

# **Scientific Documentation**

# **Calcium Propionate, Powder, FCC**

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 Propionate, Powder, FCC** (CA166)

Item Number	CA166
Item	Calcium Propionate, Powder, FCC
CAS Number	4075-81-4
Molecular Formula	C <sub>6</sub> H <sub>10</sub> CaO <sub>4</sub>
Molecular Weight	186.22
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (C <sub>6</sub> H <sub>10</sub> CaO <sub>4</sub> )	98.0	100.5 %
FLUORIDE (F)		0.003 %
LEAD (Pb)		2 mg/kg
INSOLUBLE SUBSTANCES		0.2 %
MAGNESIUM (as MgO)	TO PASS TEST (limit about 0.4 %)	
WATER		5.0 %
IDENTIFICATION	TO PASS TEST	
CERTIFIED HALAL		
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		

#### 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



# **Certificate Of Analysis**

Item Number	CA166	Lot Number	1MB0884
Item	Calcium Propionate, Powder, FCC	CAS Number	4075-81-4
Molecular Formula	C <sub>6</sub> H <sub>10</sub> CaO <sub>4</sub>	Molecular Weight	186.22

TEST	SPECIFICATION		DECULT
	MIN	MAX	RESULT
ASSAY (C <sub>6</sub> H <sub>10</sub> CaO <sub>4</sub> )	98.0	100.5 %	99.3 %
FLUORIDE (F)		0.003 %	<0.003 %
LEAD (Pb)		2 mg/kg	<2 mg/kg
INSOLUBLE SUBSTANCES		0.2 %	0.01 %
MAGNESIUM (as MgO)	TO PASS TEST (limit about 0.4 %)		PASSES TEST
WATER		5.0 %	3.9 %
IDENTIFICATION	TO PASS TEST		PASSES TEST
CERTIFIED HALAL			CERTIFIED HALAL
APPEARANCE			WHITE POWDER
EXPIRATION DATE			26-SEP-2024
DATE OF MANUFACTURE			26-SEP-2022
MONOGRAPH EDITION			(FCC) 13

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 02-MAR-23 11:22:37

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



Certificate of Analysis Results Approved By:

JRUIZ Jesus Ruiz 06-MAR-23 09:59:27

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.

# SAFETY DATA SHEET

Revision date 26-April-2022

1. Identification	
Product identifier	
Product Name	CALCIUM PROPIONATE, POWDER, FCC
Other means of identification	
Product Code(s)	CA166
Synonyms	None
Recommended use of the chemical and restrictions on use	
Recommended use	No information available
Restrictions on use	No information available
Details of the supplier of the safety data sheet	
Supplier Address Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000 Emergency telephone number	

**Emergency Telephone** 

Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

#### **Classification**

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

## Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

#### Hazard statements

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

Appearance Crystals or Crystalline powder or Powder

Physical state Solid

Odor No information available



**Revision Number** 2

Other information May be harmful if swallowed.

# 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%	Trade secret
Calcium Propionate	4075-81-4	100	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures		
Description of first aid measures		
General advice	Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.	
Inhalation	Remove to fresh air.	
Eye contact	Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.	
Skin contact	Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.	
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.	
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8). Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.	
Most important symptoms and effects, both acute and delayed		
Symptoms	No information available.	
Indication of any immediate medical attention and special treatment needed		
Note to physicians	Treat symptomatically.	

# 5. Fire-fighting measures

Suitable Extinguishing Media Large Fire	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.
Hazardous combustion products	Carbon dioxide (CO2). Hydrogen fluoride.

Sensitivity to mechanical impact none.

Sensitivity to static discharge none.

Special protective equipment for<br/>fire-fightersFirefighters should wear self-contained breathing apparatus and full firefighting turnout<br/>gear. Use personal protection equipment.

#### 6. Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.	
Other information	Refer to protective measures listed in Sections 7 and 8.	
Methods and material for containment and cleaning up		
Methods for containment	Prevent further leakage or spillage if safe to do so.	
Methods for cleaning up	Pick up and transfer to properly labeled containers.	

#### 7. Handling and storage

#### Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Take off contaminated clothing and wash before reuse.	
Conditions for safe storage, including any incompatibilities		
Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.	

#### 8. Exposure controls/personal protection

Control parameters		
Exposure Limits	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.	
Appropriate engineering controls		
Engineering controls	Showers Eyewash stations Ventilation systems.	
Individual protection measures, such as personal protective equipment		

Eye/face protection	Wear safety glasses with side shields (or goggles).
Hand protection	Wear suitable gloves. Impervious gloves.

Skin and body protection	Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.	
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.	
General hygiene considerations	Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.	

