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Final Report of the Safety Assessment of Lithium Stearate, Aluminum Distearate, Aluminum Stearate, Aluminum Tristearate, Ammonium Stearate, Calcium Stearate, Magnesium Stearate, Potassium Stearate, Sodium Stearate, and Zinc Stearate

The commercial grade of stearic acid used in cosmetics contains fatty acids that range from C_{18} (stearic) and C_{22} (behenic). The concentrations of these ingredients used in cosmetic products vary from $\leq$ 0.1 to $>$ 50%. Acute oral studies with rats indicated that the Stearates are practically nontoxic, and have a low potential for acute dermal toxicity. Skin irritation studies with rabbits demonstrated that Stearates are only minimal to slight irritants at high concentrations. Pharmaceutical vehicles containing 5.5% Magnesium Stearate were neither teratogenic nor mutagenic. In a limited study, Stearate did not increase bladder tumor incidence.

Seven out of 20 subjects exhibited minimal to mild skin erythema when tested with an aqueous solution of 1.5% Ammonium Stearate. Similar results were obtained with Sodium Stearate at 0.5 percent. In a 21-day patch test with 10 subjects, an aqueous formulation containing 0.1–0.25% Sodium Stearate caused minimal skin irritation. No sensitization was reported in 100 subjects tested with the same formulation.

On the basis of the available information presented in this report, and as qualified in the summary, it is concluded that the Stearate compounds described herein are safe as cosmetic ingredients.

CHEMICAL AND PHYSICAL PROPERTIES

The Stearates reviewed in this report are salts of stearic acid. The commercial stearic acid from which these ingredients are manufactured is a mixture of monocarboxylic acids obtained from a number of animal and vegetable fats; it contains fatty acids that range from C_{12} (lauric) to C_{22} (behenic), and the major components are C_{18} (stearic) and C_{16} (palmitic) acids. The composition of the commercial product depends primarily upon the origin of the fat. Table 1 presents the structural formulas for the 10 Stearate ingredients and stearic acid.[1-4]

The Stearates can be divided into metallic and nonmetallic groups. The metallic Stearates may be further divided into water soluble and water insoluble groups; while the former include both Potassium Stearate and Sodium Stearate, the latter include Aluminum Distearate, Aluminum Stearate, Aluminum Tristearate, Calcium Stearate, Lithium Stearate, Magnesium Stearate, and Zinc Stearate. Ammonium Stearate is non-metallic and slightly soluble in water.[1,2]

Chemical and physical properties for the individual Stearate ingredients are discussed below; additional properties are presented in Table 2.

Aluminum Distearate: Aluminum Distearate is a white to off-white fine powder with a bland fatty odor. It is soluble in hot aromatic and aliphatic hydrocarbons, and is insoluble in water, alcohol, and ether.[5,6] As determined by thermogravimetric analysis, its melting point is 120 °C with endothermic and exothermic maxima of 198 °C and 170 °C, respectively.[7] The melting point has also been reported as 145 °C[6] and 135 °–160 °C.[8]

Aluminum Stearate: Aluminum Stearate is a fine white to yellow-white, bulky powder, with a faint characteristic odor. It is insoluble in water, alcohol, and ether.[8,9]

Aluminum Tristearate: Aluminum Tristearate is a white powder soluble in alkali and petroleum, and practically insoluble in water. When freshly made, it is soluble in alcohol, benzene, oil of turpentine, and mineral oils. It forms gels with aliphatic and aromatic hydrocarbons.[6,10,11]

Ammonium Stearate: Ammonium Stearate is a white to yellowish powder free of ammonia odor. The compound gradually loses NH_3 on exposure to air,

TABLE 1. Structure.[a]

Ingredient	*Structural formula*	*Commercial product*[b]
Aluminum Distearate	$Al(OH)[OOC(CH_2)_{16}CH_3]_2$	$Al(OH)(RCOO)_2$
Aluminum Stearate	$Al(OH)_2OOC(CH_2)_{16}CH_3$	$Al(OH)_2(RCOO)$
Aluminum Tristearate	$Al[OOC(CH_2)_{16}CH_3]_3$	$Al(OH)(RCOO)_3$
Ammonium Stearate	$CH_3(CH_2)_{16}COONH_4$	–
Calcium Stearate	$[CH_3(CH_2)_{16}COO]_2Ca$	$(RCOO)_2Ca$
Lithium Stearate	$CH_3(CH_2)_{16}COOLi$	RCOOLi
Magnesium Stearate	$[CH_3(CH_2)_{16}COO]_2Mg$	$(RCOO)_2Mg$
Potassium Stearate	$CH_3(CH_2)_{16}COOK$	RCOOK
Sodium Stearate	$CH_3(CH_2)_{16}COONa$	RCOONa
Zinc Stearate	$Zn[OOC(CH_2)_{16}CH_3]_2$	$(RCOO)_2Zn$
Stearic Acid	$CH_3(CH_2)_{16}COOH$	–

[a]Data from Refs. 1–4.

[b]In the commercial product, R is a mixture of fatty acids containing predominantly stearic (C_{18}) and palmitic (C_{16}) acids, and lesser amounts of other fatty acids.

TABLE 2. Chemical and Physical Properties.

Ingredient	*Properties*	*Reported value*	*Ref.*
Aluminum Distearate $Al(OH)(C_{18}H_{35}O_2)_2$	Molecular weight	610	
	Melting point	120°C	7
		145°C	6
		135°C	8
	Specific gravity	1.009	6,8
	Separated fatty acids		
	Acid value	198.0–202.0	5
	Titer	54.0–58.0°C	5
	Screen test	20.0% max.	5
	Iodine value on separated fatty acids	2.0 max.	4
Aluminum Stearate $Al(OH)_2(C_{18}H_{35}O_2)$	Molecular weight	344	
	Melting point	173°C	8
	Specific gravity	1.010	8
	Iodine value on separated fatty acids	2.0 max.	4
	Fatty acid titer	53.6°C	8
	Iodine value	2.10	8
Aluminum Tristearate $Al(C_{18}H_{35}O_2)_3$	Percentage composition	C = 73.92%, H = 12.06%, O = 10.94%, Al = 3.08%	10
	Molecular weight	877.35	10
	Melting point	103°C	11
		113°C	8
		115°C	6
		117°–120°C	10
	Specific gravity	1.010	8,11
	Fatty acid titer	52.6°C	8
	Iodine value	5.2	8
Ammonium Stearate $CH_3(CH_2)_{16}COONH_4$	Percentage composition	C = 71.70%, H = 13.04%, N = 4.65%, O = 10.61%	4
	Molecular weight	301.5	4
	Melting point	87°C	8
		73°–75°C	6
	Specific gravity	0.89 (22°C)	6
	pH (3% dispersion)	7.6	6
	Neutralization value	70–80	6
Calcium Stearate $Ca(C_{18}H_{35}O_2)_2$	Percentage composition	C = 71.23%, H = 11.62%, Ca = 6.60%, O = 10.54%	10
	Molecular weight	607.00	10,11
	Melting point	129°C	7
		147–149°C	10
		179–180°C	6,11
	Iodine value on separated fatty acids	3.5 max.	4
	Loss on drying	3.5% max.	13
Lithium Stearate $LiC_{18}H_{35}O_2$	Molecular weight	290.41	11
	Melting point	108°C	7
		220°–221°C	6,8,11
	Specific gravity	1.025	16
Magnesium Stearate $Mg(C_{18}H_{35}O_2)_2$	Percentage composition	C = 73.13%, H = 11.93%, Mg = 4.11%, O = 10.82%	10
	Molecular weight	591.27	10,11
	Melting point	86°–88°C	11
		88.5°C (pure)	6

TABLE 2. (Continued.)

Ingredient	*Properties*	*Reported value*	*Ref.*
		115°C	7
		132°C (technical)	6
	Specific gravity	1.028	6
	Iodine value on separated fatty acids	2.0 max.	4
	Loss on drying	5.0 max.	13
Potassium Stearate $C_{17}H_{35}COOK$	Molecular weight	322.58	11
Sodium Stearate $NaOOC_{17}H_{35}$	Molecular weight	306.47	11
	Iodine value of fatty acids	"not more than 4"	9,17
	Acid value of 1 g of fatty acids	196–211	9,17
Zinc Stearate $Zn(C_{18}H_{35}O_2)_2$	Percentage composition	C = 68.38%, H = 11.16%, O = 10.12%, Zn = 10.34%	10
	Molecular weight	632.33	10,11
	Melting point	120°C	10
		126°C	8
		130°C (pure)	6,11
		132°C	7
	Specific gravity	1.095	6,8
	Iodine value on separated fatty acids	2.5 max.	4
	Loss on drying	0.5% max.	4

and it softens at 2–7 °C. At 27 °C, it is soluble in methanol and ethanol; slightly soluble in water, benzene, xylene and naphtha; and practically insoluble in acetone and carbon tetrachloride. It is soluble in water at 100 °C; in acetone at 57 °C; in ethanol at 78 °C; in methanol at 65 °C; in benzene at 80 °C; in carbon tetrachloride at 77 °C; in xylene at 82 °C; and in naphtha at 71 °C.[8,10] The dry material begins to decompose at 50 °C.[12]

