

Scientific Documentation

Glacial Acetic Acid, USP, EP, BP, JP, bioCERTIFIED (TM)

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



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Specification for Glacial Acetic Acid, USP, EP, BP, JP, bioCERTIFIED (TM) (A9004)

Item Number	A9004
Item	Glacial Acetic Acid, USP, EP, BP, JP, bioCERTIFIED (TM)
CAS Number	64-19-7
Molecular Formula	C ₂ H ₄ O ₂
Molecular Weight	60.05
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY	99.5	100.5 %
APPEARANCE	Clear and colorless	
CONGEALING TEMPERATURE	15.6°C	
NONVOLATILE RESIDUE (w/v)		0.005 %
CHLORIDE (Cl)		TO PASS TEST
CHLORIDES (EP)		25 mg/L
SULFATE (SO ₄).		TO PASS TEST
SULFATES (EP)		50 mg/L
IRON (EP)		5 ppm
READILY OXIDIZABLE SUBSTANCES		TO PASS TEST
Potassium Permanganate-reducing Substances (JP, EP)		TO PASS TEST
ELEMENTAL IMPURITIES		AS REPORTED
HEAVY METALS (JP)		10 ppm
BACTERIAL ENDOTOXINS		6.0 EU/g
MICROBIAL CONTENT:		
TAMC		1000 CFU/g
TYMC		100 CFU/g
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		

Test	Specification	
	Min	Max
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS		AS REPORTED

Spectrum Chemical Mfg Corp

<i>Corporate Headquarters:</i>	<i>West Coast Facility:</i>
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	A9004	Lot Number	4LF0033
Item	Glacial Acetic Acid, USP, EP, BP, JP, bioCERTIFIED (TM)	CAS Number	64-19-7
Molecular Formula	C ₂ H ₄ O ₂	Molecular Weight	60.05

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY	99.5	100.5 %	99.8 %
APPEARANCE	Clear and colorless		CLEAR AND COLORLESS
CONGEALING TEMPERATURE	15.6°C		18.2°C
NONVOLATILE RESIDUE (w/v)		0.005 %	0.005 %
CHLORIDE (CI)		TO PASS TEST	PASSES TEST
CHLORIDES (EP)		25 mg/L	25 mg/L
SULFATE (SO ₄).		TO PASS TEST	PASSES TEST
SULFATES (EP)		50 mg/L	50 mg/L
IRON (EP)		5 ppm	5 PPM
READILY OXIDIZABLE SUBSTANCES		TO PASS TEST	PASSES TEST
Potassium Permanganate-reducing Substances (JP, EP)		TO PASS TEST	PASSES TEST
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
HEAVY METALS (JP)		10 ppm	<0.1 PPM
BACTERIAL ENDOTOXINS		6.0 EU/g	<6.0 EU/G
MICROBIAL CONTENT:			.
TAMC		1000 CFU/g	<1000 CFU/G
TYMC		100 CFU/g	<100 CFU/G
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			23-FEB-2024
DATE OF MANUFACTURE			23-FEB-2022
RESIDUAL SOLVENTS		AS REPORTED	.
CLASS 2 (SOLVENT) / METHANOL			<3000 PPM
CLASS 3 (solvent) / FORMIC ACID			<5000 PPM

Certificate of Analysis Results Entered By:

TDAO
Tiffany DAO
26-AUG-22 14:06:22

Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
26-AUG-22 14:06:35

Spectrum Chemical Mfg Corp
777 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.

SAFETY DATA SHEET

spectrum®



Revision date 21-February-2024

Revision Number 2

1. Identification

Product identifier

Product Name GLACIAL ACETIC ACID, USP, MULTICOMPENDIAL, BIOCERTIFIED(TM)

Other means of identification

Product Code(s) A9004

UN/ID no UN2789

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use For manufacturing or laboratory use only.

