

Scientific Documentation

Quinidine Sulfate, Dihydrate, 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 Quinidine Sulfate, Dihydrate, USP (QU105)

Item Number	QU105
Item	Quinidine Sulfate, Dihydrate, USP
CAS Number	6591-63-5
Molecular Formula	$(C_{20}H_{24}N_2O_2)_2 \cdot H_2SO_4 \cdot 2H_2O$
Molecular Weight	782.94
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	99.0	101.0%
SPECIFIC ROTATION [a] _D	+275° to +288°	
WATER DETERMINATION	4.0	5.5%
RESIDUE AFTER IGNITION		0.1%
ORGANIC IMPURITIES	TO PASS TEST	
CHLOROFORM-ALCOHOL-INSOLUBLE SUBSTANCES		0.1%
ELEMENTAL IMPURITIES	AS REPORTED	
DIHYDROQUINIDINE SULFATE		20.0%
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

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	QU105	Lot Number	1ML0004
Item	Quinidine Sulfate, Dihydrate, USP	Manufacturer Lot	10361
CAS Number	6591-63-5	Manufacturer Code	14706
Molecular Formula	$(C_{20}H_{24}N_2O_2)_2 \cdot H_2SO_4 \cdot 2H_2O$	Molecular Weight	782.94

TEST	SPECIFICATION		RESULT	
IESI	MIN	MAX	RESULI	
ASSAY (ANHYDROUS BASIS)	99.0	101.0%	99.6 %	
SPECIFIC ROTATION [a] _D	+275° to +288°		+286°	
WATER DETERMINATION	4.0	5.5%	4.6 %	
RESIDUE AFTER IGNITION		0.1%	0.0 %	
ORGANIC IMPURITIES	TO PASS TEST		PASSES TEST	
CHLOROFORM-ALCOHOL-INSOLUBLE SUBSTANCES		0.1%	0.0 %	
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT (M)	
DIHYDROQUINIDINE SULFATE		20.0%	8.4 %	
IDENTIFICATION	TO PASS TEST		PASSES TEST	
EXPIRATION DATE			23-MAR-2027	
DATE OF MANUFACTURE			24-MAR-2022	
APPEARANCE			WHITE POWDER	
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST	
CLASS 2 (solvent) / TOLUENE			<890 ppm (M)	
MONOGRAPH EDITION			(USP-NF) 2023	
NOTE:All results reported with (M) are from manufacturer certificate of analysis				

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 15-FEB-24 09:06:03

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



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 Buchler GmbH at Harxbütteler Strasse 3, Chininfabrik Braunschweig, D-38110, Germany (DEU). 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.

SHANSEN Selin Hansen 15-FEB-24 14:58:03

SAFETY DATA SHEET

Revision date 23-August-2022

1. Identification	
Product identifier	
Product Name	QUINIDINE SULFATE, DIHYDRATE, USP
Other means of identification	
Product Code(s)	QU105
Synonyms	None
Recommended use of the chemica	l and restrictions on use
Recommended use	No information available
Restrictions on use	No information available
Details of the supplier of the safety	v 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

Acute toxicity - Oral

Category 4

Hazards not otherwise classified (HNOC) Not applicable

Label elements

Warning

Hazard statements Harmful if swallowed



Revision Number 2



Appearance Crystalline or powder

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product

Precautionary Statements - Response

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell Rinse mouth

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-%	Trade secret
Quinidine Sulfate, Dihydrate	6591-63-5	100	*

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

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	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.
Most important symptoms and effects, both acute and delayed	
Symptoms	No information available.
Indication of any immediate medical attention and special treatment needed	

Note to physicians Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.	
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.	
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.	
Specific hazards arising from the chemical	No information available.	
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx). Sulfur oxides.	
Explosion data Sensitivity to mechanical impac	st 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 meas	sures	

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	Keep containers tightly closed in a dry, cool and well-ventilated place. 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

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 o	chemical properties	
Physical state	Solid	
Appearance	Crystalline or powder	
Color	White to Yellow	
Odor	No information available	
Odor threshold	No information available	
Property_	Values_	Remarks • Method
pH	6-6.8 (1% solution)	None known
Melting point / freezing point	213 °C / 415.4 °F	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	no data available	None known
Water solubility	Slightly soluble in water	None known
Solubility(ies)	Soluble in Alcohol	None known
	Insoluble in Benzene	
	Insoluble in Ether	
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
Dynamic viscosity	No data available	None known
Other information		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	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 materials	None 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. Harmful if swallowed. (based on components).

