

Scientific Documentation

CA169, Calcium Stearate, NF

Not appropriate for regulatory submission. Please visit <u>www.spectrumchemical.com</u> 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

Ver4.03 9.June.2017



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving the scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

Alan Wang, MSQA, ASQ CQA Director of Technical Services techservices@spectrumchemical.com

CA169, Calcium Stearate, NF

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

Test	Specifi	ication
	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 %
HEAVY METALS		10 ppm
IDENTIFICATION		TO PASS TEST
CERTIFIED KOSHER		
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		TO PASS TEST

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000





SAFETY DATA SHEET

Preparation Date: 1/24/2014	Revision Date: 1/24/2014	Revision Number: G1	
	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 #	WI300000		
CI#:	Not available		
Recommended use of the che	mical and restrictions on use		
Recommended use:	Anti-caking or conditioning agent in certain food products. Water repellant/Waterproofing. Mold release agent.		
Uses advised against No information available			
Supplier:	Spectrum Chemicals and Laboratory Products, Inc. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000		
Order Online At:			
Emergency telephone number Contact Person:	Chemtrec 1-800-424-9300 Martin LaBenz (West Coast)		
Contact Person:	Regina Wachenheim (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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %	Trade Secret
Calcium Stearate	1592-23-0	100	*
1592-23-0			

4. FIRST AID MEASURES

First aid measures General Advice:	Poison information centres in each State capital city can provide additional assistance for scheduled poisons (13 1126)
Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention if irritation develops. Consult a physician if necessary.
Eye Contact:	Flush eye 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 Symptoms	s, both acute and delayed May cause eye/skin irritation.

Indication of any immediate medical attention and special treatment needed Notes to Physician: Treat symptomatically

Protection of first-aiders

Extinguishing Media

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

Suitable Extinguishing Media:	Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.
Unsuitable Extinguishing Media:	No information available.
Specific hazards arising from the chemical	
Hazardous Combustion Products:	Carbon monoxide; Carbron dioxide; calcium oxides
Specific hazards:	May be combustible at high temperatures. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

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 No information available.		
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. All equipment used when handling the product must be grounded. 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. Avoid dust formation. Do not ingest. Do not breathe vapours/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

U.S Occupational Exposure Limits: Not determined

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
	None	None	None	None
Calcium Stearate - 1592-23-0				

Canada

Canada Occupational Exposure Limits: Not determined

Components	Alberta	British Columbia	Ontario	Quebec
	None	None	None	None
Calcium Stearate - 1592-23-0				

Australia and Mexico

Occupational Exposure Limits for Australia and Mexico: Not determined

Components	Australia	Mexico
Calcium Stearate	None	None
1592-23-0		

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.
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Individual protection measures, such as personal protective equipment Personal Protective Equipment

Eye protection:	Safety glasses. Safety glasses with side-shields.
	curvey glaceces curvey glaceces man clac children.

Skin and body protection: Long sleeved clothing. Chemical resistant apron. Gloves.

Respiratory protection: Effective dust mask. Wear respirator with dust filter..

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid.

Odor: No information available

Flash point (°C): Not applicable

Lower Explosion Limit (%): No information available

pH: No information available

Decomposition temperature(°C/°F): No information available

Bulk density: No information available

Vapor density: No information available

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

Solubility: Very slightly soluble in water Solubility in Water: 0.004 g/100 ml at 15 deg. C Insoluble in Ether Insoluble in alcohol Appearance: Powder.

Taste No information available

Flashpoint (°C/°F): Not applicable

Upper Explosion Limit (%): No information available

Melting point/range(°C/°F): 140-179 °C/284-354.2 °F

Specific gravity: No information available

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

VOC content (g/L): No information available

Viscosity: No information available **Color:** White. Off-white. Yellowish White.

