

Scientific Documentation

Lactose, Monohydrate, NF, EP, BP, JP, bioCERTIFIED (TM)

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



Table of Contents

Product Specification
Certificate of Analysis Sample(s)
Safety Data Sheet (SDS)
Certification of Current Good Manufacturing Practices (cGMP)
Manufacturing Process Flowchart
Technical Statements
Elemental Impurities Statement
Residual Solvents Statement
General Label Information – Sample Label



Specification for Lactose, Monohydrate, NF, EP, BP, JP, bioCERTIFIED (TM) (L9010)

Item Number	L9010
Item	Lactose, Monohydrate, NF, EP, BP, JP, bioCERTIFIED (TM)
CAS Number	64044-51-5
Molecular Formula	$C_{12}H_{22}O_{11} \cdot H_2O$
Molecular Weight	360.31
MDL Number	
Synonyms	4-O-Beta-Galactopyranosyl-D-glucose; Milk Sugar

Test	Specification		
	Min	Max	
CLARITY AND COLOR OF SOLUTION	TO PASS TEST		
SPECIFIC ROTATION, [a]D20	+54.4° to +55.9°		
ACIDITY OR ALKALINITY	TO PASS TEST		
WATER DETERMINATION	4.5	5.5%	
LOSS ON DRYING		0.5 %	
RESIDUE ON IGNITION		0.1 %	
PROTEIN AND LIGHT-ABSORBING IMPURITIES		TO PASS TEST	
HEAVY METALS		5 ppm	
ELEMENTAL IMPURITIES		AS REPORTED	
MICROBIAL LIMITS			
ENDOTOXIN		2.5 EU/g	
TOTAL AEROBIC MICROBIAL COUNT		100 cfu/g	
TOTAL MOLDS AND YEASTS		10 cfu/g	
ESCHERICHIA COLI (in 10 g)		Negative	
SALMONELLA (in 50 g)		Negative	
IDENTIFICATION		TO PASS TEST	
EXPIRATION DATE			
DATE OF MANUFACTURE			
APPEARANCE			

Test	Specification	
	Min	Max
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

732.214.1300 310.516.8000



Certificate Of Analysis

Item Number	L9010	Lot Number	4MA0013
Item	Lactose, Monohydrate, NF, EP, BP, JP, bioCERTIFIED (TM)	CAS Number	64044-51-5
Molecular Formula	C ₁₂ H ₂₂ O ₁₁ •H ₂ O	Molecular Weight	360.31

TECT	SPECIFICATION		DECLUT.
TEST	MIN	MAX	RESULT
CLARITY AND COLOR OF SOLUTION	TO PASS TEST		PASSES TEST
SPECIFIC ROTATION, [a]D20	+54.4° to +55.9°		+54.6°
ACIDITY OR ALKALINITY	TO PASS TEST		PASSES TEST
WATER DETERMINATION	4.5	5.5%	5.1 %
LOSS ON DRYING		0.5 %	0.3 %
RESIDUE ON IGNITION		0.1 %	0.027 %
PROTEIN AND LIGHT-ABSORBING IMPURITIES		TO PASS TEST	PASSES TEST
HEAVY METALS		5 ppm	<5 ppm
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
MICROBIAL LIMITS			
ENDOTOXIN		2.5 EU/g	<2.5 EU/g
TOTAL AEROBIC MICROBIAL COUNT		100 cfu/g	<100 cfu/g
TOTAL MOLDS AND YEASTS		10 cfu/g	<10 cfu/g
ESCHERICHIA COLI (in 10 g)		Negative	NEGATIVE
SALMONELLA (in 50 g)		Negative	NEGATIVE
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			31-JUL-2025
DATE OF MANUFACTURE			01-AUG-2022
APPEARANCE			GRANULAR WHITE POWDER
RESIDUAL SOLVENTS		AS REPORTED	NO RESIDUAL SOLVENTS USED

Certificate of Analysis Results Entered By:

SVANGOOR Swetha Vangoor 30-JAN-23 09:06:29

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 30-JAN-23 02:20:26

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

SAFETY DATA SHEET SPECTIUM®



Revision date 28-December-2021

Revision Number 1

1. Identification

Product identifier

Product Name LACTOSE, MONOHYDRATE, NF, EP, BP, JP, bioCERTIFIED™

Other means of identification

Product Code(s) L9010

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

Combustible dust Yes

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

May form combustible dust concentrations in air

Appearance Crystalline powder Physical state Solid Odor Odorless

Precautionary Statements - Prevention

Keep away from all ignition sources including heat, sparks, and flame Keep container closed and grounded Prevent dust accumulations to minimize explosion hazard

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Lactose, Monohydrate	64044-51-5	100	*

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

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

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing mediaDo not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

Avoid generation of dust. Fine dust dispersed in air may ignite.

Explosion data

Sensitivity to mechanical impact none.

Sensitivity to static discharge yes

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. Avoid generation of dust. Avoid contact with eyes. Use

personal protective equipment as required. Do not breathe dust. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Take precautionary

measures against static discharges.

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. Prevent dust cloud.

Methods for cleaning up Take up with inert, damp, non-combustible material using clean non-sparking tools and

place into loosely covered plastic containers for later disposal. 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. Ensure adequate

ventilation. Avoid generation of dust. Do not breathe dust. Avoid contact with eyes. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use spark-proof tools and explosion-proof equipment. Take precautionary measures

against static discharges.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.

