

## **Scientific Documentation**

## Threonine, Crystal, 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 Threonine, Crystal, USP (T1056)**

Item Number	T1056
Item	Threonine, Crystal, USP
CAS Number	72-19-5
Molecular Formula	C <sub>4</sub> H <sub>9</sub> NO <sub>3</sub>
Molecular Weight	119.12
MDL Number	
Synonyms	Threonine ; L-2-Amino-3-hydroxybutyric Acid

Test	Specification		
	Min	Max	
APPEARANCE			
ASSAY (DRIED BASIS)	98.5	101.5 %	
SPECIFIC ROTATION [a]D	-26.7 to -29.1°		
pH OF A 1 IN 20 SOLUTION	5.0	6.5	
LOSS ON DRYING		0.2 %	
RESIDUE ON IGNITION		0.4 %	
CHLORIDE		0.05 %	
SULFATE		0.03 %	
IRON		30 ppm	
ELEMENTAL IMPURITIES:			
CADMIUM (Cd)	AS REPORTED		
LEAD (Pb)	AS REPORTED		
ARSENIC (As)	AS REPORTED		
MERCURY (Hg)	AS REPORTED		
RELATED COMPOUNDS:			
INDIVIDUAL IMPURITIES		0.5 %	
TOTAL IMPURITIES		2.0 %	
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE		
EXPIRATION DATE			
DATE OF MANUFACTURE			

Test	Specification	
	Min	Max
MONOGRAPH EDITION		
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	T1056	Lot Number	1MD0827
Item	Threonine, Crystal, USP	CAS Number	72-19-5
Molecular Formula	C <sub>4</sub> H <sub>9</sub> NO <sub>3</sub>	Molecular Weight	119.12

TECT	SPECIFICATION		
TEST	MIN	MAX	RESULT
APPEARANCE			WHITE CRYSTALS
ASSAY (DRIED BASIS)	98.5	101.5 %	99.3 %
SPECIFIC ROTATION [a] <sub>D</sub>	-26.7 to -29.1°		-28.2°
pH OF A 1 IN 20 SOLUTION	5.0	6.5	5.65
LOSS ON DRYING		0.2 %	0.15 %
RESIDUE ON IGNITION		0.4 %	0.04 %
CHLORIDE		0.05 %	<0.02 %
SULFATE		0.03 %	<0.02 %
IRON		30 ppm	<30 ppm
ELEMENTAL IMPURITIES:			
CADMIUM (Cd)	AS REPORTED		<0.5 µg/g
LEAD (Pb)	AS REPORTED		<0.5 µg/g
ARSENIC (As)	AS REPORTED		<1.5 µg/g
MERCURY (Hg)	AS REPORTED		<1.5 µg/g
RELATED COMPOUNDS:			
INDIVIDUAL IMPURITIES		0.5 %	< 0.5 %
TOTAL IMPURITIES		2.0 %	<0.1 µg/g
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
EXPIRATION DATE			16-NOV-2024
DATE OF MANUFACTURE			18-NOV-2022
MONOGRAPH EDITION			(USP) 2022
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 05-MAY-23 17:26:56

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.

Certificate of Analysis Results Approved By:

JAMAYA Javier Amaya 11-MAY-23 09:44:18

# SAFETY DATA SHEET **spectrum**<sup>®</sup>

Revision date 08-May-2023

1. Identification	
Product identifier	
Product Name	THREONINE, CRYSTAL, USP
Other means of identification	
Product Code(s)	T1056
Synonyms	None
Recommended use of the chemica	I 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). Not a dangerous substance or mixture according to the Globally Harmonized System (GHS).

#### 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). Not a dangerous substance or mixture according to the Globally Harmonized System (GHS).

The product contains no substances which at their given concentration, are considered to be hazardous to health.



**Revision Number** 2

#### Other information

No information available.

## 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%
L-Threonine	72-19-5	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	

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.
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, includi	ng any incompatibilities	
Storage Conditions	Keep container tightly closed in a dry and well-ventilated place.	

### 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 propertiesPhysical stateSolidAppearanceCrystallineColorWhite

Odor Odor threshold	No information available No information available		
Property	Values	Remarks • Method	
рН	no data available	None known	
Melting point / freezing point	255 - 257 °C / 491 - 494.6 °F		
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 limits	No data available		
	No data available	None known	
Vapor pressure Vapor density	no data available	None known	
Relative density	1.3	None known	
Water solubility	Soluble in water	None known	
Solubility(ies)	Insoluble in Ethanol	None known	
Partition coefficient	-2.94	None known	
	no data available	None known	
Autoignition temperature Decomposition temperature	no data avaliable	None known	
Kinematic viscosity	no data available	None known	
Dynamic 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	119.12		
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 avoidNone known based on information supplied.Incompatible materialsNone known based on information supplied.

Hazardous decomposition products None known based on information supplied.

