AMERICAN INGREDIENTS COMPANY

September 26, 2001

National Organic Standards Board
c/o Robert Pooler
Agriculture Marketing Specialist
USDA/AMS/TM/NOP
Room 2510-So.
Ag.Stop 0268
P.O. Box 96456
Washington, DC 20090-6456

Dear Mr. Pooler:

We are enclosing our petition requesting that the chemical substance Calcium Stearate be evaluated for inclusion on the National List of Allowed Substances for use in food products labeled as organic.

We have submitted all the information in duplicate, as requested. Please feel free to contact me if you have any questions, or need additional information to complete the review. My phone number is (816) 561-9050 Extension 281, and my email is akates@americaningredients.com.

Sincerely,

AMERICAN INGREDIENTS COMPANY

April F. Kates
Regulatory Affairs Consultant

Enclosures

cc: L. Skogerson (AIC)

3947 Broadway Kansas City, Missouri 64111 Telephone 816-561-9050 800-669-4092 Fax 816-561-9909

National Organic Program:

Petition for Evaluation of Substance for Inclusion on National List of Substances Allowed in Food Production and Handling

Item A:
Substance Name: Calcium Stearate

This is a nonagricultural substance. Petition is to permit calcium stearate in processed products labeled as "organic" or "made with organic (specified ingredients)". Calcium Stearate is a compound of calcium with a mixture of solid organic acids obtained from edible sources, and consists chiefly of variable proportions of calcium stearate and calcium palmitate. It occurs as a fine, white to yellowish white, bulky powder having a slight characteristic odor.

Item B:

1. **Common Name**: Calcium Stearate, as component in organic bakery product additive.

2. **Manufacturer Name, Address, Phone Number**: American Ingredients Company
   3947 Broadway
   Kansas City, MO 64111
   (816) 561-9050

3. **Intended use**: As a free-flowing agent to be used in processed food ingredients. Calcium Stearate is a nonagricultural ingredient.

4. **Handling activities for which the substance is used:** Calcium Stearate is a direct food additive, used as an anti-caking agent, binder, emulsifier, flavoring agent, release agent, stabilizer, thickening agent, adjuvant. Mode of action: Calcium Stearate is a solid-phase lubricant. It reduces friction between particles of the substance to which it is added. It is hard, high-melting and not sticky compared to the other ingredients it is mixed with.

5. **Source of substance and manufacturing procedures:** There are two major methods to produce Calcium Stearate. The first, and older method used is when calcium chloride and sodium stearate and other salts of mixed fatty acids are reacted in an aqueous solution to make calcium stearate. The precipitate is collected and washed with water to remove sodium chloride. This method is not practical for large-scale production. Calcium stearate is more frequently produced by the dry fusion process than by the precipitate method. Palm-derived stearic acid is reacted with calcium oxide under certain conditions to produce calcium stearate. No organic solvents are used for its production.

6. **Summary of previous reviews by State or private certification programs:** Not applicable.

7. **Information about EPA, FDA, and State authority registrations:** FDA: 21 CFR 184.1229, GRAS for the following uses: as a flavoring agent and adjuvant as defined in 21 CFR 170.3(o)12, a lubricant and release agent (21 CFR 170.3(o)(18)), and stabilizer and thickener, 21 CFR 170.3(o)(28). May be used in foods at levels not to exceed good manufacturing practice.

8. **CAS Number for Calcium Stearate:** 1529-23-0.
Labels of product containing calcium stearate are attached. (Attachment 1)

9. **Physical properties and chemical mode of action**:
a. Chemical interactions with other substances, especially substances used in organic production: Calcium stearate is a stable substance, and is only reactive with strong oxidizing agents.

Calcium stearate has the following physical properties:

Appearance:	white crystalline powder
Odor:	none, slight
Melting point:	179C, 354F
Solubility:	Almost insoluble in water, 0.004 G/100 CC H2O AT 15 DEG C; Insoluble in alcohol and ether. Slightly soluble in hot vegetable and Mineral oils; quite soluble in hot pyridine.
Molecular Weight:	607
Molecular Formula:	C18-H36-O2.1/2CA

b. Toxicity and environmental persistence: Calcium stearate is considered to be nontoxic. There is little to no toxicity data available about the substance. There is also no information on its environmental persistence.

c. Environmental impacts from its use or manufacture: None available in published reports. However, no solvents are used in the current manufacture of calcium stearate using dry fusion. This is environmentally beneficial; solvents are generally considered undesirable.

d. Effects on human health: Not classified as a human carcinogen. (Limited reports suggest that calcium stearate was not a skin irritant or a skin sensitizer in humans. Acute oral toxicity in rats was apparently low. Intratracheal administration to rats caused lung effects and deaths. Calcium stearate was not mutagenic in yeast or in an Ames bacterial test. (source: British Industrial Biological Research Assoc.)

e. Effects on soil organisms, crops or livestock: None available, but this product is not used on the soil, it is used in food products. It is not applied in the field. It may be present as an excipient in drugs fed to animals, but the usage in question is as a direct human food additive.

A thorough database search was conducted using the National Library of Medicine (NLM) Gateway's TOXNET for this information: Calcium stearate is not an EPA Hazardous Chemical. It is not a carcinogen. It is not present in the Hazardous Substances Data Bank of the NLM. It is not listed in IRIS, the databank for potential human health effects of environmental pollutants. It is not listed as an environmental mutagen, or as having environmental persistence. There are no animal toxicity studies, metabolism/pharmacokinetics, or pharmacology studies available that show it is harmful.

10. Safety Information:

a. MSDS. (See Attachment 2)

b. Substance report from National Institute of Environmental Health Studies: Calcium Stearate not listed in the NIEHS website.

Occupational Exposure Standards/Threshold Limit Values:
8 hr Time Weighted Avg (TWA) 10 mg/cu m /Stearates (does not include stearates of toxic metals) Excursion Limit Recommendation: Excursions in worker exposure levels may exceed three times the TLV-TWA for no more than a total of 30 min during a work day, and under no circumstances should they exceed five times the TLV-TWA, provided that the TLV-TWA is not exceeded.

(From: American Conference of Governmental Industrial Hygienists. Threshold Limit Values (TLVs) for Chemical Substances and Physical Agents Biological Exposure Indices for 1998. Cincinnati, OH: ACGIH, 1998.)

Manufacturing/Use Information:

Major Uses:

The major uses of calcium stearate are as follows: plastics additive, flow agent in dry food products, conditioning agent and emulsifier in food and drug products, waterproofing agent for fabric, cement, stucco, explosive, release agent for plastic molding powders, lubricant, flatting agent in paints, cosmetics, stabilizer in plastic compounding, lubricant in plastic compounding, bakery and confectionary release agent.

General Manufacturing Information:
There are no organic solvents used in the production of calcium stearate. It is made by the dry fusion process with stearic acid and calcium oxide. The stearic acid is derived from palm oil, soybean oil or tallow. U.S. regulations require that the fatty acids and oils used in production of the stearic acid be free of chick edema factor.

Calcium stearate, while originally produced as a precipitate, is now made using a dry fusion process, which still produces food-grade product, but on a much larger scale than originally possible using the older method. No organic solvents are used in its production.