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

Acute toxicity - Dermal	Category 4
Acute toxicity - Inhalation (Dusts/Mists)	Category 4
Skin corrosion/irritation	Category 1 Sub-category A
Serious eye damage/eye irritation	Category 1
Flammable liquids	Category 3

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Harmful in contact with skin
Harmful if inhaled

Causes severe skin burns and eye damage
Flammable liquid and vapor



Appearance clear

Physical state Liquid

Odor Vinegar-like

Precautionary Statements - Prevention

Use only outdoors or in a well-ventilated area

Do not breathe dusts or mists

Wash face, hands and any exposed skin thoroughly after handling

Wear protective gloves/protective clothing/eye protection/face protection

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

Keep container tightly closed

Ground/bond container and receiving equipment

Use explosion-proof electrical/ ventilating / lighting/ .? / equipment

Use only non-sparking tools

Take precautionary measures against static discharge

Precautionary Statements - Response

Specific treatment (see .? on this label)

Immediately call a POISON CENTER or doctor

Specific treatment (see .? on this label)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Immediately call a POISON CENTER or doctor

Call a POISON CENTER or doctor if you feel unwell

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower

Wash contaminated clothing before reuse

IF INHALED: Remove person to fresh air and keep comfortable for breathing

Immediately call a POISON CENTER or doctor

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting

In case of fire: Use CO₂, dry chemical, or foam to extinguish

Precautionary Statements - Storage

Store locked up.

Store in a well-ventilated place. Keep cool

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

May be harmful if swallowed.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
Acetic Acid, glacial	64-19-7	100

4. First-aid measures

Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance. Immediate medical attention is

required.

Inhalation	Remove to fresh air. If breathing has stopped, give artificial respiration. Get medical attention immediately. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen. Delayed pulmonary edema may occur. Get immediate medical advice/attention.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get immediate medical advice/attention.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.
Self-protection of the first aider	Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Avoid breathing vapors or mists.

Most important symptoms and effects, both acute and delayed

Symptoms Burning sensation. Coughing and/ or wheezing. Difficulty in breathing.

Indication of any immediate medical attention and special treatment needed

Note to physicians Product is a corrosive material. Use of gastric lavage or emesis is contraindicated. Possible perforation of stomach or esophagus should be investigated. Do not give chemical antidotes. Asphyxia from glottal edema may occur. Marked decrease in blood pressure may occur with moist rales, frothy sputum, and high pulse pressure.

5. Fire-fighting measures

Suitable Extinguishing Media Large Fire	Dry chemical. Carbon dioxide (CO ₂). water spray. Alcohol resistant foam. 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	risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating gases and vapors.
Hazardous combustion products	Carbon monoxide. Carbon dioxide (CO ₂).
Explosion data	
Sensitivity to mechanical impact	none.
Sensitivity to static discharge	yes.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions

Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material. Attention! Corrosive material. Avoid breathing vapors or mists.

Other information

Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up**Methods for containment**

Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor suppressing foam may be used to reduce vapors. Dike far ahead of spill to collect runoff water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal.

Methods for cleaning up

Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

7. Handling and storage**Precautions for safe handling****Advice on safe handling**

Use personal protection equipment. Avoid breathing vapors or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities**Storage Conditions**

Hygroscopic. It absorbs moisture from the air. Protect from moisture. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Store locked up. Keep out of the reach of children. Store away from other materials.

8. Exposure controls/personal protection**Control parameters****Exposure Limits**

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Acetic Acid, glacial 64-19-7	No data available	10 ppm TWA 25 mg/m ³ TWA	-

