

Scientific Documentation

Isopropyl Alcohol, 99 Percent, USP, EP, BP, JP, FCC, ACS, 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





Table of Contents

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



Specification for Isopropyl Alcohol, 99 Percent, USP, EP, BP, JP, FCC, ACS, bioCERTIFIED (TM) (I9200)

Item Number	19200
Item	Isopropyl Alcohol, 99 Percent, USP, EP, BP, JP, FCC, ACS, bioCERTIFIED (TM)
CAS Number	67-63-0
Molecular Formula	C ₃ H ₈ O
Molecular Weight	60.10
MDL Number	
Synonyms	Indena S.p.A.Isopropanol ; 2-Propanol ; Propan-2-ol ; Dimethyl Carbinol ; IPA

Test	Specification		
	Min	Max	
ASSAY (_{]3]H]8]0)}	99.7 %		
SPECIFIC GRAVITY @ 25°C	0.783	0.784	
SPECIFIC GRAVITY @ 20°C	0.785	0.788	
REFRACTIVE INDEX @ 20°C	1.376	1.378	
ACIDITY	TO PASS TEST		
SOLUBILITY	TO PASS TEST		
ACIDITY OR ALKALINITY	TO PASS TEST		
APPEARANCE	TO PASS TEST		
CLARITY OF SOLUTION	TO PASS TEST		
ABSORBANCE (at TIME OF PACKAGING)	TO PASS TEST		
Distilling Range (81°-83°C)	94 %		
Distilling Range, including 82.3°C	Within 1°C		
NONVOLATILE RESIDUE		10 ppm	
WATER		0.2 %	
Benzene and Related Substances:			
BENZENE		2 ppm	
TOTAL IMPURITIES.		0.3 %	
PEROXIDES	TO PASS TEST		

Test	Specification		
	Min	Max	
ABSORBANCE:			
@230 nm		0.30	
@250 nm		0.10	
@270 nm		0.03	
@290 nm		0.02	
@310 nm		0.01	
VOLATILE IMPURITIES:			
METHANOL		0.02 %	
Each other individual known impurity (ethyl ether, acetone, diisopropyl			
ether, 1 propanol, 2-butanol)		0.1 %	
INDIVIDUAL UNSPECIFIED IMPURITY		0.1 %	
CARBONYL COMPOUNDS:			
ACETONE		0.002 %	
PROPIONALDEHYDE		0.002 %	
TITRATABLE ACID OR BASE		0.0001 meq/g	
COLOR		10	
LEAD		1 mg/kg	
SUBSTANCES REDUCING PERMANGANATE	TO PASS TEST		
ELEMENTAL IMPURITIES	AS REPORTED		
BIOBURDEN	AS REPORTED		
BACTERIAL ENDOTOXINS	AS REPORTED		
IDENTIFICATION	TO PASS TEST		
EXPIRATION DATE			
DATE OF MANUFACTURE			
MONOGRAPH EDITION			
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	19200	Lot Number	4MJ0054
Item	Isopropyl Alcohol, 99 Percent, USP, EP, BP, JP, FCC, ACS, bioCERTIFIED (TM)	CAS Number	67-63-0
Molecular Formula	C ₃ H ₈ O	Molecular Weight	60.10

