

Scientific Documentation

Choline Chloride, USP, FCC, Dietary Supplement 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





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Specification for Choline Chloride, USP, FCC, Dietary Supplement bioCERTIFIED (TM) (C9040)

Item Number	C9040
Item	Choline Chloride, USP, FCC, Dietary Supplement bioCERTIFIED (TM)
CAS Number	67-48-1
Molecular Formula	C ₅ H ₁₄ 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 REPORT		
ARSENIC		2 ppm	
LEAD		0.3 ppm	
WATER DETERMINATION		0.5 %	
RESIDUE ON IGNITION		0.05 %	
LIMIT OF TOTAL AMINES		10 ?g/g	
1,4-Dioxane (USP)		10 ?g/g	
1,4-Dioxane (FCC)		TO PASS TEST	
CHROMATOGRAPHIC PURITY		TO PASS TEST	
MICROBIAL LIMITS:			
TOTAL AEROBIC MICROBIAL COUNT		100 cfu/g	
TOTAL COMBINED MOLDS AND YEASTS COUNT		30 cfu/g	
ESCHERICHIA COLI		Absent/10g	
SALMONELLA SPECIES		Absent/25g	
BACILLUS CEREUS		3 cfu/g	
BACTERIAL ENDOTOXINS		2.5 EU/g	
IDENTIFICATION		TO PASS TEST	

Test	Spec	ification
	Min	Max
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



Certificate Of Analysis

Item Number	C9040	Lot Number	4LL0019
Item	Choline Chloride, USP, FCC, Dietary Supplement bioCERTIFIED (TM)	CAS Number	67-48-1
Molecular Formula	C ₅ H ₁₄ CINO	Molecular Weight	139.62

TEST	SPECIFICATION		RESULT	
TEST	MIN	MAX	RESULI	
ASSAY (ANHYDROUS BASIS)	99.0	100.5 %	99.4 %	
pH OF A 1 IN 10 SOLUTION	4.0	7.0	6.0	
ELEMENTAL IMPURITIES	AS REPORT		COMPLIES WITH STANDARD	
ARSENIC		2 ppm	<0.5 ppm	
LEAD		0.3 ppm	<0.05 ppm	
WATER DETERMINATION		0.5 %	0.3 %	
RESIDUE ON IGNITION		0.05 %	0.00 %	
LIMIT OF TOTAL AMINES		10 μg/g	7 μg/g	
1,4-Dioxane (USP)		10 μg/g	<10 μg/g	
1,4-Dioxane (FCC)		TO PASS TEST	PASSES TEST (M)	
CHROMATOGRAPHIC PURITY		TO PASS TEST	PASSES TEST	
MICROBIAL LIMITS:				
TOTAL AEROBIC MICROBIAL COUNT		100 cfu/g	<100 cfu/g	
TOTAL COMBINED MOLDS AND YEASTS COUNT		30 cfu/g	<30 cfu/g	
ESCHERICHIA COLI		Absent/10g	Absent/10g	
SALMONELLA SPECIES		Absent/25g	Absent/25g	
BACILLUS CEREUS		3 cfu/g	<3 cfu/g	
BACTERIAL ENDOTOXINS		2.5 EU/g	<2.5 EU/g	
IDENTIFICATION		TO PASS TEST	PASSES TEST	
EXPIRATION DATE			16-JAN-2024	
DATE OF MANUFACTURE			16-JAN-2022	
APPEARANCE			WHITE GRANULAR POWDER	
RESIDUAL SOLVENTS		AS REPORTED	NO RESIDUAL SOLVENTS USED	
NOTE:All results reported with (M) are from manufacturer certificate of analysis				

Certificate of Analysis Results Entered By:

KMORALES Keyla Morales 15-MAR-23 15:13:05

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

EMORALES Emine Morales 17-MAR-23 05:35:10

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.





Revision date 25-August-2022

Revision Number 1

1. Identification

Product identifier

Product Name CHOLINE CHLORIDE, USP, FCC, DIETARY SUPPLEMENT, bioCERTIFIED™

Other means of identification

Product Code(s) C9040

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use Industrial.

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.

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. 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

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

No information available.

Hazardous combustion products Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx). hydrogen chloride gas.

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, including any incompatibilities

Storage Conditions Hygroscopic. It absorbs moisture from the air. Keep tightly closed.