Appropriate engineering controls**Engineering controls**

Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection	Tight sealing safety goggles. Face protection shield.
Hand protection	Wear suitable gloves. Impervious gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron. Antistatic boots.
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	Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Liquid
Appearance	clear
Color	Colorless
Odor	Vinegar-like
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	pH of a 1% solution: 2 [Acidic]	None known
Melting point / freezing point	16.6 °C / 61.9 °F	None known
Boiling point / boiling range	118 °C / 244.4 °F	None known
Flash point	40 °C / 104 °F	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 limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	1.5	None known
Vapor density	no data available	None known
Relative density	1.05	None known
Water solubility	Miscible in water	None known
Solubility(ies)	Miscible with alcohol	None known
	Miscible in Benzene	
	Soluble in Acetone	
	Soluble in Ether	
	Soluble in Glycerin	
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	60.05
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	Heat, flames and sparks. Exposure to air or moisture over prolonged periods. Excessive heat.
Incompatible materials	Acids. Bases. Oxidizing agent.
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. Corrosive by inhalation. (based on components). Inhalation of corrosive fumes/gases may cause coughing, choking, headache, dizziness, and weakness for several hours. Pulmonary edema may occur with tightness in the chest, shortness of breath, bluish skin, decreased blood pressure, and increased heart rate. Inhaled corrosive substances can lead to a toxic edema of the lungs. Pulmonary edema can be fatal. Harmful by inhalation.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye damage. (based on components). Corrosive to the eyes and may cause severe damage including blindness. May cause irreversible damage to eyes.
Skin contact	Specific test data for the substance or mixture is not available. Corrosive. (based on components). Causes burns. May be absorbed through the skin in harmful amounts. Harmful in contact with skin.
Ingestion	Specific test data for the substance or mixture is not available. Causes burns. (based on components). Ingestion causes burns of the upper digestive and respiratory tracts. May cause severe burning pain in the mouth and stomach with vomiting and diarrhea of dark blood. Blood pressure may decrease. Brownish or yellowish stains may be seen around the mouth. Swelling of the throat may cause shortness of breath and choking. May cause lung damage if swallowed. May be fatal if swallowed and enters airways.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Redness. Burning. May cause blindness. Coughing and/ or wheezing.
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Acute toxicity

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Acetic Acid, glacial 64-19-7	= 3310 mg/kg (Rat)	= 1060 mg/kg (Rabbit)	= 11.4 mg/L (Rat) 4 h

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	Classification based on data available for ingredients. Causes burns.
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Serious eye damage/eye irritation	Classification based on data available for ingredients. Risk of serious damage to eyes. Causes burns.
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.
Target organ effects	respiratory system, Eyes, Skin, Teeth.
Aspiration hazard	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 microorganisms	Crustacea
Acetic Acid, glacial 64-19-7	-	LC50: =75mg/L (96h, Lepomis macrochirus) LC50: =79mg/L (96h, Pimephales promelas)	-	EC50: =47mg/L (24h, Daphnia magna) EC50: =65mg/L (48h, Daphnia magna)

Persistence and degradability No information available.

Bioaccumulation Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Acetic Acid, glacial 64-19-7	-0.31

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers.

14. Transport information

DOT

UN/ID no	UN2789
Proper shipping name	Acetic acid, glacial
Hazard class	8
Subsidiary Class	3
Special Provisions	II
Special Provisions	A3, A7, A10, B2, IB2, T7, TP2
Marine Pollutant	Severe Marine Pollutant
Description	UN2789, Acetic acid, glacial, 8 (3), II
Emergency Response Guide Number	132

TDG

UN/ID no.	UN2789
Proper shipping name	Acetic acid, glacial
Hazard class	8
Subsidiary Class	3
Packing Group	II
Description	UN2789, Acetic acid, glacial, 8 (3), II

MEX

UN-No	UN2789
Proper Shipping Name	Acetic acid, glacial
Hazard class	8
Subsidiary Class	3
Packing Group	II
Description	UN2789, Acetic acid, glacial, 8 (3), II

ICAO (air)

UN/ID no.	UN2789
Hazard class	8
Subsidiary hazard class	3
Packing Group	II

IATA

UN number	UN2789
Hazard Class	8
Subsidiary hazard class	3
Packing group	II
Emergency Response Guide Number	8F

IMDG

UN number	UN2789
Hazard Class	8
Subsidiary hazard class	3
Packing group	II
EmS-No	F-E, S-C
Marine Pollutant	NP1

RID

UN number	UN2789
Proper shipping name	ACETIC ACID, GLACIAL
Hazard Class	8
Packing group	II
Classification code	CF1
Description	UN2789, ACETIC ACID, GLACIAL, 8 (3), II
Labels	8 + 3