	SPECIFICATION			
TEST	MIN	MAX	RESULT	
ASSAY (₃ H ₈ O)	99.7 %		100.0 %	
SPECIFIC GRAVITY @ 25°C	0.783	0.784	0.784	
SPECIFIC GRAVITY @ 20°C	0.785	0.788	0.788	
REFRACTIVE INDEX @ 20°C	1.376	1.378	1.377	
ACIDITY	TO PASS TEST		PASSES TEST	
SOLUBILITY	TO PASS TEST		PASSES TEST	
ACIDITY OR ALKALINITY	TO PASS TEST		PASSES TEST	
APPEARANCE	TO PASS TEST		PASSES TEST	
CLARITY OF SOLUTION	TO PASS TEST		PASSES TEST	
ABSORBANCE (at TIME OF PACKAGING)	TO PASS TEST		PASSES TEST	
Distilling Range (81°-83°C)	94 %		95 %	
Distilling Range, including 82.3°C	Within 1°C		WITHIN 1°C	
NONVOLATILE RESIDUE		10 ppm	<10 ppm	
WATER		0.2 %	0.05 %	
Benzene and Related Substances:				
BENZENE		2 ppm	<2 ppm	
TOTAL IMPURITIES.		0.3 %	<0.3 %	
PEROXIDES	TO PASS TEST		PASSES TEST	
ABSORBANCE:				
@230 nm		0.30	0.10	
@250 nm		0.10	0.04	
@270 nm		0.03	0.01	
@290 nm		0.02	0.002	
@310 nm		0.01	0.002	
VOLATILE IMPURITIES:				

TFCT	SPECIFICATION			
TEST	MIN	MAX	RESULT	
METHANOL		0.02 %	<0.02 %	
Each other individual known impurity				
(ethyl ether, acetone, diisopropyl				
ether, 1 propanol, 2-butanol)		0.1 %	<0.1 %	
INDIVIDUAL UNSPECIFIED IMPURITY		0.1 %	<0.1 %	
CARBONYL COMPOUNDS:				
ACETONE		0.002 %	<0.002 %	
PROPIONALDEHYDE		0.002 %	<0.002 %	
TITRATABLE ACID OR BASE		0.0001 meq/g	<0.0001 meq/g	
COLOR		10	<10	
LEAD		1 mg/kg	<1 mg/kg	
SUBSTANCES REDUCING PERMANGANATE	TO PASS TEST		PASSES TEST	
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD	
BIOBURDEN	AS REPORTED		<750 cfu/ml	
BACTERIAL ENDOTOXINS	AS REPORTED		9.9 IU/ml	
IDENTIFICATION	TO PASS TEST		PASSES TEST	
EXPIRATION DATE			05-SEP-2027	
DATE OF MANUFACTURE			06-SEP-2022	
MONOGRAPH EDITION			USP 2023, EP 11TH, BP 11TH	
MONOGRAPH EDITION.			JP 18TH, FCC 13TH	
RESIDUAL SOLVENTS	AS REPORTED		MEETS USP CHAPTER <467> REQUIREMENTS	

Certificate of Analysis Results Entered By:

MCAMACHO Matheu Camacho 08-DEC-23 05:39:57

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

GHERRERA Genaro Herrera 08-DEC-23 05:41:11

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

Revision date 01-March-2022

1. Identification	
Product identifier	
Product Name	ISOPROPYL ALCOHOL, 99%, USP, EP, BP, JP, FCC, ACS, bioCERTIFIED™
Other means of identification	
Product Code(s)	19200
UN/ID no	UN1219
Synonyms	None
Recommended use of the chemica	l and restrictions on use
Recommended use	No information available
Restrictions on use	No information available
Details of the supplier of the safety	v data sheet
Supplier Address Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000	
Emergency telephone number	
Emergency Telephone	Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Serious eye damage/eye irritation	Category 2A
Reproductive toxicity	Category 2
Specific target organ toxicity (single exposure)	Category 3
Specific target organ toxicity (repeated exposure)	Category 2
Flammable liquids	Category 2

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

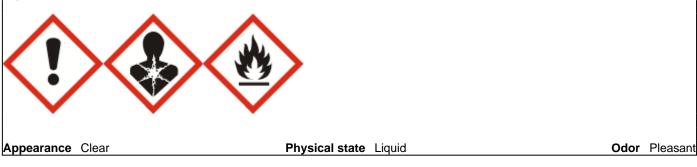
Hazard statements

Causes serious eye irritation Suspected of damaging fertility or the unborn child



