanoate,
 tridecyl laurate,*
 tridecyl myristate,*

tridecyl neopentanoate,
 tridecyl stearate.

*Not 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.

Author Contribution

M. M. Fiume contributed to conception and design; acquisition, analysis, and interpretation; and drafted the article. B. A. Heldreth contributed to conception and design; acquisition, analysis, and interpretation; drafted the article, and critically revised the article. L. Gill, W. F. Bergfeld, C. D. Klaassen, D. C. Liebler, J. G. Marks, and R. C. Shank contributed to conception and design, analysis and interpretation, and critically revised the article. D. V. Belsito, R. A. Hill, T. J. Slaga, and P. W. Snyder contributed to conception and design, analysis and interpretation, and critically revised the article. All authors gave final approval and agree to be accountable for all aspects of work ensuring integrity and accuracy.

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Unpublished sources cited in this report are available from the Director, Cosmetic Ingredient Review, 1620 L Street, NW, Suite 1200, Washington, DC 20036, USA.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The articles in this supplement were sponsored by the Cosmetic Ingredient Review. The Cosmetic Ingredient Review is financially supported by the Personal Care Products Council.

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Safety Assessment of Sorbitan Esters as Used in Cosmetics

International Journal of Toxicology
2019, Vol. 38(Supplement 2) 60S-80S
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DOI: 10.1177/1091581819871877
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Abstract

The Cosmetic Ingredient Review Expert Panel (Panel) assessed the safety of 20 sorbitan esters; this report included sorbitan esters that were reviewed in 1985 and 2002, as well as 3 previously unreviewed sorbitan esters (sorbitan undecylenate, sorbitan sesquicaprylate, and sorbitan palmate). Most of the sorbitan esters are reported to function in cosmetics as surfactant-emulsifying agents. The Panel reviewed the data from previous sorbitan ester reports, as well as additional data included in this report, to determine the safety of these ingredients. The Panel concluded that the sorbitan esters included in this safety assessment are safe in cosmetics in the present practices of use and concentration.

Keywords

safety, cosmetics, sorbitan esters

Introduction

In 1985, the Cosmetic Ingredient Review (CIR) Expert Panel (Panel) published a safety assessment of 7 sorbitan esters; based on the data presented in that assessment, the panel concluded that sorbitan stearate, sorbitan laurate, sorbitan sesquioleate, sorbitan oleate, sorbitan tristearate, sorbitan palmitate, and sorbitan trioleate were safe as cosmetic ingredients under [then] present conditions of concentration and use.¹ In 2002, the Panel considered the safety of an additional 10 sorbitan fatty acid esters and, based on new data as well as data from the 1985 review, concluded that the sorbitan fatty acid esters were safe for use in cosmetic ingredients under the [then] present practices of use.²

The Panel also determined that the data from those safety assessments, together with the new data presented on the sorbitan esters, support the safety of 3 additional esters that had not yet been reviewed (indicated below by bolded text), and the Panel reopened the safety assessment to add these esters. The ingredients included in this rereview are:

Fatty sorbitan monoesters

Sorbitan caprylate (2002)

Sorbitan undecylenate

Sorbitan laurate (1985)

Sorbitan palmitate (1985)

Sorbitan isostearate (2002)

Sorbitan oleate (1985)

Sorbitan stearate (1985)

Fatty sorbitan sesquiesters

Sorbitan sesquicaprylate

Sorbitan sesquiisostearate (2002)

Sorbitan sesquioleate (1985)

Sorbitan sesquisteate (2002)

Fatty sorbitan diesters

Sorbitan diisostearate (2002)

Sorbitan dioleate (2002)

Sorbitan distearate (2002)

Fatty sorbitan triesters

Sorbitan triisostearate (2002)

Sorbitan trioleate (1985)

Sorbitan tristearate (1985)

Mixed-chain sorbitan esters

Sorbitan cocoate (2002)

Sorbitan olivate (2002)

Sorbitan palmate

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All 20 of these ingredients share an identical sorbitan structural core and only vary by the fatty acid substituents. Most of the sorbitan esters are reported to function as a surfactant-emulsifying agent in cosmetic ingredients³ (Table 1).

Much of the new data included in this safety assessment were found on the European Chemicals Agency (ECHA) web site.⁴ The ECHA web site provides summaries of information generated by industry, and it is those summary data that are reported in this safety assessment when ECHA is cited.

Chemistry

Definition and Structure

The sorbitan esters are mono-, di-, and triesters, and mixtures thereof, of fatty acids and 1,4-sorbitan. Generally, these ingredients can be depicted using a 5-membered ring shown as the tetrahydrofuran form (Figure 1). However, some of the 6-membered ring, tetrahydropyran, may also be present.

The ingredients in this safety assessment are the reaction products of fatty acids, ranging from 8 carbons in length (ie, sorbitan caprylate) to 18 (eg, sorbitan stearate), with hexitol anhydrides derived from sorbitol (eg, sorbitan tristearate; Figure 2). "Sorbitan" is a generic name for anhydrides (ie, cyclic ether tetrahydric alcohols) derived from sorbitol by the removal of 1 molecule of water with concomitant cyclization.

Chemical and Physical Properties

Sorbitan esters are waxy solids or viscous liquids soluble in inorganic solvents (Table 2).¹ Sorbitan esters are stable at pH ranging from 2 to 12. Hydrolysis of sorbitan fatty acid esters can occur in the presence of water at excessively high or low pH. Sorbitol, the compound from which the hexitol anhydrides of the sorbitan esters are derived, is a crystalline, hexahydric alcohol.⁵

Methods of Manufacture

Sorbitan esters are manufactured by combining sorbitol with the appropriate fatty acid at elevated temperatures.¹

Composition and Impurities

Impurities such as free acid or alcohol, arsenic (3 ppm), lead (10 ppm), and water may be found in sorbitan fatty acid esters.¹ Pyranol isomers of these sorbitan esters may be present.

Use

Cosmetic

Most of the sorbitan esters are reported to function in cosmetics as surfactant-emulsifying agents (Table 1).³ In aqueous (aq.) formulations, the emulsifying agent function is a result of the classic surfactant structural combination of a polar head group (the sorbitan core) and apolar fatty chain(s).

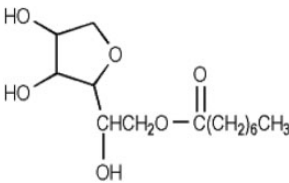
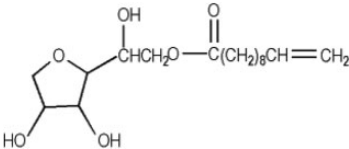
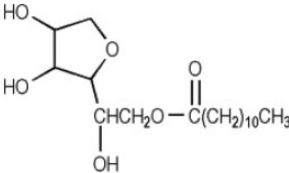
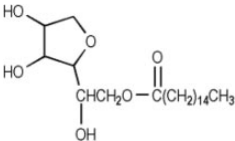
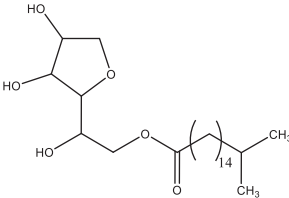
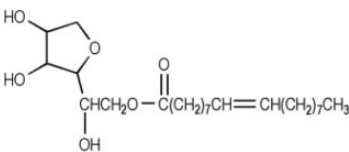
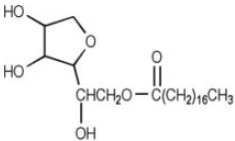
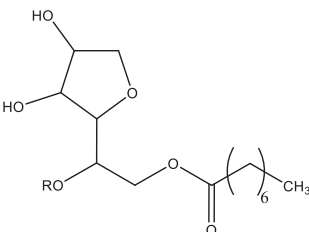
The US Food and Drug Administration (FDA) collects information from manufacturers on the use of individual ingredients in cosmetic formulations as a function of cosmetic product category in its Voluntary Cosmetic Registration Program (VCRP). The VCRP data obtained from the FDA in 2014⁶ and data received in response to a survey of the maximum reported use concentration by category conducted by the Personal Care Products Council (Council)⁷ indicate that 13 of the 20 sorbitan esters named in this safety assessment are currently used in cosmetic formulations. Sorbitan stearate has the most reported uses, 968, followed by sorbitan isostearate, 401 reported uses, and several of the sorbitan esters have a few hundred uses (Table 3). The results of the concentration of use survey indicate that the sorbitan esters are used at less than 10% in cosmetic formulations; sorbitan triisostearate has the highest reported use concentration, 9.1% in rouges. Use concentration data were reported for sorbitan caprylate, but no uses were received in the VCRP; it should be presumed that there is at least one use in every category for which a concentration is reported. The ingredients not in use according to the VCRP and industry survey are listed in Table 4.

Both historical and current use data are provided in Table 3. Concentration of use data were provided in the 1985 report, but these data were not available for the 2002 assessment; however, the 2002 assessment stated that the expected concentration of use was up to 20% in cosmetics. Additionally, it should be noted that frequency of use data for the 7 sorbitan esters included in the 1985 report were updated in the 2002 report; the updated information is included in Table 3. Although the frequency of use of these ingredients has increased, the concentration of use has not.

The sorbitan esters have many uses in the eye area; the highest concentration of use reported for eye products is 7.7% sorbitan olivate in mascara.⁷ Some sorbitan esters are reported to be used in baby products (eg, 0.99% sorbitan stearate in baby lotions, oils, and creams), in products applied to the mucous membranes, or in products that could possibly be ingested (eg, 5.3% sorbitan palmitate in lipsticks).

