

Scientific Documentation

Calcium Gluconate, Anhydrous, Powder, USP

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 Gluconate, Anhydrous, Powder, USP (C1939)

Item Number	C1939
Item	Calcium Gluconate, Anhydrous, Powder, USP
CAS Number	299-28-5
Molecular Formula	C ₁₂ H ₂₂ CaO ₁₄
Molecular Weight	430.37
MDL Number	
Synonyms	Gluconic Acid Calcium Salt

Test	Specification	
	Min	Max
ASSAY	98.0	102.0 %
LOSS ON DRYING		3.0 %
CHLORIDE (Cl)		0.07 %
SULFATE		0.05 %
ARSENIC (As)		3 ppm
ELEMENTAL IMPURITIES:		
CADMIUM (Cd)	AS REPORTED	
LEAD (Pb)	AS REPORTED	
MERCURY (Hg)	AS REPORTED	
REDUCING SUBSTANCES		1.0 %
IDENTIFICATION:A	POSITIVE FOR CALCIUM	
IDENTIFICATION:B	SPECTRUM MATCHES REFERENCE	
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

 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	C1939	Lot Number	2NA0049
Item	Calcium Gluconate, Anhydrous, Powder, USP	CAS Number	299-28-5
Molecular Formula	C ₁₂ H ₂₂ CaO ₁₄	Molecular Weight	430.37

TEST	SPECIFICATION		DECULT
IESI	MIN	MAX	RESULT
ASSAY	98.0	102.0 %	98.7 %
LOSS ON DRYING		3.0 %	0.2 %
CHLORIDE (CI)		0.07 %	<0.07 %
SULFATE		0.05 %	<0.05 %
ARSENIC (As)		3 ppm	<0.1 ppm
ELEMENTAL IMPURITIES:			COMPLIES WITH STANDARD
CADMIUM (Cd)	AS REPORTED		<0.1 ppm
LEAD (Pb)	AS REPORTED		<0.8 ppm
MERCURY (Hg)	AS REPORTED		<0.02 ppm
REDUCING SUBSTANCES		1.0 %	0.1 %
IDENTIFICATION:A	POSITIVE FOR CALCIUM		POSITIVE FOR CALCIUM
IDENTIFICATION:B	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
RETEST DATE			01-AUG-2028
DATE OF MANUFACTURE			01-SEP-2023
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS
MONOGRAPH EDITION			USP 2023

Certificate of Analysis Results Entered By:

GHERRERA Genaro Herrera 22-JAN-24 05:51:14

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



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.

Certificate of Analysis Results Approved By:

MCAMACHO Matheu Camacho 24-JAN-24 07:21:11

SAFETY DATA SHEET

Revision date 31-October-2022

1. Identification		
Product identifier		
Product Name	CALCIUM GLUCONATE, ANHYDROUS, POWDER, USP	
Other means of identification		
Product Code(s)	C1939	
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).

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Appearance Crystalline powder or Powder

Physical state Solid

Odor No information available



Revision Number 2

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
Calcium Gluconate, Anhydrous	299-28-5	100

4. First-aid measures

Description of first aid measures

Inhalation	Remove to fresh air.	
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.	
Skin contact	Wash skin with soap and water.	
Ingestion	Clean mouth with water and drink afterwards plenty of water.	
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	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	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 Monoxide, Carbon Dioxide. Calcium oxides.
Explosion data Sensitivity to mechanical impac	at none.
Sensitivity to static discharge	none.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
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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.	
Conditions for safe storage, including any incompatibilities		
Storage Conditions	Keep container tightly closed in a dry and well-ventilated place.	

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	No special protective equipment required.	
Skin and body protection	No special protective equipment required.	
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	Handle in accordance with good industrial hygiene and safety practice.	