11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including review and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on the National List: A thorough review of calcium stearate was conducted using National Library of Medicine's Gateway search engine. No entry for calcium stearate could be found in the following Databases: Chemical Carcinogens Research Information System, Environmental Mutagen System Genetic Toxicity Data Bank, Hazardous Substances Data Bank, TOXLINE. Attached is a copy of the final report of the safety assessment of calcium stearate which appeared in the Journal of the American College of Toxicology in 1982. The report states calcium stearate is safe as a cosmetic ingredient. (Attachment 3) A 1975 report by the Life Sciences Research Office/ Federation of American Societies of Experimental Biologists (FASEB) evaluated calcium stearate as a food ingredient and found it to be safe as a direct food additive. (Attachment 4)

12. Why Calcium Stearate is needed for organic products: For bakery additives, calcium stearate is used as an anti-caking and flow agent ingredient in dry blends sold to bakeries. It is used in many cosmetic and pharmaceutical ingredients, and has FDA GRAS status. In dry blends used by bakeries, such as enrichment and dough improver products, calcium stearate keeps the level of dust down. This is important because many flour improvers contain enzymes or vitamins. The dust from enzymes can cause allergies, and the dust from certain vitamins is considered harmful (thiamin is a vasodilator, for instance). Thus, it can be surmised that calcium stearate is an additive that has benefits for people working in bakeries, who would otherwise be breathing more dust.

There are no nonsynthetic ingredients that can be used to the same effect as calcium stearate. Calcium stearate is considered nontoxic and noncarcinogenic. The sources of calcium stearate can be considered somewhat natural. It is the calcium salt of stearic acid obtained from edible tallow or alternatively, soybean oil or palm oil.

REFERENCES

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"Final Report of the Safety Assessment of Lithium Stearate, Aluminum Distearate, Aluminum Stearate, Aluminum Tristearate, Ammonium Stearate, Clacium Stearate, Magnesium Stearate, Potassium Stearate, Sodium Stearate, and Zinc Stearate." Journal of the American College of Toxicology, Vol. 1, No. 2 pp.143-177, 1982

"Evaluation of Health Aspects of Tallow, Hydrogenated Tallow, and Calcium Stearate as a Food Ingredient," National Technical Information Service: LSRO/FASEB , 17 pages, 1975 .

ATTACHMENTS

Attachment 1: Label of American Ingredients' product containing Calcium Stearate

Attachment 2: MSDS for Calcium Stearate, from internet, two sources.

Attachment 3: "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."
Journal of the American College of Toxicology, Vol. 1, No. 2,
pp. 143-177, 1982.

Attachment 4: "Evaluation of Health Aspects of Tallow, Hydrogenated Tallow, and Calcium Stearate as a Food Ingredient", National Technical Information Service: Life Sciences Research Office/Federation of American Societies of Experimental Biology, 17 pages, 1975 .

ATTACHMENT 1

DOH-TONE®

CONTAINS: Wheat Starch, Enzymes, Calcium Stearate and Silicon Dioxide.

Kosher and Pareve Certified Ⓤ

DIRECTONS FOR USE : Optimum addition rates should be determined by flour performance tests. The normal addition rate is 3 to 5 grams per 100 kg of flour.

HAZARDS: Combustible dust. Can cause dust explosion. Prolonged and/or repeated contact may cause irritation of the mucous membranes. Most symptoms will be temporary.

PRECAUTIONS: Keep away from sources of high heat, open flames, sparks or other sources of ignition. Avoid direct contact and excessive generation of dust. Wear protective clothing, rubber gloves, safety glasses and approved dust mask when handling. Use in well ventilated area. Wash thoroughly after using.

FIRST AID: For eye contact, irrigate eyes with water for 15 minutes. Wash affected areas of skin with soap and water.

SEE MATERIAL SAFETY DATA SHEET

CONTIENT: farine de blé, enzymes, stéarate de calcium et dioxyde de silicium.

Certifié Cachir et Pareve Ⓤ

MODE D'EMPLOI: La quantite optimum d'addition devrait être determinée suivant le resultat des test de farine. Letaux d'addition normal est 3 à 5 grammes pour 100 kg de farine.

DANGERS: Poussiere combustible. Peut causer un coup de poussiéres. Un contact prolongé ou rétété peut causer une irritation de la peau et des membranes muqueses. La plupart des symptômes sont temporaires.

MESURES DE PRECAUTION: Conserver à l'abri la chaleur, de flammes découvertes, d'etincelles et d'autres sources d'allumage. Eviter le contact direct et la génération excessive depoussiéres. Il convient d'endasser des vetements protecteurs, de gants en caoutchouc, de lunettes protecrices et un masque anti-poussiéres apprové par pendant la menutention. Employer dans un endroit bien ventilé. Se laver soigneusement aprés avoir manipulé ce produit.

PREMIER SOINS: En cas de contact avec les yeux, rincer immédiatement avec de l'eau durant 15 minutes. Nettoyer les parties irritées de la peau avec de l'eau et du savon.

VOIR FICHE SIGNALETIQUE DE SECURITE

AIC CANADA

AIC CANADA FLOUR SERVICE DIVISION,
2500 MEADOWPINE BLVD., UNIT 3,
MISSISSAUGA, ONTARIO, L6J 5A3

25 KG (55 LB.)

L-415c Made in U.S.A.

Fabriqué aux E.U.A.

DOH-TONE®

CONTAINS: Wheat Starch, Enzymes, Calcium Stearate and Silicon Dioxide.

CONTIENT: farine de blé, enzymes, stéarate de calcium et dioxyde de silicium.

Kosher and Pareve Certified Ⓤ

Certifié Cachir et Pareve Ⓤ

DIRECTONS FOR USE : Optimum addition rates should be determined by flour performance tests. The normal addition rate is 3 to 5 grams per 100 kg of flour.

MODE D'EMPLOI: La quantite optimum d'addition devrait être determinée suivant le resultat des test de farine. Letaux d'addition normal est 3 à 5 grammes pour 100 kg de farine.

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MESURES DE PRECAUTION: Conserver à l'abri la chaleur, de flammes découvertes, d'etincelles et d'autres sources d'allumage. Eviter le contact direct et la génération excessive depoussiéres. Il convient d'endasser des vetements protecteurs, de gants en caoutchouc, de lunettes protecrices et un masque anti-poussiéres apprové par pendant la menutention. Employer dans un endroit bien ventilé. Se laver soigneusement aprés avoir manipulé ce produit.

FIRST AID: For eye contact, irrigate eyes with water for 15 minutes. Wash affected areas of skin with soap and water.

PREMIER SOINS: En cas de contact avec les yeux, rincer immédiatement avec de l'eau durant 15 minutes. Nettoyer les parties irritées de la peau avec de l'eau et du savon.

SEE MATERIAL SAFETY DATA SHEET

VOIR FICHE SIGNALETIQUE DE SECURITE

AIC CANADA

AIC CANADA FLOUR SERVICE DIVISION,
2500 MEADOWPINE BLVD., UNIT 3,
MISSISSAUGA, ONTARIO, L6J 5A3

25 KG (55 LB.)

L-415c Made in U.S.A.

Fabriqué aux E.U.A.