8. Exposure controls/personal protection

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure

limit applicable in the region for which this safety data sheet is intended or other

recommended limit. At this time, the other relevant constituents have no known exposure

limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protectionNo special protective equipment required.

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

Crystalline powder **Appearance**

Color White

Odor No information available No information available **Odor threshold**

Property Values Remarks • Method

no data available Hq None known 302 - 305 °C / 575.6 - 581 °F Melting point / freezing point 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 None known 1.1 None known Water solubility Soluble in water Soluble in Alcohol Solubility(ies) None known

Soluble in Dimethyl Sulfoxide

None known

Partition coefficient -377

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

No information available **Explosive properties Oxidizing properties** No information available No information available Softening point

Molecular weight 139.62

VOC Content (%) No information available **Liquid Density** No information available No information available **Bulk density**

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 No information available.

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.

Specific test data for the substance or mixture is not available. Skin contact

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.

Reproductive toxicity No information available.

STOT - single exposure
STOT - repeated exposure
Aspiration hazard

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.

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

KECL Complies 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

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

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)

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 25-August-2022

Revision Note No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
C9040	Choline Chloride, USP, FCC, Dietary Supplement
	bioCERTIFIED (TM)

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

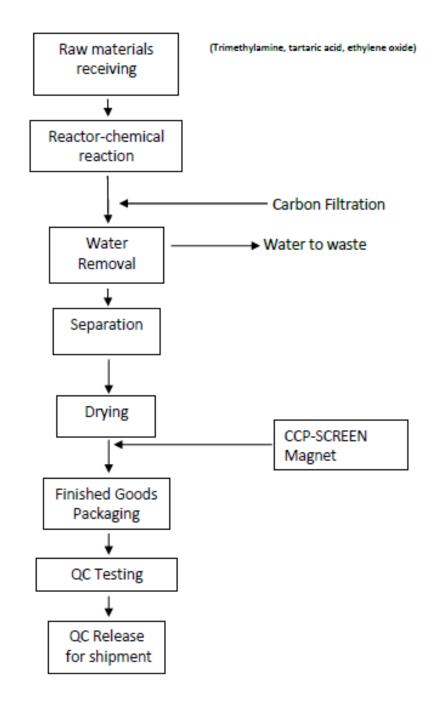
Quality Assurance Specialist

Order Clony



Manufacturing Process Flowchart

Choline Chloride, USP, FCC, Dietary Supplement bioCERTIFIED™ (Cat# C9040)



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



C9040, Choline Chloride, USP, FCC, Dietary Supplement bioCFRTIFIED™

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

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

Allergen Statement

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

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

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

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the 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 been tested on animals for regulatory compliance purposes.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Choline Chloride, USP, FCC, Dietary Supplement bioCERTIFIED ™ (Cat# C9040)

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 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

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



RE: Residual Solvents - Choline Chloride, USP, FCC, Dietary Supplement bioCERTIFIED ™ (Cat# C9040)

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.

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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.

USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards * and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

KEEP FROM CHILDREN WARNING:

Cancer and Reproductive Harmwww.P65Warnings.ca.gov

SIZ SY C9040 **Choline Chloride**

[(2-Hydroxyethyl)trimethylammonium Chloride] USP, FCC, Dietary Supplement,

bioCERTIFIED™ KSA CAS 67-48-1

Sheet (SDS) prior to use.



CAUTION: For manufacturing, processing or repacking.

Read and understand the label and Safety Data

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

C ₅ H ₁₄ CINO	F.W. 139.62
Not sterile.	
Assay (Anhydrous Basis) pH of a 1 in 10 Solution Elemental Impurities Arsenic tage de Arsenic Lead Water Determination Residue on Ignition Limit of Total Amines 1,4-Dioxane (ICSP) 1,4-Dioxane (ICSP) 1,4-Dioxane (ICSP) 1,4-Dioxane (ICSP) Indicate the second s	99.0-100.5%
Sulfite reducing <i>Clostridi</i>	3 cfu/g um10 cfu/g
Coliform	Absent/10g
	2.5 EU/g
HYGROSCOPIC: Keep tight	
G 1/L10GHS ?	Lot No. XQ####

Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave.

New Brunswick, NJ 08901

310.516.8000

732.214.1300