Calcium Stearate: Calcium Stearate is a granular fatty powder soluble in hot pyridine; slightly soluble in hot alcohol, hot vegetable and mineral oils; and practically insoluble in water, ether, chloroform, acetone, and cold alcohol. The commercial preparation, which contains some palmitate salt, is a fine, white bulky powder.[10,13-15] Its melting point as determined by thermogravimetric analysis is 129 °C with endothermic and exothermic maxima of 177 °C and 162.5 °C, respectively.[7] The melting point, as determined by gradient bar, is 147 °–149 °C.[10] It has also been reported that Calcium Stearate melts at 179 °–180 °C.[6,11]

Lithium Stearate: Lithium Stearate is a white crystalline material insoluble in cold or hot water, alcohol, and ethyl acetate. It forms gels with mineral oils.[6] The melting point as determined by thermogravimetric analysis is 108 °C with endothermic and exothermic maxima of 184 °C and 202.5 °C, respectively.[7] The melting point of Lithium Stearate has also been reported as 220 °–221 °C.[6,8,11]

Magnesium Stearate: Magnesium Stearate is a fine, unctuous, white powder with a faint, characteristic odor. It is insoluble in water, alcohol, and ether, and decomposes in dilute acids. The commercial product is a combination of variable proportions of Magnesium Stearate and magnesium palmitate. The

melting point as determined by thermogravimetric analysis is 115 °C. One source reports that the melting point of the pure salt is 88.5 °C, and that the melting point of the technical grade (which may contain small amounts of the oleate salt and 7% magnesium oxide) is 132 °C. Magnesium Stearate has also been reported to melt at 86 °–88 °C.[3,6-10,15]

Potassium Stearate: Potassium Stearate is a white crystalline powder which has a slight fatty odor. It is slowly soluble in cold water, and readily soluble in hot water, alcohol, ether, chloroform, and carbon disulfide. While the aqueous solution is strongly alkaline to litmus or phenolphthalein, the alcoholic solution is only slightly alkaline to phenolphthalein. The commercial product contains a "considerable proportion" of palmitic salt.[6,10,11]

Sodium Stearate: Sodium Stearate is a white powder with a slight tallow-like odor and soapy feel. While it is slowly soluble in cold water or cold alcohol, this salt is freely soluble in hot solvents. In many organic solvents, it is insoluble. As a result of hydrolysis, the aqueous solution is strongly alkaline. The alcohol solution is practically neutral.[5,9-11,17]

Zinc Stearate: Zinc Stearate is a fine, white, hydrophobic powder which has a faint, characteristic odor. It is soluble in benzene, acids, and common solvents and insoluble in water, alcohol, and ether. Zinc Stearate is decomposed by dilute acids and is neutral to moist litmus paper. One hundred percent of the material will pass through a 325 sieve.[6,8-11,13] The melting point as determined by thermogravimetric analysis is 132 °C with an exothermic maximum of 197 °C.[7] The melting point of this Stearate has also been reported as 126 °C[8] and as 130 °C.[6,11]

Reactivity

No information was reported on the chemical reactivity of these ingredients. The low iodine number of stearates indicates a small amount of unsaturated fatty acids; therefore these ingredients would not be expected to undergo significant autoxidation.[13]

Analytical Methods

Analytical methods for the determination of several Stearate compounds and stearic acid are presented below. No information was reported for Aluminum Distearate, Aluminum Tristearate, Ammonium Stearate, or Potassium Stearate.

Stearic Acid: Stearic acid can be separated from these salts by acidification and solvent extraction, and then analyzed by gas chromatography with a flame-ionization detector.[9]

Aluminum Stearate: The United States Pharmacopeia XIX method for identifying Aluminum Stearate requires acid hydrolysis to separate the fatty acids. The quantitative tests for aluminum acetate solutions require acidification and addition of ethylenediamine–tetraacetate, followed by titration with zinc sulfate.[9].

Calcium Stearate: The method for identifying Calcium Stearate reported by *The National Formulary XIV*[14] and *The Food Chemicals Codex II*[15] is the same as that for identifying Aluminum Stearate (discussed above), except insofar as the specific qualitative and quantitative tests for calcium are concerned.

An IR spectrophotometric method was described for the quantitative determination of $\geq 0.5\%$ by weight Calcium Stearate in butyl rubber. The procedure has a relative error of 10%.[18]

A method using flame photometry has been described to determine Calcium Stearate in structural plastics.[19]

Lithium Stearate: Norwitz and Gordon[20,21] described a method for determining Lithium Stearate in sebacate-base semifluid lubricants. The sample is treated with dilute hydrochloric acid and extracted with ethyl ether to remove diisopropyl phosphite. The aqueous extract is then evaporated with perchloric acid, and the lithium determined by atomic absorption.

Magnesium Stearate: The *U.S. Pharmacopeia XIX*[9] and *The Food Chemicals Codex II*[15] report the same tests for Magnesium Stearate as those described above for Aluminum Stearate, except insofar as the specific qualitative and quantitative tests for magnesium are concerned. It is possible to quantify magnesium in an ammonia–ammonium chloride buffer by titrating with disodium ethylenediamine-tetraacetate.

Sodium Stearate: The National Formulary XIII[17] and the *U.S. Pharmacopeia XIX*[9] report a test for qualitatively identifying the stearate portion by means of acid hydrolysis, and a determination of the melting point of the liberated fatty acids. No quantitative tests were found for Sodium Stearate.

Zinc Stearate: The qualitative analytical tests for Zinc Stearate included in the *U.S. Pharmacopeia XIX*[9] are the same as those given for Aluminum Stearate. The zinc content of a fatty acid salt can be quantitatively measured by hydrolysis with 0.1 N sulfuric acid; the fatty acid then is removed by solvent extraction, and the excess sulfuric acid titrated with 0.1 N sodium hydroxide.

A method was reported for determining fatty acids of Zinc Stearate, that involved extraction with acetone, evaporation of the acetone, addition of ethyl alcohol, and titration with 0.05 N KOH. Water-soluble salts were determined as NaCl by extraction with boiling H_2O, passage of the material through a cation-exchange column, and titration with NaOH in the presence of Tashiro's reagent. The moisture content was determined by weighing the material followed by drying at 80 °C to constant weight. The amount of Zinc Stearate was calculated by the difference.[22]

Method of Manufacture and Impurities

The water-soluble metallic stearates are usually manufactured by reacting a selected grade of commercial stearic acid with a strong caustic (either potassium or sodium hydroxide) in an aqueous system, and producing the respective potassium and sodium soap in solution. The solvent is then evaporated off and the solid product milled to a suitable particle size.[1,2]

The insoluble metallic stearates are produced by reacting a selected grade of stearic acid with a caustic (usually sodium hydroxide) in an aqueous system. This produces a solution containing the soluble sodium salt of stearic acid. The insoluble metallic stearate precipitates out when a solution containing the desired metal is added to the sodium stearate solution. The insoluble stearate is then washed free of the water-soluble impurities, dried, milled, and packaged. The packaged compounds are fine, white, fluffy powders with slight fatty odors; the size of particles generally ranges between 0.25 and 10 microns.[1,2]

The method of manufacture and the known impurities for each of the *individual* stearate ingredients are presented below. The manufacturing processes just described and those that follow are not the only ones in use; rather, these are given here as representative examples of major production methods.[1]

Aluminum Distearate: Aluminum Distearate is produced by the reaction of water-soluble aluminum salt and sodium stearate in aqueous media. The precipitate is then filtered, washed, and dried.[4]

The following impurities have been reported:[4,5]

Assay (as Al_2O_3)	8.0–12.0%
Free Fatty Acids (predominantly a mixture of C_{18} and C_{16} fatty acids with minor amounts of other fatty acids)	8.0% max.
Moisture	3.5% max.
Heavy Metals (calculated as Pb)	50 ppm max.
Total Ash	11.5–13.5%
Washed Ash	8.0–10.0%
Soluble Ash (water-soluble salts)	3.5% max.

Aluminum Stearate: Aluminum Stearate is produced by the reaction of sodium stearate and water-soluble aluminum salt in aqueous media. The precipitate is then filtered and dried.[4]

The following impurities have been reported:[4,8]

Assay (as Al_2O_3)	13–17%
Free Fatty Acids (predominantly a mixture of C_{18} and C_{16} fatty acids with minor amounts of other fatty acids)	6.0 percent max.
Moisture	3.5%
Heavy Metals (calculated as Pb)	50 ppm max.
Total Ash	12.6%
Water-soluble Salts	0.5%

Aluminum Tristearate: Aluminum Tristearate is produced by the reaction of water-soluble aluminum salt and sodium stearate in aqueous media. The precipitate is then filtered, washed and dried.[4]

The following impurities have been reported:[4,8]

Assay (as Al_2O_3)	4–8.0 percent max.
Free Fatty Acids (predominantly a mixture of C_{18} and C_{16} fatty acids with minor amounts of other fatty acids)	35 percent max.
Moisture	3.5 percent max.
Heavy Metals (calculated as Pb)	10 ppm max.
Total Ash	5.7 percent
Water-soluble Salts	0.1 percent

Ammonium Stearate: To prepare Ammonium Stearate, stearic acid can be treated with excess 28–30% NH_3 solution. Ammonium Stearate can also be prepared by reacting stearic acid with ammonium carbonate.[1,2,10]

Calcium Stearate: Calcium Stearate is produced by the reaction of water-soluble calcium salt and sodium stearate. The precipitate is then filtered, washed, and dried.[4]

$$CaX_2 + 2(C_{17}H_{35}COONa) \xrightarrow{H_2O} Ca(C_{17}H_{35}COO)_2\downarrow + 2NaX$$

(assuming X is monovalent).

