

# **Scientific Documentation**

# Hydroxyurea, 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 Hydroxyurea, USP (H1181)

Item Number	H1181
Item	Hydroxyurea, USP
CAS Number	127-07-1
Molecular Formula	$\mathrm{CH_4N_2O_2}$
Molecular Weight	76.05
MDL Number	
Synonyms	Hydroxycarbamide; Hydroxymocovina

Test	Specificat	tion
	Min	Max
ASSAY (DRIED BASIS)	97.0	103.0%
LOSS ON DRYING		1.0 %
RESIDUE ON IGNITION		0.50 %
ELEMENTAL IMPURITIES:		
NICKEL (Ni)	AS REPORTED	
MOLYBDENUM (Mo)	AS REPORTED	
CHROMIUM (Cr)	AS REPORTED	
UREA AND RELATED COMPOUNDS		0.5 % each
IDENTIFICATION	SPECTRUM MATCHES REFERENCE	
EXPIRATION 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 08901 Gardena, CA 90248
732.214.1300 310.516.8000



# **Certificate Of Analysis**

Item Number	H1181	Lot Number	1MJ0030
Item	Hydroxyurea, USP	Manufacturer Lot	2120003003
CAS Number	127-07-1	Manufacturer Code	14523
Molecular Formula	$CH_4N_2O_2$	Molecular Weight	76.05

TECT	SPECIFICATION		DECLUT	
TEST	MIN	MAX	RESULT	
ASSAY (DRIED BASIS)	97.0	103.0%	102.1 %	
LOSS ON DRYING		1.0 %	0.2 %	
RESIDUE ON IGNITION		0.50 %	<0.5 %	
ELEMENTAL IMPURITIES:				
NICKEL (Ni)	AS REPORTED		<0.1 μg/g	
MOLYBDENUM (Mo)	AS REPORTED		<1.0 μg/g	
CHROMIUM (Cr)	AS REPORTED		<0.1 μg/g	
UREA AND RELATED COMPOUNDS		0.5 % each	<0.5 %	
IDENTIFICATION	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE	
EXPIRATION DATE			19-SEP-2026	
DATE OF MANUFACTURE			13-OCT-2021	
APPEARANCE			WHITE POWDER	
RESIDUAL SOLVENTS	AS REPORTED			
CLASS 3 (solvent) / ETHANOL			<5000 ppm	
MONOGRAPH EDITION			(USP-NF) 2023	

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 31-OCT-23 13:41:02

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



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 19-APR-24 16:24:51

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.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Olon SpA at Via Della Vittoria 89, Cassino D'Alberi Mulazzano, LO 26837, Italy (ITA). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

# SAFETY DATA SHEET SPECTRUM®



Revision date 31-October-2022

**Revision Number** 2

#### 1. Identification

**Product identifier** 

Product Name HYDROXYUREA, USP

Other means of identification

Product Code(s) H1181

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

Germ cell mutagenicity	Category 1A
Reproductive toxicity	Category 1A

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

Danger

#### Hazard statements

May cause genetic defects
May damage fertility or the unborn child



**Appearance** Granular or Crystalline powder or 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

Chemical name	CAS No	Weight-%
Hydroxyurea	127-07-1	100

#### 4. First-aid measures

#### **Description of first aid measures**

**General advice** Show this safety data sheet to the doctor in attendance.

**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 Monoxide, Carbon Dioxide. Nitrogen oxides (NOx).

**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. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove

contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store locked up. Hygroscopic. It absorbs moisture from the air. Moisture sensitive. Keep

tightly closed.

# 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.

**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 Granular or Crystalline powder or Powder

ColorWhite to Off-WhiteOdorNo information availableOdor thresholdNo information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

no data available Ha None known >130 °C / °F Melting point / freezing point None known None known no data available Boiling point / boiling range Flash point None known no data available **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 None known Solubility(ies) Soluble in hot alcohol **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 (%)

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 materials** Oxidizing or reducing agents.

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

**Component Information** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Hydroxyurea	= 5760 mg/kg (Rat)	-	-
127-07-1			

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

Germ cell mutagenicity Contains a known or suspected mutagen. Classification based on data available for

ingredients. May cause genetic defects.

**Carcinogenicity** No information available.

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

Chemical name	ACGIH	IARC	NTP	OSHA
Hydroxyurea	-	Group 3 - Not classifiable	-	-
127-07-1		- Monograph 76 [2000]		

Legend

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available

for ingredients. May damage fertility or the unborn child.

STOT - single exposureNo information available.STOT - repeated exposureNo information available.Aspiration hazardNo 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

<u>IMDG</u> not regulated

RID not regulated

<u>ADR</u> not regulated

<u>ADN</u> not regulated

# 15. Regulatory information

#### **International Inventories**

TSCA Not listed

Note \*Contact supplier for details. One or more substances in this product are either not listed

on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise

exempted from inventory listing requirements

DSL/NDSL Complies EINECS/ELINCS Complies

ENCS This product complies with ENCS:

IECSC This product does not comply 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 contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Hydroxyurea - 127-07-1	developmental toxicity

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

Chemical name	New Jersey	Massachusetts	Pennsylvania
Hydroxyurea	-	Present	-
127-07-1			

#### 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 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 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
H1181	Hydroxyurea, 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 <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a>

Sincerely,

Oralia Chavez

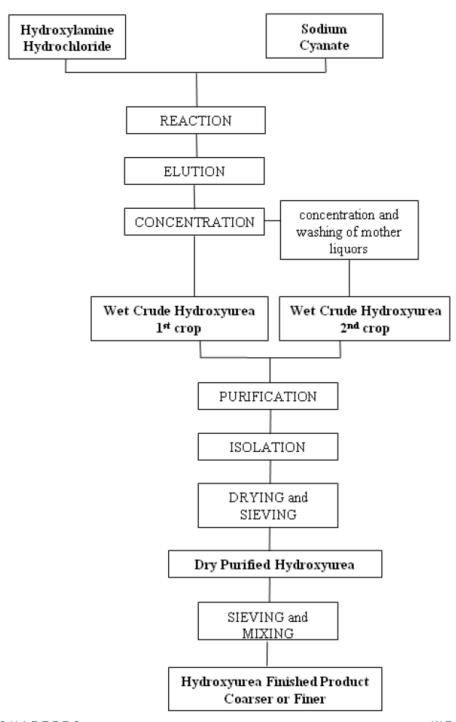
**Quality Assurance Specialist** 

Order Clony



# **Manufacturing Process Flowchart**

Hydroxyurea, USP (Cat# H1181)



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



# H1181, Hydroxyurea, 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
- 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 manufacturing process 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



RE: Elemental Impurities - Hydroxyurea, USP (Cat# H1181)

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 <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



## RE: Residual Solvents - Hydroxyurea, USP (Cat# H1181)

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
Ethanol	3	< 3000 ppm

No Class 1, 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.

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# **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
- 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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