

Scientific Documentation

Alcohol, 190 Proof, USP

Not appropriate for regulatory submission. Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

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





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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 Alcohol, 190 Proof, USP (ET108)

Item Number	ET108
Item	Alcohol, 190 Proof, USP
CAS Number	64-17-5
Molecular Formula	C ₂ H ₅ OH
Molecular Weight	46.07
MDL Number	
Synonyms	Grain Derived Alcohol ; Ethanol

Test	Specification			
	Min	Max		
ASSAY (by VOLUME)	94.9	96.0 %		
CLARITY OF SOLUTION	NO MORE OPALESCENCE THAN STANDARD			
COLOR OF SOLUTION	NOT MORE THAN STANDARD			
SPECIFIC GRAVITY @ 15.56°C	0.812	0.816		
ACIDITY OR ALKALINITY	SOLUTION IS COLORLESS THEN PINK			
ULTRAVIOLET ABSORPTION :				
240 nm		0.40		
250 - 260 nm		0.30		
270 - 340 nm		0.10		
NONVOLATILE RESIDUE		2.5 mg		
ELEMENTAL IMPURITIES	AS REPORTED			
ORGANIC IMPURITIES:				
METHANOL		200 µL/L		
ACETALDEHYDE AND ACETAL		10 µL/L		
BENZENE		2 µL/L		
SUM OF ALL OTHER IMPURITIES		300 µL/L		
IDENTIFICATION (A)	0.812	0.816		
IDENTIFICATION (B)	SPECTRUM MATCHES REFERENCE			

Test	Specification	
	Min	Max
IDENTIFICATION (C) LIMIT OF METHANOL		200 µL/L
CERTIFIED KOSHER		
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS		AS REPORTED
CLASS 3 (solvent) / 1-PROPANOL	•	
CLASS 3 (solvent) / 2-PROPANOL	•	
MONOGRAPH EDITION		

Spectrum Chemical Mfg Corp

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



Certificate Of Analysis

Item Number	ET108	Lot Number	2MK0238
Item	Alcohol, 190 Proof, USP	CAS Number	64-17-5
Molecular Formula	C ₂ H ₅ OH	Molecular Weight	46.07

TECT	SPECIFICATION		
TEST	MIN	MAX	RESULT
ASSAY (by VOLUME)	94.9	96.0 %	95.02 %
CLARITY OF SOLUTION	NO MORE OPALESCENCE THAN STANDARD		NO MORE OPALESCENCE THAN STANDARD
COLOR OF SOLUTION	NOT MORE THAN STANDARD		NOT MORE THAN STANDARD
SPECIFIC GRAVITY @ 15.56 ⁰ C	0.812	0.816	0.8158
ACIDITY OR ALKALINITY	SOLUTION IS COLORLESS THEN PINK		SOLUTION IS COLORLESS THEN PINK
ULTRAVIOLET ABSORPTION :			
240 nm		0.40	0.16
250 - 260 nm		0.30	0.06
270 - 340 nm		0.10	0.01
NONVOLATILE RESIDUE		2.5 mg	0.0 mg
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
ORGANIC IMPURITIES:			
METHANOL		200 μL/L	1 μL/L
ACETALDEHYDE AND ACETAL		10 µL/L	0 μL/L
BENZENE		2 μL/L	0 μL/L
SUM OF ALL OTHER IMPURITIES		300 µL/L	0 μL/L
IDENTIFICATION (A)	0.812	0.816	0.815
IDENTIFICATION (B)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE

тест	SPECIFICATION		DECLUIT
TEST	MIN	MAX	RESULT
IDENTIFICATION (C) LIMIT OF METHANOL		200 µL/L	<200 µL/L
CERTIFIED KOSHER			CERTIFIED KOSHER
APPEARANCE			COLORLESS LIQUID
EXPIRATION DATE			22-OCT-2026
DATE OF MANUFACTURE			23-OCT-2023
RESIDUAL SOLVENTS		AS REPORTED	
CLASS 3 (solvent) / 1-PROPANOL	•		<300 ppm
CLASS 3 (solvent) / 2-PROPANOL	•		<300 ppm
MONOGRAPH EDITION			USP 2023

Certificate of Analysis Results Entered By:

