

# **Scientific Documentation**

## Cholesterol, NF

Not appropriate for regulatory submission.

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

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





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# **Specification for Cholesterol, NF (CH135)**

Item Number	CH135	
Item	Cholesterol, NF	
CAS Number	57-88-5	
Molecular Formula	C <sub>27</sub> H <sub>46</sub> O	
Molecular Weight	386.65	
MDL Number		
Synonyms	(3Beta)-Cholest-5-en-3-ol; Cholesterin	

Test	Specificati	on
	Min	Max
ASSAY (DRIED BASIS)	95.0	102.0 %
MELTING RANGE	147°	150°C
SPECIFIC ROTATION	-34° to -38°	
SOLUBILITY IN ALCOHOL	NO DEPOSIT OR TURBIDITY FORMS	
ACIDITY		0.3 ml
LOSS ON DRYING		0.3%
RESIDUE ON IGNITION		0.1%
RELATED STEROLS AND OTHER ORGANIC IMPURITIES:		
?-CHOLESTANOL (5a-CHOLESTAN-3?- ol,DIHYDROCHOLESTEROL)		0.6 %
DESMOSTEROL		4 %
LATHOSTEROL		2 %
24-DEHYDROLATHOSTEROL (5a-CHOLESTA-7,24 DIEN3?-ol )		0.2 %
4-METHYLCHOLEST-5-EN-3?-OL		0.5 %
TOTAL IMPURITIES INCLUDING RELATED STEROLS		5 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	-34° to -38°	

Test	Specification		
	Min	Max	
IDENTIFICATION (C)	147 - 150 C		
RETEST DATE			
DATE OF MANUFACTURE			
APPEARANCE			
RESIDUAL SOLVENTS:	AS REPORTED		

## Spectrum Chemical Mfg Corp

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

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# **Certificate Of Analysis**

Item Number	CH135	Lot Number	2MH0106
Item	Cholesterol, NF	CAS Number	57-88-5
Molecular Formula	C <sub>27</sub> H <sub>46</sub> O	Molecular Weight	386.65

TECT	SPECIFICATION		DECLUT
TEST	MIN	MAX	RESULT
ASSAY (DRIED BASIS)	95.0	102.0 %	96.1 %
MELTING RANGE	147°	150°C	148°149°C
SPECIFIC ROTATION	-34° to -38°		-36°
SOLUBILITY IN ALCOHOL	NO DEPOSIT OR TURBIDITY FORMS		NO DEPOSIT OR TURBIDITY IS FORMED
ACIDITY		0.3 ml	0.1 ml
LOSS ON DRYING		0.3%	<0.1 %
RESIDUE ON IGNITION		0.1%	<0.1 %
RELATED STEROLS AND OTHER ORGANIC IMPURITIES:			
β-CHOLESTANOL (5a-CHOLESTAN-3β- ol,DIHYDROCHOLESTEROL)		0.6 %	0.3 %
DESMOSTEROL		4 %	2 %
LATHOSTEROL		2 %	1 %
24-DEHYDROLATHOSTEROL (5a-CHOLESTA-7,24 DIEN3β-ol )		0.2 %	0.1 %
4-METHYLCHOLEST-5-EN-3β-OL		0.5 %	0.2 %
TOTAL IMPURITIES INCLUDING RELATED STEROLS		5 %	4 %
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	-34° to -38°		-36°
IDENTIFICATION (C)	147 - 150 C		148°149°C

TEST	SPECIFICATION		DECLUT
lesi	MIN	MAX	RESULT
RETEST DATE			12-SEP-2025
DATE OF MANUFACTURE			13-SEP-2022
APPEARANCE			WHITE PEARLY CRYSTALS
RESIDUAL SOLVENTS:	AS REPORTED		
CLASS 3 (solvent) / ACETONE			<5000 ppm
CLASS 3 (solvent) / ETHANOL			<5000 ppm
CLASS 3 (solvent) / HEPTANE			<5000 ppm
MONOGRAPH EDITION			USP NF 2023

Certificate of Analysis Results Entered By:

SVANGOOR Swetha Vangoor 15-AUG-23 06:08:37

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

KMORALES Keyla Morales 19-SEP-23 09:24:02

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.





Revision date 31-October-2022

Revision Number 2

#### 1. Identification

**Product identifier** 

Product Name CHOLESTEROL, NF

Other means of identification

Product Code(s) CH135

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 Crystals or granules

Physical state Solid

Odor Mild or Odorless

#### Other information

No information available.

## 3. Composition/information on ingredients

#### **Substance**

Chemical name	CAS No	Weight-%
Cholesterol	57-88-5	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

## 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 Carbon dioxide (CO2).

**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.

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 Protect from light.