ATTACHMENT 2

ASTRO PRODUCT CODE # 25035

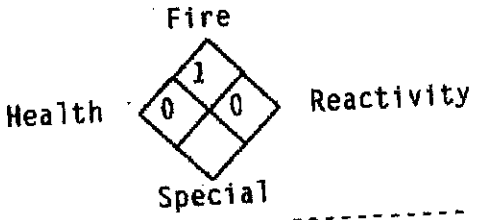
WITCO MATERIAL SAFETY DATA SHEET

Calcium Stearate (All Grades)

Product Code: 043 0250

CAS NO:1592-23-0

NFPA HAZARD RATING
4 - Extreme
3 - High
2 - Moderate
1 - Slight
0 - Insignificant



HMIS HAZARD INDEX
Hazardous Materials Identification System
4 - Severe
3 - Serious
2 - Moderate
1 - Slight
0 - Minimal

HMIS RATINGS
Health.....0
Flammability.....1
Reactivity.....0
Personal protection.....F*
*See last page for Code Table.

DIVISION AND LOCATION---SECTION I

Division: OLEOCHEMICALS/SURFACTANTS GROUP
Location: CUST. SERVICE: 800-494-8287
3230 BROOKFIELD ST.,HOUSTON,TX,77045
Emergency Telephone Number: (908) 826-6600
Transportation Emergency: CHEMTREC 1-(800) 424-9300 (U.S. and Canada)

CHEMICAL AND PHYSICAL PROPERTIES---SECTION II

Chemical Name:
octadecanoic acid, calcium salt
Formula: $(C_{17}H_{35}COO)_2Ca$
Hazardous Decomposition Products:
as with any organic material, combustion will produce carbon dioxide (CO2) and probably carbon monoxide (CO).
Incompatibility (Keep away from):
Keep away from flame, heat (200½F max.) and strong oxidizing agents.
Toxic and Hazardous Ingredients:
none
Form: powder
Odor: slight fatty odor
Appearance: white powder
Color: white
Specific Gravity (water=1): 1.03
Boiling Point: not applicable
Melting Point: 160°C (320°F)
Solubility in Water (by weight %): negligible
Volatile (by weight %): 1.0 moisture
Evaporation Rate: nil
Vapor Pressure (mm Hg at 20°C): nil
Vapor Density (air=1): no data available
pH (as is): no data available
Stability: Product is stable under normal conditions
Viscosity SUS at 100°F: not applicable

(Continued on next page)

ASTRO PRODUCT CODE # 25035

FIRE AND EXPLOSION DATA---SECTION III

Special Fire Fighting Procedures:
Firefighters must be equipped to prevent breathing of vapors or products of combustion. Wear an approved self-contained breathing apparatus and protective clothing.

Unusual Fire and Explosion Hazards:
Only usual hazards associated with organic dusts. The possibility of explosion exists under dusty conditions. Avoid dusting when handling and avoid all possible sources of ignition (spark or flame).

Flashpoint: (Method Used) Cleveland open cup greater than 177°C (350°F)

Flammable limits %:
not applicable

Extinguishing agents:
Drychemical or Waterspray or CO_2 or Foam

HEALTH HAZARD DATA---SECTION IV

Permissible concentrations (air):
Particulates not otherwise regulated: Total dust TWA: 15mg/m3 Respirable Fraction: 5mg/m3 (OSHA)

Chronic effects of overexposure:
respiratory congestion due to dust

Acute toxicological properties:
no data available

Emergency First Aid Procedures:
Eyes: Immediately flush with large quantities of water for at least 15 minutes and call a physician.
Skin Contact: Wash with detergent and water.
Inhalation: Remove subject to fresh air.
If Swallowed: Call a physician immediately.

SPECIAL PROTECTION INFORMATION---SECTION V

Ventilation Type Required (Local,mechanical,special):
Local exhaust suggested to prevent dust build up.

Respiratory Protection (Specify type):
Use NIOSH/MSHA certified dust mask and/or respirator where appropriate.

Protective Gloves:
rubber

Eye Protection:
chemical safety goggles

Other Protective Equipment:
neoprene protective type apron.

(Continued on next page)

ASTRO PRODUCT CODE # 25035

HANDLING OF SPILLS OR LEAKS---SECTION VI

Procedures for Clean-Up:
Sweep or scoop up using non-sparking equipment and place in double polyethylene bags. Isolate contaminated containers to a safe place for disposal.

Waste Disposal:
Dispose of in accordance with all applicable federal, state and local regulations.

SPECIAL PRECAUTIONS---SECTION VII

Precautions to be taken in handling and storage:
Avoid dusting. Under dusty conditions avoid all sources of ignition, including sparks and static electricity.

TRANSPORTATION DATA---SECTION VIII

D.O.T.: Not Regulated
Reportable Quantity: not applicable
Freight Classification: Metallic soaps of fatty acids
Special Transportation Notes:
none

ENVIRONMENTAL/SAFETY REGULATIONS---SECTION IX

Section 313 (Title III Superfund Amendment and Reauthorization Act):
This product does not contain any chemical subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

COMMENTS

PENNSYLVANIA WORKER AND COMMUNITY RIGHT TO KNOW ACT: This product does not contain any ingredient(s) listed in Appendix A Hazardous Substance List. This product contains the following ingredients at 3% concentration or greater:
calcium stearate 1592-23-0

(Continued on next page)

ASTRO PRODUCT CODE # 25035

WITCO MATERIAL SAFETY DATA SHEET

Calcium Stearate (All Grades) Product Code: 043 0250

(COMMENTS continued)

Prepared by: Charles Green
Title: Group Manager - Oleochemicals/Surfactants
Original Date:
Revision Date: 09/08/95
Supersedes: 06/01/92
Date Sent:

Sent to:

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage, or expense, direct or consequential, arising out of their use.

LETTER DESIGNATIONS OF PERSONAL PROTECTIVE EQUIPMENT	
Safety Glasses	A
Safety Glasses, Gloves	B
Safety Glasses, Gloves, Synthetic Apron	C
Face Shield, Gloves, Synthetic Apron	D
Safety Glasses, Gloves, Dust Respirator	E
Safety Glasses, Gloves, Synthetic Apron, Dust Respirator	F
Safety Glasses, Gloves, Vapor Respirator	G
Splash Goggles, Gloves, Synthetic Apron, Vapor Respirator	H
Safety Glasses, Gloves, Combination Dust and Vapor Respirator	I
Splash Goggles, Gloves, Synthetic Apron, Combination Dust and Vapor Respirator	J
Airline Hood or Mask, Gloves, Full Protective Suit, Boots	K
Situations Requiring Specialized Handling	X

American International Chemical, Inc.
17 Strathmore Road, Natick, MA 01760
(800) 238-0001 (508) 655-5805 **FAX** (508) 655-0927
Web Site: www.aicma.com **Email:** info@aicma.com

MATERIAL SAFETY DATA SHEET

CALCIUM STEARATE

SECTION 1 - CHEMICAL PRODUCT AND COMPANY INFORMATION

American International Chemical, Inc.	**Emergency Number: Chemtrec 800-424-9300**
17 Strathmore Road	
Natick, MA 01760	**Information Number: 800-238-0001**

Date: November 28, 1995

Synonyms: Stearic Acid, Calcium Salt

CAS #: 1592-23-0

DOT Hazard Class: Not Regulated

SECTION 2 - COMPOSITION AND INFORMATION ON INGREDIENTS

Calcium Stearate 99.0% min. TLV 10 mg/m^3

SECTION 3 - HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: White powder with a mild fatty odor. Dust can cause an explosion under certain conditions.

