

Scientific Documentation

Calcium Carbonate, Heavy 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 Carbonate, Heavy Powder, USP (CA131)

Item Number	CA131
Item	Calcium Carbonate, Heavy Powder, USP
CAS Number	471-34-1
Molecular Formula	CaCO ₃
Molecular Weight	100.09
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	100.5 %
LOSS ON DRYING		2.0 %
ACID-INSOLUBLE SUBSTANCES		0.2 %
FLUORIDE		0.005 %
ARSENIC (As)		3 ppm
BARIUM	NO GREEN COLOR	
LEAD (Pb)		3 ppm
IRON (Fe)		0.1 %
MERCURY		0.5 ppm
ELEMENTAL IMPURITIES	AS REPORTED	
MAGNESIUM AND ALKALI SALTS		1.0 %
IDENTIFICATION	PRODUCES EFFERVESCENCE AND POSITIVE FOR CALCIUM	
EXPIRATION 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	CA131	Lot Number	2NA0246
Item	Calcium Carbonate, Heavy Powder, USP	CAS Number	471-34-1
Molecular Formula	CaCO ₃	Molecular Weight	100.09

TECT	SPECIFICATION		DECHIT	
TEST	MIN	MAX	RESULT	
ASSAY (DRIED BASIS)	98.0	100.5 %	99.3 %	
LOSS ON DRYING		2.0 %	0.1 %	
ACID-INSOLUBLE SUBSTANCES		0.2 %	0.10 %	
FLUORIDE		0.005 %	<0.005 %	
ARSENIC (As)		3 ppm	<3 ppm	
BARIUM	NO GREEN COLOR		NO GREEN COLOR	
LEAD (Pb)		3 ppm	0.1 ppm	
IRON (Fe)		0.1 %	<0.1 %	
MERCURY		0.5 ppm	0.01 ppm	
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD	
MAGNESIUM AND ALKALI SALTS		1.0 %	0.5 %	
IDENTIFICATION	PRODUCES EFFERVESCENCE AND POSITIVE FOR CALCIUM		PRODUCES EFFERVESCENCE AND POSITIVE FOR CALCIUM	
EXPIRATION DATE			29-AUG-2026	
DATE OF MANUFACTURE			30-AUG-2023	
APPEARANCE			WHITE POWDER	
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED	
MONOGRAPH EDITION			USP 2023	

Certificate of Analysis Results Entered By:

MCAMACHO Matheu Camacho 31-JAN-24 12:08:38

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

GHERRERA Genaro Herrera 31-JAN-24 13:20:35

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 SPECTRUM®



Revision date 06-June-2022 Revision Number 2

1. Identification

Product identifier

Product Name CALCIUM CARBONATE, HEAVY POWDER, USP

Other means of identification

Product Code(s) CA131

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on useNo 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

Carcinogenicity Category 1A

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

May cause cancer



Appearance Powder Physical state Solid Odor No information available

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage

Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

Not applicable.

<u>Mixture</u>

Chemical name	CAS No	Weight-%	Trade secret
Calcium Carbonate	471-34-1	100	*
Quartz (Crystalline Silica)	14808-60-7	0.1 - 1	*

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

4. First-aid measures

Description of first aid measures

General advice IF exposed or concerned: Get medical advice/attention.

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 physiciansTreat symptomatically.

5. Fire-fighting measures

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 Chloroform does not burn, but may decompose upon heating to produce the following if

involved in a fire: carbon monoxide, carbon dioxide, hydrogen chloride and chlorine.

Carbon dioxide (CO2). Hydrogen fluoride.

Explosion data

Sensitivity to mechanical impact 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.

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.

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 LimitsThe 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.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Quartz (Crystalline Silica)	No data available	50 μg/m³ TWA	-
14808-60-7		(250)/(%SiO2 + 5) mppcf	
		TWArespirable fraction	
		(10)/(%SiO2 + 2) mg/m ³	
		TWArespirable fraction	

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.

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

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 Do not eat, drink or smoke when using this product. 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 Powder
Color White

OdorNo information availableOdor thresholdNo information available

<u>Property</u>	<u>values</u>	Remarks • Method
- _		

рΗ no data available None known Melting point / freezing point no data available 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

No data available None known Vapor pressure Vapor density no data available None known Relative density 2.7 - 2.8None known Water solubility Insoluble in water None known Solubility(ies) no data available None known 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

None known

None known

None known

Other information

Explosive properties

Oxidizing properties

No information available
VOC Content (%)
No information available
Liquid Density
No information available
Bulk density
No information available

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 materialsNone 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 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

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Calcium Carbonate	= 6450 mg/kg (Rat)	-	-
471-34-1			

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.