Revision Number 1

May cause damage to organs through prolonged or repeated exposure May cause respiratory irritation. May cause drowsiness or dizziness Highly flammable liquid and vapor



Precautionary Statements - Prevention

Obtain special instructions before use Do not handle until all safety precautions have been read and understood Wear protective gloves/protective clothing/eye protection/face protection Wash face, hands and any exposed skin thoroughly after handling Do not breathe dust/fume/gas/mist/vapors/spray Use only outdoors or in a well-ventilated area 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

IF exposed or concerned: Get medical advice/attention IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing If eye irritation persists: Get medical advice/attention IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower IF INHALED: Remove person to fresh air and keep comfortable for breathing 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. May be harmful in contact with skin. Causes mild skin irritation.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Isopropyl Alcohol	67-63-0	100	*

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

4. First-aid measures

Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.	
Inhalation	Remove to fresh air. IF exposed or concerned: Get 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 medical attention if irritation develops and persists.	
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.	
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.	
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.	
Most important symptoms and effe	cts, both acute and delayed	
Symptoms	May cause redness and tearing of the eyes. Burning sensation. Prolonged contact may cause redness and irritation.	
Indication of any immediate medical attention and special treatment needed		
Note to physicians	Treat symptomatically.	

5. Fire-fighting measures

Suitable Extinguishing Media Large Fire	Dry chemical. Carbon dioxide (CO2). 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.	
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide.	
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.
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 with local exhaust ventilation. 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. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.				
Conditions for safe storage, including any incompatibilities					

Storage ConditionsKeep 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.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Isopropyl Alcohol	No data available	400 ppm TWA	-
67-63-0		980 mg/m³ 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.	
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.	

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.

9. Physical and chemical properties

Information on basic physical and o Physical state Appearance Color Odor Odor threshold	chemical properties Liquid Clear Colorless Pleasant No information available	
Property pH Melting point / freezing point Boiling point / boiling range Flash point Evaporation rate Flammability (solid, gas) Flammability Limit in Air Upper flammability or explosive limits	<u>Values</u> no data available -88.5 °C / -127.3 °F 78.3 °C / 172.9 °F 12 - 14 °C / 53.6 - 57.2 °F 1.7 - 2.3 (n-butyl acetate = 1) no data available 12.7%	Remarks • Method None known None known None known None known None known None known
Lower flammability or explosive limits Vapor pressure Vapor density Relative density Water solubility Solubility(ies) Partition coefficient Autoignition temperature Decomposition temperature Kinematic viscosity Dynamic viscosity	2% 4.4 2.07 0.78505 No data available no data available 0.05 - 0.1 399 °C / 750.2 °F no data available No data available	None known None known None known None known None known None known None known None known None known
Other information Explosive properties Oxidizing properties Softening point Molecular weight VOC Content (%) Liquid Density Bulk density	No information available No information available No information available 60.1 No information available No information available No information available	
10. Stability and reactivity		
Reactivity Chemical stability	No information available. Stable under normal conditions.	

None under normal processing.

Conditions to avoid Heat, flames and sparks.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Possibility of hazardous reactions

Information on likely routes of exposure

Product Information		
Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.	
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.	
Skin contact	Specific test data for the substance or mixture is not available. May cause irritation. Prolonged contact may cause redness and irritation. Causes mild skin irritation. May be harmful in contact with skin.	
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May be harmful if swallowed.	
Symptoms related to the physical,	chemical and toxicological characteristics	
Symptoms	May cause redness and tearing of the eyes. Prolonged contact may cause redness and irritation.	