The following impurities have been reported:[4,9]

Assay (as CaO)	7–11%
Free Fatty Acids (predominantly a mixture of C_{18} and C_{16} fatty acids with minor amounts of other fatty acids)	3.5% max.

Composition of Free Fatty Acids:

C_{12}	0.5% max.
C_{14}	10.5% max.
C_{15}	1.5% max.
C_{16}	22.0–35.0%
C_{18}	56.0–71.0%
$C_{18:1}$	2.5% max.
$C_{16} + C_{17} + C_{18}$	90.0% max.
C_{20}	1.0% max.
Moisture	4.0% max.
Arsenic (as As)	3 ppm max.
Lead (as Pb)	10 ppm max.

Lithium Stearate: Lithium Stearate is the reaction product of lithium hydroxide and stearic acid in aqueous media.[4]

$$LiOH + C_{17}H_{35}COOH \xrightarrow{H_2O} (C_{17}H_{35}COO)Li + H_2O$$

The following impurities have been reported:[4]

Free Fatty Acids (predominantly a mixture of C_{18} and C_{16} fatty acids with minor amounts of other fatty acids)	3.5% max.
Moisture	2.0% max.

Magnesium Stearate: Magnesium Stearate is produced by the reaction of water-soluble magnesium salt and sodium stearate. The precipitate is then filtered, washed, and dried.[4]

$$MgX_2 + 2(C_{17}H_{35}COONa) \xrightarrow{H_2O} Mg(C_{17}H_{35}COO)_2\downarrow + 2NaX$$

(assuming X is monovalent).

The following impurities have been reported:[4,13]

Assay (as MgO)	6.4–8.0%
Free Fatty Acids (predominantly a mixture	3.5%

of C_{18} and C_{16} fatty acids with minor amounts of other fatty acids)

Composition of Free Fatty Acids:

C_{12}	0.4%
$C_{14} + C_{15}$	6.2% max.
C_{16}	24.0–34.0%
C_{18}	58.0–71.0%
$C_{16} + C_{17} + C_{18}$	90.0% max.
C_{20}	4.0% max.
Moisture	5.0% max.
Arsenic (as As)	3 ppm max.
Lead (as Pb)	10 ppm max.

Potassium Stearate: Potassium Stearate is produced by the reaction of potassium hydroxide and stearic acid in aqueous media.[4]

$$KOH + C_{17}H_{35}COOH \xrightarrow{H_2O} C_{17}H_{35}COOK + H_2O$$

The following impurities have been reported:[4]

Free Fatty Acids (predominantly a mixture of C_{18} and C_{16} fatty acids with minor amounts of other fatty acids)	1.0% max.
Moisture	3.0% max.

Other sources report that the commercial product contains a considerable portion of palmitate salt.[6,10]

Sodium Stearate: Sodium Stearate is the reaction product of sodium hydroxide and stearic acid:[4]

$$NaOH + C_{17}H_{35}COOH \xrightarrow{H_2O} C_{17}H_{35}COONa + H_2O$$

The following impurities have been reported:[4]

Free Fatty Acids (predominantly a mixture of C_{18} and C_{16} fatty acids with minor amounts of other fatty acids)	1.3%
Moisture	3.0%

Zinc Stearate: Zinc Stearate is produced by the reaction of water-soluble zinc salt and sodium stearate. The precipitate is then filtered, washed, and dried.[4]

$$ZnX_2 + 2(C_{17}H_{35}COONa) \xrightarrow{H_2O} Zn(C_{17}H_{35}COO)_2\downarrow + 2NaX$$

(assuming X is monovalent).

The following impurities have been reported:[4,8,13]

Assay (as ZnO)	13.0–15.0%
Free Fatty Acids (predominantly a mixture of C_{18} and C_{16} fatty acids with minor amounts of other fatty acids)	0.2–2.0%

Composition of Free Fatty Acids:

C_n ($n \leq 12$)	0.2%
$C_{14} + C_{15}$	6.0% max.
C_{16}	26.0–32.0%
C_{18}	60.0–72.0%
$C_{16} + C_{17} + C_{18}$	91.0% min.
C_{20}	2.0% max.
Moisture	1.5% max.
Arsenic (as As)	3 ppm max.
Cadmium (as Cd)	15 ppm max.
Lead (as Pb)	10 ppm max.
Total Ash	15%
Water-Soluble Salts	0.2%

USE

Purpose in Cosmetics

Although the Stearates perform a number of functions in cosmetic formulations, they are principally used for their lubricating properties. The water-insoluble metallic stearates are widely employed because they are water repellent and adhesive in nature and have good "covering" properties.[1,2] The uses for each of the individual ingredients are discussed below.

Aluminum Distearate: Aluminum Distearate is used in toilet preparations as an emulsifier of water-in-oil and as an agent to increase the viscosity of oils. This compound forms a "medium" gel in oils.[8]

Aluminum Stearate: Aluminum Stearate is used for increasing the viscosity of oils, and for its ability to act as an emulsifier of water-in-oil; it forms a thick gel in oils.[8] In hair grooming products, 7–10% (by weight) Aluminum Stearate has been employed to impart a gel structure to heavy mineral oil. In hair straighteners, the compound functions as a water repellent.[23]

Aluminum Tristearate: Aluminum Tristearate is used in cosmetics for its ability to act as an emulsifier of water-in-oil solutions and for its capacity to increase the viscosity of oils. It forms a thin gel in oils.[8]

Ammonium Stearate: Ammonium Stearate is used as an alcoholic emulsifier in hand creams.[23]

Calcium Stearate: Calcium Stearate is used as an opacifying agent in shampoos and as a water-in-oil emulsifier in hair grooming products.[23]

Lithium Stearate: Lithium Stearate is used as a lubricant in baby powders. It imparts a high degree of water repellency and oil absorbency to the powder, and provides a long lasting film which reportedly prevents chafing and reduces the

possibility of irritation caused by wet diapers.[23] This compound is also used as an emulsifying agent.[6,8]

Magnesium Stearate: Magnesium Stearate is widely used because of its adhesive and waterproofing properties. In powders, it imparts a velvety smoothness to the skin and acts as a dry lubricant which prevents chafing and absorbs moisture. In face powders, it serves as a dry binder. In dentrifices, it functions as a stabilizer to prevent caking, crystal formation, grittiness, and "setting up" of toothpaste and powders. It is used as an opacifying agent in shampoos.[23]

Potassium Stearate: Potassium Stearate serves as an emulsifier in hand creams, and a Potassium Stearate-stearic acid combination serves as a vanishing base for deodorant creams.[23]

Sodium Stearate: Sodium Stearate is used in solid fragrances as a solidifying agent, in hand creams as an anionic emulsifier, and in shampoos as a soluble soap that provides both thickness and opacity.[23]

Zinc Stearate: Zinc Stearate is widely used for its adhesive and water repellent properties, as well as for its "smoothing" qualities. It has been used in baby toiletries and bath powders as a dry lubricant to absorb moisture and prevent chafing. While it acts as a lubricant and improves adhesion in pre-shave preparations, Zinc Stearate serves as an opacifying agent in cleansing creams and shampoos. In hair grooming products, it is used as a water-in-oil emulsifier. In deodorant creams, it functions as an absorbent; and in deodorant powders, it acts as a mild astringent and antiseptic. In face powders, this compound serves as a dry binding agent. When used in "excess", Stearates may create a blotchy effect; but, in "moderate" amounts (4–15%), they (in particular Zinc Stearate) contribute to the adherent qualities of face powder.[8,23]

Scope and Extent of Use in Cosmetics

Table 3 presents FDA product formulation data for each of the Stearate ingredients.[24] Limited product data reported by sources other than FDA are presented in Table 4.[2,6,10,23] Voluntary filing of product-formulation data with the FDA by cosmetic manufacturers and formulators conforms to the prescribed format of present concentration ranges and product categories as described in Title 21 Part 720.4 of the Code of Federal Regulations (21 CFR 720.4). Since certain cosmetic ingredients are supplied by the manufacturer at less than 100% concentration, the concentration reported by the cosmetic formulator may not necessarily reflect the true, effective concentration found in the finished product; the effective concentration in such a case would be a fraction of that reported to the FDA. The fact that data are only submitted within the framework of preset concentration ranges also provides the opportunity for overestimation of the actual concentration of an ingredient in a particular product. An entry at the lowest end of a concentration range is considered the same as one entered at the highest end of that range, thus introducing the possibility of a two- to ten-fold error in the assumed ingredient concentration.

Since there were no petitions requesting their use in 1976, Aluminum, Lithium, Magnesium and Zinc Stearates were deleted from the list of color additives permitted in cosmetics under the Federal Food, Drug and Cosmetic Act.[25]

The Stearates are applied to or come in contact with skin surfaces, eyes, mucous membranes, and respiratory epithelia (see Tables 3 and 4). Small amounts could be ingested in dentrifices and lipsticks.