Carcinogenicity Contains a known or suspected carcinogen. Classification based on data available for

ingredients. May cause cancer.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

		<u> </u>		
Chemical name	ACGIH	IARC	NTP	OSHA

Quartz (Crystalline Silica)	-	Group 1 - Carcinogenic	-	-
14808-60-7		to humans - Monograph		1
		100C [2012] Crystalline		
		silica inhaled in the form		
		of quartz or cristobalite		
		from occupational		
		sources		
		Monograph 68 [1997]		

Legend

Reproductive toxicity No information available.

STOT - single exposureNo information available.STOT - repeated exposureNo information available.Target organ effectsrespiratory system, Eyes, Skin.

Aspiration hazard 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

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: IECSCThis 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

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 contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Quartz (Crystalline Silica) - 14808-60-7	carcinogen

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Quartz (Crystalline Silica)	1660	Present	Present
14808-60-7			

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 * 1 Flammability 0 Physical hazards 0 Personal protection X

Chronic Hazard Star Legend *= Chronic Health Hazard

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA 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

Revision date 06-June-2022

Revision 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



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	
CA131	Calcium Carbonate, Heavy 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: 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,

Oralia Chavez

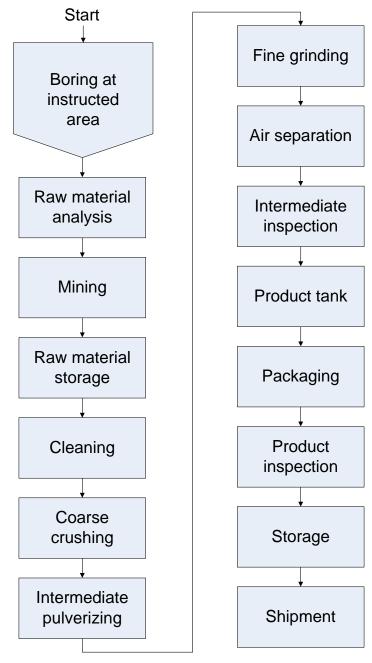
Quality Assurance Specialist

Order Clony



Manufacturing Process Flowchart

Calcium Carbonate, Heavy Powder, USP - CA131



Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.

New Brunswick, NJ 08901

West Coast Facility:

14422 S. San Pedro St. Gardena, CA 90248

310.516.8000

732.214.1300



CA131, Calcium Carbonate, Heavy Powder, USP

Source Statement

The above mentioned catalog item is manufactured from mineral origin (limestone). 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
- 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 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Calcium Carbonate, Heavy Powder, USP (Cat# CA131)

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	< 2.0 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 0.75 ppm
Selenium	Se	2B	Not tested
Barium	Ва	3	Not tested
Copper	Cu	3	Not tested
Chromium	Cr	3	Not tested

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 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 Carbonate, Heavy Powder, USP (Cat# CA131)

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
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CORPORATE HEADQUARTERS

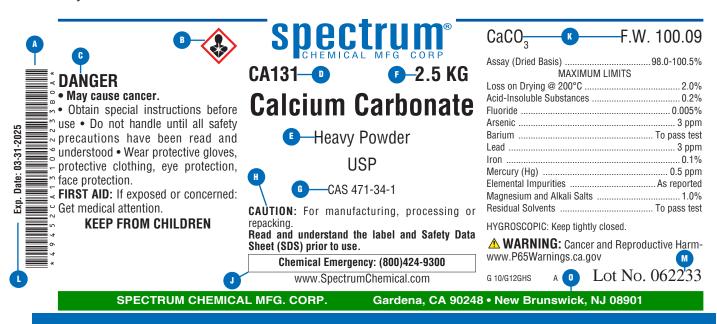
769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

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



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.



- A Bar Code
- GHS Hazard Pictograms
- Warning, Safety Data and Precautionary Information
- Product Catalog Number
- Item Name, Form, Grade
- Size/Quantity

- Chemical Abstracts Service (CAS) Registry Number
- Caution Information
- DOT Shipping Information
- Toll-Free 24-Hour Chemical Emergency Telephone Number
- Empirical Formula, Formula Weight and Technical Specifications Panel
- Expiration Information
- Lot Number
- Kosher Certified by Kosher Supervision of America (KSA).
- Storage Color Band
- Halal Certified by IFANCA
- bioCertified

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

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