GHERRERA Genaro Herrera 29-DEC-23 12:11:09

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

MCAMACHO Matheu Camacho 02-JAN-24 06:27:16

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

SAFETY DATA SHEET

Revision date 12-May-2022

1. Identification Product identifier **Product Name** ALCOHOL, 190 PROOF, USP Other means of identification Product Code(s) ET108 UN/ID no UN1170 Synonyms None Recommended use of the chemical and restrictions on use **Recommended use** No information available **Restrictions on use** No information available Details of the supplier of the safety data sheet Supplier Address Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000 Emergency telephone number **Emergency Telephone** Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Serious eye damage/eye irritation	Category 2A
Reproductive toxicity	Category 1A
Specific target organ toxicity (single exposure)	Category 3
Specific target organ toxicity (repeated exposure)	Category 1
Flammable liquids	Category 2

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

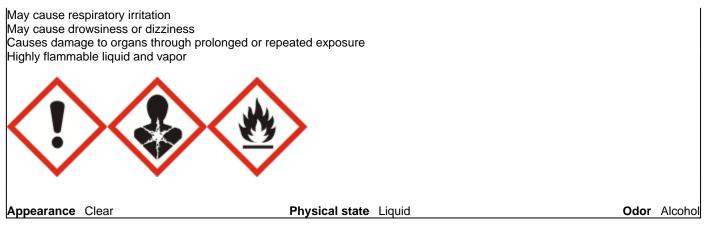
Danger

Hazard statements

Causes serious eye irritation May damage fertility or the unborn child



Revision Number 5



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 Do not eat, drink or smoke when using this product 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 Keep cool

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 container tightly closed

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

Toxic to aquatic life with long lasting effects. Toxic to aquatic life. Can burn with an invisible flame.

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical name	CAS No	Weight-%	Trade secret
Ethyl Alcohol 200 proof	64-17-5	80 - 100	*
Water	7732-18-5	5 - <10	*

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

4. First-aid measures

Description of first aid measures

General advice	IF exposed or concerned: Get medical advice/attention. 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 effects, both acute and delayed		
Symptoms	May cause redness and tearing of the eyes. Burning sensation. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.	
Indication of any immediate medica	al 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 impac	t 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 containm	ent 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. In case of insufficient ventilation, wear suitable respiratory equipment. Conditions for safe storage, including any incompatibilities **Storage Conditions** 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.

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.

Keep in an area equipped with sprinklers. Store in accordance with the particular national

regulations. Store in accordance with local regulations. Store locked up.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Ethyl Alcohol 200 proof	No data available	1000 ppm TWA	-
64-17-5		1900 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.
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.

9. Physical and chemical properties

Information on basic physical and o	chemical properties	
Physical state	Liquid	
Appearance	Clear	
Color	Colorless	
Odor	Alcohol	
Odor threshold	No information available	
Property_	Values	Remarks • Method
Hq	no data available	None known
Melting point / freezing point	-114 °C / -173.2 °F	None known
Boiling point / boiling range	79 °C / 174.2 °F	None known
Flash point	17 °C / 62.6 °F	CC (closed cup)
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	19%	
limits		
Lower flammability or explosive	3.3%	
limits		
Vapor pressure	5.8	None known
Vapor density	1.6	None known
Relative density	0.8	None known
Water solubility	Miscible in water	None known
Solubility(ies)	Miscible with many organic solvents	None known
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	No information available	
VOC Content (%)	94+ % .?	
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.	
Incompatible materials	None known based on information supplied.	
Hazardous decomposition products None known based on information supplied.		

11. Toxicological information

Information on likely routes of exposure

Product Information	
Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract. May cause drowsiness or dizziness.
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.
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
Symptoms related to the physical,	chemical and toxicological characteristics
Symptoms	May cause redness and tearing of the eyes. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.
Acute toxicity	

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document .

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Ethyl Alcohol 200 proof 64-17-5	= 7060 mg/kg (Rat)	-	124.7 mg/L (Rat)4 h
Water 7732-18-5	90 mL/kg (Rat)	-	-

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	No information available. No information available. Contains a known or suspected carcinogen. Classification based on data available for ingredients. May cause cancer.			
Chemical name	ACGIH IARC NTP OSI		OSHA	
Ethyl Alcohol 200 proof	-	Group 1 - Monograph	-	-
64-17-5		100E [2012] in alcoholic		
		beverages		

Monograph 96 [2010] in

	alcoholic beverages	
Legend		
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child.	
STOT - single exposure STOT - repeated exposur Target organ effects	May cause respiratory irritation. May cause drowsiness or dizziness. Causes damage to organs through prolonged or repeated exposure. liver, respiratory system, Eyes, Skin, central nervous system, blood, Reproductive System.	
Aspiration hazard	No information available.	
Other adverse effects	No information available.	
Interactive effects	No information available.	

