

Scientific Documentation

Dehydrated Alcohol, 200 Proof, USP, EP, BP

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 Dehydrated Alcohol, 200 Proof, USP, EP, BP (E1068)

Item Number	E1068
Item	Dehydrated Alcohol, 200 Proof, USP, EP, BP
CAS Number	64-17-5
Molecular Formula	C ₂ H ₅ OH
Molecular Weight	46.07
MDL Number	
Synonyms	Ethanol ; Ethyl Alcohol ; Anhydrous Ethanol ; Grain Derived Alcohol

Test	Specification	
	Min	Max
APPEARANCE		
IDENTIFICATION (A)		0.7962
IDENTIFICATION (B)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (C) LIMIT OF METHANOL		200 µL/L
IDENTIFICATION (D)	0.790	0.793
IDENTIFICATION (E)	INTENSE BLUE COLOR	
IDENTIFICATION (F)	YELLOW PRECIPITATE FORMS	
ASSAY (by VOLUME)	99.5%	
CLARITY OF SOLUTION	NOT GREATER THAN STANDARD SUSPENSION	
COLOR OF SOLUTION	NOT GREATER THAN STANDARD SOLUTION	
ACIDITY OR ALKALINITY		30 ug/g
RELATIVE DENSITY	0.790	0.793
SPECIFIC GRAVITY @ 15.56°C		0.7962
UV ABSORPTION	NO PEAKS OR SHOULDERS	
240 nm		0.40
250 - 260 nm		0.30
270 - 340 nm		0.10

Test	Specification	
	Min	Max
VOLATILE IMPURITIES:		
METHANOL		200 µL/L
ACETALDEHYDE AND ACETAL		10 µL/L
BENZENE		2 µL/L
TOTAL IMPURITIES		300 µL/L
NONVOLATILE RESIDUE		2.5 mg
ELEMENTAL IMPURITIES	AS REPORTED	
RESIDUAL SOLVENTS	AS REPORTED	
CLASS 3 (solvent) / 1-PROPANOL	.	
CLASS 3 (solvent) / 2-PROPANOL	.	
MONOGRAPH EDITION		
MONOGRAPH EDITION.		
MONOGRAPH EDITION..		
EXPIRATION DATE		
DATE OF MANUFACTURE		

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	E1068	Lot Number	2NA0196
Item	Dehydrated Alcohol, 200 Proof, USP, EP, BP	CAS Number	64-17-5
Molecular Formula	C ₂ H ₅ OH	Molecular Weight	46.07

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			COLORLESS LIQUID
IDENTIFICATION (A)		0.7962	0.7920
IDENTIFICATION (B)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (C) LIMIT OF METHANOL		200 µL/L	< 200 µL/L
IDENTIFICATION (D)	0.790	0.793	0.792
IDENTIFICATION (E)	INTENSE BLUE COLOR		INTENSE BLUE COLOR
IDENTIFICATION (F)	YELLOW PRECIPITATE FORMS		YELLOW PRECIPITATE FORMS
ASSAY (by VOLUME)	99.5%		99.99 %
CLARITY OF SOLUTION	NOT GREATER THAN STANDARD SUSPENSION		NOT GREATER THAN STANDARD
COLOR OF SOLUTION	NOT GREATER THAN STANDARD SOLUTION		NOT GREATER THAN STANDARD SOLUTION
ACIDITY OR ALKALINITY		30 ug/g	< 30 ug/g
RELATIVE DENSITY	0.790	0.793	0.7905
SPECIFIC GRAVITY @ 15.56°C		0.7962	0.7937
UV ABSORPTION	NO PEAKS OR SHOULDERS		NO PEAKS OR SHOULDERS