Acute toxicity

Numerical measures of toxicity

Component Information

Chemical name Oral LD50		Dermal LD50	Inhalation LC50	
Isopropyl Alcohol 67-63-0	= 1870 mg/kg (Rat)	= 4059 mg/kg (Rabbit)	= 72600 mg/m³(Rat)4 h	

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 Carcinogenicity The table below indicates whether e

May cause skin irritation. Classification based on data available for ingredients. Classification based on data available for ingredients. Causes serious eye irritation. No information available. No information available. No information available.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Isopropyl Alcohol	-	Group 3 - Not classifiable	-	-
67-63-0		- Monograph 71 [1999]		
		Supplement 7 [1987]		
		Monograph 15 [1977]		

Legend

Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.
STOT - single exposure STOT - repeated exposure Target organ effects	No information available. May cause damage to organs through prolonged or repeated exposure. respiratory system, Eyes, Skin.
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	Crustacea
				microorganisms	
Г	Isopropyl Alcohol	EC50: >1000mg/L (72h,	LC50: =11130mg/L (96h,	-	EC50: =13299mg/L (48h,
	67-63-0	Desmodesmus	Pimephales promelas)		Daphnia magna)
		subspicatus) EC50:	LC50: =9640mg/L (96h,		_
		>1000mg/L (96h,	Pimephales promelas)		
		Desmodesmus	LC50: >1400000µg/L		
		subspicatus)	(96h, Lepomis		
			macrochirus)		

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Isopropyl Alcohol	0.05
67-63-0	

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 of weld containers.	

14. Transport information

DOT UN/ID no Proper Shipping Name: Hazard class Packing group: Special Provisions Marine Pollutant Description: Emergency Response Guide Number	UN1219 Isopropanol 3 II IB2, T4, TP1 Severe Marine Pollutant UN1219, Isopropanol, 3, II 129
<u>TDG</u> UN-No: Proper Shipping Name: Hazard class Packing Group: Description:	UN1219 Isopropanol 3 II UN1219, Isopropanol, 3, II
<u>MEX</u> UN-No Proper Shipping Name Hazard class Packing Group Description	UN1219 Isopropanol 3 II UN1219, Isopropanol, 3, II
ICAO (air) UN-No: Proper Shipping Name:	UN1219 Isopropanol

Hazard class Packing Group: Special Provisions Description:	3 II A180 UN1219, Isopropanol, 3, II
IATA_ UN number Proper Shipping Name: Transport hazard class(es) Packing group Description:	UN1219 Isopropanol 3 II UN1219, Isopropanol, 3, II
IMDG UN number Proper shipping name Transport hazard class(es) Packing group EmS-No Marine pollutant Description	UN1219 Isopropanol 3 II F-E, S-D NP1 UN1219, Isopropanol, 3, II, (12°C c.c.)
<u>RID</u> UN number Proper Shipping Name: Transport hazard class(es) Packing group Classification code Special Provisions Description: Labels	UN1219 Isopropanol 3 II F1 601 UN1219, Isopropanol, 3, II 3
ADR UN number Proper Shipping Name: Transport hazard class(es) Packing group Classification code Tunnel restriction code Special Provisions Description: Labels	1219 Isopropanol 3 II F1 (D/E) 601 1219, Isopropanol, 3, II, (D/E) 3
ADN UN/ID No Proper shipping name Transport hazard class(es) Packing Group Classification code Special Provisions Description Hazard label(s) Limited quantity (LQ) ventilation Equipment Requirements	UN1219 Isopropanol 3 II F1 601 UN1219, Isopropanol, 3, II 3 1 L VE01 PP, EX, A

15. Regulatory information

International Inventories

TSCA

Complies

DSL/NDSL EINECS/ELINCS Complies Complies

ENCS IECSC	This 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

US Federal Regulations

<u>SARA 313</u>

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Chemical name	SARA 313 - Threshold Values %
Isopropyl Alcohol - 67-63-0	1.0

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

	Chemical name	New Jersey	Massachusetts	Pennsylvania
Γ	Isopropyl Alcohol	1076	Present	Environmental hazard
	67-63-0			

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA Health hazards 2 Flammability 3 Instability 0 Physical and chemical properties -<u>HMIS</u> Health hazards 2 * Flammability 3 Physical hazards 0 Personal protection X *Chronic Hazard Star Legend* *= *Chronic Health Hazard*