POTENTIAL HEALTH EFFECTS:
Eyes and Skin: May cause mild irritation.
Inhalation: May cause mild irritation to the upper respiratory tract.
Ingestion: May be harmful if swallowed in quantities.
CARCINOGENICITY: Not listed under OSHA, ACGIH.

SECTION 4 - FIRST AID MEASURES

Eyes: Flush immediately with plenty of water for at least 10 minutes.
Skin: Wash off with soap and water.
Inhalation: Remove to the fresh air.
Ingestion: Dilute with plenty of water.

With All Of The Above: Seek medical attention if symptoms persist.

SECTION 5 - FIRE FIGHTING MEASURES

Flash Point: > 500°F

Flammable Limits: Not Applicable

Extinguishing Media: Use media that is appropriate to treat surrounding fire.

Special Fire Fighting Procedures: Wear full protective clothing and NIOSH self breathing apparatus.

Unusual Fire Explosion Hazard: Dust explosions may occur under high concentrations in the presence of an ignition source.

Auto Ignition Temperature: Not Applicable

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Isolate hazard area and deny entry to unnecessary or unprotected personnel.
Contain spill, sweep up, collect and place in a disposal container. Avoid runoff into storm sewers and ditches which lead to waterways.

SECTION 7 - HANDLING AND STORAGE

Avoid contact with skin, eyes and clothing. Avoid breathing dust. Use normal personal hygiene and housekeeping. Store in cool dry area away from other incompatible materials. Avoid making a dust cloud in the presence of an ignition source.

SECTION 8 - EXPOSURE CONTROLS, PERSONAL PROTECTION

RESPIRATORY PROTECTION: Use NIOSH/MSHA approved respirators.

VENTILATION REQUIREMENTS: Ventilate as necessary to eliminate dust from the work area.

SKIN AND EYE PROTECTION:
Use rubber or neoprene gloves, chemical goggles and clothing sufficient to protect skin from dust.

WORK, HYGIENIC PRACTICES:
As required to protect skin and eyes from dust, safety showers and/or eye wash should be available. Do not leave food or smoke in work area. Wash thoroughly and remove or clean any contaminated clothing.

EXPOSURE LIMITS: None Established

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point: Not Applicable

Vapor Pressure (MM Hg): Not Applicable

Vapor Density (AIR=1): Not Applicable

Specific Gravity (H20=1): 1.0

Bulk Density: Not Available

Percent Volatile by Volume (%): Not Applicable

Melting Point: ~ 155°C or 311°F

Evaporation Rate (Butyl Acetate=1): Not Applicable

Solubility in Water: Negligible

pH: Not Applicable

SECTION 10 - STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable under normal temperatures and pressures.

HAZARDOUS POLYMERIZATION: Will not occur under normal conditions.

HAZARDOUS DECOMPOSITION PRODUCTS: Carbon Monoxide and Calcium Oxide.

KEEP AWAY FROM: Strong oxidizers.

SECTION 11 - TOXICOLOGICAL INFORMATION

Not Available

SECTION 12 - ECOLOGICAL INFORMATION

Not available

SECTION 13 - DISPOSAL CONSIDERATIONS

Dispose of in accordance with all federal, state and local regulations.

RCRA WASTE #: Not Listed

SECTION 14 - TRANSPORTATION INFORMATION

D.O.T. SHIPPING NAME:.....Calcium Stearate - Not Regulated

SECTION 15 - REGULATORY INFORMATION

TSCA (TOXIC SUBSTANCE CONTROL ACT):
This product is listed on the TSCA Inventory.

CERCLA REPORTABLE REQUIREMENTS: (RQ) None

SARA TITLE III INFORMATION:

Section 302 Extremely Hazardous Substance: Unlisted

Section 313 Toxic Chemicals: Unlisted

Section 311/312 Hazard Category: Fire hazard.

SECTION 16 - OTHER INFORMATION

Reason for Issue: New Form

This information is given without any warranty or representation. It is believed to be correct but does not claim to be all inclusive and shall be used only as a guide. American International Chemical, Inc., shall not be held liable for any damage resulting from handling or contact with the above product. It is offered solely for your consideration, investigation and verification.

ATTACHMENT 3

FROM: Journal Of The American College of Toxicology
Vol 1, No. 2 143-177, 1982

9

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
	Percentage composition	C = 73.92%, H = 12.06%, O = 10.94%, Al = 3.08%	10
Aluminum Tristearate $Al(C_{18}H_{35}O_2)_3$	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
	Percentage composition	C = 71.70%, H = 13.04%, N = 4.65%, O = 10.61%	4
Ammonium Stearate $CH_3(CH_2)_{16}COONH_4$	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
	Percentage composition	C = 71.23%, H = 11.62%, Ca = 6.60%, O = 10.54%	10
Calcium Stearate $Ca(C_{18}H_{35}O_2)_2$	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
	Molecular weight	290.41	11
Lithium Stearate $LiC_{18}H_{35}O_2$	Melting point	108°C	7
		220°–221°C	6,8,11
	Specific gravity	1.025	16
	Percentage composition	C = 73.13%, H = 11.93%, Mg = 4.11%, O = 10.82%	10
Magnesium Stearate $Mg(C_{18}H_{35}O_2)_2$	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
	Molecular weight	322.58	11
Potassium Stearate $C_{17}H_{35}COOK$	Molecular weight	306.47	11
Sodium Stearate $NaOOC_{17}H_{35}$	Iodine value of fatty acids	"not more than 4"	9,17
	Acid value of 1 g of fatty acids	196–211	9,17
	Percentage composition	C = 68.38%, H = 11.16%, O = 10.12%, Zn = 10.34%	10
Zinc Stearate $Zn(C_{18}H_{35}O_2)_2$	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.[3,9-11,17]

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 ≥ 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
Tonics, dressings, and other hair grooming aids	>1–5	1
Hair bleaches	>1–5	2
Blushers (all types)	>0.1–1	2
	>1–5	1
Lipstick	≤0.1	1
Makeup bases	>1–5	9
	≤0.1	1
Other personal cleanliness products	>0.1–1	11
	Total	1
		19
		1
		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
Other bath preparations	>1–5	2
Eyeliner	>1–5	1
Eyeshadow	>5–10	2
	>10–25	1
	>5–10	30
	>1–5	25
	>0.1–1	1
	>0.1–1	1
Mascara	>0.1–1	4
Other fragrance preparations	>0.1–1	2
Shampoos	>5–10	1
Blushers	>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
Cleansing (cold creams, cleansing lotions, liquids, and pads)	>10–25	1
	≤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
	≤0.1	1
Blushers (all types)	>1–5	2
Face powders	>0.1–1	3
Foundations	≤0.1	24
	>10–25	9
Eyeshadow	>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.[8,33]

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 eyeshadow 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]