## 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 properties

Physical state Solid

**Appearance** Crystalline powder or Crystals or granules

ColorWhite Pale YellowOdorMild or Odorless

Odor threshold No information available

Property Values Remarks • Method

no data available None known pН 147 - 150 °C / 296.6 - 302 °F Melting point / freezing point 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 1.067 None known Insoluble in water None known Water solubility Solubility(ies) no data available None known None known No data available Partition coefficient None known no data available **Autoignition temperature Decomposition temperature** None known

Kinematic viscosityno data availableNone knownDynamic viscosityNo data availableNone known

Other information

Explosive properties
Oxidizing properties
No information available
No information available
No information available

Molecular weight 386.65

VOC Content (%)
Liquid Density

Bulk density

No information available
No information available
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 materials** Strong oxidizing agents.

Hazardous decomposition products None known based on information supplied.

#### 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** 

No information available

#### 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
Carcinogenicity

No information available.
No information available.
No information available.
No information available.

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

	Chemical name	ACGIH	IARC	NTP	OSHA
I	Cholesterol	-	Group 3 - Supplement 7	-	-
	57-88-5		[1987]		
			Monograph 31 [1983]		

Legend

Reproductive toxicity No information available.

STOT - single exposure
STOT - repeated exposure
Aspiration hazard

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

TDG not regulated

MEX not regulated

ICAO (air) not regulated

<u>IATA</u> 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 IECSC**This product complies with ENCS:
This product complies with China:

KECL Complies PICCS Complies

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

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

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 31-October-2022 Revision Note No 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
CH135	Cholesterol, NF

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

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

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

Sincerely,

Oralia Chavez

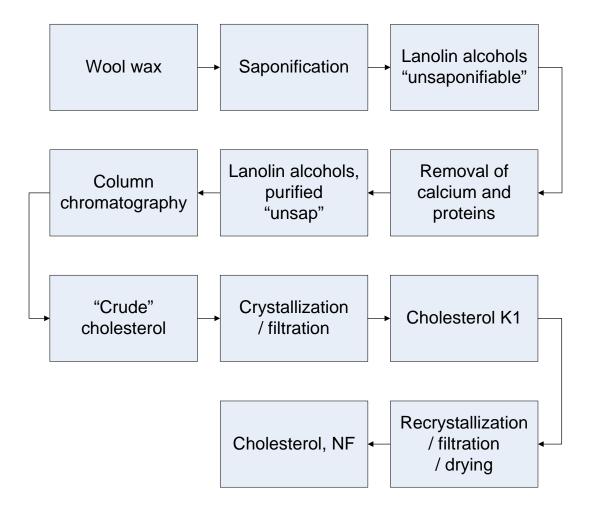
**Quality Assurance Specialist** 

Order Clony



## **Manufacturing Process Flowchart**

## **Cholesterol, NF - CH135**



#### Spectrum Chemical Mfg Corp



## CH135, Cholesterol, NF

#### **Source Statement**

The above mentioned catalog item is manufactured from animal origin (Sheep wool grease). No plant derived products are used in the manufacturing process.

## **BSE/TSE Statement**

The above mentioned catalog item is manufactured using animal derived material and appropriate measures are in place to mitigate BSE/TSE risk and therefore, is 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 above mentioned catalog item 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 - Cholesterol, NF (Cat# CH135)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are 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 - Cholesterol, NF (Cat# CH135)

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 USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Acetone	3	< 5000 ppm
Ethanol	3	< 5000 ppm
Heptane	3	< 5000 ppm

No Class1, Class 2 or other solvents are used or produced in the manufacturing process of this material.

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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

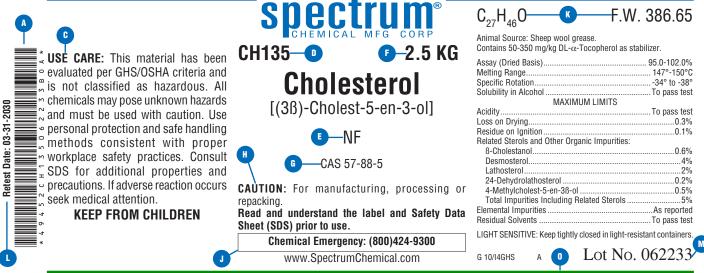
769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

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



## **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.



SPECTRUM CHEMICAL MFG. CORP.

Gardena, CA 90248 • New Brunswick, NJ 08901

- A Bar Code
- GHS Hazard Pictograms
- Warning, Safety Data and Precautionary Information
- Product Catalog Number
- Item Name, Form, Grade
- Storage Color Band

- Size/Quantity
- Chemical Abstracts Service (CAS) Registry Number
- Caution Information
- DOT Shipping Information
- J 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).

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.

# YELLOW: Oxidizer RED: Flammable GREEN: General Storage BLUE: Health Hazard WHITE: Corrosive

## Spectrum Chemical Mfg Corp

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