# 9. Physical and chemical properties

Information on basic physical and chemical properties				
Physical state	Solid			
Appearance	Crystals or Crystalline powder or Powder			
Color	White; to; Cream			
Odor	No information available			
Odor threshold	No information available			
Property_	Values	Remarks • Method		
pH	no data available	None known		
Melting point / freezing point	380 °C / 716 °F	None known		
Boiling point / boiling range	no data available	None known		
Flash point	no data available	None known		
Evaporation rate	no data available	None known		
Flammability (solid, gas)	no data available	None known		
Flammability Limit in Air		None known		
Upper flammability or explosive	No data available			
limits				
Lower flammability or explosive	No data available			
limits				
Vapor pressure	No data available	None known		
Vapor density	no data available	None known		
Relative density	1.4	None known		
Water solubility	Soluble in water	None known		
Solubility(ies)				
	Practically insoluble in Benzene			
	Slightly soluble in Methanol			
Partition coefficient	No data available	None known		
Autoignition temperature	no data available	None known		
Decomposition temperature		None known		
Kinematic viscosity	no data available	None known		
Dynamic viscosity	No data available	None known		
Other information				
Explosive properties				
Oxidizing properties				
Softening point				
Molecular weight				
	OC Content (%) No information available			
Liquid Density	No information available			
Bulk density	No information available			
10 Stability and reactivity				

# 10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.

Incompatible materials

None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information			
Information on likely routes of exposure			
Product Information			
Inhalation	Specific test data for the substance or mixture is not available.		
Eye contactSpecific test data for the substance or mixture is not available.Skin contactSpecific test data for the substance or mixture is not available. Toxic in contact with sk (based on components).			
		Ingestion	May be harmful if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics			
Symptoms No information available.			
Acute toxicity			

#### Numerical measures of toxicity

1	Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
	Calcium Propionate 4075-81-4	= 3920 mg/kg(Rat)	= 500 mg/kg(Rabbit)	> 19.7 mg/L (Rat)1 h

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

Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity	No information available. No information available. No information available. No information available.
Reproductive toxicity	No information available.
STOT - single exposure STOT - repeated exposure Aspiration hazard	No information available. No information available. No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

# 12. Ecological information

#### Ecotoxicity

	•			
Chemical name	Algae/aquatic plants	uatic plants Fish Toxici		Crustacea
			microorganisms	
Calcium Propionate	EC50: >500mg/L (72h,	LC50: >10000mg/L (96h,	-	EC50: >500mg/L (48h,
4075-81-4	Desmodesmus	Leuciscus idus)		Daphnia magna)
	subspicatus)			

#### **Bioaccumulation**

Inherently biodegradable.

No information available.

Other adverse effects

 13. Disposal considerations

 Waste treatment methods

 Waste from residues/unused products
 Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

 Contaminated packaging
 Do not reuse empty containers.

#### 14. Transport information

DOT	not regulated
TDG	not regulated
MEX	not regulated
ICAO (air)	not regulated
IATA	not regulated
IMDG	not regulated
RID	not regulated
ADR	not regulated
ADN	not regulated

# 15. Regulatory information

#### International Inventories

TSCA

Complies

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Does not Comply
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical
	Substances (AICS).

Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

#### US Federal Regulations

#### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

#### US State Regulations

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

#### 16. Other information

<u>NFPA</u> Health hazards 0 Flammability 0 Instability 0 Physical and chemical properties -				
HMIS				
Health hazards 0				
Flammability 0				
Physical hazards 0				
Personal protection X				
Key or legend to abbreviations and acronyms used in the safeLegend Section 8: EXPOSURE CONTROLS/PERSONAL PROTWATWA (time-weighted average)CeilingMaximum limit value		STEL (Short Term Exposure Limit)		
Key literature references and sources for data used to compile the SDSAgency for Toxic Substances and Disease Registry (ATSDR)U.S. Environmental Protection Agency ChemView DatabaseEuropean Food Safety Authority (EFSA)EPA (Environmental Protection Agency)Acute Exposure Guideline Level(s) (AEGL(s))U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act				

U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization

Revision date26-April-2022Revision NoteNo information available.Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

# spectrum

#### 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
CA166	Calcium Propionate, Powder, FCC

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 <u>gualityassurance@spectrumchemical.com</u>

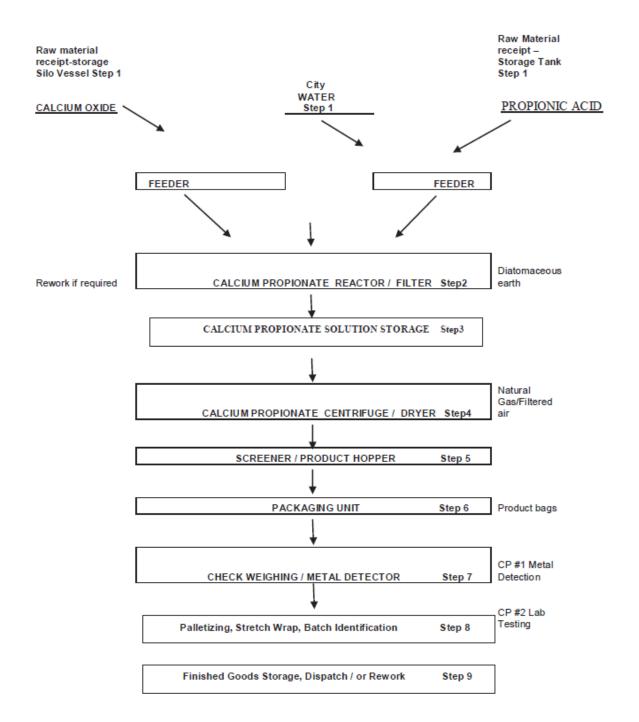
Sincerely,

Oulu Clamy

Oralia Chavez Quality Assurance Specialist



# Manufacturing Process Flowchart Calcium Propionate, Powder, FCC (Cat# CA166)



#### 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

# CA166, Calcium Propionate, Powder, FCC

# **Source Statement**

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant 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

spectrum

- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- 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 24 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

# spectrum®

C<sub>6</sub>H<sub>6</sub>CaO, F.W. 186.22

# **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.

#### 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