ADR

UN number	UN2789
Proper shipping name	Acetic acid, glacial
Hazard Class	8
Subsidiary hazard class	3
Packing group	II
Classification code	CF1
Tunnel restriction code	(D/E)

Description Labels UN2789, Acetic acid, glacial, 8 (3), II, (D/E)
8 + 3

ADN

UN/ID No UN2789
Proper shipping name Acetic acid, glacial
Hazard Class 8
Packing Group II
Classification code CF1
Description UN2789, Acetic acid, glacial, 8 (3), II
Hazard label(s) 8 + 3
Limited quantity (LQ) 1 L
ventilation VE01
Equipment Requirements PP, EP, EX, A

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 Complies
AICS All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

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

SARA 311/312 Hazard Categories

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

CWA (Clean Water Act)

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

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Acetic Acid, glacial 64-19-7	5000 lb final RQ 2270 kg final RQ	-

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Acetic Acid, glacial 64-19-7	0004	Present	Environmental hazard

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 3

Flammability 2

Instability 0

Physical and chemical properties -

HMIS

Health hazards 3

Flammability 2

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

21-February-2024

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
A9004	Glacial Acetic Acid, USP, EP, BP, JP bioCERTIFIED™

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

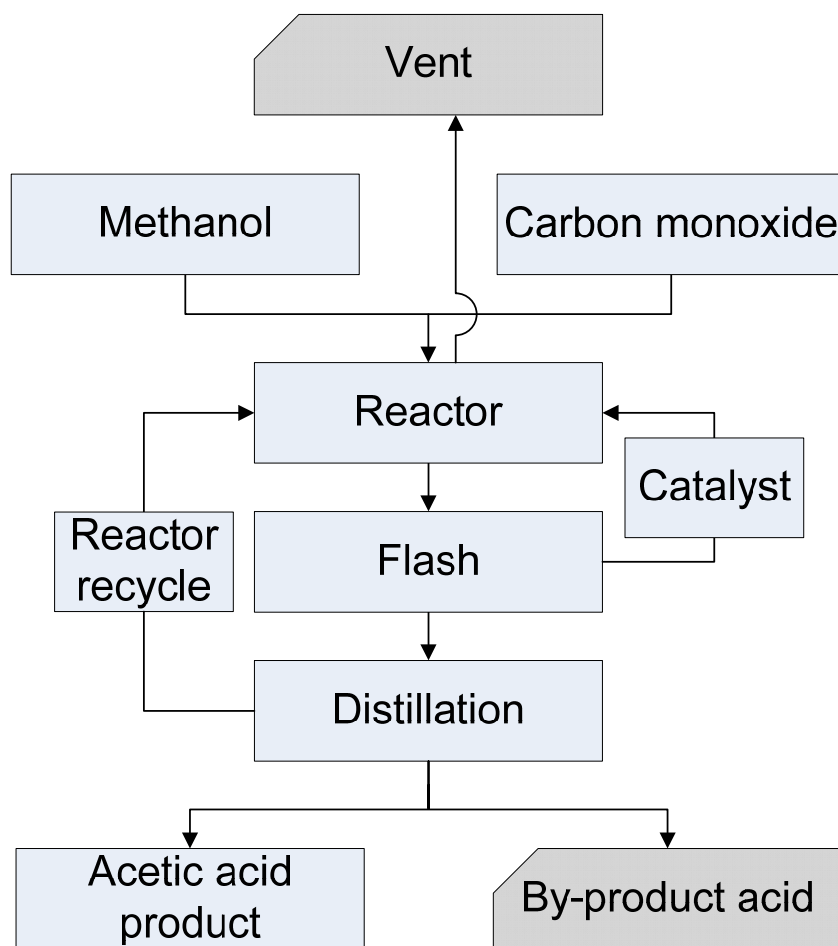
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Glacial Acetic Acid, USP, EP, BP, JP, bioCERTIFIED™ – A9004



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

A9004, Glacial Acetic Acid, USP, EP, BP, JP, bioCERTIFIED™

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 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 | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



**RE: Elemental Impurities - Glacial Acetic Acid, USP, EP, BP, JP, bioCERTIFIED™
(Cat# A9004)**

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 - Glacial Acetic Acid, USP, EP, BP, JP, bioCERTIFIED™
(Cat# A9004)**

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
Methanol	2	< 3000 ppm
Formic Acid	3	< 5000 ppm

No Class 1 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 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.

