

Scientific Documentation

Calcium Stearate, NF

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



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Specification for Calcium Stearate, NF (CA169)

Item Number	CA169
Item	Calcium Stearate, NF
CAS Number	1592-23-0
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Octadecanoic Acid Calcium Salt

Test	Specification	
	Min	Max
CALCIUM (DRIED BASIS)	6.4	7.4 %
STEARIC ACID AND PALMITIC ACID	90.0 %	
STEARIC ACID	40.0 %	
LOSS ON DRYING		4.0 %
ELEMENTAL IMPURITIES:		
LEAD (Pb)	AS REPORTED	
NICKEL (Ni)	AS REPORTED	
COPPER (Cu)	AS REPORTED	
CHROMIUM (Cr)	AS REPORTED	
IDENTIFICATION (A)	POSITIVE FOR CALCIUM	
IDENTIFICATION (B)	RETENTION TIMES CORRESPOND TO STANDARD	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	
MONOGRAPH EDITION		

Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave.
New Brunswick, NJ 08901

West Coast Facility: 14422 S. San Pedro St.
Gardena, CA 90248

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:

732.214.1300

310.516.8000

Certificate Of Analysis

Item Number	CA169	Lot Number	1NC0122
Item	Calcium Stearate, NF	CAS Number	1592-23-0

TEST	SPECIFICATION		RESULT
	MIN	MAX	
CALCIUM (DRIED BASIS)	6.4	7.4 %	7.2 %
STEARIC ACID AND PALMITIC ACID	90.0 %		98.22 %
STEARIC ACID	40.0 %		54.35 %
LOSS ON DRYING		4.0 %	3.2 %
ELEMENTAL IMPURITIES:			.
LEAD (Pb)	AS REPORTED		<2 µg/g
NICKEL (Ni)	AS REPORTED		<1 µg/g
COPPER (Cu)	AS REPORTED		<1 µg/g
CHROMIUM (Cr)	AS REPORTED		<5 µg/g
IDENTIFICATION (A)	POSITIVE FOR CALCIUM		POSITIVE FOR CALCIUM
IDENTIFICATION (B)	RETENTION TIMES CORRESPOND TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
EXPIRATION DATE			12-APR-2026
DATE OF MANUFACTURE			12-APR-2023
APPEARANCE			FINE WHITE POWDER
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT
MONOGRAPH EDITION			(USP-NF) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
25-APR-24 09:12:03

Certificate of Analysis Results Approved By:

SHANSEN
Selin Hansen
26-APR-24 08:45:01

Spectrum Chemical Mfg Corp
14422 South San Pedro Street
Gardena 90248 CA



All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

SAFETY DATA SHEET

Preparation Date: 1/24/2014

Revision date 11/6/2019

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: CA169
Product Name: CALCIUM STEARATE, NF

Other means of identification

Synonyms: Octadecanoic Acid, Calcium Salt
 Calcium distearate
 Calstar
CAS #: 1592-23-0
RTECS # WI3000000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Anti-caking or conditioning agent in certain food products. Water repellent/Waterproofing. Mold release agent.

Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Tom Tyner (USA - West Coast)

Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Not classified

Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Product code: CA169

Product name: CALCIUM
 STEARATE, NF

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Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Calcium Stearate	1592-23-0	100

4. FIRST AID MEASURES

First aid measures

General Advice:	National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.
Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.
Eye Contact:	Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
Inhalation:	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms	May cause eye/skin irritation
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Indication of any immediate medical attention and special treatment needed

Notes to Physician:	Treat symptomatically.
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Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media:	Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.
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Unsuitable Extinguishing Media:	No information available.
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Specific hazards arising from the chemical

Hazardous combustion products	Carbon Monoxide, Carbon Dioxide. Calcium oxides.
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Specific hazards	May be combustible at high temperatures.
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Special Protective Actions for Firefighters

Specific Methods:

No information available

Special Protective Equipment for Firefighters:

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures****Personal Precautions:**

Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Remove all sources of ignition.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

Methods and material for containment and cleaning up**Methods for containment**

Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up

Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE**Precautions for safe handling****Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice:

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities**Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:

Acids
Alkalis
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Control parameters****National occupational exposure limits****United States**

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Calcium Stearate	1592-23-0	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Calcium Stearate	1592-23-0	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Calcium Stearate	1592-23-0	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Safety glasses with side-shields. or Goggles
Skin and body protection:	Long sleeved clothing Chemical resistant apron Gloves
Respiratory protection:	Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
Hygiene measures:	Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Powder.	Color: White. Off-white. Yellowish White.
Odor: No information available.	Taste No information available.	Formula No information available
Molecular/Formula weight (g/mole): No information available	Flammability (solid, gas) no data available	Flashpoint (°C/°F): No information available
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 140-179 °C/284-354.2 °F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F):		

No information available

Bulk density:
No information available

Density (g/cm³):
No information available

Specific gravity:
No information available

pH
No information available

Vapor pressure @ 20°C (kPa):
No information available

Evaporation rate:
No information available

Vapor density:
No information available

VOC content (g/L):
No information available

Odor threshold (ppm):
No information available

**Partition coefficient
(n-octanol/water):**
No information available

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Very slightly soluble in water
Solubility in Water: 17% at 10°C; 23%
at 20°C; 28% at 37°C
Insoluble in Ether
Insoluble in Alcohol

10. STABILITY AND REACTIVITY

Reactivity

Reactive with acids
Reactive with alkalis
Reactive with oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Incompatible materials.