Substance	*Numbers of Mice*[b]			Tumor incidence (%)
	Surviving 30 wks	w/adenoma or papilloma	w/carcinoma	
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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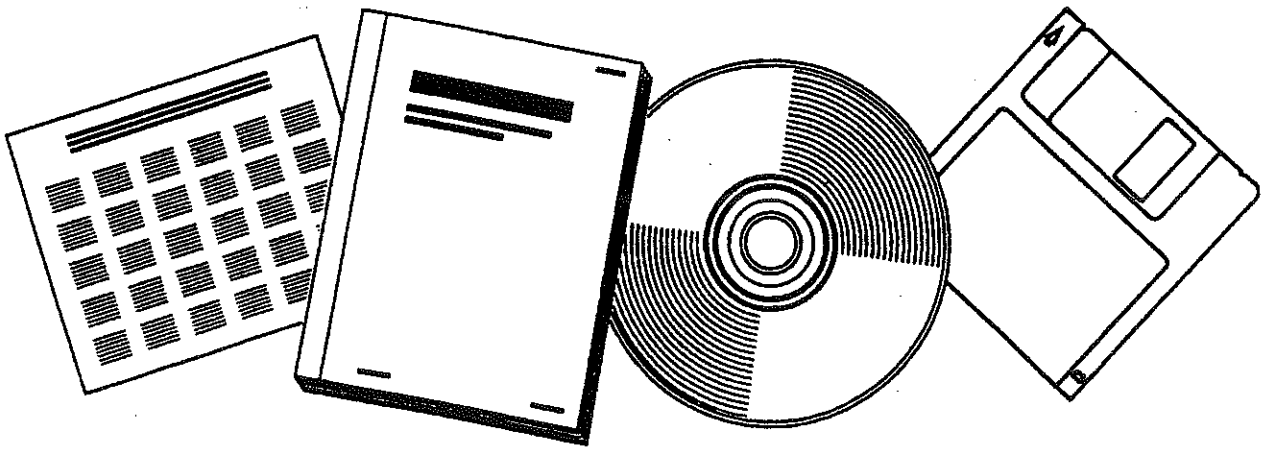
ATTACHMENT 4

PB262661

EVALUATION OF THE HEALTH ASPECTS OF TALLOW, HYDROGENATED TALLOW, STEARIC ACID, AND CALCIUM STEARATE AS FOOD INGREDIENTS

FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY, BETHESDA, MD. LIFE SCIENCES RESEARCH OFFICE

1975



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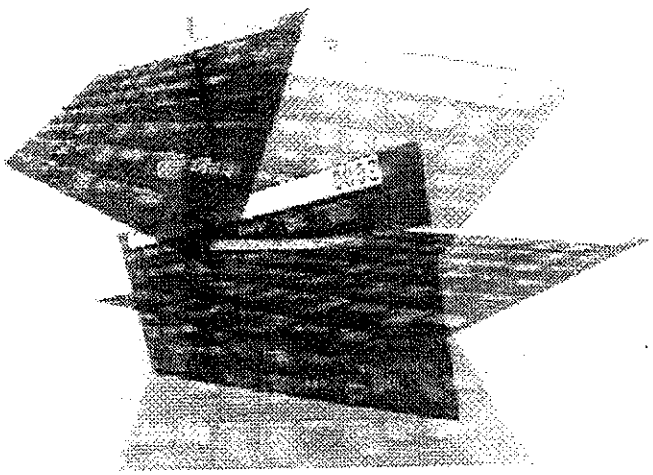

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SCOGS-54

EVALUATION OF THE HEALTH ASPECTS OF TALLOW, HYDROGENATED TALLOW, STEARIC ACID, AND CALCIUM STEARATE AS FOOD INGREDIENTS

1975

Prepared for

Bureau of Foods
Food and Drug Administration
Department of Health, Education, and Welfare
Washington, D. C.

Contract No. FDA 223-75-2004

LIFE SCIENCES RESEARCH OFFICE
FEDERATION OF AMERICAN SOCIETIES
FOR EXPERIMENTAL BIOLOGY
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15. Supplementary Notes

16. Abstracts

This report by a group of qualified scientists, designated the Select Committee on GRAS Substances (SCOGS), provides an independent evaluation on the safety of Tallow, Hydrogenated Tallow, Stearic Acid, and Calcium Stearate in food at its present or projected levels of use.

17. Key Words and Document Analysis. 17a. Descriptors

17b. Identifiers/Open-Ended Terms

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William L. Jackson DATE 1/13/77

WILLIAM L. JACKSON
DIRECTOR, FDA/PRDC (NTIS)

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NOTICE

This report is one of a series of evaluations of the health aspects of the Generally Recognized as Safe (GRAS) or prior sanctioned food substances being made by the Federation of American Societies for Experimental Biology (FASEB) under contract no. 223-75-2004 with the Food and Drug Administration (FDA), U.S. Department of Health, Education, and Welfare. The Federation recognizes that the safety of GRAS substances is of national significance, and that its resources are particularly suited to marshalling the opinions of knowledgeable scientists to assist in these evaluations. The Life Sciences Research Office (LSRO), established by FASEB in 1962 to make scientific assessments in the biomedical sciences, is conducting these studies.

Qualified scientists were selected as consultants to review and evaluate the available information on each of the GRAS substances. These scientists, designated the Select Committee on GRAS Substances, were chosen for their experience and judgment with due consideration for balance and breadth in the appropriate professional disciplines. The Select Committee's evaluations are being made independently of FDA or any other group, governmental or nongovernmental. The Select Committee accepts responsibility for the content of each report. Members of the Select Committee who have contributed to this report are named in Section VII.

Tentative reports are made available to the public for review in the Office of the Hearing Clerk, Food and Drug Administration, after announcement in the Federal Register, and opportunity is provided for any interested person to appear before the Select Committee at a public hearing to make oral presentation of data, information, and views on the substances covered by the report. The data, information, and views presented at the hearing are considered by the Select Committee in reaching its final conclusions. Reports are approved by the Select Committee and the Director of LSRO, and subsequently reviewed and approved by the LSRO Advisory Committee (which consists of representatives of each constituent society of FASEB) under authority delegated by the Executive Committee of the Federation Board. Upon completion of these review procedures the reports are approved and transmitted to FDA by the Executive Director of FASEB.

While this is a report of the Federation of American Societies for Experimental Biology, it does not necessarily reflect the opinion of all of the individual members of its constituent societies.

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CONTENTS

I. INTRODUCTION

This report concerns the health aspects of using tallow, hydrogenated tallow (including tallow flakes), stearic acid and calcium stearate as food ingredients. It has been based partly on the information contained in a scientific literature review (monograph) furnished by FDA (1), which summarizes the world's scientific literature from 1920 through 1972.* To assure completeness and currency as of the date of this report this information has been supplemented by searches of over 30 scientific and statistical reference sources and compendia that are generally available; use of new, relevant books and reviews and the literature citations contained in them; consideration of current literature citations obtained through computer retrieval systems of the National Library of Medicine; searches for relevant data in the files of FDA; and by the combined knowledge and experience of members of the Select Committee and the LSRO staff. In addition, an announcement was made in the Federal Register of February 10, 1976 (41 FR 5862 and 5863) that opportunity would be provided for any interested person to appear before the Select Committee at a public hearing to make oral presentation of data, information and views on the health aspects of using tallow, hydrogenated tallow, stearic acid and calcium stearate as food ingredients. The Select Committee received no requests for such a hearing on tallow, hydrogenated tallow, stearic acid and calcium stearate as food ingredients.