## 11. Toxicological information

#### Information on likely routes of exposure

Specific test data for the substance or mixture is not available.		
Specific test data for the substance or mixture is not available.		
Specific test data for the substance or mixture is not available.		
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	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information		
Ecotoxicity	The environmental impact of this product has not been fully investigated.	
Persistence and degradability Bioaccumulation	No information available.	
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

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

#### 15. Regulatory information

#### International Inventories

TSCA
IJUA

Complies

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical
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 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 STEL (Short Term Exposure Limit) TWA TWA (time-weighted average) STEL 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** 08-May-2023

Revision date 08-May-2023 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



December 15, 2021

### 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
T1056	Threonine, Crystal, 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>gualityassurance@spectrumchemical.com</u>

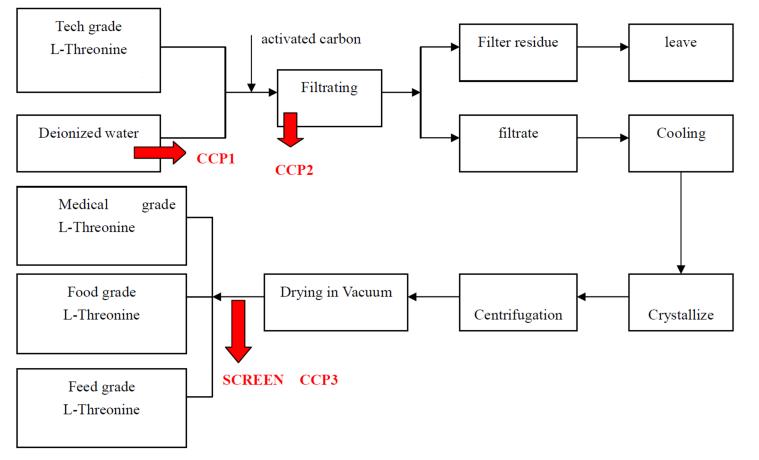
Sincerely,

Outer Clamy

Oralia Chavez Quality Assurance Specialist



## Manufacturing Process Flowchart Threonine, Crystal, USP (Cat #T1056)



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AN ISO 9001:2015 REGISTERED COMPANY

www.spectrumchemical.com

## spectrum

## T1056, Threonine, Crystal, USP

## **Source Statement**

The above mentioned catalog item is manufactured by fermentation of corn. 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
- Celery
- Mustard
- Sesame Seed
- 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 24 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
- Bisphenol A (BPA)
- CMR Substances
- Parabens

- Pesticides
- Phthalates
- Preservatives

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## RE: Elemental Impurities - Threonine, Crystal, USP (Cat# T1056)

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	< 1.5 ppm
Cobalt	Co	2A	Not tested
Vanadium	V	2A	Not tested
Nickel	Ni	2A	Not tested
Thallium	TI	2B	Not tested
Gold	Au	2B	Not tested
Palladium	Pd	2B	Not tested
Iridium	lr	2B	Not tested
Osmium	Os	2B	Not tested
Rhodium	Rh	2B	Not tested
Ruthenium	Ru	2B	Not tested
Selenium	Se	2B	Not tested
Silver	Ag	2B	Not tested
Platinum	Pt	2B	Not tested
Lithium	Li	3	Not tested
Antimony	Sb	3	Not tested
Barium	Ba	3	Not tested
Molybdenum	Мо	3	Not tested
Copper	Cu	3	Not tested
Tin	Sn	3	Not tested
Chromium	Cr	3	Not tested

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These

CORPORATE HEADQUARTERS

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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.

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## RE: Residual Solvents - Threonine, Crystal, USP (Cat# T1056)

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

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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YELLOW: Oxidizer

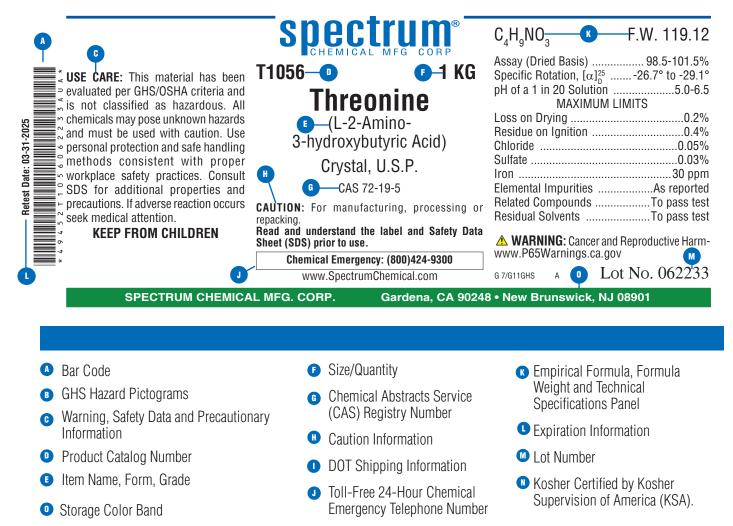
RED: Flammable

**GREEN:** General Storage

BLUE: Health Hazard WHITE: Corrosive

## **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.



This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

### Spectrum Chemical Mfg Corp

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