

# **Scientific Documentation**

# **Choline Chloride, USP Dietary Supplement**

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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Product Specification Certificate of Analysis 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 Kosher Certification



## **Specification for Choline Chloride, USP Dietary Supplement (C2058)**

Item Number	C2058
Item	Choline Chloride, USP Dietary Supplement
CAS Number	67-48-1
Molecular Formula	C <sub>5</sub> H <sub>14</sub> CINO
Molecular Weight	139.62
MDL Number	
Synonyms	(2-Hydroxyethyl)trimethylammonium Chloride

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	99.0	100.5 %
pH OF A 1 IN 10 SOLUTION	4.0	7.0
ELEMENTAL IMPURITIES	AS REPORTED	
ARSENIC		2 ppm
LEAD		0.3 ppm
WATER DETERMINATION		0.5 %
RESIDUE ON IGNITION		0.05 %
LIMIT OF TOTAL AMINES		10 µg/g
1,4-DIOXANE		10 µg/g
CHROMATOGRAPHIC PURITY :		
INDIVIDUAL IMPURITIES		0.3 %
TOTAL IMPURITIES		2.0 %
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	POSITIVE FOR CHLORIDE	
CERTIFIED KOSHER		
APPEARANCE		
RETEST DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	

Test	Specification	
	Min	Max
MONOGRAPH EDITION		

#### 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	C2058	Lot Number	2MG0060
Item	Choline Chloride, USP Dietary Supplement	CAS Number	67-48-1
Molecular Formula	C <sub>5</sub> H <sub>14</sub> CINO	Molecular Weight	139.62

TECT	SPECIFICATION			
TEST	MIN	MAX	RESULT	
ASSAY (ANHYDROUS BASIS)	99.0	100.5 %	99.4 %	
pH OF A 1 IN 10 SOLUTION	4.0	7.0	5.2	
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITES PRESENT	
ARSENIC		2 ppm	<0.5 ppm	
LEAD		0.3 ppm	<0.05 ppm	
WATER DETERMINATION		0.5 %	0.4 %	
RESIDUE ON IGNITION		0.05 %	0.00 %	
LIMIT OF TOTAL AMINES		10 µg/g	<10 µg/g	
1,4-DIOXANE		10 µg/g	<10 µg/g	
CHROMATOGRAPHIC PURITY :				
INDIVIDUAL IMPURITIES		0.3 %	<0.3 %	
TOTAL IMPURITIES		2.0 %	<2.0 %	
IDENTIFICATION (A)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE	
CERTIFIED KOSHER			CERTIFIED KOSHER	
APPEARANCE			WHITE CRYSTALLINE POWDER	
RETEST DATE			16-JAN-2024	
DATE OF MANUFACTURE			16-JAN-2022	
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENT PRESENT	
MONOGRAPH EDITION			USP 2023	

Certificate of Analysis Results Entered By:

GHERRERA Genaro Herrera 31-JUL-23 07:48:11

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



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:

BPATEL Bhargavi Patel 31-JUL-23 12:29:40

# SAFETY DATA SHEET

Revision date 28-May-2021

Choline Chloride, USP
C2058
None
and restrictions on use
No information available
No information available
data sheet

**Emergency Telephone** 

Chemtrec 1-800-424-9300

#### 2. Hazard(s) identification

#### **Classification**

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

#### Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

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

Appearance Crystalline powder

Physical state Solid

Odor No information available



**Revision Number** 2

#### Other information

No information available.

#### 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%	Trade secret
Choline Chloride	67-48-1	100	*

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

4. Fii	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 effect	cts, 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). hydrogen chloride gas.
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 measures

#### Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
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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
 Handle in accordance with good industrial hygiene and safety practice.

 Conditions for safe storage, including any incompatibilities
 Hygroscopic. It absorbs moisture from the air. Protect from moisture. 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, suc	ch as personal protective equipment
Eye/face protection	No special protective equipment required.
Skin and body protection	No special protective equipment required.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

#### 9. Physical and chemical properties

Information on basic physical and chemical properties Physical state Solid

Appearance Color Odor Odor threshold	Crystalline powder White No information available No information available	
Property pH Melting point / freezing point Boiling point / boiling range Flash point Evaporation rate Flammability (solid, gas) Flammability Limit in Air	<u>Values</u> no data available 302 - 305 °C / 575.6 - 581 °F no data available no data available no data available no data available	Remarks • Method None known None known None known None known None known None known None known
Upper flammability or explosive limits Lower flammability or explosive limits	No data available No data available	New years
Vapor pressure Vapor density Relative density Water solubility Solubility(ies) Partition coefficient Autoignition temperature Decomposition temperature Kinematic viscosity	No data available no data available 1.1 No data available no data available -3.77 no data available no data available	None known None known None known None known None known None known None known
Dynamic viscosity <u>Other information</u> Explosive properties Oxidizing properties Softening point Molecular weight VOC Content (%) Liquid Density Bulk density	No data available No information available No information available 139.62 No information available No information available No information available	None known

#### 10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under recommended storage 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

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
Choline Chloride	= 3400 mg/kg (Rat)	-	-
67-48-1			

#### 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 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

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Choline Chloride	EC50: >500mg/L (72h,	LC50: >10000mg/L (96h,	-	EC50: >320mg/L (48h,
67-48-1	Desmodesmus	Leuciscus idus)		Daphnia magna) EC50:
	subspicatus)			>500mg/L (48h, Daphnia
				magna Straus)

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Choline Chloride	-3.77
67-48-1	

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
IMDG	not regulated
RID	not regulated
ADR	not regulated
ADN	not regulated

#### 15. Regulatory information

International Inventories

**TSCA** 

Complies

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS AICS	Complies All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

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

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

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances **ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances Complies

#### US Federal Regulations

#### SARA 313

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

#### SARA 311/312 Hazard Categories

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

#### CWA (Clean Water Act)

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

#### **CERCLA**

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

#### US State Regulations

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

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

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

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

#### 16. Other information

NFPA Health hazards 0 Flammability 0 Instability 0 Physical and chemical properties -HMIS Health hazards 0 Flammability 0 Physical hazards 0 Personal protection X Key or legend to abbreviations and acronyms used in the safety data sheet Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit) Ceilina 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, Fundicide, 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-May-2021

No information available.