As indicated in the Food, Drug, and Cosmetic Act [21 USC 321(s)], GRAS substances are exempt from the premarketing clearance that is required for food additives. It is stated in the Code of Federal Regulations 21 CFR 121.1, revised April 1, 1975, that GRAS means general recognition of safety by experts qualified by scientific training and experience to evaluate the safety of substances on the basis of scientific data derived from published literature. This section of the Code also indicates that expert judgment is to be based on the evaluation of results of credible toxicological testing or, for those substances used in food prior to January 1, 1958, on a reasoned judgment founded in experience with common food use, and is to take into account reasonably anticipated patterns of consumption, cumulative effects in the diet, and safety factors appropriate for the utilization of animal experimentation data. FDA recognizes further (21 CFR 121.3) that it is impossible to provide assurance that any substance is absolutely safe for human consumption.

The Select Committee on GRAS Substances of LSRO is making its evaluations of these substances in full recognition of the foregoing provisions. In reachings its conclusions on safety the Select Committee, in accordance with FDA's guidelines, is relying primarily on the absence of substantive evidence of, or reasonable grounds to suspect, a significant

*The document (PB-223 859/0) is available from the National Technical Information Service, U.S. Department of Commerce, P.O. Box 1553, Springfield, Virginia 22161.

risk to the public health. While the Select Committee realizes that a conclusion based on such reasoned judgment is expected even in instances where the available information is qualitatively or quantitatively limited, it recognizes that there can be instances where, in the judgment of the Select Committee, there are insufficient data upon which to base a conclusion. The Select Committee, aware that biological testing is dynamic, bases its conclusions on information now available; it cannot anticipate the results of experiments not yet conducted or those of tests that may be reconducted, using new technologies. These conclusions will need to be reviewed as new or better information becomes available.

In this context, the LSRO Select Committee on GRAS Substances has reviewed the available information on tallow, hydrogenated tallow (including tallow flakes), stearic acid and calcium stearate and submits its interpretation and assessment in this report, which is intended for the use of FDA in determining the future status of these substances under the Federal Food, Drug, and Cosmetic Act.

II. BACKGROUND INFORMATION

In North America, tallow generally refers to fat rendered from cattle and sheep tissues; thus, in unrefined animal fat it is a natural constituent of foods. The major constituents of tallow are glycerides of oleic acid (36 to 50 percent), palmitic acid (23 to 37 percent), stearic acid (6.0 to 20 percent), myristic acid (1.0 to 8.0 percent), palmitoleic acid (1.5 to 6.0 percent) and linoleic acid (0.5 to 5.0 percent). Minor constituents include arachidic, linolenic and eicosenoic acids (2).

In hydrogenated tallow the content of oleic, linoleic and other unsaturated acids has been reduced by addition of hydrogen to the double bonds of these glyceridic acids. Tallow flakes are fully hydrogenated tallow in flaked form (3).

Stearic acid, or n-octadecanoic acid, $CH_3(CH_2)_{16}COOH$, is naturally present in the glycerides of animal fats and most vegetable oils. Some is produced commercially by the hydrogenation of the unsaturated 18-carbon fatty acids of soybean or other vegetable oils. When obtained from animal fats by hydrolysis and fractional crystallization, commercial stearic acid is a mixture of solid organic acids, chiefly palmitic and stearic acids. Commercial products containing about 90 percent stearic acid are produced by the hydrolysis and crystallization of a completely hydrogenated vegetable oil or by the fractional distillation of fatty acid mixtures obtained from tallow (4). The Food Chemicals Codex (5) specifies acid, iodine and saponification values and solidification point range for food grade stearic acid and permits not more than 3 ppm of arsenic and 10 ppm of heavy metals (as lead).

Calcium stearate is a compound of calcium with variable proportions of stearic and palmitic acids. It is insoluble in water, in alcohol and ether. Food Chemicals Codex provides specifications for the food grade product (6).

Stearic acid, beef tallow, hydrogenated tallow, and tallow flakes appear in the FDA GRAS list among substances migrating to food from cotton and cotton fabrics used in dry food packaging [21 CFR 121.101(i)] (7). Calcium stearate is included on a partial listing of substances presumed to be GRAS by FDA but not published (8). Stearic acid also is included among regulated additives that are permitted in food (21 CFR 121.1070) with the provisos that it should contain not over 2 percent unsaponifiable matter, should contain no chick-edema factor, and should be used with suitable labeling as a lubricant, binder, or defoaming agent in accordance with good manufacturing practice, or as a component of other food-grade additives (7). Tallow and hydrogenated tallow are regulated additives permitted as components of paper and paperboard in contact with aqueous and fatty foods (21 CFR 121.2526); beef tallow and fatty acids derived therefrom as defoaming agents in the manufacture of paper and paperboard for use in packaging, transporting and holding food (21 CFR 121.2519); hydrogenated tallow, fatty acids and calcium stearate as components of defoaming agents in the processing of beet sugar and yeast (21 CFR 121.1099); and calcium stearate and the aluminum, magnesium, potassium, and sodium salts of stearic acid conforming with 21 CFR 121.1070 are regulated additives permitted for use as binders, emulsifiers, or anticaking agents in food (21 CFR 121.1071)(7).

The present report concerns the health aspects of tallow, tallow flakes, hydrogenated tallow, and stearic acid only in their GRAS listing as used in cotton food packaging, and calcium stearate as a general purpose food additive.

III. CONSUMER EXPOSURE DATA

Stearic acid is regularly consumed as a glyceride component of the fat in meat, table spreads, and other foods. Tallow is eaten as a constituent of the fat in beef and as an ingredient in oleomargarine and shortening. In 1972, 495 million pounds (220 million kg) of tallow were used in the manufacture of shortening and 10 million pounds (4.5 million kg) in the manufacture of oleomargarine (9). Daily per capita intake of these products would provide approximately 30 grams of tallow containing about 4 grams stearic acid. No data are available on the use of tallow flakes in food or on the intake of stearic acid, tallow or tallow flakes from the consumption of foods packaged in cotton fabrics containing these products. However, for comparative purposes a survey of the food industry by a National Research Council (NRC) subcommittee (10), indicated 26,198 kg of stearic acid were used by the food industry in 1970. Although the NRC survey questionnaire did not request information on stearic acid, three or fewer companies volunteered information on the poundage they used in 1970. Based on a U.S. population of 205 million, this quantity would provide 0.35 mg stearic acid per capita daily. It is the opinion of the Select

Committee, however, that the daily intake of stearic acid, tallow or hydrogenated tallow from that which may migrate to food from packaging materials is small in comparison to the intake of these substances from meat, margarine, and shortening.

The NRC subcommittee survey of the food industry indicated 280,000 kg of calcium stearate were used in 1970 (10). This was 2.8 times that used in 1960 based on reports of those respondents who submitted information for both 1960 and 1970. Reported functions of calcium stearate in food products were as an emulsifier, flavoring agent adjuvant, formulation aid, lubricant and stabilizer or thickener. Table I lists the level of addition of calcium stearate to foods in several food categories. Based on information supplied by those manufacturers who reported adding calcium stearate to at least one food in a category, the NRC subcommittee calculated a weighted mean for the usual addition level of this substance to food products in each category.