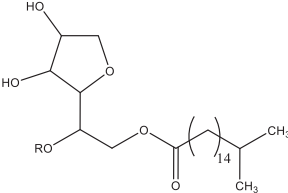
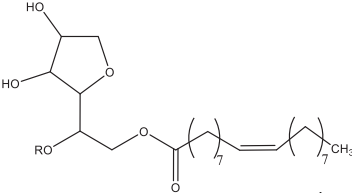
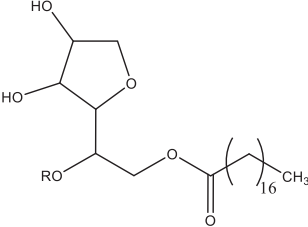
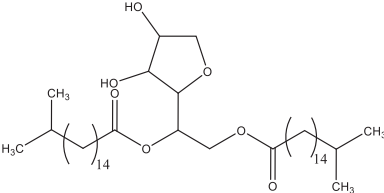
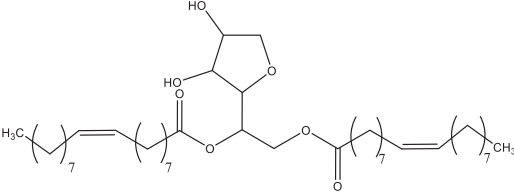
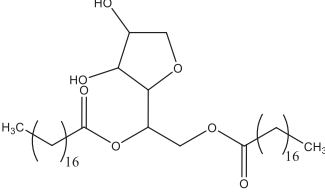
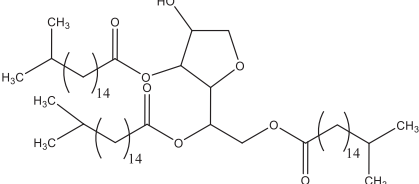
Additionally, some of the sorbitan esters are used in cosmetic sprays and could possibly be inhaled; for example, sorbitan isostearate is reported to be used at 2.3% in pump hair sprays. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 μm , with propellant sprays yielding a greater fraction of droplets/particles <10 μm compared to pump sprays.^{8,9} Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable (ie, they would not enter the lungs) to any appreciable amount.^{10,11} 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.¹⁰ 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. All of the sorbitan

Table I. Definition, Structure, and Function.

Ingredient (CAS No.)	Definition ^{3,a}	Structure ^{3,b}	Function(s) ³
Fatty sorbitan monoesters			
Sorbitan caprylate [95508-00-2]	The monoester of caprylic acid and hexitol anhydrides derived from sorbitol		Surfactant-emulsifying agent
Sorbitan undecylenate (93963-92-9)	The monoester of undecylenic acid and the hexitol anhydrides derived from sorbitol		Surfactant-emulsifying agent
Sorbitan laurate (1337-30-0; 1338-39-2; 5959-89-7)	The monoester of lauric acid and hexitol anhydrides derived from sorbitol		Surfactant-emulsifying agent
Sorbitan palmitate (26266-57-9; 5050-91-9)	The monoester of palmitic acid and hexitol anhydrides derived from sorbitol		Surfactant-emulsifying agent
Sorbitan isostearate (54392-26-6; 71902-01-7)	The monoester of isostearic acid and hexitol anhydrides derived from sorbitol	 (one example of an "iso")	Surfactant-emulsifying agent
Sorbitan oleate (1338-43-8; 37318-79-9)	The monoester of oleic acid and hexitol anhydrides derived from sorbitol		Fragrance ingredient; surfactant-emulsifying agent
Sorbitan stearate (1338-41-6; 5093-91-4; 56451-84-4)	The monoester of stearic acid and hexitol anhydrides derived from sorbitol		Fragrance ingredient; surfactant-emulsifying agent
Fatty sorbitan sesquiesters			
Sorbitan sesquicaprylate (91844-53-0)	A mixture of mono- and diesters of caprylic acid and hexitol anhydrides derived from sorbitol	 wherein R is hydrogen or caprylate ^b	Skin-conditioning agent—misc.; surfactant-solubilizing agent; viscosity-increasing agent—aq.

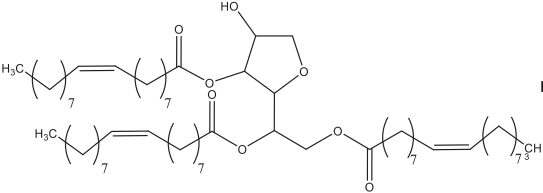
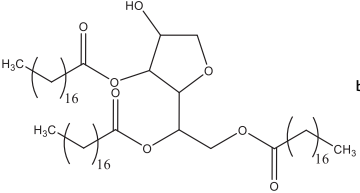
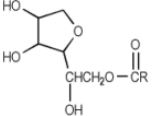
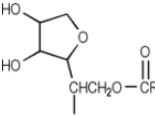
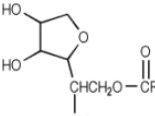
(continued)

Table I. (continued)

Ingredient (CAS No.)	Definition ^{3,a}	Structure ^{3,b}	Function(s) ³
Sorbitan sesquiossearate (71812-38-9)	A mixture of mono- and diesters of isostearic acid and hexitol anhydrides derived from sorbitol	 <p>wherein R is hydrogen or isostearate (one example of an "iso")^b</p>	Surfactant-emulsifying agent
Sorbitan sesquioleate (8007-43-0)	A mixture of mono- and diesters of oleic acid and hexitol anhydrides derived from sorbitol	 <p>wherein R is hydrogen or oleate^b</p>	Surfactant-emulsifying agent
Sorbitan sesquistearate (51938-44-4)	A mixture of mono and diesters of stearic acid and hexitol anhydrides derived from sorbitol	 <p>wherein R is hydrogen or stearate^b</p>	Surfactant-emulsifying agent
Fatty sorbitan diesters Sorbitan diisostearate (68238-87-9)	The diester of isostearic acid and hexitol anhydrides derived from sorbitol		Surfactant-emulsifying agent
Sorbitan dioleate (29116-98-1)	The diester of oleic acid and hexitol anhydrides derived from sorbitol		Surfactant-emulsifying agent
Sorbitan distearate (36521-89-8)	The diester of stearic acid and the hexitol anhydrides derived from sorbitol		Surfactant-emulsifying agent
Fatty sorbitan triesters Sorbitan triisostearate (54392-27-7)	The triester of isostearic acid and hexitol anhydrides derived from sorbitol	 <p>(one example of an "iso")^b</p>	Surfactant-emulsifying agent

(continued)

Table I. (continued)

Ingredient (CAS No.)	Definition ^{3,a}	Structure ^{3,b}	Function(s) ³
Sorbitan trioleate (26266-58-0)	The triester of oleic acid and hexitol anhydrides derived from sorbitol		Surfactant-emulsifying agent
Sorbitan tristearate (26658-19-5)	The triester of stearic acid and hexitol anhydrides derived from sorbitol		Surfactant-emulsifying agent
Mixed chain length sorbitan monoesters			
Sorbitan cocoate (68154-36-9)	The monoester of coconut acid and hexitol anhydrides derived from sorbitol: <i>The fatty acid residues from coconut acid are primarily comprised of caprylate, caprate, laurate, myristate, palmitate, stearate, and oleate</i>	 where RCO— represents the fatty acid radical derived from coconut acid (ranging in chain length from 8 to 18 carbons ^a)	Surfactant-emulsifying agent
Sorbitan olivate (223706-40-9)	The monoester of the fatty acids derived from olive oil and hexitol anhydrides derived from sorbitol: <i>The fatty acid residues from olive oil are primarily comprised of palmitate, palmitoleate, stearate, oleate, linoleate, and linolenate</i>	 where RCO— represents the fatty acid radical derived from olive oil (ranging in chain length from 16 to 18 carbons ^a)	Surfactant-emulsifying agent
Sorbitan palmate [37318-29-9]	The monoester of palm acid and hexitol anhydrides derived from sorbitol: <i>The fatty acid residues from palm acid are primarily comprised of myristate, palmitate, stearate, oleate, and linoleate</i>	 where RCO— represents the fatty acid radical derived from elaeis guineensis (palm) oil (ranging in chain length from 14 to 18 carbons ^a)	Emulsion stabilizer; skin conditioning agent—emollient

Abbreviations: aq., aqueous; misc., miscellaneous.

^aInformation in italics was provided by the Cosmetic Ingredient Review (CIR) Chemist.

^bThese structures were provided by the CIR Chemist.

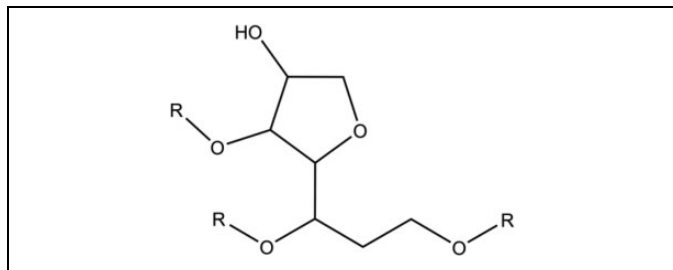


Figure 1. Sorbitan esters, wherein R represents either a fatty acid residue or hydrogen.

esters named in this report are listed in the European Union inventory of cosmetic ingredients.¹²

Noncosmetic

As described in the 1985 safety assessment, sorbitan esters are direct and indirect food additives.¹ Additionally, several sorbitan esters are inactive ingredients in drugs.¹³ These ingredients are used in drugs that are administered via most possible routes, including topical, transdermal, inhalation oral, and/or across mucous membranes (Table 5). The greatest maximum potency concentration used in topically administered drugs is 8% sorbitan stearate and in orally administered drugs is 15% sorbitan oleate. Additionally, sorbitan oleate, sorbitan stearate, and sorbitan tristearate are diluents in color additive mixtures for drug use exempt from certification (ingested drugs) (21CFR73.1001).

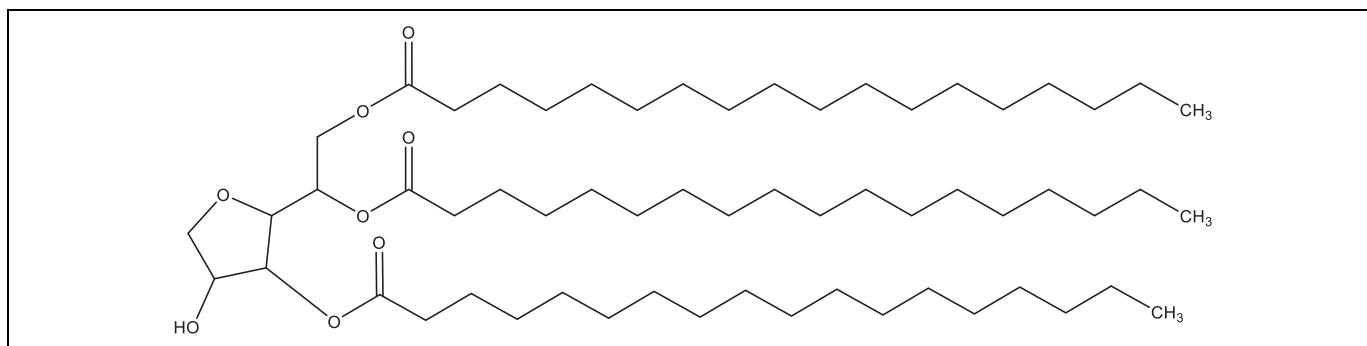


Figure 2. Sorbitan tristearate.