Revision Note 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

# spectrum

#### 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	
C2058	Choline Chloride, USP Dietary Supplement

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: Spectrum-New Brunswick, NJ: 2020632 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,

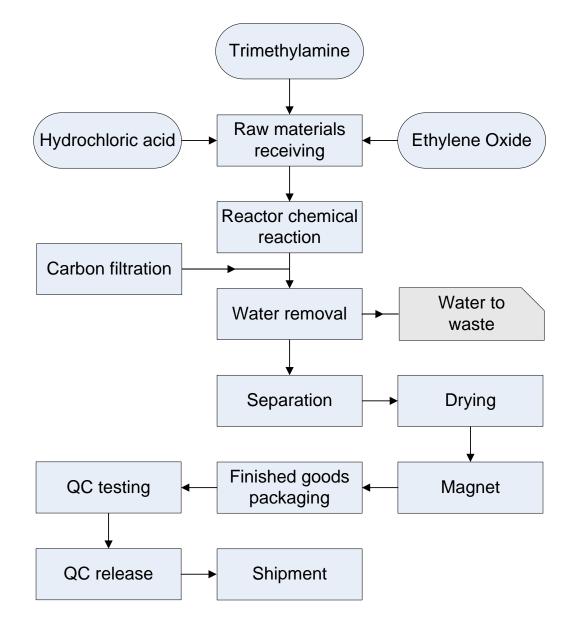
Oulu Clamy

Oralia Chavez Quality Assurance Specialist



### **Manufacturing Process Flowchart**

### **Choline Chloride, USP - C2058**



#### Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave. New Brunswick, NJ 08901 732.214.1300 *West Coast Facility:* 14422 S. San Pedro St. Gardena, CA 90248 310.516.8000

### C2058, Choline Chloride, USP Dietary Supplement

#### **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

spectrum

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

#### **EU Fragrance Allergen Statement**

The above mentioned catalog item does contain Choline chloride, one of the 26 EU fragrance allergens listed in Annex III lines 67-92.

#### **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 been tested on animals.

#### **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, or sewage sludge. Please note that Ethylene Oxide is used to synthesize Choline Chloride, but not used as a sterilant.

#### **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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

# spectrum®

RE: Elemental Impurities - Choline Chloride, USP Dietary Supplement (Cat# C2058)

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

# spectrum

#### RE: Residual Solvents - Choline Chloride, USP Dietary Supplement (Cat# C2058)

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.

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

#### CORPORATE HEADQUARTERS

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#### WEST COAST FACILITY

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AN ISO 9001:2015 REGISTERED COMPANY

# spectrum®

YELLOW: Oxidizer

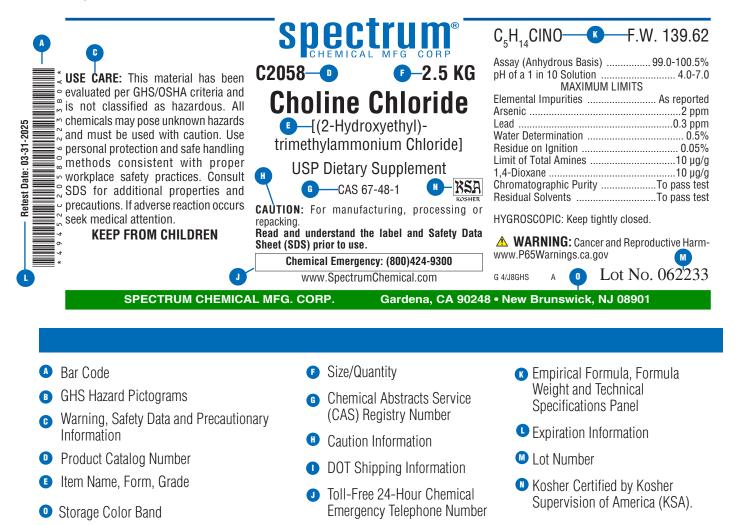
RED: Flammable

**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

*Corporate Headquarters:* 769 Jersey Ave. New Brunswick, NJ 08901

732.214.1300

West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248 310.516.8000



בס"ד Jan 18, 2024

The following product(s) prepared by the named company are certified kosher with the stated requirements:

#### **Spectrum Laboratory Products, Inc.**

S-0032

14422 South San Pedro Street, Gardena, CA 90248 755-769 Jersey Ave. New Brunswick NJ 08901 USA	Product Name Brand UKD-ID D/P/M	C2058, Choline Chloride, USP Dietary Supplement Spectrum KSAV3-K4U6J96 P
	Symbol Required	KSA
This certificate expires on <b>Feb 01, 2025</b>	Special Conditions	

Rabbi Binyomin Lisbon Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.

Decument id: -1105820 P.O.Box 35721, Los Angeles, Ca 90035 - (310) 282-0444 - Fax (310) 282-0505 - Email info@ksakosher.com - www.ksakosher.com