Keep out of the reach of children.

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

Eve/face protection Wear safety glasses with side shields (or goggles).

Skin and body protectionNo special protective equipment required.

exceeded or irritation is experienced, ventilation and evacuation may be required.

None known

General hygiene considerations Do not breathe dust.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

Appearance Crystalline powder

Color White Odor Odorless

Odor threshold No information available

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

pH Slightly acidic None known
Melting point / freezing point 202 - 214 °C / 395.6 - 417.2 None known
°F

Boiling point / boiling rangeno data availableNone knownFlash pointno data availableNone knownEvaporation rateno data availableNone knownFlammability (solid, gas)no data availableNone knownFlammability Limit in AirNone 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 1.5 None known Water solubility Soluble in water None known Solubility(ies) no data available None known Partition coefficient No data available None known 470 °C / 878 °F **Autoignition temperature** None known **Decomposition temperature** None known Kinematic viscosity no data available None known

Dynamic viscosity

No data available

Other information

Explosive propertiesNo information availableOxidizing propertiesNo information availableSoftening pointNo information available

Molecular weight 360.31

VOC Content (%)
Liquid 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 Excessive heat. Heating in air. dust formation.

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. May cause irritation of

respiratory tract.

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

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

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 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 Does not Comply EINECS/ELINCS Does not Comply

ENCS IECSCThis product complies with ENCS: This product complies with China:

KECL Does not Comply

PICCS Complies

AICS All the constituents of this material are listed on the Australian Inventory of Chemical

Substances (AICS).

Legend:

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

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

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

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

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

SARA 311/312 Hazard Categories

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

CWA (Clean Water Act)

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

CERCLA

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

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

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

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 0 Flammability 1 Instability 0

Physical and chemical properties -

HMIS

Health hazards 0 Flammability 1 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 28-December-2021 Revision Note 28-December-2021 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
L9010	Lactose, Monohydrate, USP/NF, EP, JP, ChP bioCERTIFIED ™

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

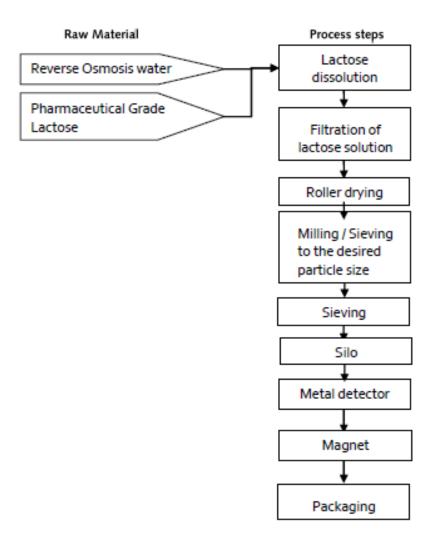
Quality Assurance Specialist

Order Clony



Manufacturing Process Flowchart

Lactose, Monohydrate, USP/NF, EP, JP, ChP bioCERTIFIED™ (Cat# L9010)



CORPORATE HEADQUARTERS

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



L9010, Lactose, Monohydrate, USP/NF, EP, JP, ChP bioCFRTIFIFD™

Source Statement

The above mentioned catalog item is manufactured by animal derived product (cow milk). No plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item is BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Soy
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

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.



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 48 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:

- Bisphenol A (BPA)
- CMR Substances
- Preservatives

- Parabens
- Phthalates



RE: Elemental Impurities - Lactose, Monohydrate, USP/NF, EP, JP, ChP bioCERTIFIED™ (Cat# L9010)

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	< 0.5 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 ppm
Mercury	Hg	1	< 3 ppm
Cobalt	Co	2A	< 5.0 ppm
Vanadium	V	2A	< 10 ppm
Nickel	Ni	2A	< 20 ppm
Selenium	Se	2B	< 15 ppm
Lithium	Li	3	< 55 ppm
Antimony	Sb	3	< 120 ppm
Barium	Ba	3	< 140 ppm
Molybdenum	Мо	3	< 300 ppm
Copper	Cu	3	< 300 ppm
Tin	Sn	3	< 600 ppm
Chromium	Cr	3	< 1100 ppm

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.

CORPORATE HEADQUARTERS

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



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



RE: Residual Solvents - Lactose, Monohydrate, USP/NF, EP, JP, ChP bioCERTIFIED™ (Cat# L9010)

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
Spectrum Chemical Mfg. Corp.

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

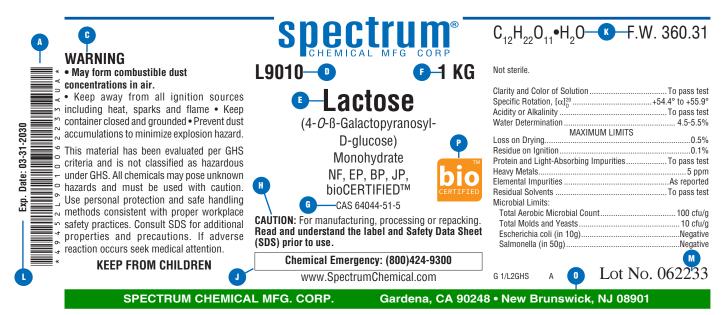
CORPORATE HEADQUARTERS

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



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
- 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

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