Incompatible Materials: Acids
Alkalis
Strong oxidizing agents

Hazardous decomposition products: Carbon monoxide. Carbon dioxide. Calcium oxides. When heated to decomposition it emits acrid smoke and irritating fumes.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion. Inhalation.

Acute Toxicity

Component Information

Product code: CA169

Product name: CALCIUM
STEARATE, NF

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Calcium Stearate	
CAS No	1592-23-0

LD50/oral/rat = > 10 g/kg Oral LD50 Rat
LD50/oral/mouse = >10000 mg/kg
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
Value - Acute Toxicity = > 10000 mg/kg

LD50/oral/mouse =
Value - Acute Tox = >10000 mg/kg

LD50/dermal/rabbit
Value - Acute Toxicity = No information available

LD50/dermal/rat
VALUE - Acute Tox = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact:	May cause skin irritation.
Eye Contact:	May cause eye irritation.
Inhalation	May cause irritation of respiratory tract. Symptoms may include coughing and sneezing.
Ingestion	Health injuries are not known or expected under normal use. Not expected to be a health hazard.
Aspiration hazard	No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity	No information available.
Sensitization:	No information available.
Mutagenic Effects:	No information available

Carcinogenic effects: No information available.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Calcium Stearate	1592-23-0	Not listed	A4 - Not Classifiable as a Human Carcinogen by ACGIH (for stearates)	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity No data is available

Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.
STOT - repeated exposure No information available.
Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility in soil No information available
Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Calcium Stearate	1592-23-0	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class No information available
Subsidiary Class No information available
Packing group: No information available
Emergency Response Guide Number No information available
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions No Information available
Symbol(s): No information available
Description: No information available

TDG (Canada)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No Information available
Description: No information available

ADR

UN Number Not regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Packing group No information available
Subsidiary Risk: No information available

IMDG

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No information available

RID

UN Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available

ICAO (air)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class No information available
Subsidiary Risk: No information available
Packing Group: No information available

IATA

UN Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available
Precautionary Statements - Response No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
Calcium Stearate	1592-23-0	PresentACTIVE	Present KE-26347	Present	Present (9)-1677,(2)-611	Present	Present	Present 216-472-8

U.S. Regulations*Calcium Stearate*

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1229

FDA - Direct Food Additives 21 CFR 173.340

FDA - 21 CFR - Total Food Additives 169.179, 172.863, 173.340, 175.300, 177.2410, 177.2600, 178.1010, 178.2010, 179.45,

- List Sourced from EAFUS 181.29, 184.1229

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.**Chemicals Known to the State of California to Cause Cancer:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Calcium Stearate	1592-23-0	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Calcium Stearate	1592-23-0	None	None	None	None	None

U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Calcium Stearate	1592-23-0	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

Not a dangerous product according to HPR classification criteria.

Component
Calcium Stearate
1592-23-0 (100)

WHMIS 2015 Hazard Classification
Combustible Dust - Category 1: May form combustible dust concentrations in air (factors such as combustibility and explosiveness of dusts including composition and shape and size of particles could cause substance to belong to 'Combustible dust' hazard class)

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Calcium Stearate	1592-23-0	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Calcium Stearate	1592-23-0	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Calcium Stearate	1592-23-0	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Calcium Stearate	1592-23-0	

EU - CLP (1272/2008)

R-phrases(s)

not determined (not applicable)

S -phrase(s)

none

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Calcium Stearate	1592-23-0		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

None
Not dangerous

16. OTHER INFORMATION

Preparation Date: 1/24/2014
Revision date 11/6/2019

Product code: CA169

Product name: CALCIUM
STEARATE, NF

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Prepared by:

Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
CA169	Calcium Stearate, NF

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

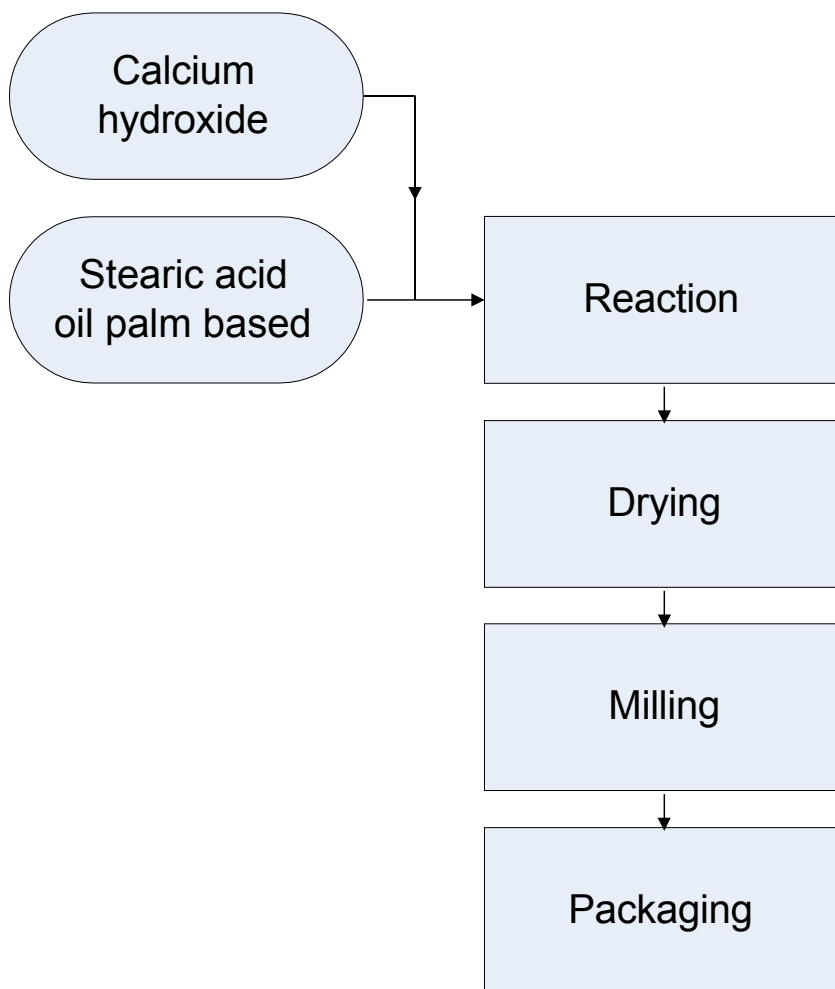
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Calcium Stearate, NF - CA169



Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

CA169, Calcium Stearate, NF

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis using plant derived material from Palm Oil. No animal derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Calcium Stearate, NF (Cat# CA169)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 1 ppm
Lead	Pb	1	< 2 ppm
Arsenic	As	1	< 3 ppm
Cobalt	Co	2A	< 1 ppm
Vanadium	V	2A	< 1 ppm
Lithium	Li	3	< 1 ppm
Antimony	Sb	3	< 1 ppm
Barium	Ba	3	< 1 ppm
Molybdenum	Mo	3	< 5 ppm
Copper	Cu	3	< 1 ppm
Tin	Sn	3	< 1 ppm
Chromium	Cr	3	< 5 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



RE: Residual Solvents - Calcium Stearate, NF (Cat# CA169)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

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PHONE 310.516.8000

FAX 310.516.9843

Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

<p>USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.</p> <p>KEEP FROM CHILDREN</p>	<p>CA169</p> <p>SIZ SY</p> <p>Calcium Stearate (Octadecanoic Acid Calcium Salt)</p> <p>NF</p> <p>CAS 1592-23-0</p> <p>CAUTION: For manufacturing, processing or repacking. Read and understand the label and Safety Data Sheet (SDS) prior to use.</p> <div style="border: 1px solid black; padding: 2px; text-align: center;"> Chemical Emergency: (800)424-9300 www.SpectrumChemical.com </div>	<p>Vegetable origin.</p> <table border="0"> <tr> <td>Calcium (Dried Basis)</td> <td>6.4-7.4%</td> </tr> <tr> <td>Stearic Acid and Palmitic Acid</td> <td>Min. 90.0%</td> </tr> <tr> <td>Stearic Acid</td> <td>?</td> </tr> </table> <p>MAXIMUM LIMITS</p> <table border="0"> <tr> <td>Loss on Drying</td> <td>4.0%</td> </tr> <tr> <td>Elemental Impurities</td> <td>As reported</td> </tr> <tr> <td>Residual Solvents</td> <td>To pass test</td> </tr> </table> <p>WARNING: Cancer and Reproductive Harm- www.P65Warnings.ca.gov</p>	Calcium (Dried Basis)	6.4-7.4%	Stearic Acid and Palmitic Acid	Min. 90.0%	Stearic Acid	?	Loss on Drying	4.0%	Elemental Impurities	As reported	Residual Solvents	To pass test
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