Table 2. Physical and Chemical Properties.

Property	Description	Reference
Sorbitan laurate		
Physical characteristics	Amber-colored oily viscous liquid, light cream to tan beads or flakes, or a hard waxy solid with a slight odor	41
Molecular weight	346.46 Da	5
Solubility	Soluble in mineral oil, cottonseed oil, methanol, ethanol, isopropyl alcohol, ethylene glycol; insoluble in water and propylene glycol; dispersible in hot and cold water	5,41
Sorbitan palmitate		
Physical characteristics	Light cream to tan beads or flakes, or a hard waxy solid with a slight odor	42
Congealing range	45°C-47°C	42
Solubility	Soluble at temperatures above its melting point in ethanol, methanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether, and carbon tetrachloride; insoluble in cold water; dispersible in warm water	42
Sorbitan oleate		
Physical characteristics	Amber-colored oily viscous liquid, light cream to tan beads or flakes, or a hard waxy solid with a slight odor	43
Molecular weight	428.61 Da	5
Solubility	Soluble in ethanol and isopropyl alcohol; miscible with mineral and vegetable oils; insoluble in water and propylene glycol; soluble at temperatures above its melting point in ethanol, ether, ethyl acetate, aniline, toluene, dioxane, petroleum ether, and carbon tetrachloride; insoluble in cold water; dispersible in warm water	5,43
Sorbitan stearate		
Physical characteristics	Light cream to tan beads or flakes or a hard waxy solid with a slight characteristic odor	44
Molecular weight	430.63 Da	5
Melting point	49°C-65°C	5
Congealing range	50°C-52°C	44
Solubility	Soluble at temperatures above its melting point in toluene, dioxane, carbon tetrachloride, ether, methanol, ethanol, and aniline; soluble with haze at temperatures above 50°C in mineral oil and ethyl acetate; insoluble in cold water; dispersible in warm water	44
Sorbitan tristearate		
Physical characteristics	Light cream to tan beads or flakes or a hard waxy solid	45
Congealing range	47°C-50°C	45
Solubility	Slightly soluble in toluene, ether, carbon tetrachloride, and ethyl acetate; dispersible in petroleum ether, mineral oil, vegetable oils, acetone, and dioxane; insoluble in water, methanol, and ethanol	45

Sorbitan sesquioleate is used as an emulsifier in fragrance mix I, a mixture used in patch testing.¹⁴ Sorbitan laurate and sorbitan palmitate are used as emulsifiers in niosomes (nonionic surfactant-based vesicles).^{15,16} Niosomes are microscopic vesicles composed of nonionic surface active agent bilayers, and the intended use of these vesicles is as a drug delivery system.

Toxicokinetics

Sorbitan stearate is hydrolyzed to stearic acid and anhydrides of sorbitol when ingested.¹ Approximately 90% of the sorbitan

stearate is absorbed and hydrolyzed when fed to rats in oil solution, and 50% is absorbed and hydrolyzed when given as a water emulsion. Sorbitan stearate does not accumulate (<0.5%) to any appreciable amount in the fat stores of the rat body. Prolonged feeding (8 weeks) of sorbitan stearate to rats did not affect growth, and other studies indicated that sorbitan stearate had nutritive value for rats and dogs.

Toxicological Studies

The results of oral toxicity studies of sorbitan fatty acid esters indicated that these sorbitans in low concentration were

Table 3. Current and Historical Frequency and Concentration of Use According to Duration and Exposure.

	# of uses		Max conc. of use (%)		# of uses		Max conc. of use (%)	
	Sorbitan caprylate				Sorbitan laurate			
	2014 ⁶	1998 ²	2014 ⁷	1999 ²	2014 ⁶	1998 ²	2014 ⁷	1981 ¹
Totals ^a	NR	NR	1-1.5	NA	118	93	0.00003-3	0.1-10
Duration of use								
Leave-on	NR	NR	1-1.5	NA	106	81	0.00003-3	0.1-10
Rinse-off	NR	NR	1	NA	11	12	0.0009-3	0.1-5
Diluted for (bath) use	NR	NR	NR	NA	1	NR	0.02	NR
Exposure type								
Eye area	NR	NR	1.5	NA	17	9	0.00003-0.3	0.1-10
Incidental ingestion	NR	NR	NR	NA	1	15	NR	0.1-5
Incidental inhalation— spray	NR	NR	NR	NA	1; 26 ^b ; 33 ^c	5; 13 ^b ; 7 ^c	NR	0.1-5 ^b ; 1-5 ^c
Incidental inhalation— powder	NR	NR	1-1.5 ^d	NA	2; 33 ^c	7 ^c	0.03-1 ^d	1-5 ^c
Dermal contact	NR	NR	1-1.5	NA	105	74	0.00003-3	0.1-10
Deodorant (underarm)	NR	NR	NR	NA	NR	NR	NR	NR
Hair—noncoloring	NR	NR	NR	NA	3	2	NR	0.1-5
Hair—coloring	NR	NR	NR	NA	NR	NR	0.0009	NR
Nail	NR	NR	NR	NA	NR	NR	0.000075	NR
Mucous membrane	NR	NR	NR	NA	3	15	0.02	0.1-5
Baby products	NR	NR	NR	NA	1	NR	NR	0.1-1
	Sorbitan palmitate				Sorbitan isostearate			
	2014 ⁶	1998 ²	2014 ⁷	1981 ¹	2014 ⁶	1998 ²	2014 ⁷	1999 ²
Totals ^a	109	39	0.00003-5.5	0.1-5	401	37	0.00038-6.5	NA
Duration of use								
Leave-on	92	26	0.00003-5.5	0.1-5	382	36	0.00038-6.5	NA
Rinse-off	17	12	1.8	0.1-5	19	1	0.003-1	NA
Diluted for (bath) use	NR	1	NR	NR	NR	NR	NR	NA
Exposure type								
Eye area	22	10	0.00003-5.5	0.1-1	49	16	0.00038-4	NA
Incidental ingestion	3	3	2.3-5.3	NR	119	NR	0.0005-2.2	NA
Incidental inhalation— spray	32 ^b ; 29 ^{c,e}	1; 6 ^b ; 1 ^c	NR	0.1-5 ^b ; 1-5 ^c	78 ^b ; 45 ^c	1 ^b ; 1 ^c	Pump: 2.3; aerosol: 1.4; 0.03-3; 0.09-3 ^b	NA
Incidental inhalation— powder	29 ^{c,e}	1 ^c	0.03-1.5 ^d	1-5 ^c	4; 1 ^d ; 45 ^c	1 ^c	0.001-1; 0.001-2.6 ^d	NA
Dermal contact	103	34	0.00003-5.5	0.1-5	255	36	0.00038-6.5	NA
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NA
Hair—noncoloring	3	2	NR	0.1-5	9	1	0.09-2.3	NA
Hair—coloring	NR	NR	NR	NR	8	NR	NR	NA
Nail	NR	NR	0.000075	NR	NR	NR	NR	NA
Mucous membrane	3	4	1.8-5.3	NR	120	1	0.0005-2.2	NA
Baby products	NR	NR	NR	NR	1	3	NR	NA

(continued)

relatively nontoxic via ingestion.¹ The lowest rat lethal dose, 50% (LD₅₀) in the 20 sorbitan ester studies reported was 31 g/kg for sorbitan stearate. In subchronic feeding experiments of sorbitan laurate in a variety of species (chickens, rats, monkeys, and hamsters), no toxic effects were noticed when the ester concentration in the feed was less than 10%. When the feed concentration of sorbitan laurate was ≥10%, growth depression, decreased organ weights, diarrhea, unkempt appearance, hepatic and renal abnormalities, and gastrointestinal tract

irritation were generally observed. Subchronic feeding of sorbitan oleate to rats produced no abnormalities until the ester was at least 10% of the feed. At this concentration, the same types of abnormalities occurred as those observed in the sorbitan laurate-fed animals.

Chronic feeding studies have been conducted with 3 sorbitans. At a 5% dietary concentration, sorbitan laurate and sorbitan oleate had no adverse effect on rats over a 2-year period. Dogs fed 5% sorbitan stearate for 20 months had no compound-related

Table 3. (continued)