Molecular/Formula weight: No information available

Flash Point Tested according to: Not applicable

Autoignition Temperature (°C/°F): No information available

Boiling point/range(°C/°F): No information available

Density (g/cm3): No information available

Evaporation rate: No information available

Odor threshold (ppm): No information available

Miscibility: No information available

10. STABILITY AND REACTIVITY

Reactivity Reactive with acids Reacts with alkalis Reactive with oxidizing agents	
Chemical stability	
Stability:	Stable at normal conditions
Possibility of Hazardous Reactions:	Hazardous polymerization does not occur
Conditions to avoid:	Heat. Avoid dust formation. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
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

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

Calcium Stearate - 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 infomation available Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat = VALUE- Acute Tox Oral = >10000mg/kg

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

LD50/dermal/rabbit VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat VALUE -Acute Tox Dermal = 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 a	s well as chronic effects from short and long-term exposure
Chronic Toxicity Sensitization:	No information available. No information available
Mutagenic Effects:	No information available

Carcinogenic effects: No information available.

Components	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Calcium Stearate	A4 - Not Classifiable as a Human Carcinogen by ACGIH (for stearates)	Not listed	Not listed	Not listed	Not listed	Not listed

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:	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.

Product code: CA169

Product name: CALCIUM STEARATE,

Contaminated packaging:

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

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Calcium Stearate	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Proper Shipping Name: Hazard Class: Subsidiary Risk: Packing Group: Marine Pollutant	Not regulated No information available No information available Not applicable None No data available
Marine Pollutant ERG No:	No data available
DOT RQ (lbs):	No information available

TDG (Canada)

Not Regulated
No information available

ADR

IMO / IMDG

UN-No:
Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
Description:
IMDG Page:
Marine Pollutant
MFAG:
Maximum Quantity:

RID

UN-No: Proper Shipping Name: Hazard Class: Subsidiary Risk: Packing Group:

No information available Not Regulated No information available No information available No information available

Not Regulated

No information available No information available

No information available

14. TRANSPORT INFORMATION

Classification Code:	No information available
Description:	No information available
ICAO	
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
Description:	No information available
ΙΑΤΑ	
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
Description:	No information available

15. REGULATORY INFORMATION

International Inventories

Components	U.S. TSCA	Philippines (PICCS)	KOREA KECL	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Calcium Stearate	Present	Present	Present KE- 26347	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

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)

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Calcium Stearate	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

• • • • •	Substances and their	Hazardous	Section 302 Extremely Hazardous Substances and RQs	Chemical Category	Section 313 - Reporting de minimis
	Reportable Quantities	Substances and TPQS	Substances and Rus		
Calcium Stearate	None	None	None	None	None

U.S. TSCA

•	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Calcium Stearate	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

Non-controlled

Calcium Stearate

Uncontrolled product according to WHMIS classification criteria

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components		Canada (NDSL)
Calcium Stearate	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Manditory Reporting
Calcium Stearate	Not listed	Not listed

EU Classification

<u>R-phrase(s)</u>

not determined

S -phrase(s)

none

Components	Classification	Concentration Limits:	Safety Phrases
Calcium Stearate		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

16. OTHER INFORMATION		
NFPA	HMIS	Personal Protective Equipment
10	Health Hazard1Fire Hazard1Reactivity0	
		See Section 8.
Preparation Date: 1/24	/2014	

1/24/2014 Sonia Owen

Preparation Date: Revision Date: Prepared by:

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 Material Safety Data Sheet



Manufacturer

Product Covered: CA169, Calcium Stearate, NF

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

Alan Wang, MSQA, ASQ CQA Director of Technical Services techservices@spectrumchemical.com

Certificate of Registration



This is to certify that the quality management system of

Spectrum Chemicals and Laboratory Products, Frc

Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA

Additional Sites: 13915 South Main Street, Los Angeles, California, 90061, USA 755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA 769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA 7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001:2008

The quality management system is applicable to

California and New Jersey sites: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

Arizona site: Supporting Spectrum's two manufacturing facilitates by: selecting and gualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and guotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01 Initial Certification Date: 27 December 1994 Certificate Issue Date: Certificate Expiry Date:

29 January 2016 14 September 2018

Calin Moldovean, President

Intertek Testing Services NA, Inc.

900 Chelmsford Street, Suite 301-3, Lowell, MA, USA



CERTIFICATION



Intertek Intertek

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

Certificate of Registration



This is to certify that the quality management system of

Spectrum China Ltd.