TABLE 3. Product Formulation Data.[a]

Ingredient/ Cosmetic product type	Concentration (%)	No. of product formulations
Aluminum Distearate		
Eyeliner	>1–5	23
Mascara	>1–5	18
Hair bleaches	>1–5	2
Foundations	>0.1–1	3
Lipstick	>1–5	17
Makeup bases	>0.1–1	1
Cleansing (cold creams, cleansing lotions, liquids, and pads)	>0.1–1	2
Moisturizing	>0.1–1	1
	Total	67
Aluminum Stearate		
Bath oils, tablets, and salts	>1–5	1
Eyeliner	>1–5	14
Eyeshadow	>1–5	2
Eye makeup remover	>1–5	2
Mascara	>1–5	65
	>0.1–1	5
Other eye makeup preparations	>5–10	1
	>1–5	1
Tonics, dressings, and other hair grooming aids	>1–5	2
	>0.1–1	2
Hair bleaches	>1–5	1
Blushers (all types)	>1–5	1
	≤0.1	9
Lipstick	>1–5	1
	≤0.1	11
Makeup bases	>1–5	1
	≤0.1	19
Other personal cleanliness products	>0.1–1	1
	Total	139
Lithium Stearate		
Lipstick	>0.1–1	1
Makeup bases	≤0.1	20
Rouges	≤0.1	2
Makeup fixatives	≤0.1	1
Moisturizing	>0.1–1	2
Other skin care preparations	>0.1–1	1
	Total	98
Magnesium Stearate		
Lotions, oils, powders, and creams	>10–25	1
	>1–5	2
Other bath preparations	>1–5	1
Eyeliner	>5–10	2
Eyeshadow	>10–25	1
	>5–10	30
	>1–5	25
	>0.1–1	1
Mascara	>0.1–1	1
Other fragrance preparations	>0.1–1	4
Shampoos	>0.1–1	2
Blushers	>5–10	1
	>1–5	8

TABLE 3. (Continued.)

Ingredient/ Cosmetic product type	*Concentration (%)*	*No. of product formulations*
Face powders	>5–10	3
	>1–5	59
Foundations	>1–5	1
Makeup bases	>1–5	9
Rouges	>1–5	1
Feminine hygiene deodorants	>0.1–1	1
Other personal cleanliness products	≤0.1	4
Preshave lotions (all types)	>1–5	1
Cleansing (cold creams, cleansing lotions, liquids, and pads)	>1–5	1
Face, body, and hand (excluding shaving preparations)	>1–5	1
	>0.1–1	3
Other skin care preparations	>1–5	1
	>0.1–1	3
	Total	167
Potassium Stearate		
Face, body, and hand (excluding shaving preparations)	>10–25	1
	>0.1–1	1
Moisturizing	>1–5	1
	Total	3
Sodium Stearate		
Colognes and toilet waters	>10–25	1
	>5–10	9
	>1–5	1
Sachets	>5–10	1
Other fragrance preparations	>5–10	12
	>1–5	5
Hair conditioners	>1–5	1
Shampoos (noncoloring)	>10–25	1
	>5–10	6
	>1–5	1
	>0.1–1	1
Shampoos (coloring)	>1–5	1
Hair lighteners with color	>1–5	1
Hair bleaches	>10–25	3
	>1–5	1
Blushers (all types)	>5–10	7
	>1–5	1
Makeup bases	>10–25	2
Other makeup preparations	>5–10	1
Dentifrices (aerosol, liquid, pastes, and powders)	>0.1–1	1
Bath soaps and detergents	>1–5	5
Deodorants (underarm)	>5–10	35
	>1–5	3
Other personal cleanliness products	>5–10	4
Cleansing (cold creams, cleansing lotions, liquids, and pads)	>0.1–1	2
	≤0.1	1
Face, body, and hand (excluding shaving preparations)	>0.1–1	3

TABLE 3. (Continued.)

Ingredient/ Cosmetic product type	*Concentration (%)*	*No. of product formulations*
Moisturizing	>5–10	1
	>1–5	1
	>0.1–1	3
	≤0.1	1
Night cream	>0.1–1	1
Other skin care preparations	>0.1–1	1
Other suntan preparations	>5–10	1
	Total	119
Zinc Stearate		
Lotions, oils, powders and creams	>50	1
	>1–5	1
Bubble baths	>1–5	2
Eyebrow pencil	>10–25	1
	>5–10	11
	>1–5	7
Eyeliner	>10–25	6
	>5–10	8
	>1–5	21
	>0.1–1	1
	Total	59
Aluminum Tristearate		
Eye lotion	>5–10	1
	>0.1–1	6
Makeup bases	>1–5	1
	Total	8
Ammonium Stearate		
Hair straighteners	>5–10	2
Hair bleaches	>10–25	1
	Total	3
Calcium Stearate		
Eyebrow pencil	>25–50	12
Mascara	>1–5	1
	>0.1–1	2
Hair conditioners	>5–10	1
	>1–5	1
Other hair preparations	>0.1–1	1
Hair bleaches	>1–5	1
Face powders	>10–25	1
Other makeup preparations	>25–50	1
	>10–25	1
Cleansing (cold creams, cleansing lotions, liquids, and pads)	≤0.1	1
	Total	23
Lithium Stearate		
Eyeshadow	>1–5	9
	>0.1–1	2
	≤0.1	2
Powders (dusting and talcum) (excluding aftershave talc)	>1–5	6
	>0.1–1	22
Blushers (all types)	≤0.1	1
Face powders	>1–5	2
Foundations	>0.1–1	3
	≤0.1	24
Eyeshadow	>10–25	9
	>5–10	492

TABLE 3. (Continued.)

Ingredient/ Cosmetic product type	*Concentration (%)*	*No. of product formulations*
	>1–5	197
	>0.1–1	8
	≤0.1	1
Eye makeup remover	>1–5	1
Mascara	>1–5	12
	>0.1–1	1
Other eye makeup preparations	>10–25	5
	>5–10	10
	>1–5	4
	>0.1–1	2
Perfumes	>1–5	1
Powders (dusting and talcum)	>5–10	12
	>1–5	109
	>0.1–1	53
	≤0.1	4
Shampoos (noncoloring)	>1–5	1
	>0.1–1	2
Blushers (all types)	>10–25	1
	>5–10	46
	>1–5	45
	>0.1–1	15
Face powders	>10–25	3
	>5–10	99
	>1–5	123
Foundations	>5–10	3
	>1–5	16
	>0.1–1	1
Lipstick	>1–5	2
Makeup bases	>1–5	10
	≤0.1	1
Rouges	>10–25	5
	>5–10	1
	>1–5	8
	>0.1–1	2
	≤0.1	7
Other makeup preparations	>0.1–1	1
Deodorants (underarm)	>10–25	1
Feminine hygiene deodorants	>0.1–1	1
Other personal cleanliness products	>5–10	1
	>1–5	2
Men's talcum	>5–10	1
	>1–5	4
Preshave lotions (all types)	>1–5	1
Cleansing (cold creams, cleansing lotions, liquids, and pads)	>5–10	1
	>0.1–1	1
Face, body, and hand (excluding shaving preparations)	>10–25	1
	>5–10	2
	>1–5	3
Foot powders and sprays	>1–5	2
Moisturizing	>1–5	2
	≤0.1	1
Night cream	>10–25	1
	Total	1,397

[a]Data from Ref. 24.

TABLE 4. Product Data.[a]

Ingredient/ Cosmetic product type	*Concentration (%)*
Aluminum Stearate	
Hair straighteners	5–25
Hair bleaches	5–25
Vanishing creams	5–25
Ammonium Stearate	
Eyeliners	0.1–10
Mascaras	0.1–10
Lipsticks	0.1–10
Blushers	0.1–10
Makeup bases	0.1–10
Shaving creams	–
Vanishing creams	–
Calcium Stearate	
Eyebrow pencils	1–50
Mascaras	1–50
Other makeup preparations	1–50
Lithium Stearate	
Eyeshadows	0.1–5
Blushers	0.1–5
Foundations	0.1–5
Makeup bases	0.1–5
Dusting powders	–
Magnesium Stearate	
Eyeshadows	0.1–5
Dusting and talcum powders	0.1–5
Blushers	0.1–5
Makeup bases	0.1–5
Baby dusting powders	–
Cleansing creams	–
Foundations	–
Potassium Stearate	
Shaving preparations	–
Bath soaps	–
Sodium Stearate	
Shampoos	1.0–25
Underarm stick deodorants	1.0–10
Antiperspirants	1.0–10
Foundations	–
Bath soaps	–
Zinc Stearate	
Eyeliner	0.1–5
Eyeshadows	0.1–5
Eyebrow pencils	0.1–5
Dusting and talcum powders	0.1–5
Blushers	0.1–5
Mascaras	0.1–5
Face powders	0.1–5
Foundations	0.1–5

[a]Data from Refs. 2, 6, 10, and 23.

Product formulations containing one or more of these ingredients may be used from once a week up to several times a day. Many of the products may remain in contact with body surfaces for as briefly as a few minutes to as long as a few days (see Tables 3 and 4). Each product could potentially be applied hundreds of times over the course of several years.