	# of uses		Max conc. of use (%)		# of uses		Max conc. of use (%)	
	Sorbitan oleate				Sorbitan stearate			
	2014 ⁶	1998 ²	2014 ⁷	1981 ¹	2014 ⁶	1998 ²	2014 ⁷	1981 ¹
Totals ^a	311	68	0.0025-7	≤0.1-25	968	308	0.00000072-5	≤0.1-25
Duration of use								
Leave-on	205	59	0.0025-3	≤0.1-25	738	266	0.00000072-5	≤0.1-25
Rinse-off	106	9	0.013-7	0.1-10	230	42	0.0013-3.5	≤0.1-10
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	0.1-1
Exposure type								
Eye area	12	5	0.0081-0.08	≤0.1-25	109	41	0.001-3.2	0.1-25
Incidental ingestion	2	1	0.8	≤0.1	5	NR	NR	≤0.1
Incidental inhalation— spray	131 ^b ; 34 ^c	4; 23 ^b ; 4 ^c	Aerosol: 0.018; pump: 0.02; 0.05-3 ^b	0.1-1 ^b ; 0.1-5 ^c	3; 305 ^b ; 217 ^{c,e}	9; 78 ^b ; 78 ^{c,e}	0.00000072 -1.7; pump: 0.4; 0.0002-2.4 ^b	0.1-5; 0.1-10 ^b ; ≤0.1-5 ^c
Incidental inhalation— powder	1; 34 ^c	4 ^c	0.0025-2.7 ^d	0.1 -1; 0.1-5 ^c	15; 6 ^d ; 217 ^{c,e}	78 ^{c,e}	0.001-2.1; 0.013-4 ^d	≤0.1-5 ^c
Dermal contact	200	59	0.0025-7	≤0.1-25	756	284	0.00000072-5	≤0.1-25
Deodorant (underarm)	NR	NR	0.06 (not spray)	NR	9 ^b	5 ^b	0.5 (not spray)	0.1-1 ^b
Hair—noncoloring	20	5	0.01-3	0.1-5	19	9	0.0002-3	0.1-5
Hair—coloring	87	NR	NR	NR	160	NR	0.0013-1.5	1-5
Nail	2	3	NR	0.1-5	1	3	1-1.5	NR
Mucous membrane	3	1	0.8	≤0.1-1	9	NR	NR	≤0.1-1
Baby products	NR	NR	NR	0.1-1	6	5	0.8-0.99	0.1-1
	Sorbitan sesquiossearate				Sorbitan sesquioleate			
	2014 ⁶	1998 ²	2014 ⁷	1999 ²	2014 ⁶	1998 ²	2014 ⁷	1981 ¹
Totals ^a	340	16	0.005-3	NA	323	170	0.005-8	≤0.1-10
Duration of use								
Leave-on	339	16	0.005-3	NA	305	157	0.005-8	≤0.1-10
Rinse-off	1	NR	1	NA	17	12	0.35	≤0.1-10
Diluted for (bath) use	NR	NR	NR	NA	1	1	NR	0.1-1
Exposure type								
Eye area	240	6	0.005-3	NA	91	42	0.01-5	0.1-10
Incidental ingestion	2	NR	3	NA	18	16	0.0051-3	0.1-5
Incidental inhalation— spray	6 ^c	NR	NR	NA	24 ^b ; 17 ^c	32 ^b ; 9 ^c	8 ^b	≤0.1-10 ^b ; 0.1-5 ^c
Incidental inhalation— powder	13; 6 ^c	3	2; 2-3 ^d	NA	31; 17 ^c	10; 2 ^d ; 9 ^c	0.016-1; 0.25-2 ^d	0.1-5; 0.1-5 ^c
Dermal contact	338	16	0.005-3	NA	267	130	0.005-5	≤0.1-10
Deodorant (underarm)	NR	NR	3 (not spray)	NA	NR	NR	0.009-2 (not spray); aerosol: 0.0064	0.1-1 ^b
Hair—noncoloring	NR	NR	NR	NA	6	2	8	≤0.1-10
Hair—coloring	NR	NR	1	NA	NR	NR	NR	NR
Nail	NR	NR	NR	NA	1	2	NR	NR
Mucous membrane	2	NR	3	NA	22	17	0.0051-3	0.1-5
Baby products	NR	NR	NR	NA	5	2	4	NR

(continued)

changes. A feed concentration of ≥10% sorbitan stearate was required to produce depressed growth and hepatic and renal abnormalities. Mice appeared more sensitive to toxic effects of sorbitan stearate than rats. A 0.5% dietary concentration produced growth depression in male rats, and a 4% dietary concentration produced renal abnormalities as well.

Subchronic dermal studies of 2% sorbitan palmitate and 4% sorbitan palmitate were negative for any systemic toxicity. No

systemic toxicity was observed with dermal application of 5% sorbitan trioleate for 93 days.

Three clinical assessments have evaluated the oral toxicity of sorbitan stearate. One acute dose of 20 g was administered to 5 subjects, 2 of whom had increased gastric motility. One subject had an increase in free gastric acidity, and all subjects had normal gastric juices. Nine patients were given 3 g sorbitan stearate twice daily for 28 days. Seven patients had normal gas

Table 3. (continued)

	# of uses		Max conc. of use (%)		# of uses		Max conc. of use (%)	
	Sorbitan triisostearate				Sorbitan trioleate			
	2014 ⁶	1998 ²	2014 ⁷	1999 ²	2014 ⁶	1998 ²	2014 ⁷	1981 ¹
Totals ^a	4	NR	0.24-9.1	NA	36	20	0.00001-5	≤0.1-10
Duration of use								
Leave-on	3	NR	0.24-9.1	NA	16	18	0.00001-2.5	0.1-10
Rinse-off	1	NR	NR	NA	16	2	1-5	≤0.1-5
Diluted for (bath) use	NR	NR	NR	NA	4	NR	NR	NR
Exposure type								
Eye area	1	NR	NR	NA	4	1	0.00001-2.5	NR
Incidental ingestion	2	NR	0.24-2	NA	NR	NR	0.3	NR
Incidental inhalation— spray	NR	NR	NR	NA	NR	3 ^b ; 1 ^c	NR	0.1-5 ^b ; 0.1-1 ^c
Incidental inhalation— powder	NR	NR	NR	NA	NR	1; 1 ^c	0.3; 0.5-2.5 ^d	0.1-1; 0.1-1 ^c
Dermal contact	2	NR	4.2-9.1	NA	30	19	0.00001-5	≤0.1-10
Deodorant (underarm)	NR	NR	NR	NA	NR	NR	NR	NR
Hair—noncoloring	NR	NR	NR	NA	6	1	NR	1-5
Hair—coloring	NR	NR	NR	NA	NR	NR	NR	NR
Nail	NR	NR	NR	NA	NR	NR	0.000025	NR
Mucous membrane	2	NR	0.24-2	NA	4	NR	0.3	≤0.1-1
Baby products	NR	NR	NR	NA	NR	NR	NR	NR
	Sorbitan tristearate				Sorbitan olivate			
	2014 ⁶	1999 ²	2014 ⁷	1981 ¹	2014 ⁶	1998 ²	2014 ⁷	1999 ²
Totals ^a	100	8	0.13-2.6	≤0.1-5	214	NR	0.004-7.7	NA
Duration of use								
Leave-on	99	6	0.13-2.6	≤0.1-5	179	NR	0.004-7.7	NA
Rinse-off	1	2	0.13	NR	35	NR	0.7-0.88	NA
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NA
Exposure type								
Eye area	36	NR	0.4-2.6	0.1-1	36	NR	0.014-7.7	NA
Incidental ingestion	2	NR	0.7-1	NR	10	NR	0.018-1	NA
Incidental inhalation— spray	17 ^b ; 38 ^c	3 ^b ; 1 ^c	NR	1-5; 0.1-5 ^b	41 ^b ; 61 ^c	NR	1.6-4 ^b	NA
Incidental inhalation— powder	38 ^c	1 ^c	0.5-2 ^a	NR	1; 61 ^c	NR	0.015-1.9 ^d	NA
Dermal contact	88	8	0.13-2.6	≤0.1-5	192	NR	0.004-7	NA
Deodorant (underarm)	NR	NR	NR	NR	3 ^b	NR	NR	NA
Hair—noncoloring	NR	NR	NR	NR	3	NR	1.6-4	NA
Hair—coloring	NR	NR	NR	NR	NR	NR	NR	NA
Nail	1	NR	NR	NR	NR	NR	NR	NA
Mucous membrane	2	NR	0.13-1	NR	18	NR	0.018-1	NA
Baby products	NR	NR	NR	NR	3	NR	NR	NA

(continued)

patterns (determined radiographically), one had more, and one had less at the end of the observation period. Seven patients had no change in gall bladder function, the eighth had increased emptying time, and the ninth patient had fainter visualization. Normal radiographic intestinal patterns were observed for all 9 patients. In an additional study, 42 subjects ingested 6 g sorbitan stearate daily for 28 days. Eleven subjects had albumin in their urine at the end of the study, and 4 had glycosuria; however, 1 of the 4 patients with glycosuria was diabetic, and

another had an abnormal glucose tolerance test. No significant changes were found in hemoglobin content, hematocrit, red cell count, or red cell fragility; other blood chemistry values were normal except in 1 patient who had slightly elevated total serum bilirubin.

The no-effect dose of sorbitan stearate was 7.5 g/kg/d using rats fed the ingredient for 2 years.² The acute oral LD₅₀ of sorbitan sesquiosostearate was 25 mL/kg in a study using female ddY mice.

Table 3. (continued)

	# of uses	Max conc. of use (%)	# of uses	Max conc. of use (%)
	Sorbitan palmate			
	2014 ⁶	2014 ⁷		
Totals ^a	NR	0.45-0.75		
Duration of use				
Leave-on	NR	0.45-0.75		
Rinse-off	NR	NR		
Diluted for (bath) use	NR	NR		
Exposure type				
Eye area	NR	0.75		
Incidental ingestion	NR	NR		
Incidental inhalation— spray	NR	NR		
Incidental inhalation— powder	NR	0.45-0.75 ^a		
Dermal contact	NR	0.45-0.75		
Deodorant (underarm)	NR	NR		
Hair—noncoloring	NR	NR		
Hair—Coloring	NR	NR		
Nail	NR	NR		
Mucous membrane	NR	NR		
Baby products	NR	NR		

Abbreviations: NA, at the time of the original safety assessment, concentration of use data were not reported by the Food and Drug Administration; NR, not reported use.

^aBecause 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.

^bIncludes products that can be sprays, but it is not known whether the reported uses are sprays.

^cNot specified whether this product is a spray or a powder or neither, but it is possible it may be a spray or a powder, so this information is captured for both categories of incidental inhalation.

^dIncludes products that can be powders, but it is not known whether the reported uses are powders.

^eHas reported use as a foot powder/spray.

Table 4. Ingredients Not Reported to Be Used.

Sorbitan undecylenate
Sorbitan sesquicaprylate
Sorbitan sesquistearate
Sorbitan diisostearate
Sorbitan dioleate
Sorbitan distearate
Sorbitan cocoate

Single-Dose (Acute) Toxicity

The original safety assessments of the sorbitan esters included data that indicated that this group of ingredients was relatively nontoxic upon ingestion of a single dose. Additional oral studies in mice and rats on sorbitan laurate, sorbitan palmitate, sorbitan isostearate, sorbitan stearate, sorbitan sesquioleate, and sorbitan tristearate support those findings (Table 6).¹⁷⁻²² In 4-hour inhalation exposure studies, sorbitan laurate and sorbitan trioleate had an lethal concentration 50% (LC₅₀) in rats that was ≥ 5 mg/L.^{17,23}

Repeated Dose Toxicity

Oral. Male rats (number not specified) were fed a diet containing 5% sorbitan palmitate for 2 years.¹⁸ The no-observable

adverse effect level (NOAEL) was 5%. Thirty male rats were fed a diet with 5% sorbitan stearate, equivalent to 5,000 mg/kg body weight (bw)/d, for 2 years.²⁰ No effects on clinical signs, mortality, bw, feed consumption, hematology, clinical chemistry, gross or microscopic lesions, or pathology were reported. Sorbitan tristearate, 5% (equivalent to 5,000 mg/kg bw/day), was also administered in the diet to a group of 30 male rats for 2 years.²² No effects on clinical signs or mortality, bw or weight gains, or gross or microscopic lesions were reported.