A **DANGER**

• Causes severe skin burns and eye damage •
Flammable liquid and vapor • Harmful in contact with skin or if inhaled • May be harmful if swallowed.

• Keep away from heat, sparks, open flames, hot surfaces
 • No smoking • Ground container and receiving equipment
 • Use explosion-proof equipment • Use only non-sparking tools • Take precautionary measures against static discharge
 • Wear protective gloves, protective clothing, eye protection, face protection • Do not breathe mist or vapors • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Wash contaminated clothing before reuse. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth. DO NOT induce vomiting. If conscious, give water or milk. Never give anything by mouth to an unconscious person. IN CASE OF FIRE: Use dry chemical, water spray, alcohol-resistant foam or CO₂ to extinguish.

L **KEEP FROM CHILDREN**

spectrum®
CHEMICAL MFG CORP

A9004 **D** **F** **20 L**

Glacial Acetic Acid

E — USP, EP, BP, JP, bioCERTIFIED™ **Q** **bio** CERTIFIED

G — CAS 64-19-7

H **CAUTION:** For manufacturing, processing or repacking. Rx only. Further processing and testing required for use in parenteral applications.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

I DOT: UN2789, Acetic acid, glacial, 8 (3), PG II

J **Chemical Emergency: (800)424-9300**

www.SpectrumChemical.com

K **C₂H₄O₂** **F.W. 60.05**

Not sterile.
 Manufacturer/Supplier Code ?
 Manufacturer Lot Number ?

Assay 99.5-100.5%
 Appearance Clear and colorless
 Congealing Temperature Min. 15.6°C

MAXIMUM LIMITS

Nonvolatile Residue (w/v) 0.005%
 Chloride (Cl) To pass test
 Chlorides (EP) 25 mg/L
 Sulfate (SO₄) To pass test
 Sulfates (EP) 50 mg/L
 Iron (EP) 5 ppm
 Readily Oxidizable Substances To pass test
 Potassium Permanganate-Reducing Substances (JP, EP) As reported
 Elemental Impurities 10 ppm
 Heavy Metals (JP) To pass test
 Residual Solvents 6.0 EU/g
 Bacterial Endotoxins 1000 CFU/g
 Microbial Content:
 TAMC 100 CFU/g
 TYMC 100 CFU/g

HYGROSCOPIC: Keep tightly closed.

M **Repackaged by Spectrum as:**
O **Lot No. 062233**

N **W 1/K8GHS-A A**

SPECTRUM CHEMICAL MFG. CORP.

Gardena, CA 90248 • New Brunswick, NJ 08901

- | | | |
|--|---|---|
| <p>A Bar Code</p> <p>B GHS Hazard Pictograms</p> <p>C Warning, Safety Data and Precautionary Information</p> <p>D Product Catalog Number</p> <p>E Item Name, Form, Grade</p> <p>O Storage Color Band</p> | <p>F Size/Quantity</p> <p>G Chemical Abstracts Service (CAS) Registry Number</p> <p>H Caution Information</p> <p>I DOT Shipping Information</p> <p>J Toll-Free 24-Hour Chemical Emergency Telephone Number</p> | <p>K Empirical Formula, Formula Weight and Technical Specifications Panel</p> <p>L Expiration Information</p> <p>M Lot Number</p> <p>N Kosher Certified by Kosher Supervision of America (KSA).</p> |
|--|---|---|

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

- YELLOW:** Oxidizer
- RED:** Flammable
- GREEN:** General Storage
- BLUE:** Health Hazard
- WHITE:** Corrosive

Spectrum Chemical Mfg Corp

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