TABLE I

Level of Addition of Calcium Stearate to Foods by Food Category (10)

Food category	Weighted mean percent
Baked goods, baking mixes	1.03
Fats and oils	0.06
Meat products	0.02
Poultry products	0.02
Eggs, egg products	0.02
Fish products	0.02
Soft candy	0.92
Soups, soup mixes	0.02
Snack foods	0.02
Gravies, sauces	0.03
Hard candy	0.08
Chewing gum	***
Seasoning and flavors	0.64

Asterisks (***) in the table mean that there were insufficient data on which to base an estimate. Level of addition of calcium stearate is the weighted mean of the levels reported by manufacturers as their usual addition to one or more products in a food category. For discussion of weighted mean see Section X and Exhibit 50 of reference 10.

The NRC subcommittee estimated possible average daily intakes of calcium stearate (Table II) from Market Research Corporation of America data on mean frequency of eating foods by food category, U.S. Department of Agriculture data on mean portion size of foods in these categories, and the assumption that all foods within a category contained the substance at the levels shown in Table I. Such an assumption is likely to lead to overestimation of intake. The NRC subcommittee has recognized that in most cases its calculations of possible intake are overstated, often by considerable margins.*

TABLE II

Possible Average Daily Intake of Added Calcium Stearate by Age Group (10)

Age group	Intake mg
0-5 mo	38
6-11 mo	290
12-23 mo	610
2-65+ yr	1500

Because of factors detailed in Section XI of the NRC report (10), the subcommittee stated that the possible average estimated dietary intakes (Table II) are likely to be much higher than would the intake achieved through consumption of a diet consisting totally of processed foods to which the substance had been added at maximum levels reported. That the values in Table II are probably generous overestimates of intake is indicated by computation of per capita daily intake, 4 mg, from the estimated food industry usage (280,000 kg) of calcium stearate in 1970 and a U.S. population of 205 million. The Select Committee considers the latter value as a more realistic estimate of the intake of calcium stearate by the 2 to 65+ year age group.

*An explanation for such overstatements is detailed in Section XI, "Significance and Use of Data in Safety Evaluations," of the NRC subcommittee report (10). The Select Committee finds this explanation reasonable and concurs in the first recommendation of Section XII of the same report that "In order to conduct a more accurate survey on the intake of substances used in food processing, food consumption data collected specifically for this purpose are needed."

IV. BIOLOGICAL STUDIES

Absorption, metabolism, excretion

Several studies have been reported in the literature on the use of tallow in animal feed, especially for poultry. Depending upon the age of the chicken, feeding tests have suggested that about one-half to four-fifths of the tallow is absorbed (11-14). When chicks were fed 10 to 20 percent beef tallow (estimated to be 12.5 to 25 g per kg body weight) in the diet, the apparent absorbability increased from about 53 percent at 1 week of age to about 76 percent at 12 weeks (11). Similar results were obtained in another test involving chicks on diets containing 21.7 percent tallow (12). Absorbability of beef tallow increased from 70 percent at 2 weeks to 80 percent in 8-week-old chicks. At 8 weeks, chicks were able to utilize tallow as well as adult hens. The metabolizable energy for tallow was found to be 6.56 to 7.32 kcal per g in 2- to 8-week-old chicks (12, 14).

Digestibility of hydrogenated animal fat, m.p. 55 °C, fed at 12 percent level in the diet of chicks was 44 percent for one sample and 23 percent for another as determined after feeding for 2 to 4 weeks (13).

The digestibility of tallow was 87.6 percent when fed to calves at a level of 5 percent in an all-concentrate diet. When hay was added so that the proportion of hay to concentrates containing 5 percent tallow was 1:2, the digestibility of the tallow increased to 90.5 percent (15). In 60-pound pigs fed 5 percent beef tallow in a barley-soy meal ration, apparent digestibility of tallow was 65 percent (16). Apparent digestiblity of tallow was 47 percent in pigs 2 to 3 weeks old fed 10 percent tallow in a basal ration consisting of corn starch, dextrose, and soy protein concentrate plus vitamin and mineral supplements (17).

In contrast to tallow, the digestibility of stearic acid is quite low. It was reported as zero for stearic acid, 90 percent purity, in 3- to 4- week-old chicks (18), 31 percent (apparent digestiblity) for 70 percent purity stearic acid in 60-pound pigs (16), and 9.4 to 21 percent for rats fed a diet supplemented with 5 percent stearic acid-olive oil mixtures containing 5 and 15 percent stearic acid, respectively (19). Bayley and Lewis (16) found no significant difference in digestibility between stearic acid in the free form and as tristearin in the pig but Carroll and Richards (20) reported that tristearin was less well digested than free stearic acid in the rat. It has been suggested that the apparent low digestiblity of stearic acid and the apparent high digestibility of oleic and linoleic acids when present together in a diet may result from the hydrogenating activity of the microflora in the lower digestive system which converts unsaturated acids to stearic acid rather than the relative absorbability of fatty acids in the intestines (17).

The digestibility of stearic acid fed to adult female rats as a mixture of calcium stearate and the free acid was less than when fed as the free acid in semi-synthetic rations. Digestibility was 9.5 percent for stearic acid in a ration containing 10.47 percent calcium stearate and 5.21 percent stearic acid (equivalent to 14.94 percent stearic acid) as compared to 15.8 percent digestibility in a ration containing 15 percent stearic acid and free of both calcium and magnesium. Inclusion of the Osborne-Mendel salt mixture in the stearic acid ration to provide 0.6 percent calcium and 0.09 percent magnesium reduced the digestibility to 14.4 percent suggesting interaction of these minerals with stearic acid during digestion. Fecal fat excreted in the form of soaps was greater for the rations containing calcium than for the calcium-free ration (21).

In man, after ingestion, fat glycerides separate in the intestine into two phases: one is an oil phase containing diglycerides, triglycerides, and some fatty acids; the other is a micellar phase consisting of bile salts, free fatty acids, and monoglycerides. The monoglycerides and free fatty acids from the micellar solutions are absorbed through the intestinal wall, leaving the bile salts within the intestinal lumen to form additional micelles. In rats, free fatty acids of less than 12 carbon atoms in length are preferentially absorbed directly into the portal blood (19). The longer chain fatty acids are primarily incorporated into triglycerides and appear in lymph chylomicrons (22).

Fatty acids can be both lengthened and shortened during metabolism. When labeled palmitic acid is fed to rats, appreciable amounts of the tagged carbon are found in the stearic and myristic acids of the body. Conversely, when labeled stearic acid is fed, labeled carbon is found in the palmitic acid fraction. It is also found in oleic acid (23).

There is some evidence that tallow and stearic acid may be thrombogenic when included in hyperlipemic diets of rats. Stearic acid fed at 3 to 6 percent in such diets exerted strong thrombotic and atherogenic effects. Bovine tallow was relatively less thrombogenic (24-26).

The Select Committee is aware of the concern over the role of saturated versus polyunsaturated fatty acids in the etiology of arteriosclerosis and associated vascular diseases. There is no consensus on this point. Nutrition is considered only one of the risk factors of this complex of diseases; a cause and effect relationship is not clearly established. While it is reasonable for some physicians and nutrition scientists to recommend curtailment of fat intake and control over the type of fatty acids ingested, the present state of knowledge is such that the term "toxicity" is not appropriate in describing the relationship between saturated fatty

acids and arteriosclerosis or cardiovascular disease.