Reproductive and Developmental Toxicity

Fatty acids are normal components of diet for which (at the time of this report) no data were available concerning reproductive or developmental toxicity.² Sorbitol (2.5% to 10%) had no adverse effects on the reproduction of CD rats during a multigenerational feeding study. Hydrogenated starch hydrolysates (~7% sorbitol) were not reproductive toxins at doses of 3,000 to 7,000 mg/kg/d for 2 years.

Gravid female Wistar rats, 20 per group, were dosed once daily by gavage with 0, 500, or 1,000 mg/kg bw/d sorbitan stearate on days 0 to 20 of gestation, and the animals were killed.²⁰ The NOAEL for maternal toxicity and for teratogenicity was 1,000 mg/kg bw/d. No test article-related embryotoxic results were reported.

Table 5. Inactive Ingredient in Drugs.

Ingredient	Route	Dosage form(s)	Maximum potency (per route) ¹³
Sorbitan laurate	Topical	Gel; aerosol; emulsion, aerosol foam	4.74% (aerosol)
	Oral	Suspension; syrup; tablet; granule	0.05% (suspension); 83.9 mg (tablet)
	Ophthalmic	Ointment	Ns
Sorbitan palmitate	Topical	Lotion; cream emulsion; patch	2% (cream emulsion); 10.5 mg (patch)
	Intramuscular	Injection	NS
Sorbitan isostearate	Topical	Lotion	NS
Sorbitan oleate	Topical	Cream; lotion; emulsion; ointment	7% (lotion)
	Transdermal	Controlled release film	NS
	Oral	Solution; suspension; tablet; capsule	15% (solution); 153.9 mg
	Rectal	Suppository	22 mg
Sorbitan stearate	Topical	Lotion; ointment; cream emulsion; suspension; solution	8% (cream emulsion)
	Oral	Suspension	1.25%
	Vaginal	Augmented cream; cream emulsion; tablet	5% (cream emulsion)
Sorbitan sesquioleate	Topical	Ointment	2%
	Rectal	Ointment	2%
Sorbitan trioleate	Oral	Syrup; tablet; capsule; powder (for suspension)	0.03% (powder for suspension)
	Inhalation	Metered aerosol	0.0694%
	Nasal	Metered aerosol	0.0175%
Sorbitan tristearate	Topical	Augmented cream	0.5%

Abbreviation: NS, not specified.

Table 6. Acute Toxicity Studies.

Ingredient	Animals	No./group	Vehicle	Concentration/dose/protocol	LD ₅₀ or LC ₅₀ /results	Reference
Oral						
Sorbitan laurate	Wistar rats	2/sex		2 g/kg by gavage	>2 g/kg	17
Sorbitan laurate	Rats	10/sex	None	16 g/kg by gavage	>16 g/kg	17,a
Sorbitan palmitate	NMRI mice	5 males	Corn oil	5 g/kg by gavage	>5 g/kg	18
Sorbitan palmitate	Rats	10/sex	Vegetable oil	16 g/kg of an 80% solution by gavage	>16 g/kg	18,a
Sorbitan isostearate	CFY rats	5/sex	Neat	16.5 g/kg by gavage	>16.5 g/kg	19
Sorbitan stearate	Wistar rats	2/sex	Peanut oil	2 g/kg by gavage	>2 g/kg	20
Sorbitan stearate	Rats	10/sex	CMC	30%; 17.8 g/kg by gavage	>17.8 g/kg	20,a
Sorbitan stearate	Wistar Rats	10/sex	Water	90%; 16 g/kg by gavage (high application dose administered in 2 portions)	>16 g/kg	20,a
Sorbitan stearate	Male rats	Not specified	Neat	31 g/kg by gavage	>31 g/kg	20
Sorbitan sesquioleate	Mice	10 males	Not specified	31.6 g/kg; route not specified	>31.6 g/kg	21,a
Sorbitan sesquioleate	Wistar rats	2/sex	Peanut oil	5 g/kg by gavage	>5 g/kg	21
Sorbitan sesquioleate	Rats	5/sex	Not specified	31.6 g/kg; route not specified	>31.6 g/kg	21,a
Sorbitan tristearate	Wistar rats	5/sex	CMC	100 g/L, 2 g/kg bw vehicle by gavage	>2 g/kg bw	22
Inhalation						
Sorbitan laurate	Wistar rats	3/sex	Air	5 mg/l; 4-hour nose-only exposure; 40% particles were <4 μm; MMAD/GSD: 4.6 and 4.7 μm/2.0 and 2.1 μm	>5 mg/L	17
Sorbitan trioleate	Wistar rats	3/sex	Air	5.27 mg/l; 4-hour nose-only exposure; particle size distribution: 73.8% inhalable fraction (<4 μm); MMAD/GSD: 2.14 μm/2.68 μm	>5.27 mg/L	23

Abbreviations: bw, body weight; CMC, carboxymethylcellulose; GSD, geometric standard deviation; MMAD, mean mass aerodynamic diameter.

^aStudy disregarded by European Chemicals Agency applicant because only a short abstract was available (reason may have included no data on analytical purity of test substance, no gross pathology performed, no necropsy).

Groups of 12 male and 12 female Sprague Dawley rats were dosed by gavage once daily with 0, 40, 200, or 1,000 mg/kg bw/d sorbitan stearate in water.²⁰ The females were dosed 2 weeks prior to mating until day 4 of lactation; the males were dosed for 42 days. No signs of toxicity; no effects on mortality, bw, or bw gains; and no gross or microscopic lesions were observed.

Effects on feed consumption, hematology, and clinical chemistry were not examined.

Genotoxicity

Sorbitan stearate was not mutagenic in bacteria with or without metabolic activation systems.¹ Sorbitan stearate did not

transform primary Syrian golden hamster embryo cells in vitro. Sorbitan oleate at a concentration of 0.01% inhibited in vitro DNA repair.

An unspecified sorbitan fatty acid ester had equivocal results in an Ames test and chromosome aberration assay using Chinese hamster fibroblasts.² In a feeding study using rats, the ester altered pharmacokinetic activity in the liver.

Sorbitan laurate, sorbitan palmitate, sorbitan stearate, sorbitan sesquicaprylate, sorbitan sesquioleate, and sorbitan trioleate were not mutagenic in the Ames test, with or without metabolic activation (Table 7).^{17,18,20,21,23,24} Sorbitan laurate was not genotoxic to peripheral human lymphocytes in a chromosomal aberration assay,¹⁷ but the results of a chromosomal aberration assay in Chinese hamster cells with sorbitan stearate were ambiguous.²⁰

Carcinogenicity

Mice fed $\leq 4\%$ sorbitan stearate for 80 weeks had no difference in tumor type and incidence when compared to control animals.¹ Sorbitan laurate was inactive as a carcinogen or tumor promoter when painted on mice skin for 70 weeks. However, in another study, sorbitan laurate was a tumor promoter when applied twice daily to mice skin after initiation by 7,12 dimethylbenz[a]anthracene (DMBA). In the same study, sorbitan oleate and sorbitan trioleate were inactive as tumor promoters. In undiluted form, sorbitan laurate and sorbitan trioleate were active as cocarcinogens on mouse skin when applied with DMBA (0.003%).

The sorbitan fatty acid esters had no antitumor activity against Ehrlich ascites tumors in mice. Sorbitan stearate was neither a mouse skin carcinogen nor tumor promoter. Sorbitan laurate and sorbitan trioleate were co-carcinogens in one mouse skin study, but the latter ester and sorbitan oleate were not tumor promoters in another.

Irritation and Sensitization

Dermal

Nonhuman. Numerous skin irritation studies in animals indicate that the sorbitans are minimal to mild irritants.¹ Skin irritation tests in which up to 60% sorbitan stearate in petrolatum and up to 100% sorbitan laurate, sorbitan oleate, and sorbitan trioleate were applied for 30 days produced no visible changes at 3 days but erythema and edema after 10 days. A formulation containing 4% sorbitan stearate applied for 7 days resulted in mild irritation. The dermal irritation in rabbits of a formulation containing 3% sorbitan sesquioleate was minimal. Undiluted sorbitan oleate was minimally irritating to rabbit skin when applied for 24 hours. Sorbitan palmitate, 50%, was not irritating to rabbit skin when applied for 24 hours. Sorbitan tristearate, 30%, was nonirritating when applied to the skin of rabbits for 24 hours.

Sorbitan isostearate, however, was a moderate irritant in one study using rabbits; intradermal injections of the ingredient

caused mild to severe irritation in a study using guinea pigs.² Concentrations up to 100% sorbitan isostearate had low sensitization potential in guinea pigs. Sorbitan isostearate and sorbitan sesquiosostearate (10%) were non- to weak irritants to the intact and abraded skin of rabbits. The same concentrations caused weak cumulative irritation in a study using guinea pigs. In other studies, the ingredient did not produce significant irritation, sensitization, or comedone formation.

In studies published since the original assessments, several of the sorbitan esters were considered not irritating to rabbit skin (Table 8). Sorbitan palmitate, sorbitan isostearate, and sorbitan stearate were applied at concentrations of up to 100% using 24-hour occlusive patches.¹⁸⁻²⁰ Sorbitan sesquioleate was applied for 24 hours using a semioclusive patch,²¹ 40% aq. sorbitan tristearate was applied using a 24-hour occlusive patch,²² and undiluted sorbitan sesquicaprylate and sorbitan trioleate were applied with a 4-hour semioclusive patch.^{23,24} Sorbitan sesquicaprylate was not a sensitizer in a guinea pig maximization test (GPMT); intradermal induction was conducted at a concentration of 5%, and topical induction and challenge were performed at 100%.²⁴ In a GPMT of sorbitan trioleate, intradermal induction (2%), topical induction (100%), and challenge (50% and 100%) resulted in slight to moderate erythema and slight edema were observed in test and control animals²³; at re-challenge (25 and 50%), slight erythema was observed in 2 test animals.