12. Ecological information

Ecotoxicity

Toxic to aquatic life. Toxic to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Ethyl Alcohol 200 proof	-	LC50: 12.0 - 16.0mL/L	-	LC50: 9268 - 14221mg/L
64-17-5		(96h, Oncorhynchus		(48h, Daphnia magna)
		mykiss) LC50: 13400 -		EC50: =10800mg/L (24h,
		15100mg/L (96h,		Daphnia magna) EC50:
		Pimephales promelas)		=2mg/L (48h, Daphnia
		LC50: >100mg/L (96h,		magna)
		Pimephales promelas)		,

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Ethyl Alcohol 200 proof	-0.32
64-17-5	

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.

П

14. Transport information

DOT

UN/ID no	UN1170	
Proper Shipping Name:	Ethanol solution	
Hazard class	3	
Packing group:	II	
Special Provisions	24, IB2, T4, TP1	
Marine Pollutant	Severe Marine Pollutant	
Description:	UN1170, Ethanol solution, 3,	

Emergency Response Guide 127 Number

TDG

UN-No:	UN1170
Proper Shipping Name:	Ethanol solution
Hazard class	3
Packing Group:	II
Description:	UN1170, Ethanol solution, 3, II

UN1170

UN1170 Ethanol solution

UN1170

F-E, S-D

Ethanol solution

3

Ш

3 11

3

Ш

144

NP1

Ethanol solution

A58, A180, A3

UN1170, Ethanol solution, 3, II

UN1170, Ethanol solution, 3, II

UN1170, Ethanol solution, 3, II, (17°C c.c.)

MEX

UN-No	UN1170
Proper Shipping Name	Ethanol solution
Hazard class	3
Special Provisions	144
Packing Group	II
Description	UN1170, Ethanol solution, 3, II
•	

ICAO (air)

UN-No: Proper Shipping Name: Hazard class Packing Group: Special Provisions Description:

<u>IATA</u>

UN number	
Proper Shipping Name:	
Transport hazard class(es)	
Packing group	
Description:	

IMDG

UN number Proper shipping name Transport hazard class(es) Packing group EmS-No Special Provisions Marine pollutant Description

<u>RID</u>

UN number	UN1170
Proper Shipping Name:	Ethanol solution
Transport hazard class(es)	3
Packing group	II
Classification code	F1
Special Provisions	144, 601
Description:	UN1170, Ethanol solution, 3, II
Labels	3

<u>ADR</u>

UN number	1170
Proper Shipping Name:	Ethanol solution
Transport hazard class(es)	3
Packing group	II
Classification code	F1
Tunnel restriction code	(D/E)
Special Provisions	144, 601
Description:	1170, Ethanol solution, 3, II, (D/E)
Labels	3

ADN

UN/ID No

UN1170

Proper shipping name	Ethanol solution
Transport hazard class(es)	3
Packing Group	II
Classification code	F1
Special Provisions	144, 601
Description	UN1170, Ethanol solution, 3, II
Hazard label(s)	3
Limited quantity (LQ)	1 L
ventilation	VE01
Equipment Requirements	PP, 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
AICS	Substances (AICS).

Legend:

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

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

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

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

SARA 311/312 Hazard Categories

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

CWA (Clean Water Act)

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

CERCLA

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

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Ethyl Alcohol 200 proof - 64-17-5	developmental toxicity
	carcinogen

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Ethyl Alcohol 200 proof	0844	Present	Present
64-17-5			