Key or legend to abbreviations and acronyms used in the safety data sheet

LegendSection 8: EXPOSURE CONTROLS/PERSONAL PROTECTIONTWATWA (time-weighted average)STELCeilingMaximum limit value

STEL (Short Term Exposure Limit)

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	01-March-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

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
19200	Isopropyl Alcohol, 99 Percent, USP, EP, BP, JP, FCC, ACS, 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: 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>gualityassurance@spectrumchemical.com</u>

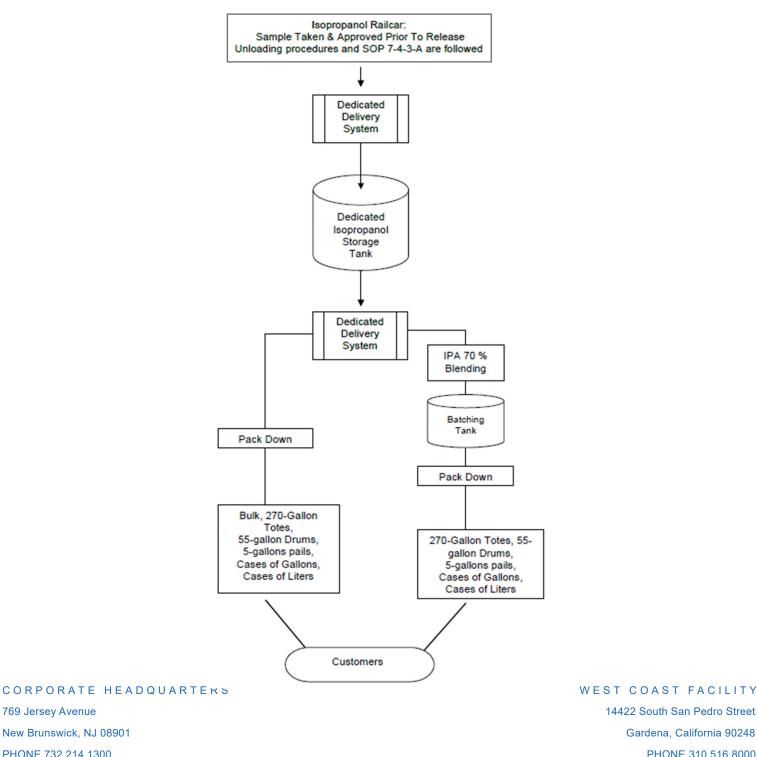
Sincerely,

Oulu Clamy

Oralia Chavez Quality Assurance Specialist



Manufacturing Process Flowchart Isopropyl Alcohol, 99 Percent, USP, EP, BP, JP, FCC, ACS, bioCERTIFIED ™ (Cat# I9200)



New Brunswick, NJ 08901 PHONE 732.214.1300

FAX 732.246.7132

769 Jersey Avenue

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

Spectrum I9200, Isopropyl Alcohol, 99%, USP, EP, BP, JP, FCC, ACS, bioiCERTIFIED™

Source Statement

The above-mentioned catalog item is manufactured by chemical synthesis, followed by distillation. 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 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

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

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

- Parabens
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Isopropyl Alcohol, 99 Percent, USP, EP, BP, JP, FCC, ACS, bioCERTIFIED ™ (Cat# I9200)

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



RE: Residual Solvents - Isopropyl Alcohol, 99 Percent, USP, EP, BP, JP, FCC, ACS, bioCERTIFIED ™ (Cat# I9200)

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
Benzene	1	< 2 ppm *
Methanol	2	< 0.02% *
Acetone	3	< 5000 ppm
Ethanol	3	< 5000 ppm
1-Propanol	3	< 5000 ppm

* Benzene and Methanol are present below the limits provided in the product specifications.

No other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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®

Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.



Spectrum Chemical Mfg Corp

Corporate Headquarters:

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

732.214.1300