The status of knowledge has been interpreted in a joint statement of the Food and Nutrition Board, National Academy of Sciences, National Research Council, and the Council on Foods and Nutrition of the American Medical Association which states that "In 'risk categories' it is important to decrease substantially the intake of saturated fat and to lower cholesterol consumption. In practice this entails substituting polyunsaturated vegetable oils for part of the saturated fat in the diet" (27). This issue has been reviewed by Reiser (28) and a vigorous challenge has been made by Keys et al. (29). These opposing views from responsible investigators reflect the difference in interpretation of present knowledge.

Short-term studies

The LD_{50} of a stearic acid emulsion was 23 mg per kg body weight when it was injected intravenously into mice (30).

Day-old chicks were fed 5 percent prime tallow, No. 1 tallow, hydrogenated fat or stearic acid in the diet for 4 weeks. This is estimated to be about 6 g of these substances per kg body weight per day. No deleterious effects were noted. Feed utilization was improved by tallow, but not by hydrogenated fat or stearic acid (31). Newly hatched cockerels were fed diets containing 5 percent tallow for 12 weeks; there was no effect on growth rate, but feed conversion when measured as pounds of feed consumed per pound of gain was improved over that of controls (32).

Chicks were fed from 1 day to 8 weeks of age on rations containing 4 or 8 percent of animal tallow. At 8 weeks, the consumption of tallow was approximately 1.5 g and 3 g per kg body weight per day respectively, for the 4 percent and 8 percent dietary levels. Increased weight gain and feed efficiency were observed at the 8 percent level but not at the 4 percent level (33).

Groups of 25 one-week-old chicks were fed for 9 weeks on diets containing 7, 11, and 15 percent tallow; at the end of this time they were consuming about 5.9, 9.3, and 12.7 g per kg body weight per day, respectively. Tallow increased the feed efficiency but did not affect the rate of growth (34).

A few reports of short-term feeding studies have been published in which dogs, pigs, and rats were the experimental animals. Anorexia, constipation, listlessness and fever were observed in dogs given 5 percent stearic acid in the diet (35).

Feeding beef tallow at a level of 15 percent of the diet to miniature pigs for a year significantly decreased the blood clotting time as compared

to pigs fed 15 percent safflower oil in the same basal diet. The maximum effect on blood clotting occurred 3 hours after feeding (36).

When rats were kept on a diet containing 0.3 percent stearic acid for 209 days, anorexia, severe pulmonary infections, and high mortality were observed. The mean survival time of five male rats, which consumed an average of about 15 g of the diet per day including about 45 mg stearic acid (about 0.3 g per kg body weight) was 107 days. That of five female rats, which consumed an average of about 13.5 g of the diet per day including about 41 mg stearic acid, was 127 days. No gross or microscopic pathological lesions attributable to the stearic acid were found (37). Pulmonary infections also occurred in rats fed octadecylamine in concurrent experiments and it is unlikely that these infections and high mortality rates were associated with stearic acid in the diet.

When half of the total food given to young white rats consisted of stearic acid (about 50 g per kg of body weight) with the other half as casein, glucose, cellulose, and salt and vitamin mixtures, the males died within an average of 8.2 days and the females after 10.2 days. Death was considerably delayed when the stearic acid was reduced to three-tenths of the initial dose. When as little as 5 percent corn oil was added to the diet, the deleterious effects of the high concentrations of stearic acid were markedly reduced (38).

Male and female weanling rats were fed a diet containing 50 percent stearic acid (about 50 g per kg of body weight at start of the experiment) for 8 weeks. Microscopic examination of their fatty tissues showed a foreign body reaction. The lesion was usually located within the fat cell membrane. No evidence of acute inflammatory reactions, hemorrhages, or birefringent material was noted. No foreign body reactions were observed in the controls whose diets contained 50 percent lard (39).

Long-term studies

No long-term animal studies on the feeding of tallow, hydrogenated tallow, stearic acid or calcium stearate were available to the Select Committee.

Special studies

In a carcinogenicity test, 92 mice divided into seven test groups of 10 to 16, received subcutaneous injections of 0, 0.05, 0.5, and 1.0 mg of stearic acid (estimated to be 2.5, 25, and 50 mg per kg body weight per day) once, twice, or three times weekly. The number of injections per test group varied from 26 to 114. Only one group of 10 mice developed four subcutaneous sarcomas in the 18-month experimental period, as compared to one sarcoma in one of the control groups. This reacting treatment group had been given 0.05 mg twice a week for a total of 114 injections. No mouse in the other six groups developed any sarcomas, 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. There was no explanation for the apparently anomalous finding of four sarcomas in the one test group (40).

To clarify the picture, the investigators conducted a joint study with another laboratory. Stearic acid was tested for carcinogenicity in mice, again by subcutaneous injections once weekly for 26 weeks at concentrations of 0.05 to 0.5 mg. No sarcomas were observed at the site of injection. The authors concluded that stearic acid was noncarcinogenic under the conditions of their tests (41).

Other tests on carcinogenicity also were negative. No tumors were found in ten rats fed 0.3 percent of stearic acid in the basal diet for 209 days (37).

A recent epidemiological study suggests an association between colon cancer and saturated fat and cholesterol in the diet, but the authors caution against incrimination of particular dietary factors until further studies are conducted (42).

No reports have been found on the mutagenicity and teratogenicity of tallow, hydrogenated tallow, stearic acid or calcium stearate or on the carcinogenicity of tallow, hydrogenated tallow and calcium stearate.

The Joint FAO/WHO Expert Committee on Food Additives considered salts of myristic, palmitic and stearic acids (including calcium salts) to be equivalent to normal products of digestion of fats with cations that are normally encountered in the diet; consequently the Joint Committee considered it unnecessary to establish an acceptable daily intake (43).

V. OPINION

Tallow and stearic acid, one of its chemical components, are consumed as part of normal human diets primarily in meats and in smaller quantities as ingredients of shortening and oleomargarine. Calcium stearate appears to be a normal product of digestion of diets containing calcium and stearic acid. Hydrogenated tallow, including tallow flakes, is used to some extent in the manufacture of shortening.

Feeding tests with animals show a high utilization of tallow as an energy source, but a relatively low digestibility of hydrogenated tallow, stearic acid, and calcium stearate. None of the feeding tests involving amounts of these substances comparable to those estimated to be consumed as food additives showed any toxic effects. Furthermore, the toxicity of stearic acid at very high concentrations is markedly reduced by the presence in the diet of glycerides of substantially lower melting point, such as those containing unsaturated fatty acids. Carcinogenicity tests of stearic acid have shown negative results.

This report is directed toward the GRAS status of tallow, hydrogenated tallow, and stearic acid as given in the Code of Federal Regulations 121.101(i) as substances migrating to food from cotton and cotton fabrics used in dry food packaging and calcium stearate as a GRAS substance (unpublished). Even at the levels estimated as being consumed by man from all added sources of these substances there is no evidence to demonstrate a hazard to the public.

In light of these observations, the Select Committee concludes that:

> As substances that may migrate to foods from cotton or cotton fabrics, there is no evidence in the available information on tallow, hydrogenated tallow, or stearic acid that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public, when they are used at levels that are now current or that might reasonably be expected in the future.
>
> There is no evidence in the available information on calcium stearate that demonstrates, or suggests reasonable grounds to suspect a hazard to the public, when it is used as a direct food additive at levels that are now current or that might reasonably be expected in the future.

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