Noncosmetic Uses

Aluminum Distearate: Aluminum Distearate is used as a thickener in paints, inks, and greases, and as a lubricant in plastics and ropes. It is also used in waterproofing fabrics and in producing cement.[6,8]

Aluminum Stearate: Aluminum Stearate is used in paint and varnish driers, and as a waterproofing agent in fabrics and ropes.[8] It is also a direct food additive for which regulations have been issued under the Food, Drug and Cosmetic Act (21 CFR 173.340, 172.863). In this last capacity, Aluminum Stearate functions as a binding, emulsifying, and anticaking agent. In the processing of beet sugar and yeast, it acts as a defoaming agent. No limits are established for the use of this ingredient as a food additive.[26]

Aluminum Tristearate: Aluminum Tristearate is used as a thickener in lubricating oils; as a cement additive, a lubricant, and a "flatting" agent; as a waterproofing agent for fabrics and ropes; and as an additive for chewing gums. It is also used in paint and varnish driers, greases, pharmaceuticals, and in light-sensitive photographic compositions.[6,8,10]

Ammonium Stearate: Ammonium Stearate is used as a waterproofing agent for concrete, cement, stucco, paper, and textiles.[6,8,10]

Calcium Stearate: Calcium Stearate is used for waterproofing fabrics, cements, stucco, and explosives. It is used as a releasing agent for plastic molding powders; a stabilizer for polyvinyl chloride resins; a tablet lubricant in pharmaceuticals; and as a flatting agent in paints. It is also used in pencils and wax crayons.[6,8,10,14]

Calcium Stearate is a direct food additive, for which regulations have been issued under the Food, Drug and Cosmetic Act (21 CFR 169.179, 173.340, 172.863, 573.280). In the processing of beet sugar and yeast, it functions as an antifoaming agent and may be used in accordance with good manufacturing practices. When used as an anticaking agent in vanilla powder, it is restricted to quantities of $\leq 2\%$ by weight. As long as good manufacturing processes are maintained, Calcium Stearate can be employed as an anticaking agent in animal feeds. This compound is also used as a food binder and emulsifer.[15,26]

Calcium Stearate's safety as a food ingredient has recently been reviewed. Concentrations in food range from 0.02% to 1.03%, with average daily intake possibly reaching as much as 38 mg for infants and up to 1500 mg for persons over two years. These are considered "generous estimates"; however, a more realistic estimate of daily intake may be close to 4 mg for people 2–65 years old.[27]

Lithium Stearate: Lithium Stearate is used as a high-temperature lubricant; a plasticizer, an emulsifier, a corrosion inhibitor in petroleum, a flatting agent in varnishes and lacquers, and a lubricant in powder metallurgy. It is also used in waxes and greases.[6,8]

Magnesium Stearate: Magnesium Stearate is used as a flatting agent, a drier in paints and varnishes, a lubricant in pharmaceutical tablets, and a stabilizer and lubricant for plastics.[6,8-10]

Magnesium Stearate is also a GRAS (Generally Recognized As Safe) substance and a direct food additive, for which regulations have been issued under the Food, Drug and Cosmetic Act (21 CFR 172.863, 173.340). It is used in foods as an anticaking agent, binder, emulsifier, stabilizer, and defoaming agent.[6,15,26]

Magnesium Stearate's safety as a food ingredient has recently been reviewed. Its use in food ranges from 0.01% to 1%, and the possible average daily intake

ranges from as much as 1 mg/kg for infants up to 41 mg/kg for persons over two years. These estimates are considered to be of maximum possible intakes; more realistically, a person is likely to take in close to 2.4 mg of Magnesium Stearate as a food additive.[28]

Potassium Stearate: Commonly known as a soap, Potassium Stearate is used in a wide range of household and industrial cleaning products.[1] It is also a direct food additive for which regulations have been issued under the Food, Drug and Cosmetic Act (21 CFR 172.863, 173.340, 172.615, 172.863). In this last capacity, Potassium Stearate functions as a binding, emulsifying, anticaking, or defoaming agent and must be used in accordance with good manufacturing practices.[26] The compound is also used as a water corrective[6] and as a component of chewing gum[26] and of textile softeners.[6,10]

Sodium Stearate: Sodium Stearate is used as a waterproofing and gelling agent, as a stabilizer in plastics, and as an emulsifying and stiffening agent in pharmaceuticals. It is used in the preparation of alcohol pencils for impetigenous dermatoses, in glycerol suppositories, and in toothpastes.[6,8,10] Classified as a soap, Sodium Stearate is used in a variety of household and industrial cleaning products.[1]

Sodium Stearate is also a direct food additive, for which regulations have been issued under the Food, Drug and Cosmetic Act (21 CFR 172.615, 172.863). As a food additive, it functions as a binder, emulsifier or anticaking agent and must be used in accordance with good manufacturing practices.[26]

Zinc Stearate: Zinc Stearate is used as a dry lubricant and dusting agent for rubber; a flatting and sanding agent in lacquers; a waterproofing agent for concrete, rock wool, paper and textiles; a plastic mold releasing agent; a heat and light stabilizer; an antifoamer; and a filler. It is used in powder metallurgy and in pharmaceutical tablets, ointments, and powders. This Stearate is a mild antiseptic and astringent, and it has been used as a local soothing application for inflammatory and irritating skin diseases. Zinc Stearate is also a GRAS food nutrient and/or supplement and is required by law to be free of chick edema factor.[6,8-10,26]

In addition to the *direct* food additive and GRAS status of a number of the ingredients just discussed, suitable grades of fatty acids and their aluminum, ammonium, calcium, magnesium, potassium, sodium, and zinc salts have various approvals for specific *indirect* food additive uses as well.[1]

BIOLOGICAL PROPERTIES

General Effects

Aluminum Stearates: Aluminum Distearate, Stearate, and Tristearate have astringent properties.[8]

Sodium Stearate: Sodium Stearate was added to Novikoff hepatoma cells in culture at concentrations of 0, 25, 50, 75, and 100 μg/ml of growth medium. At concentrations of 50 μg/ml and above, the compound caused a reduction in the rate of cell growth as well as a delay in the time taken to reach maximum cell numbers. The authors suggested that Sodium Stearate exerts its effect on the growth rate of heptoma cells either by acting as a detergent and causing lysis, or by coating the cell surface and thereby reducing the uptake of such essential nutrients as glucose.[29]

Cultures of rat heart muscle and endothelioid cells were treated for 30 minutes with Sodium Stearate in a free fatty acid/albumin ration of 6:1 at concentrations of 5×10^{-6}–$5 \times 10^{-4}M$. Sodium Stearate labilized rat heart muscle at $5 \times 10^{-6}M$. Both endothelioid and rat heart muscle cell mitochondria were significantly labilized by Sodium Stearate at $5 \times 10^{-5}M$.[30]

Sodium Stearate induced a significant increase in fibrinogen biosynthesis in vitro when introduced into the plasma sample of a "young normal subject" at a level of 0.118 microequiv./ml.[31]

Zinc Stearate: Zinc Stearate is reported to be a mild astringent and an antiseptic.[8,23]

Absorption, Metabolism, and Excretion

Calcium Stearate: The influence of bile and bile acid on the absorption of insoluble calcium salts in isolated dog intestine was studied. It was reported that Calcium Stearate "Seems to be slightly absorbed by the supplementation of some bile".[32]

Sodium Stearate: The rate of penetration of 0.5% Sodium Stearate in aqueous solution through human skin was determined to be 0.1 mg/100 ml/min.[33]

The distribution, metabolism, excretion, and storage of radiolabeled ^{14}C-Sodium Stearate were investigated as follows: three rats were injected subcutaneously and three intraperitoneally with 0.1 or 0.5 ml aqueous samples containing 0.18 mg ^{14}C-Sodium Stearate. Negligible amounts (0.1% of the 0.18 mg doses) of the ^{14}C appeared in the urine or feces. Expired CO_2 contained 38 ± 9%, and the carcass retained 56 ± 16% of the applied dose.[34]

Radiolabeled ^{14}C-Sodium Stearate was administered by stomach tube to rats at a dose of 10 μci 100 g of body weight. The animals were sacrificed thereafter at intervals of 1, 2, 4, or 24 hours and their livers were removed. Two phospholipids (phosphatidyl choline and phosphatidyl ethanolamine) of the isolated liver mitochondria had incorporated ^{14}C of the Sodium Stearate.[35]

The results of the studies on percutaneous absorption of radiolabeled ^{14}C-Sodium Stearate through isolated rat skin and human epidermis and in live rats are listed below.

In-Vitro Absorption–Rat Skin: A 0.25 ml sample containing 1.8 mg ^{14}C-labeled Sodium Stearate/ml of aqueous solution was applied over 4.9 cm^2 of excised rat skin. Twenty-four hours after application, the skin surface was rinsed with distilled water and monitored for ^{14}C. Over 24 hours, <0.1 μg/cm^2 had penetrated the skin.[34]

In-Vitro Absorption–Human Epidermis: A 0.1 ml sample containing 1.8 mg of ^{14}C-labeled Sodium Stearate/ml of aqueous solution was applied over 0.78 cm^2 of skin excised from the human abdomen. Twenty-four hours later, the skin was rinsed with distilled water and the epidermal sample monitored for ^{14}C. In 24 hours, 0.1 ± 0.1 μg/cm^2 had penetrated the epidermis.[34]

In-Vivo Absorption–Rat Skin: A 0.1 ml aqueous sample containing 184 μg of ^{14}C-labeled Sodium Stearate was applied over 7.5 cm^2 of clipped rat skin for 15 minutes. After six hours, the treated skin was excised and monitored for ^{14}C. Autoradiographs showed "heavy deposition" (2–5 μg/cm^2) of ^{14}C on the stratum corneum, at the entrances of hair follicles, and in the hair follicles. Traces were also seen in the epidermis, but not in the dermis. The amount of ^{14}C recovered in the expired CO_2, urine, feces, and carcass was 0.53 ± 0.14 μg.[34]

Animal Toxicology

General Studies

Oral toxicity: acute

Aluminum, Ammonium, Lithium, Magnesium, Sodium and Zinc Stearates taken orally were practically nontoxic to rats (see Table 5).[36-46]