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001: 2008

The quality management system is applicable to:

Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.

Organization Code: Certificate Number: Certificate Issue Date: Certificate Expiry Date: 77762704-8 111310001-01 17 November 2015 14 September 2018



014

Authorised Signature: Calin Moldovean – President, Business Assurance Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at <u>certificate.validation@intertek.com</u> or by scanning the code to the right with a smartphone. The annual validity of the certificate a also be checked through the website <u>http://www.cnca.gov.cn</u> of CNCA in China.



The certificate remains the property of Intertek, to whom it must be returned upon request.



January 03, 2017

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certifies that our USP, NF, FCC, EP, BP, JP, and food grade products are 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.

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

Spectrum Gardena, California: <u>2020632</u> Spectrum New Brunswick, New Jersey: <u>2246824</u>

Thank you for your interest with Spectrum products. Please feel free to contact me at 310-516-8000, extension 5610 or via email at <u>mdang@spectrumchemical.com</u> if I may be of further assistance.

Sincerely,

Michael Dang Manager, GMP Compliance

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



July 18, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify 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:

2020632 2246824 3006174778

Spectrum-Gardena, CA:
Spectrum-New Brunswick, NJ:
Spectrum-Shanghai, China:

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Oula Clamy

Oralia Chavez Quality Assurance Specialist



June 17, 2016

Re: Calcium Stearate, NF- CA169

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Calcium Stearate, NF- CA169

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <u>techservices@spectrumchemical.com</u>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

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



June 14, 2016

Re: Calcium Stearate, NF- CA169

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO₂; Lupin; Tree nuts; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Sesame Seed).

Calcium Stearate, NF- CA169

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at <u>techservices@spectrumchemical.com</u>.

Sincerely,

Darlene Dagdag-Lyudmirskiy Technical Services Spectrum Chemical Mfr. Corp.

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

Spectrum®

Certificate Of Analysis

Item Number	CA169	Lot Number	2GD0171
Item	Calcium Stearate, NF		
CAS Number	1592-23-0		
Molecular Formula		Molecular Weight	

Test	Specification		Result
	min	max	
CALCIUM (DRIED BASIS)	6.4 - 7.4 %		6.80 %
STEARIC ACID AND PALMITIC ACID	90.0 %		99.08 %
STEARIC ACID	40.0 %		46.76 %
LOSS ON DRYING		4.0 %	3.4 %
HEAVY METALS		10 ppm	<10 ppm
IDENTIFICATION		TO PASS TEST	PASSES TEST
CERTIFIED KOSHER			KOSHER
RETEST DATE			30-JUN-2019
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
APPEARANCE			FINE WHITE POWDER
DATE OF MANUFACTURE			01-JUL-2014

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate Of Analysis Results Certified by

Ibad Tirmizi Director of Quality Spectrum Chemical Mfg. Corp.

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

Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.



GREEN: General Storage

BLUE: Health Hazard WHITE: Corrosive

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.



This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave. New Brunswick, NJ 08901 West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248

732.214.1300

310.516.8000



January 26, 2016

RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

1 = Gardena, CA Facility 2 = New Brunswick, NJ Facility 3 = China Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at <u>qualityassurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

1 lan

Michael Dang Manager, GMP Compliance



Stability – Shelf Life Guidance

Product Covered: CA169, Calcium Stearate, NF

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, CA169, Calcium Stearate, NF, is assigned a 60 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez Quality Control Manager

San & Mana (

Corporate Headquarters 769 Jersey Avenue New Brunswick, NJ 08901-3605



בס"ד Feb 28, 2017

The following product(s) prepared by the named company are certified kosher with the stated requirements:

Spectrum Laboratory Products, Inc.

S-0032

14422 S. San Pedro Street Gardena CA 90248 USA	Product Name	Calcium Stearate, NF - CA169	
	Brand	Spectrum	
	UKD-ID	KSAV3-F4I4S7	
	D/P/M	P	
	Symbol Required	KSA	
This certificate expires on Feb 01, 2018	Special Conditions		

Rabbi Binyomin Lisbon Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.