Human. The sorbitans are minimal to mild skin irritants in humans.¹ Results from 3 human repeated insult patch tests (HRIPTs; involving a total of 420 patients) indicated that sorbitan stearate at up to 4% is not a sensitizer. Products containing 2% to 4% of sorbitan stearate were mild irritants in 21-day cumulative irritation studies. A Schwartz prophetic patch test with 30% sorbitan laurate produced no irritation. Human skin tests for sensitivity to sorbitan sesquioleate were negative; 2 Schwartz prophetic patch tests with undiluted sorbitan sesquioleate produced no reactions; and in 5 HRIPTs, products containing 1% to 3% sorbitan sesquioleate were not sensitizers, but some patients did experience mild irritation. Several products containing 1.75% to 2.0% sorbitan oleate have been tested on humans. In four, 21-day cumulative irritation studies, the products tested were mildly irritating; in these tests using entire product formulations, the specific ingredient(s) causing irritation was not determined. Formulations containing up to 2% sorbitan oleate were nonsensitizers in several HRIPTs. No irritation was observed in a maximization test with a formulation containing 1.75% sorbitan oleate, but in a product usage test, a cream containing 1.75% sorbitan oleate produced mild irritation in 2 of 53 individuals. A Schwartz prophetic patch test with undiluted sorbitan tristearate produced no irritation in 201 patients. Formulations containing 4% sorbitan palmitate were found to be slightly irritating in humans in 21-day cumulative irritation tests (34 patients total). In a Shelanski/Jordan RIPT (206 patients), a skin care product containing 4% sorbitan palmitate was nonirritating and nonsensitizing. Several products containing 5%

Table 7. Genotoxicity Studies.

Test article	Concentration/ vehicle	Procedure	Test system	Results	Reference
In vitro					
Sorbitan laurate	0.1-333 µg/mL (without) 10-350 µg/mL (with) in DMSO	Mammalian cell gene mutation assay, with and without metabolic activation; with valid positive controls	Mouse lymphoma L5178Y cells	Negative	17
Sorbitan laurate	33-500 µg/mL in DMSO	Chromosomal aberration assay (OECD guideline 473), with and without metabolic activation; with valid positive controls	Peripheral human lymphocytes	Negative	17
Sorbitan palmitate	Not specified	Ames test, with and without metabolic activation; no data were available on the use of valid positive controls	<i>Salmonella</i> <i>typhimurium</i> TA98, TA100	Negative	18
Sorbitan stearate	3-5,000 µg/plate in DMSO	Ames test, with and without metabolic activation; valid controls were used	<i>S typhimurium</i> TA1535, TA1537, TA98, TA100, TA102	Negative	20
Sorbitan stearate	8-5,000 µg/plate in DMSO	Ames test, with and without metabolic activation; valid controls were used	<i>S typhimurium</i> TA1535, TA1537, TA1538, TA98, TA100	Negative	20
Sorbitan stearate	313-5,000 µg/plate in DMSO	Ames test, with and without metabolic activation; valid controls were used	<i>S typhimurium</i> TA1535, TA1537, TA98, TA100, <i>Escherichia coli</i> wp2 uvrA	Negative	20
Sorbitan stearate	0.13-0.5 mg/mL (without) 1.1-4.3 mg/mL (with) in CMC sodium solution	Chromosomal aberration assay, with and without metabolic activation; with positive controls, <i>submitter disregarded the study for relevant methodological deficiencies (analytical purity of test substance not specified, limited documentation, cyclophosphamide was used as positive control both with and without metabolic activation, and did not induce a stat. sig. increase in the total number of aberrant cells in the presence of metabolic activation system)</i>	Chinese hamster cells	Results were considered ambiguous; stat. sig. increase in cells with aberrations with 0.13 mg/mL without and with all doses with activation, but no sig. increases with positive controls	20,a
Sorbitan sesquicaprylate	Not specified	Ames test, with and without metabolic activation; no data were available on the use of valid positive controls. <i>Submitter disregarded study because only a short abstract was available</i>	<i>S typhimurium</i> TA98, TA100	Negative	24,a
Sorbitan sesquicaprylate	3-5,000 µg/plate in DMSO	Ames test, with and without metabolic activation; valid controls were used	<i>S typhimurium</i> TA1535, TA1537, TA98, TA100, TA102	Negative	24
Sorbitan sesquioleate	Not specified	Ames test, with and without metabolic activation	<i>S typhimurium</i> TA98, TA100	Negative	21
Sorbitan sesquioleate	8-5,000 µg/plate in DMSO	Ames test, with and without metabolic activation; valid controls were used	<i>S typhimurium</i> TA1535, TA1537, TA1538, TA98, TA100	Negative	21
Sorbitan trioleate	Not specified	Ames test, with and without metabolic activation	<i>S typhimurium</i> TA98, TA100	Negative	23

Abbreviations: CMC, carboxymethylcellulose; DMSO, dimethyl sulfoxide; stat. sig., statistically significant.

^aStudy disregarded by European Chemicals Agency applicant.

Table 8. Dermal Irritation and Sensitization.

Test article	Concentration/dose	Test population	Procedure	Results	Reference
Nonhuman					
Sorbitan palmitate	Neat	6 male NZW rabbits	24-hour occlusive application to shaved and abraded skin; the test sites were scored at 24 and 72 hours	Not irritating	18
Sorbitan isostearate	Neat; 0.5 mL	6 albino rabbits	24-hour occlusive application to shaved and abraded skin; the test sites were scored at 24 and 72 hours	Erythema score—1.78/4; edema score—0.94/4. Neither erythema nor edema was fully reversible after 72 hours	19
Sorbitan stearate	10 in peanut oil, 25% in peanut oil	10 male hairless mice, 5 male hairless mice	2 open applications/day for 10 days. <i>Disregarded because only a short abstract was available (limited documentation, repeated application, up to 25% test substance evaluated, test substance purity not specified)</i>	No adverse effects reported	20,a
Sorbitan stearate	Neat, 0.5 g	6 NZW rabbits	4-hour semioclusive patches to shaved and abraded skin	Not irritating Erythema score—0.3/4, fully reversible after 72 hours Edema score—0/4	20
Sorbitan stearate	0.5 mL	NZW rabbits, 3/sex	24-hour occlusive patch to intact and abraded skin	Not irritating Erythema score—0.7/4, fully reversible after 72 hours in 4/6 animals; edema score—0/4	20
Sorbitan sesquicaprylate	Neat; 0.5 mL	NZW rabbits, 1 male and 2 females	4-hour semioclusive application to clipped skin; test sites scored at 1, 24, 48, and 72 hours after patch removal	Classified as not irritating Erythema and edema scores—0/4	24
Sorbitan sesquicaprylate	Intradermal induction: 5% topical induction: 100%; challenge: 100%; vehicle: peanut oil	10 guinea pigs	GPMT induction: intradermal, 3 pairs of 0.1 mL injection, with 1:1 FCA/saline, test article, and FCA/vehicle; topical induction, 48-hour patch 7 days after intradermal induction; challenge: after 14 days, 24-hour patch	Not a sensitizer. No reactions were observed during induction or challenge	24
Sorbitan sesquioleate	Neat; 0.5 mL	6 male NZW rabbits	24-hour semioclusive application to shaved and abraded skin; the test sites were scored at 24 and 72 hours	Classified as not irritating Erythema score—1.89/4; edema score—0.78/4 Neither erythema or edema were fully reversible after 72 hours	21
Sorbitan trioleate	Neat, 0.5 mL	2 NZW rabbits	4-hour semioclusive application to clipped skin; test sites scored at 1, 24, 48, and 72 hours after patch removal	Classified as not irritating Erythema and edema scores—0/4	23

(continued)

sorbitan trioleate were tested on humans; these products were slightly irritating in 21-day cumulative irritation tests, Shelanski/Jordan HRIPT, modified Schwartz-Peck predictive patch tests, and in a 4-week usage test.

Photosensitization assessments on products containing 2% sorbitan stearate or 2% sorbitan oleate classified both products as nonphototoxic and nonphotoallergenic. Sorbitan laurate, sorbitan sesquioleate, sorbitan palmitate, and sorbitan trioleate

did not absorb radiation in the UV-A and UV-B range in UV spectral analysis.

In clinical studies, the sorbitan fatty acid esters were generally minimal to mild skin irritants in humans, and 20% sorbitan sesquioleate increased the incidence of irritation or sensitization reactions produced in 709 patients with suspected contact dermatitis.² Cross-sensitization was reported after 1,206 patients with eczema were treated with 5% to 20% sorbitans

Table 8. (continued)

Test article	Concentration/dose	Test population	Procedure	Results	Reference
Sorbitan trioleate	Induction: intradermal, 2% in olive oil; topical, 100% in liquid paraffin; challenge: 50% and 100% in liquid paraffin; rechallenge: 25% and 50% in liquid paraffin	10 male Dunkin-Hartley guinea pigs	GPMT induction: intradermal, 3 pairs of 0.1 mL injection, with 1:1 FCA/saline, test article, and 50% FCA/4% test article; topical induction, two 48-hour patches; challenge: on day 20, 24-hour patches; rechallenge: on day 28, 24-hour patches	Induction: No signs of irritation during induction; challenge: slight to moderate erythema that decreased in occurrence with time, but was still present at in some animals at 72 hours, and slight edema at 24 hours only was reported for both control and test groups; rechallenge: slight erythema was observed in test animals at 24 hours (25%, 1 animal; 50%, 2 animals) and at 48 hours (50%, 1 animal); no reactions were observed in the negative controls	23
Sorbitan tristearate	40% aq.; 0.5 mL	6 NZW rabbits	24-hour occlusive application to shaved and abraded skin; the test sites were scored at 24 and 72 hours	Not irritating Erythema and edema scores—0/4	22
Human					
Sorbitan palmitate	30% in water	1 male; 9 females	Occlusive patch applied for 5 days	Not an irritant	18
Sorbitan palmitate	50% in water	50 subjects (gender not specified)	72-hour occlusive application using a 1 sq. in cotton pad	Not an irritant	18
Sorbitan stearate	30% in olive oil; 0.1 g	25 subjects	HRIPT; 6 patches over 15 days with Finn chambers	Not an irritant	20
Sorbitan stearate	30% aq.	10 subjects	Patch test; 5-day initial application, 48-hour challenge performed after a 10-day nontreatment period	Not a sensitizer	20
Sorbitan stearate	30% aq.	50 subjects	3-day initial occlusive patch, 3-day challenge performed after a 7-day nontreatment period	Not an irritant or sensitizer	20
Sorbitan sesquioleate	30% aq.	10 subjects	Occlusive patch test; 5-day initial application, 48-hour challenge after a 10-day non-treatment period	Not an irritant or sensitizer	21
Sorbitan trioleate	30% aq.	10 subjects	Patch test; 5-day initial application, 48-hour challenge performed after a 10-day nontreatment period	Not a sensitizer	23
Sorbitan trioleate	30% aq.	50 subjects	3-day initial occlusive patch, 3-day challenge performed after a 7-day nontreatment period	Not an irritant or sensitizer	23

Abbreviations: aq., aqueous; GPMT, guinea pig maximization test; NACDG, North American Contact Dermatitis Group; NZW, New Zealand white; ROAT, repeated open application test; TRUE, thin-layer rapid use epicutaneous.