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 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
<u>MEX</u>	not regulated
ICAO (air)	not regulated
IATA	not regulated
IMDG_	not regulated
RID	not regulated
ADR	not regulated
ADN	not regulated

15. Regulatory information

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TSCA Note Not listed

*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	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
AICS	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

HMIS Health hazards Flammability 0 Physical hazards Personal protect	emical properties - 0 s 0 ion X		
	abbreviations and acronyms used in 8: EXPOSURE CONTROLS/PERSON		_
TWĂ	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		
Agency for Toxic U.S. Environment European Food S EPA (Environmen	Ferences and sources for data used t Substances and Disease Registry (ATS al Protection Agency ChemView Datab afety Authority (EFSA) tal Protection Agency) Guideline Level(s) (AEGL(s))	SDR)	
	al Protection Agency Federal Insecticid		nticide Act
U.S. Environment	al Protection Agency High Production \	/olume Chemicals	

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	23-August-2022
Revision Note	No information available.
<u>Disclaimer</u>	

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

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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
QU105	Quinidine Sulfate, Dihydrate, 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:2020632Spectrum-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 <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

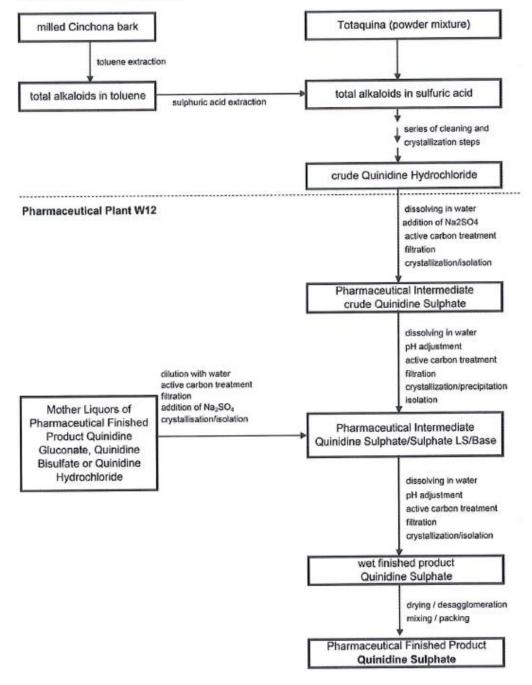
Oulu Clamy

Oralia Chavez Quality Assurance Specialist



Manufacturing Process Flowchart Quinidine Sulfate, Dihydrate, USP (Cat# QU105)

Extraction/Chemical Plant W18



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

QU105, Quinidine Sulfate, Dihydrate, USP

Source Statement

The above mentioned catalog item is manufactured by extraction from the natural source of cinchona bark. No animal derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

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

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

• Cereals containing Gluten

spectrum

- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.



Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

spectrum®

RE: Elemental Impurities - Quinidine Sulfate, Dihydrate, USP (Cat# QU105)

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

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

AN ISO 9001:2015 REGISTERED COMPANY

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RE: Residual Solvents - Quinidine Sulfate, Dihydrate, USP (Cat# QU105)

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
Toluene	2B	< 890 ppm

No Class 1, Class 3 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 <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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CORPORATE HEADQUARTERS

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

WEST COAST FACILITY

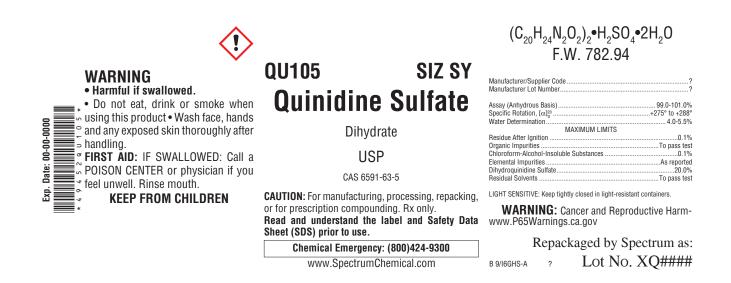
14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843

AN ISO 9001:2015 REGISTERED COMPANY

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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. Below you will find a typical label example for this catalog item.



Spectrum Chemical Mfg Corp

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