Dermal toxicity: acute

Studies with guinea pigs demonstrated that 100% Aluminum and Ammonium Stearates have a low potential for acute dermal toxicity. Studies conducted in rabbits showed that product formulations containing Sodium and Zinc Stearates also have a low potential for dermal toxicity (see Table 6).[38,43-45,47,48]

Dermal corrosion: acute

Magnesium and Zinc Stearates were noncorrosive to the skin of rabbits according to 49 CFR 173.240 (a)(1) (see Table 7).[40,49,50]

Skin irritation: acute

In rabbit studies, 10% Aluminum Distearate in corn oil and 100% Ammonium Stearate were minimal and slight skin irritants, respectively; whereas, 100% Magnesium, Sodium, and Zinc Stearates were nonirritants (see Table 8).[40,44,45,47,49-55]

Eye irritation: acute

In rabbit studies, 10% Aluminum Distearate in corn oil and 100% Ammonium, Sodium, and Zinc Stearates were minimal to mild eye irritants; 100% Magnesium Stearate was a nonirritant (see Table 9).[37,40,44,45,47,49,50,52,53,55-57]

Inhalation toxicity: acute

In studies with albino rats, Magnesium and Zinc Stearates were determined to be nontoxic by inhalation (see Table 10).[39,40]

Miscellaneous toxicity studies

Magnesium Stearate: A commercial Magnesium Stearate powder was introduced into the peritoneal cavity (50 mg) and into skin wounds (10 mg) of kittens, rabbits, guinea pigs, rats, and mice. When the animals were sacrificed six to nine weeks later, none of them showed signs of fibrosis or irritation of the skin or peritoneum.[58]

Sodium Stearate: An aqueous solution containing 0.1% Sodium Stearate (0.97 *M*) produced extensive thrombosis and death when given intravenously to dogs at a dose of 10 ml/kg over a five-minute period.[59,60]

An aqueous suspension of 0.1% Sodium Stearate (pH 7.4) injected intravenously into mice at a dose of 0.01 ml/kg of body weight resulted in generalized thrombosis and sudden death.[61]

An aqueous solution containing 0.66 m*M* Sodium Stearate administered intravenously to rabbits at a dose of 3.5 ml/kg within a 30- to 45-second interval induced reversible thrombopenia.[62]

Intravascular injection into rabbits of 100 mg of a fine colloidal suspension of Sodium Stearate in deproteinized rabbit serum at doses of 28.0 or 32.2 mg/kg caused immediate vascular damage to the vessels nearest the site of injection.[63]

TABLE 5. Acute Oral Toxicity.

Ingredient	*Concentration (%)*	*No. of rats*	*Methods*	*Comments*	*LD50*	*Ref.*
Aluminum Stearate	100	–	–	–	>5.0g/kg	38
Ammonium Stearate	100	–	–	–	>5.0 g/kg	47
Lithium Stearate	Unspec. conc. in propylene glycol vehicle	30 albino	–	Animals fasted for 24 hrs. and then given dosages ranging from 0.05 to 15.0 g/kg. Animals dosed at 0.05, 1.0 and 3.0 g/kg showed no toxic effect; all animals administered 15 g/kg died within 16 hrs. having exhibited unkempt coats, impaired locomotion and lethargy prior to death.	>5.0 g/kg but <15.0 g/kg	39
Magnesium Stearate	25 susp. in corn oil	albino	Hagan; Litchfield and Wilcoxon	Animals fasted overnight and then given doses ranging from 0.05 to 10.0 g/kg. Animals observed daily for 14 days. All animals at 10.0 g/kg exhibited mold diarrhea.	>10 g/kg	40–42
Sodium Stearate	25 in propylene glycol	6	–	Material administered at a dose level of 5.0 g/kg. There were no remarkable clinical or necropsy findings.	>5.0 g/kg	36
Sodium Stearate	7.0 in stick deodorant form	10 albino	–	All animals receiving 10 ml/kg showed moderate or marked depression, labored respiration and "depressed righting and placement reflexes" immediately after intubation. All animals recovered within 24 hrs. and appeared normal during remainder of study. Necropsies performed at day 14 revealed no abnormal gross pathology.	>10 ml/kg (formulation)	43
Sodium Stearate	10–25 in bath soap detergent form	–	–	–	>5 g/kg (formulation)	46

Zinc Stearate	25 susp. in corn oil	albino	Hagan; Litchfield and Wilcoxon	Animals fasted for 24 hrs. and then given doses ranging from 0.05 to 10.0 g/kg. During 14 days of observation, all animals appeared normal; there were no mortalities.	>10 g/kg	41,42,49
Zinc Stearate	100	–	–	–	>5.0 g/kg	37
Zinc Stearate	10 in eye-shadow form	10	–	–	>5.0 g/kg	44,45

TABLE 6. Acute Dermal Toxicity.

Ingredient	*Concentration (%)*	*Animal*	*Comments*	*LD50*	*Ref.*
Aluminum Stearate	100	Guinea pigs	Dermal contact with the test material was maintained for 24 hrs.	>3.0 g/kg	38
Ammonium Stearate	100	Guinea pigs	Dermal contact with the test material was maintained for 24 hrs.	>3.0 g/kg	47
Sodium Stearate	7 in a stick deodorant form.	4 rabbits/ albino	A single application of the undiluted formulation was made to the intact skin for a 24 hr. exposure period. After 24 hrs. all animals showed depression and labored respiration but completely recovered by day three; there were no gross signs of systemic toxicity during remainder of study. Necropsies at day 14 revealed pitted and edematous kidneys in one animal.	>10 ml/kg (formulation)	43
Sodium Stearate	10–25 in a 20% bath and soap and detergent form	Rabbits	–	>3.0 g/kg (formulation)	48
Zinc Stearate	10 in eyeshadow form	10 rabbits	–	>2.0 g/kg (formulation)	44,45

TABLE 7. Acute Dermal Corrosion.

Ingredient	*Concentration (%)*	*No of. Rabbits*	*Method*	*Comments*	*Result*	*Refs.*
Magnesium Stearate	100	6 albino	Draize	Material 0.5 ml (0.5 g) applied in a single dose under occlusive conditions for 4 hrs; one-half test sites abraded and one-half intact. PII = 0.0	Noncorrosive under 49 CFR 173.240(a)(1)	40,50
Zinc Stearate	100	6 albino	Draize	Material 0.5 ml (0.5 g) applied in a single dose under occlusive conditions for four hrs. PII = 0.0.	Noncorrosive under 49 CFR 173.240(a)(1)	49,50

TABLE 8. Skin Irritation.

Ingredient	*Concentration (%)*	*No. of rabbits*	*Method*	*Comments*	*Result*	*Ref.*
Aluminum Distearate	10 susp. in corn oil	–	–	Material applied in a single dose under occlusive conditions. PII = 0.06 (max. = 8)	Minimal irritation	52
Ammonium Stearate	100	–	–	Material applied in a single dose under occlusive conditions. PII = 0.62 (max. = 8)	Slight irritation	47
Magnesium Stearate	100	6 albino	Draize	Material applied under occlusive patch for 24 hrs; one-half test sites abraded and one-half intact. PII = 0.0 (max. = 8)	No irritation	40,50
Sodium Stearate	100	6 albino	–	Material applied in a single dose under occlusive conditions. PII = 0.0 (max. = 8)	No irritation	51
Sodium Stearate	7 in a stick deodorant form	4 albino	Draize	The undiluted formulation (0.5 ml) applied to abraded and intact skin for 24 hr. exposure period. PII of formulation = 2.6 (max. = 8)	Moderate irritation (formulation)	51,53
Sodium Stearate	10–25 in a bath soap and detergent form	6	Draize	PII = 2.2 (max. = 8)	Mild irritation (formulation)	50,55
Zinc Stearate	100	6 albino	Draize	Material applied under occlusive conditions to abraded and intact skin for 24 hr. exposure period. PII = 0.0 (max. = 8)	No irritation	49,50
Zinc Stearate	10 in eye-shadow form	6	–	PII = 0.0 (max. = 8)	No irritation (formulation)	45,54

TABLE 9. Eye Irritation.

Ingredient	*Concentration (%)*	*No. of rabbits*	*Method*	*Comments*	*Result*	*Ref.*
Aluminum Distearate	10 susp. in corn oil	–	Draize	Eyes were unrinsed. Scores were 1, 1, and 0 on Days 1, 2, and 3, respectively	Minimal irritation	50,52
Ammonium Stearate	100	–	Draize	Eyes were rinsed. Scores were 3, 1, and 0 on Days 1, 2, and 3, respectively.	Minimal irritation	47,50
Ammonium Stearate	100	–	Draize	Eyes were unrinsed. Scores were 22, 16, 5, 3, and 1 on Days 1, 2, 3, 4, and 7, respectively.	Mild irritation	47,50
Magnesium Stearate	100	6 albino	Draize	Eyes were unrinsed. The score was 0 on days 1, 2, and 3.	No irritation	40,53
Sodium Stearate	100	6	Draize	On day one, 2/6 conjunctivae appeared necrotic. Scores were 22, 12, 3, 1, and 1 on Days 1, 2, 3, 4, and 7, respectively. This corresponded to moderate irritation initially but was considered negligible by Day 4.	Negligible irritation	56
Sodium Stearate	7 in an undiluted stick deodorant form	5 albino	Draize	Eyes were rinsed. Scores were 29, 27, 21, 16, 13, and 7, at the 1 hr, 1, 2, 3, 4, and 7 day readings, respectively.	–	50,57
Sodium Stearate	7 in an undiluted stick deodorant form	5 albino	Draize	Eyes were unrinsed. Scores were 29, 31, 24, 21, 15, and 8, at the 1 hr, 1, 2, 3, 4, and 7 day readings, respectively.	–	50,57
Sodium Stearate	10–25 in a bath and soap detergent form	–	Draize	Eyes were unrinsed.	Mild irritation (formulation)	50,55
Zinc Stearate	100	6 albino	Draize	Eyes were unrinsed. The score was 0 on Days 1, 2, and 3, respectively.	No irritation	49,53
Zinc Stearate	100	6	Draize	Eyes were unrinsed. Scores were 2 and 0 on Days 1 and 2, respectively.	Minimal irritation	37,50
Zinc Stearate	10 in undiluted eye-shadow form.	6	–	The score was 0 in all animals at 24, 48, and 72 hrs.	No irritation (formulation)	44,45

TABLE 10. Acute Inhalation Toxicity.