^aStudy disregarded by European Chemicals Agency applicant.

stearate, oleate, and sesquioleate, as well as 2 polysorbates. Sorbitan isostearate and sorbitan sesquiosostearate (10%) were nonirritating in a 24-hour occlusive patch test using 56 patients.

In clinical testing published since the original assessments, 30% sorbitan palmitate, 30% sorbitan stearate, 30% sorbitan sesquioleate, and 30% sorbitan trioleate were not irritants or sensitizers when applied for up to 5 days, followed by a

challenge application after 7 to 10 days (Table 8).^{18,20,21,23} Sorbitan palmitate, 50%, also was not an irritant after a 72-hour occlusive application.¹⁸

Sorbitan sesquioleate is an emulsifier at a concentration of 5% in fragrance mix I, a mixture used as part of a patch test series.¹⁴ Some researchers have stated that evidence has suggested that sensitization to sorbitan sesquioleate has been

increasing, and the researchers have hypothesized that the increase may be due to an increased use of sorbitan sesquioleate as an emulsifier in corticosteroids.^{14,25} Therefore, several researchers have postulated that a positive allergic reaction to a test mixture actually could be due to the emulsifier and reiterated the importance of patch testing the individual components of the mixture, in addition to the test mixture itself, to properly identify the contact allergen.^{14,25-29}

Case reports. Several case studies of patients with diseased skin have been described (Table 9). Positive reactions to sorbitan laurate (0.4% incidence),³⁰ sorbitan oleate (0.6% incidence with 5%; up to 2.7% incidence with 20%),^{14,30-33} sorbitan stearate (2.3% incidence with 5%),³² and sorbitan sesquioleate (up to 9.8% incidence with 20%) were observed in provocative tests in patients with contact allergy and contact dermatitis.^{14,31-34}

Case reports of contact dermatitis to sorbitan laurate, sorbitan oleate, and sorbitan sesquioleate have been described. For example, reactions to 2%³⁵ or 5% aq. sorbitan laurate³⁶ used as an emulsifier in a hydrocortisone cream have been reported; 3 of 23 patients with chronic leg ulcers had an allergic reaction to 20% sorbitan oleate in petrolatum³⁷; 3 patients with recalcitrant wounds from sensitization to a nonadhering dressing had positive reactions to sorbitan sesquioleate, a component of the dressing³⁸; and 6 pediatric patients with recalcitrant dermatitis had positive reactions to 20% sorbitan sesquioleate in petrolatum.³⁹

Effect on nonimmunologic immediate contact reactions. A 10 × 20 cm² area of skin on the backs of 6 male and 6 female subjects was treated with 0.5 mL of sorbitan sesquioleate in petrolatum (20:80) 3 times per day for 2 days; a contralateral site was treated in a similar manner with petrolatum only.⁴⁰ On day 3, 10 µL of 31, 62, 125, 250, or 500 mM benzoic acid in petrolatum only or petrolatum containing 20% sorbitan sesquioleate was applied without occlusion to the pretreated areas on the back of each subject. Each site was scored visually for irritation 40 minutes after application of the benzoic acid. Additionally, cutaneous blood flow to the test sites was measured using laser Doppler flowmetry (LDF). When assessed with LDF, reactions to 125 or 250 mM benzoic acid in petrolatum only were stronger on the sites that were pretreated with sorbitan sesquioleate when compared to the areas pretreated with petrolatum only; these differences were not apparent using visual observation. No differences were observed with the lower concentrations of benzoic acid. However, a weaker reaction was observed, visually and with LDF, when 31 or 62 mM benzoic acid in petrolatum containing sorbitan sesquioleate was applied to skin pretreated with sorbitan sesquioleate and petrolatum alone, when compared to application of benzoic acid in petrolatum alone.

Ocular Irritation

Draize and modified Draize ocular irritation studies using rabbits were performed with all of the sorbitans in the original report.¹ One study of 30% sorbitan stearate was negative for

ocular irritation, and a cream product containing 4% sodium stearate caused slight conjunctival irritation. Undiluted sorbitan sesquioleate produced no ocular irritation. A study with 30% sorbitan laurate and studies with up to undiluted sorbitan oleate, 40% sorbitan tristearate, and 30% sorbitan palmitate were negative for ocular irritation in the rabbit.

The sorbitan fatty acid esters were generally not ocular irritants.² In one study, sorbitan isostearate (10%) was nonirritating to the eyes of rabbits, whereas the same concentration of sorbitan sesquiosostearate was minimally irritating. In studies published since the original assessments, undiluted sorbitan stearate, sorbitan sesquicaprylate, sorbitan sesquioleate, and sorbitan trioleate were classified as not irritating to rabbit eyes following a single instillation without rinsing (Table 10).^{20,21,23,24}

Summary

In 1985, the Panel reviewed the safety of the cosmetic use of 7 sorbitan esters, and in 2002, the Panel reviewed the safety of another 10 sorbitan esters; in both instances, the Panel concluded that the sorbitan fatty acid esters were safe as used in cosmetic ingredients. An additional 3 sorbitan esters have been identified and are reviewed in this assessment; all 20 of these esters share an identical sorbitan structural core and only vary by fatty acid substituents. Most of the sorbitan esters are reported to function as a surfactant-emulsifying agent in cosmetic ingredient

The VCRP data obtained from the FDA, and data received in response to surveys of the maximum reported use concentration by category that were conducted by the Council, indicate that 13 of the 20 sorbitan esters included in this safety assessment are used in cosmetic formulations. Sorbitan stearate has the most reported uses, 968, followed by sorbitan isostearate, 401 reported uses; several of the sorbitan esters have a few hundred uses. The sorbitan esters are used at less than 10% in cosmetic formulations; sorbitan triisostearate has the highest reported use concentration, 9.1% in rouges. The frequency of use of these ingredients has increased since the original safety assessments, but the concentration of use has not.

Sorbitan laurate, sorbitan palmitate, sorbitan isostearate, sorbitan stearate, sorbitan sesquioleate, and sorbitan tristearate were relatively nontoxic in mice and rats following a single oral exposure. In single-exposure inhalation studies, the LC₅₀ in rats was ≥5 mg/L for sorbitan laurate and sorbitan trioleate. Administration of a diet containing 5% sorbitan palmitate, 5% sorbitan stearate, or 5% sorbitan tristearate to rats for 2 years did not result in any adverse effects. In oral reproductive toxicity studies in rats, the NOAEL for sorbitan stearate was 1,000 mg/kg bw/d, the highest dose administered.

Sorbitan laurate, sorbitan palmitate, sorbitan stearate, sorbitan sesquicaprylate, sorbitan sesquioleate, and sorbitan trioleate were not mutagenic in the Ames test, with or without metabolic activation. Sorbitan laurate was not genotoxic to peripheral human lymphocytes in a chromosomal aberration assay; the results of a chromosomal aberration assay in Chinese hamster cells with sorbitan stearate were ambiguous.

Table 9. Case Studies of Patients With Diseased Skin.

Test article	Concentration/ dose	Test population	Procedure	Results	Reference
Sorbitan laurate	Not specified, but assumed neat	475 patients with contact allergy	European retrospective survey of allergic contact reactions to cosmetics	2 patients had a positive reaction (0.4%)	30
Sorbitan oleate	Not specified, but assumed neat	475 patients with contact allergy	European retrospective survey of allergic contact reactions to cosmetics	2 patients had a positive reaction (0.4%)	30
Sorbitan oleate	5% (vehicle not specified)	945 patients with contact dermatitis	Occlusive patches using Finn chambers were applied for 48 hours; reactions were evaluated at 48-72 hours and 96-168 hours	6 patients reacted positively (0.6%); 3 reactions were identified as macular erythema, 3 reactions were weak, 1 was strong	33
Sorbitan oleate and sorbitan sesquioleate	Sorbitan oleate: 20% in petrolatum; sorbitan sesquioleate: 5% pet	112 patients with dermatitis	48-hour occlusive application using Finn chambers; test sites were scored at 48 and 72 hours; a modified NACDG standard series, a cosmetic series (which included the sorbitan esters), and a fragrance series were tested	1 subject (0.9%) reacted to sorbitan oleate only; 10 subjects (8.9%) reacted to sorbitan sesquioleate only; 2 subjects (1.8%) reacted to both at 72 hours, all but one reaction to the sesquioleate were +; the other reaction was +++	14
Sorbitan oleate and sorbitan sesquioleate	Sorbitan oleate: 20% in petrolatum; sorbitan sesquioleate: 5% pet	591 patients with contact dermatitis	Sites were scored at 48 and 72 hours; a modified NACDG standard and a cosmetic series were tested, but specific information on the testing protocol was not provided	1 subject (0.17%) reacted to sorbitan oleate only; 19 subjects (3.2%) reacted to sorbitan sesquioleate only; 4 subjects (0.68%) reacted to both at 72 hours, all but 2 reactions were +; 2 subjects had a ++ reaction to sorbitan oleate +,+++ reaction in 2 subjects (2.3%)	31
Sorbitan oleate and sorbitan stearate	5% (each) in petrolatum	86 patients with dermatoses	Patch test; 24-hour occlusive application using Finn chambers	2 patients with positive reactions	32
Sorbitan sesquioleate	20% in petrolatum	86 patients with dermatoses	Patch test; 24-hour occlusive application using Finn chambers	ROAT; 0.1 mL applied 2×/day for 7 days to a 5 cm ² area of the forearm	32
Sorbitan sesquioleate	20% in petrolatum	9 patients with positive reactions	ROAT; 0.1 mL applied 2×/day for 7 days to a 5 cm ² area of the forearm	Equivocal reaction—2 subjects (2.3%); questionable reaction—2 subjects (2.3%); positive (+,+,+++) reaction—5 subjects (5.8%)	32
Sorbitan sesquioleate	20% in petrolatum	4,469 patients with eczematous dermatitis	24-hour occlusive application using Finn chambers; test sites were scored at 72 or 96 hours	?,+ reactors—1 negative and 3 positive reactions; ++,+++ reactors—all positive	34
Sorbitan sesquioleate	20% (vehicle not specified)	870 patients with contact dermatitis	TRUE test; occlusive patches using Finn chambers were applied for 48 hours; reactions were evaluated at 48-72 hours and 96-168 hours	25 patients had an allergic response, + or stronger (0.6%)	33
Sorbitan sesquioleate	20% (vehicle not specified)	870 patients with contact dermatitis	TRUE test; occlusive patches using Finn chambers were applied for 48 hours; reactions were evaluated at 48-72 hours and 96-168 hours	9 patients reacted positively (0.7%); 6 reactions were identified as macular erythema, 2 reactions were weak, 1 was strong	33