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA				
Health hazards	2			
Flammability 3	-			
Instability 0				
•	mical properties	-		
HMIS				
Health hazards	2 *			
Flammability 3	-			
Physical hazards	. 0			
Personal protect				
Chronic Hazard Star		* = Chronic Health Hazar	rd	
	-			
Key or legend to	abbreviations and	acronyms used in the	safety data sheet	
	8: EXPOSURE CO	NTROLS/PERSONAL P		
TWA	TWA (time-weight		STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit val	ue		
Kov literatura raf		as far data used to se	muile the SDS	
		es for data used to con ease Registry (ATSDR)	inplie the 5D5	
		ChemView Database		
	afety Authority (EFS			
	tal Protection Agence			
	uideline Level(s) (A			
		/ Federal Insecticide, Fu	Indicide and Roder	aticide Act
		/ High Production Volum		
Food Research Jo			le onemicais	
Hazardous Substa				
		ation Database (IUCLID))	
Japan GHS Class				
		s Notification and Asses	sment Scheme (NI	CNAS)
		ional Safety and Health)		,
	Medicine's ChemIE			
		d database (NLM PUBM	IED)	
National Toxicolog	y Program (NTP)			
New Zealand's Ch	emical Classification	n and Information Datab	ase (CCID)	
				and Safety Publications
				me Chemicals Program
		on and Development So	creening Information	n Data Set
World Health Orga	anization			
Devicie: dete		40 May 2020		
Revision date		12-May-2022		

Revision uale	12=1VIdy=2022
Revision Note	No information available.
<u>Disclaimer</u>	

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
ET108	Alcohol, 190 Proof, USP

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

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

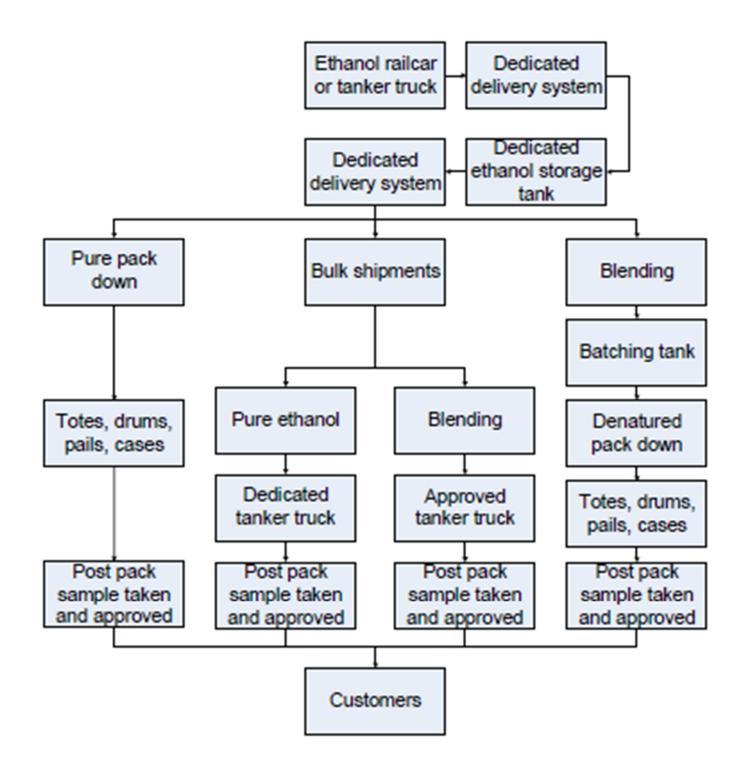
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely, Quality Assurance Spectrum Chemical Mfg. Corp.

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



Manufacturing Process Flowchart - Alcohol, 190 Proof, USP (Catalog No. ET108)





Source Statement

spect

The above-mentioned catalog item is manufactured by fermentation of plant derived material (corn kernels). No animal derived products are used in the manufacturing process.

BSE/TSE Statement

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

Allergen Statement

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

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

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 with the use of genetically modified organisms but no detectable levels of GMO are expected to be present.

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 the above-mentioned material.

Animal Testing Statement

The above-mentioned catalog item has not been tested on animals.

Celery
Mustand

Cereals containing Gluten

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



Organic Compliance Statement

The above-mentioned catalog item has not been produced using irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above-mentioned catalog item is typically assigned a shelf life of 36 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



Elemental Impurities - Alcohol, 190 Proof, USP (Catalog No. ET108)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. 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 the 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.



Residual Solvents - Alcohol, 190 Proof, USP (Catalog No. ET108)

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
1-Propanol	3	< 300 ppm
2-Propanol	3	< 300 ppm

No Class 1, Class 2 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.

Sincerely, Technical Services Spectrum Chemical Mfg. Corp.

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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.



Spectrum Chemical Mfg Corp

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