Ingredient	*No. of albino rats*	*Chamber conc. (mg/l)*	*Comments*	*LC50*	*Ref.*
Magnesium Stearate	2 groups of 10	200 or 2	At end of single 1-hr. exposure to 200 mg/l, 7/10 rats were dead; an 8th rat died on day 14. In a similar exposure to 2 mg/l, 2/10 deaths occurred in the 2nd week. Material considered nontoxic under Dept. of Transportation regulations.	>2 mg/l	40
Zinc Stearate	10	200	Single 1-hr. exposure; 1/10 rats died during 2-wk. observation period. Material was considered nontoxic by investigators.	>200 mg/l	49

Zinc Stearate: Zinc Stearate was acutely irritating when injected into the lungs of rats and the peritoneum of guinea pigs. When 50 mg suspended in 1 ml of skim milk and saline was injected into the lungs of 50 rats, 20 died in less than 24 hours. Examination of the lungs revealed severe edema, congestion, and small hemorrhages. Animals that survived demonstrated no abnormality of the lungs after 14 or 259 days. When 100 mg Zinc Stearate suspended in 1 ml of tap water was injected into the lungs of six rats, all died as a result of acute edema of those organs. Guinea pigs injected intraperitoneally with either 50 mg (six guinea pigs) or 100 mg (six guinea pigs) Zinc Stearate suspended in 1 ml of tap water developed granulomata of the peritoneum. No permanent fibrosis resulted from the single injection of Zinc Stearate into the lungs of rats or into the peritoneum of guinea pigs.[64]

Subchronic studies

Calcium Stearate: An emulsion of Calcium Stearate (unspecified concentration) in egg yolk and water was applied to the skin of six guinea pigs daily, for 14 days. After only six days of exposure, the body weight of treated animals decreased significantly relative to that of controls. The average body weight change reported on day six for control animals was 56g ± 4.85, while that reported for exposed animals was 29 g ± 10.12 ($p = 0.05$).[65]

Calcium Stearate (50 mg in 0.5 ml of saline and 0.01 ml of egg yolk) administered intratracheally to rats for two months caused severe lesions of blood vessels in the pulmonary tissue. Results for the control animals were not given.[65]

Zinc Stearate: An emulsion of Zinc Stearate (unspecified concentration) in egg yolk and water was applied daily for 14 days to the skin of six guinea pigs. After only four days of exposure, the body weight of treated animals increased significantly over that of controls. The average body weight change reported for animals on day four was 17 g ± 3.84, while that reported for exposed animals was 37 g ± 4.8 ($p = 0.02$).[65]

Chronic studies

Calcium Stearate: Calcium Stearate (50 mg in 0.5 ml of saline and 0.01 ml of egg yolk) administered intratracheally to rats for six months caused " . . . peribronchial sclerosis, foci of alveolar emphysema, single small areas of

hemorrhage, and pigment aggregations . . .". Results for the control animals were not given.[65]

Calcium Stearate (10 mg in 0.5 ml of saline and 0.01 ml of egg yolk) was administered intratracheally to rats for four or eight months; this caused varying degrees of lung pathology, including peribronchial sclerosis, alveolar atelectasis, and diffuse brochiectasis. Results for the control animals were not given.[65]

Sodium Stearate: A formulation "bath soap and detergent" containing 10–25% Sodium Stearate was used to conduct a dermal toxicity study in rabbits. Formulations for 3 months' doses of 2.0 g/kg were applied to the skin by syringe daily, five days a week. No "untoward reactions" were observed.[66]

Zinc Stearate: Intratracheal administration of Zinc Stearate (50 mg in 0.5 ml of saline and 0.01 ml egg yolk) to rats for two months caused varying degrees of lung pathology, including plasmorrhagia in the walls of arteries, alveolar atelectasis, alveolar emphysema, bronchitis, diffuse bronchiectasis, and hyperplasia of lymphoid tissue. Results for the control animals were not given.[65]

Special Studies

Teratogenesis

Magnesium Stearate: A vehicle used in coated pharmaceutical tablets was assayed for teratogenicity in rabbits. The vehicle consisted of polyethylene glycol 4000, starch, talcum, silica gel and 5.5% Magnesium Stearate. Fourteen females received the vehicle per os at a dose of 2.5 mg/kg 70 hours post coitus whereas 13 females were given the same dose 192 hours post coitus. Compared with anomalies in the fetuses from 16 untreated mothers (12 of 112 offspring had anomalies) the vehicle containing 5.5% Magnesium Stearate induced anomalies in 9 out of 86 and 11 out of 90 fetuses respectively, thus demonstrating the absence of a teratogenic effect.[67]

Mutagenesis

Magnesium Stearate: Magnesium Stearate was not a mutagen in microbial tests with *Salmonella typhimurium* TA-1535, TA-1537, TA-1538, and *Saccharomyces cerevisiae* D4 with or without metabolic activation by liver and lung preparations from rats, mice, and monkeys.[28,68]

Carcinogenesis

Stearic Acid: Ninety-two mice [Swiss Webster female mice and BALB/C (mammary tumor virus-free) female mice, seven test groups of 10–16 animals each] received subcutaneous injections of 0, 0.05, 0.5, and 1.0 mg stearic acid (corresponding to approximate total doses of 0, 2.5, 25, and 50 mg/kg, once, twice, or three times weekly). The number of injections per test group varied from 26 to 114. One mouse in the control group developed a subcutaneous sarcoma during the 18 months of observation. In the test group of 10 mice receiving 0.05 mg twice a week for a total of 114 injections, four subcutaneous sarcomas developed during the 18-month period. No sarcomas developed in the mice in the other six test groups, including those given 0.5 mg twice a week for a total of 114 injections or 1.0 mg twice a week for a total of 82 injections. The occurrence of four sarcomas in the one test group was not explained.[27,69] Clayson[70] regards the induction of localized sarcomas in mice upon repeated subcutaneous injection of test solutions as "notoriously unreliable as an indicator of car-

cinogenicity." Furthermore, he considers "the results of individual experiments as extremely variable."

The foregoing test was repeated in mice; this time the animals were given weekly injections of 0.05 and 0.5 mg for 26 weeks. No sarcomas developed at the site of injection, and it was concluded that stearic acid was not a carcinogen by these procedures.[27,71]

Ten rats fed stearic acid as 0.3% of their diet for 209 days developed no tumors.[27,72]

In a search for carrier materials for introducing potential carcinogens into the urinary bladders of mice, stearic acid and other "inert vehicles" were tested for their ability to produce bladder tumors (See Table 11). Pellets of stearic acid implanted in the bladders of 62 mice for 30 weeks produced a bladder tumor incidence of 13%.[73]

Magnesium Stearate: Pellets of Magnesium Stearate implanted in bladders of 41 mice for 30 weeks produced a 5% incidence of bladder tumors. The incidence of bladder tumors in mice implanted with Magnesium Stearate was similar to that produced by smooth glass beads (See Table 11).[73]

Magnesium Stearate pellets containing different compounds were also implanted into mouse bladders. A significant number of tumors (26%) was produced by 1-methoxy-2-naphthylamine using Magnesium Stearate as a vehicle.

Although Magnesium Stearate pellets containing indoxyl sulfate, hippuric acid, or 3-hydroxyanthranilic acid produced more tumors (the incidence was 19%, 17%, and 19%, respectively) than did Magnesium Stearate alone (5%), the differences according to the authors, were not significant.[73]

Clinical Assessment of Safety

Primary Irritation and Sensitization

Ammonium Stearate: The skin-irritation potential of 1.5% Ammonium Stearate in aqueous solution was determined in 20 subjects using a single insult, 24-hour, occlusive patch test. The test material caused no irritation in 13 subjects, minimal erythema in one, and mild erythema in six. The Primary Irritation Index (PII) was determined to be 0.33, indicating minimal irritation.[74]

TABLE 11. Incidence of Bladder Tumors in Mice Implanted with Inert Materials.[a]

	Numbers of Mice[b]			
Substance	Surviving 30 wks	w/adenoma or papilloma	w/carcinoma	Tumor incidence (%)
Magnesium Stearate	41	1	1	5
Cholesterol	77	4	5	12
Stearic Acid	62	5	3	13
n-Hexadecanol	69	2	6	12
n-Octadecanol	50	7	6	26
Naphthalene	23	0	1	4
Smooth glass	67	–	3	4
Roughened glass	63	–	18	29

[a]Data from Ref. 73.
[b]Stock mice were bred in the Chester Beatty Research Institute.