Several of the sorbitan esters were considered not irritating to rabbit skin; sorbitan palmitate, sorbitan isostearate, and sorbitan stearate were applied at concentrations of up to 100% using 24-hour occlusive patches, sorbitan sesquioleate was applied for 24 hours using a semioclusive patch, 40% aq. sorbitan tristearate was applied under a 24-hour occlusive patch, and undiluted sorbitan sesquicaprylate and sorbitan trioleate were applied with a 4-hour semioclusive patch. Sorbitan sesquicaprylate was not a sensitizer in a

GPMT; intradermal induction was conducted at a concentration of 5%, and topical induction and challenge were performed at 100%. In a GPMT of sorbitan trioleate, concentration of 2% were used for intradermal induction, 100% for topical induction, 50% and 100% at challenge, and 25% and 50% at rechallenge. Slight to moderate erythema and slight edema were observed in test and control animals; at rechallenge, slight erythema was observed in only 2 test animals.

Table 10. Ocular Irritation Studies.

Test article	Concentration/ dose	Animals	Method	Results	Reference
Alternative studies Sorbitan sesquicaprylate	Neat; 200 μ L	Chicken eggs	In vitro; test substance was applied to the chorioallantoic membrane	Slightly irritating; score of 3.83/21	24
Nonhuman studies Sorbitan stearate	10% in peanut oil; 0.1 mL	6 male NZW rabbits	Single instillation; eyes were not rinsed. <i>Disregarded because only a short abstract was available (limited data; no scores available for assessment, no data on test substance purity)</i>	Not irritating	20,a
Sorbitan stearate	0.1 g	6 female NZW rabbits	Single instillation; eyes were not rinsed. <i>Disregarded because of limited documentation (no data on test substance purity)</i>	Not irritating	20,a
Sorbitan stearate	Neat, 0.1 mL	NZW rabbits, 3 males and 3 females	Single instillation; eyes were not rinsed	Not irritating	20
Sorbitan stearate	neat, 0.1 mL	6 female Vienna white rabbits	Single instillation; eyes were not rinsed	Not irritating	20
Sorbitan stearate	Neat, 0.1 g	NZW rabbits, 5 males and 1 female	Single instillation; eyes were not rinsed	Not irritating	20
Sorbitan stearate	Neat, 0.1 g	NZW rabbits, 4 males and 5 females	Single instillation; eyes were not rinsed for 6/9 animals	Not irritating	20
Sorbitan sesquicaprylate	Neat, 0.1 mL	NZW rabbits, 1 male and 2 females	Single instillation; eyes were not rinsed	Not irritating. All animals had a slight ocular reaction 1 and 24 hours after instillation; no irritation was observed day 7	24
Sorbitan sesquioleate	10% in peanut oil; 0.1 mL	6 male NZW rabbits	Single instillation; eyes were not rinsed. <i>Disregarded because "does not meet important criteria of today standard methods" (only tested at a concentration of 10%)</i>	No signs of irritation	21,a
Sorbitan sesquioleate	30% in distilled water; 0.1 mL	9 male NZW rabbits	Single instillation; eyes were not rinsed for 6/9 animals. <i>Disregarded because "does not meet important criteria of today standard methods" (only tested at a concentration of 30%)</i>	No signs of irritation	21,a
Sorbitan trioleate	30% in distilled water; 0.1 mL	9 male NZW rabbits	Single instillation; eyes were not rinsed for 6/9 animals. <i>Disregarded because "does not meet important criteria of today standard methods" (only tested at a concentration of 30%)</i>	No signs of irritation	23,a
Sorbitan trioleate	Neat, 0.1 mL	2 NZW rabbits	Single instillation; eyes were not rinsed	Not irritating	23

^aStudy disregarded by European Chemicals Agency applicant.

In clinical testing, sorbitan palmitate, sorbitan stearate, sorbitan sesquioleate, and sorbitan trioleate, all tested at 30%, were not irritants or sensitizers when applied for up to 5 days, followed by a challenge application after 7 to 10 days. Sorbitan palmitate, 50%, was also not an irritant after a 72-hour occlusive application. Case studies were performed in patients with diseased skin; reactions were observed in patients with contact allergy and contact dermatitis with sorbitan laurate (0.4% incidence), sorbitan oleate (0.6% incidence with 5%; up to 2.7% incidence with 20%), sorbitan stearate (2.3% incidence with 5%), and sorbitan sesquioleate (up to 9.8% incidence with

20%). Undiluted sorbitan stearate, sorbitan sesquicaprylate, sorbitan sesquioleate, and sorbitan trioleate were classified as not irritating to rabbit eyes following a single instillation without rinsing.

Discussion

In 1985, the Panel determined that 7 sorbitan esters were safe as used in cosmetic ingredients. In 2002, the Panel reviewed the safety of 10 additional sorbitan esters and issued an addendum to the 1985 report, concluding that the sorbitan fatty acid esters

were safe as used in cosmetic ingredients. The Panel reaffirmed the safe as used conclusions of the 1985 and 2002 safety assessments. The Panel also determined that the data from those safety assessments, together with the new data presented on the sorbitan esters, support the safety of 3 additional esters that had not yet been reviewed, and the Panel reopened the safety assessment to add these esters.

Some of the components of the sorbitan esters are botanical ingredients. The Panel expressed concern regarding pesticide residues and heavy metals that may be present in botanical ingredients. They stressed that the cosmetics industry should continue to use the necessary procedures to limit these impurities in the ingredient before blending into cosmetic formulation.

The Panel stated that some of the sorbitan esters are used in products that could be incidentally inhaled, for example, sorbitan isostearate is reported to be used at 2.3% in pump hair sprays. Because single-dose, 4-hour inhalation studies of sorbitan laurate and sorbitan trioleate reported LC₅₀ values > 5 mg/L, and because sorbitan trioleate has been reported to be used as an inactive ingredient in drugs at a maximum concentration of 0.0694% in a nasal aerosol product, the Panel was not concerned with the use of these ingredients in formulations that might be inhaled. The Panel also noted that in aerosol products, 95% to 99% of droplets/particles would not be respirable to any appreciable amount. Furthermore, droplets/particles deposited in the nasopharyngeal or bronchial regions of the respiratory tract present no toxicological concerns based on the chemical and biological properties of these ingredients. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at <http://www.cir-safety.org/cir-findings>.

Conclusion

The Panel concluded that the following 20 sorbitan esters are safe in cosmetics in the present practices of use and concentration described in this safety assessment.

Sorbitan caprylate
 Sorbitan cocoate*
 Sorbitan diisostearate*
 Sorbitan dioleate*
 Sorbitan distearate*
 Sorbitan isostearate
 Sorbitan laurate
 Sorbitan oleate
 Sorbitan olivate
 Sorbitan palmate
 Sorbitan palmitate
 Sorbitan sesquicaprylate*

Sorbitan sesquiosostearate
 Sorbitan sesquioleate
 Sorbitan sesquisteate*
 Sorbitan stearate
 Sorbitan triisostearate
 Sorbitan trioleate
 Sorbitan tristearate
 Sorbitan undecylenate*

*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.

Author's Note

Unpublished sources cited in this report are available from the Executive Director, Cosmetic Ingredient Review, 1620 L Street, NW, Suite 1200, Washington, DC 20036, USA.

Author Contributions

M. Fiume contributed to conception and design, contributed to acquisition, analysis, and interpretation, drafted manuscript, and critically revised manuscript. W. Bergfeld contributed to conception and design, contributed to analysis and interpretation, and critically revised the manuscript. D. Belsito contributed to conception and design, contributed to analysis and interpretation, and critically revised the manuscript. R. Hill contributed to conception and design, contributed to analysis and interpretation, and critically revised the manuscript. C. Klaassen contributed to conception and design, contributed to analysis and interpretation, and critically revised the manuscript. D. Liebler contributed to conception and design, contributed to analysis and interpretation, and critically revised the manuscript. J. Marks contributed to conception and design, contributed to analysis and interpretation, and critically revised the manuscript. R. Shank contributed to conception and design, contributed to analysis and interpretation, and critically revised the manuscript. T. Slaga contributed to conception and design, contributed to analysis and interpretation, and critically revised the manuscript. P. Snyder contributed to conception and design, contributed to analysis and interpretation, and critically revised the manuscript. L. Gill contributed to analysis and interpretation and critically revised the manuscript. B. Heldreth contributed to analysis and interpretation and critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of work ensuring integrity and accuracy.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The articles in this supplement were sponsored by the Cosmetic Ingredient Review. The Cosmetic Ingredient Review is financially supported by the Personal Care Products Council.

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