9. Physical and chemical properties

Information on basic physical and chemical propertiesPhysical stateSolidAppearanceCrystalline powder or Powder

White Color No information available Odor **Odor threshold** No information available Property Values pН Neutral 120 °C / 248 °F Melting point / freezing point Boiling point / boiling range no data available Flash point no data available **Evaporation rate** no data available Flammability (solid, gas) no data available Flammability Limit in Air Upper flammability or explosive No data available limits Lower flammability or explosive No data available limits Vapor pressure No data available Vapor density no data available **Relative density** 1.7 Water solubility Soluble in water Solubility(ies) Insoluble in Ethanol Partition coefficient No data available no data available Autoignition temperature **Decomposition temperature** Kinematic viscosity no data available No data available **Dynamic viscosity** Other information **Explosive properties** No information available **Oxidizing properties** No information available Softening point No information available

Remarks • Method

None known

None known

None known

None known None known None known None known None known None known None known None known None known None known None known None known

10. Stability and reactivity

Molecular weight

VOC Content (%)

Liquid Density

Bulk density

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.

No information available

No information available

No information available

No information available

11. Toxicological information

Information on likely routes of exposure

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

No information available.

Acute toxicity

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Calcium Gluconate, Anhydrous 299-28-5	> 5000 mg/kg (Rat)	-	-

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	The environmental impact of this product has not been fully investigated.
Persistence and degradability Bioaccumulation	No information available. Inherently biodegradable.
Other adverse effects	No information available.

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
<u>TDG</u>	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	Complies
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

Complies

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

NFPA 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 safety data sheet Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION TŴĂ TWA (time-weighted average) STEL STEL (Short Term Exposure Limit) Ceiling Maximum limit value Key literature references and sources for data used to compile the SDS Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European 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 31-October-2022 **Revision date**

Revision Note 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.

No information available.

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
C1939	Calcium Gluconate, Anhydrous, Powder, USP

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: Spectrum-New Brunswick, NJ: 2020632 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>qualityassurance@spectrumchemical.com</u>

Sincerely,

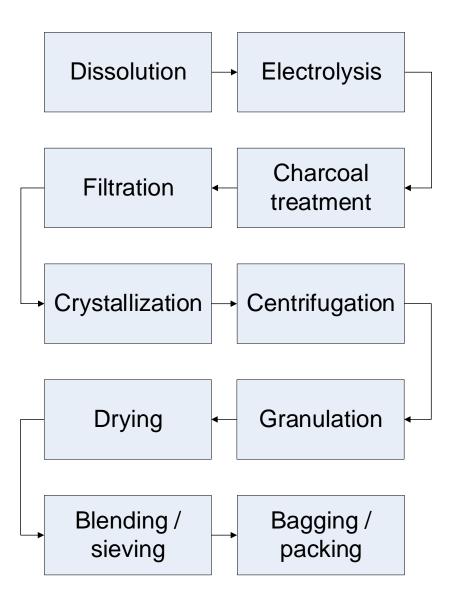
Oulu Clamy

Oralia Chavez Quality Assurance Specialist



Manufacturing Process Flowchart

Calcium Gluconate, Anhydrous, Powder, USP - C1939



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

C1939, Calcium Gluconate, Anhydrous, Powder, USP

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 60 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®

RE: Elemental Impurities - Calcium Gluconate, Anhydrous, Powder, USP (Cat# C1939)

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	< 0.01 ppm
Lead	Pb	1	< 0.05 ppm
Mercury	Hg	1	< 0.05 ppm

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

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

Sincerely,

Technical Services

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



Spectrum Chemical Mfg. Corp.

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CORPORATE HEADQUARTERS

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WEST COAST FACILITY

14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843

AN ISO 9001:2015 REGISTERED COMPANY



RE: Residual Solvents - Calcium Gluconate, Anhydrous, Powder, USP (Cat# C1939)

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

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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

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WEST COAST FACILITY

14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843

AN ISO 9001:2015 REGISTERED COMPANY

spectrum®

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.

	G 3/E1GHS A O Lot No. 062233
ww.SpectrumChemical.com P. Gardena, CA 90	0248 • New Brunswick, NJ 08901
Size/Quantity	🛚 Empirical Formula, Formula
 G Chemical Abstracts Service (CAS) Registry Number 	Weight and Technical Specifications Panel
Caution InformationDOT Shipping Information	 Expiration Information Lot Number
	 Size/Quantity Chemical Abstracts Service (CAS) Registry Number Caution Information

Spectrum Chemical Mfg Corp

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

732.214.1300

storing hazardous chemicals.

West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248 310.516.8000

the customer to check with their local fire department for possible conflicts with our recommendations when