Sodium Stearate: A single insult, 24-hour, occlusive patch test was conducted on 20 human subjects to determine the skin irritation potential of 0.5% Sodium Stearate in aqueous solution. The test solution produced no irritation in 16 subjects, and minimal to moderate erythema in four. The investigators concluded that Sodium Stearate "exhibited an acceptable and typical soap response."[75]

A stick deodorant containing 7% Sodium Stearate was tested for skin irritation and sensitization potential in 212 subjects. The undiluted formulation was applied to the medial surface of the upper arm of each subject four days a week for two weeks for a total of eight 12-hour patches. After a two-week rest, one 24-hour challenge patch was applied and read at 24, 48, and 72 hours. During the two-week induction period, a total of 61 erythema reactions occurred, 59 of them slight, one moderate, and one severe. The challenge application caused in seven slight erythema reactions by the 24-hour reading and one slight erythema reaction by the 48-hour reading; all eight sites were negative by 72 hours.[76-78]

In a 21-day patch test, a "bath soap and detergent" formulation at a level of 1% in aqueous solution was minimally irritating to 10 subjects. The diluted formulation contained 0.1–0.25% Sodium Stearate.[79] When they were tested with the same formulation at 3% in aqueous solution, 100 subjects showed no sensitization; the diluted formulation contained 0.3–0.75% Sodium Stearate.[80]

Zinc Stearate: Two eyeshadow formulations, each containing 10% Zinc Stearate, were tested by means of the Schwartz–Peck Prophetic Patch Test and the Draize–Shelanski Repeated Insult Patch Test. The former test resulted in "virtually 0 reactions in 202 subjects," whereas the latter one brought about "virtually 0 reactions in 99 subjects."[81,82] One of the formulations was applied twice a day for 28 days to 52 female panelists. Each subject was then examined at baseline and one, two, three, and four weeks after application. "No irritation or sensitization potential was exhibited by the panelists using this product under conditions of this test."[83]

Phototesting: No studies relating to phototoxicity or photo-contact allergenicity were available to the Panel.

Miscellaneous Studies

Sodium Stearate: Nonallergic granulomas of the skin were produced in 9 out of 10 subjects following dermal injections of 0.2 *M* Sodium Stearate at a dose of 0.1 ml. Biopsy specimens of representative areas at the two to four and five week periods revealed a "distinct epithelioid reaction with occasional giant cells and some round cell infiltration"; in some instances there were "fragmentation and degeneration of collagen fibers." The length of duration of the granulomas depended on the time required for the ingestion and metabolism of the compound by reticuloendothelial cells. The authors concluded that the "granulomagenic capacity" of Sodium Stearate was related to its "ability to form colloidal systems composed of micellar particles."[84]

An emulsion of 2.5 *M* Sodium Stearate in NaCl and albumin was given intraduodenally to healthy males and to patients with healed duodenal ulcers in a dose of 0.5 g. The emulsion was administered after a plateau of gastric acid secretion induced by a continuous infusion of pentagastrin had been reached. The test material provoked only a slight inhibition of gastric acid secretion; no vomiting or nausea occurred.[85]

Zinc Stearate: Harding[64] described a case of "pneumoconiosis with probable heart failure" in a rubber factory worker who had been occupationally exposed to Zinc Stearate dust for 29 years. Histological examination of lungs revealed bleeding, a significant increase in connective tissue, and chronic inflammation; likewise, numerous "granules and needles" in the fibrotic tissue that contained zinc were also observed.

Weber et al.[86] described a case of pulmonary fibrosis in a chemical worker who had been occupationally exposed to Zinc Stearate dust for seven years. The amount of zinc retained in the lungs of the deceased worker (6.2 mg/100 g of dry lung tissue) was not significantly different than that retained in the lungs of persons who had not been occupationally exposed. It was the authors' opinion that Zinc Stearate was not the cause of lung fibrosis.

Murray[87] reported that between 1919 and 1924, a Toronto hospital admitted three cases of "drug poisoning" caused by aspiration and ingestion of Zinc Stearate powder. One of the patients, a 14-month old infant, developed diffuse bronchopneumonia and died within two days of the accident.

Heiman and Aschner[88] reported 12 cases in which infants developed fever, rapid respiration, dyspnea, cyanosis, bronchopneumonia, and acute toxemia after incidentally aspiring Zinc Stearate powder. One eight-month-old infant died within 24 hours of the accident. In eight cases, " . . . the initial partial asphyxia was followed by a gradual recovery without definite involvement of the lungs. The rapid respirations and cyanosis which followed immediately on the inhalation of the powder subsided during the course of three days."

The *Handbook of Cosmetic Materials*[8] states that Zinc Stearate is an "extremely tenacious powder which can be harmful when inhaled." Lesions resulting from aspiration of the powder resemble those from aspiration of talc; but the former type of lesions is generally more severe than the latter.[89] *The U.S. Pharmacopeia XIX*[9] reports that the compound is not to be inhaled by or used on infants.

SUMMARY

The Stearates reviewed in this report are salts of stearic acid. They are fine, white powders with a slight fatty odor. The commercial stearic acid from which the Stearates are manufactured is a mixture of monocarboxylic acids obtained from animal and vegetable sources. The commercial grade of stearic acid contains fatty acids that range from C_{12} (lauric) to C_{22} (behenic), and the major components are C_{18} (stearic) and C_{16} (palmitic) acids.

Stearates are generally used for their lubricating properties, but they may also function as emulsifiers, stabilizers, and opacifiers. The range of concentrations of these ingredients in cosmetic products varies from ≤ 0.1 to $> 50\%$.

Aluminum, Calcium, Magnesium, Potassium, and Sodium Stearates have been approved for use as food additives, and regulations governing such use have been issued under the Food, Drug and Cosmetic Act. Magnesium and Zinc Stearates are GRAS (Generally Recognized As Safe) compounds.

Limited absorption studies indicated that Calcium Stearate is slightly absorbed by isolated dog intestine, and that Sodium Stearate is absorbed through both rat and human skin.

Acute oral studies with rats showed that Aluminum, Ammonium, Lithium, Magnesium, Sodium, and Zinc Stearates are practically nontoxic. Studies with

guinea pigs demonstrated that 100% Aluminum and Ammonium Stearates have a low potential for acute dermal toxicity. When tested on rabbit skin at concentrations of 100%, Magnesium and Zinc Stearates were found to be noncorrosive. Skin irritation studies with rabbits demonstrated that 10% Aluminum Distearate in corn oil and 100% Ammonium Stearate were minimal and slight irritants, respectively, whereas 100% Magnesium, Sodium, and Zinc Stearates were nonirritants. Eye irritation studies with rabbits showed that 10% Aluminum Distearate in corn oil and 100% Ammonium, Sodium, and Zinc Stearates were minimal to mild irritants; 100 percent Magnesium Stearate was a nonirritant.

An emulsion of Calcium Stearate in egg yolk and water applied to the skin of guinea pigs for 14 days caused a significant decrease in body weight, whereas a similar emulsion containing Zinc Stearate caused a significant increase in body weight.

Zinc Stearate administered intratracheally to rats for two months and Calcium Stearate administered simililarly to rats for two, four, six and eight months, caused varying degrees of lung pathology.

When fed to pregnant rabbits, a pharmaceutical vehicle containing 5.5% by weight Magnesium Stearate was not teratogenic. Magnesium Stearate was not mutagenic in microbial tests with *Salmonella typhimurium* or *Saccharomyces cerevisiae*. Mice surviving 30-week implants of Magnesium Stearate pellets in the bladder had a bladder tumor incidence of 5.0%, but the incidence was no different than that caused by glass beads.

In a clinical study, seven out of 20 subjects exhibited minimal to mild skin erythema when tested with an aqueous solution of 1.5% Ammonium Stearate in a single-insult, 24-hour patch test. In a similar study with 0.5 percent Sodium Stearate in aqueous solution, four out of 20 subjects demonstrated minimal to moderate skin erythema. In a 21-day patch test with 10 subjects, an aqueous "bath soap and detergent" solution containing 0.1–0.25% Sodium Stearate caused minimal skin irritation. An aqueous solution of the same formulation containing 0.3–0.75% Sodium Stearate caused no sensitization in 100 subjects. A stick deodorant containing 7% Sodium Stearate, and eye shadow formulations containing 10% Zinc Stearate demonstrated low potential for human skin irritation and sensitization. There were several reported instances of infant bronchopneumonia and death due to accidental inhalation of Zinc Stearate powder.

The opinion expressed in the conclusion below is based on a composite of available animal and human data. However, the Panel felt that a number of the reported clinical studies for primary skin irritation and sensitization were suboptimal or inadequate in terms of number of subjects tested, concentrations tested and/or test protocols employed. Data for the purpose of assessing the human skin sensitization potential of the Stearates were also limited in that only product formulation data were available. Further, no clinical studies relating to phototoxicity or photocontact allergenicity were reported. Despite these limitations and/or deficiencies in the clinical data, it is the Panel's opinion that sufficient animal and human data are available to assess the safety of the Stearates as comsetic ingredients.

CONCLUSION

On the basis of the available information presented in this report, and as the information is qualified in the summary, the Panel concludes that the Stearate com-

pounds described herein are safe as cosmetic ingredients in the present practices of use and concentration.

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