TEST	SPECIFICATION		RESULT
	MIN	MAX	
240 nm		0.40	0.28
250 - 260 nm		0.30	0.11
270 - 340 nm		0.10	0.02
VOLATILE IMPURITIES:			.
METHANOL		200 µL/L	1 µL/L
ACETALDEHYDE AND ACETAL		10 µL/L	0 µL/L
BENZENE		2 µL/L	0 µL/L
TOTAL IMPURITIES		300 µL/L	2 µL/L
NONVOLATILE RESIDUE		2.5 mg	0.0 mg
ELEMENTAL IMPURITIES	AS REPORTED		AS REPORTED
RESIDUAL SOLVENTS	AS REPORTED		AS REPORTED
CLASS 3 (solvent) / 1-PROPANOL	.		< 300 ppm
CLASS 3 (solvent) / 2-PROPANOL	.		< 300 ppm
MONOGRAPH EDITION			USP 2023
MONOGRAPH EDITION.			EP 11
MONOGRAPH EDITION..			BP 2024
EXPIRATION DATE			14-JAN-2027
DATE OF MANUFACTURE			14-JAN-2024
COUNTRY OF ORIGIN			CANADA

Certificate of Analysis Results Entered By:

CMARIN
Catherine Marin
26-FEB-24 13:33:55

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

MCAMACHO
Matheu Camacho
27-FEB-24 06:07:15

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

spectrum®



Revision date 23-May-2022

Revision Number 16

1. Identification

Product identifier

Product Name DEHYDRATED ALCOHOL, 200 PROOF, USP, EP, BP

Other means of identification

Product Code(s) E1068

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

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



Appearance Clear

Physical state Liquid

Odor Alcohol

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

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Ethyl Alcohol 200 proof	64-17-5	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 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.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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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.
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.
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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. 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. 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
Ethyl Alcohol 200 proof 64-17-5	No data available	1000 ppm TWA 1900 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.

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 chemical properties

Physical state	Liquid
Appearance	Clear
Color	Colorless
Odor	Alcohol
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	no data available	None known
Boiling point / boiling range	78 - 79 °C / 172.4 - 174.2 °F	None known
Flash point	12 - 14 °C / 53.6 - 57.2 °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	19 %	
Lower flammability or explosive limits	3.3 %	
Vapor pressure	5.7 - 5.866	None known
Vapor density	1.59	None known
Relative density	0.79	None known
Water solubility	Miscible in water	None known
Solubility(ies)	Miscible with many organic solvents	None known
Partition coefficient	-0.31	None known
Autoignition temperature	363 - 426 °C / 685.4 - 798.8 °F	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	46.07
VOC Content (%)	99+ %
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.
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Acute toxicity

Numerical measures of toxicity

Component Information

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

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

Skin corrosion/irritation	May cause skin irritation.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.

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

Chemical name	ACGIH	IARC	NTP	OSHA
Ethyl Alcohol 200 proof 64-17-5	-	Group 1 - Monograph 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.
Developmental toxicity	May cause harm to the unborn child.
STOT - single exposure	May cause respiratory irritation. May cause drowsiness or dizziness.
STOT - repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Target organ effects	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

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

Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.

Component Information

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

Other adverse effects	No information available.
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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	UN1170
Proper Shipping Name:	Ethanol
Hazard class	3
Packing group:	II
Special Provisions	24, IB2, T4, TP1
Marine Pollutant	Severe Marine Pollutant
Description:	UN1170, Ethanol, 3, II
Emergency Response Guide Number	127

TDG

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

MEX

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

ICAO (air)

UN-No:	UN1170
Proper Shipping Name:	Ethanol
Hazard class	3
Packing Group:	II
Special Provisions	A58, A180, A3
Description:	UN1170, Ethanol, 3, II

IATA

UN number	UN1170
Proper Shipping Name:	Ethanol
Transport hazard class(es)	3
Packing group	II
Description:	UN1170, Ethanol, 3, II

IMDG

UN number	UN1170
Proper shipping name	Ethanol
Transport hazard class(es)	3
Packing group	II
EmS-No	F-E, S-D
Special Provisions	144
Marine pollutant	NP1
Description	UN1170, Ethanol, 3, II, (12°C c.c.)

RID

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

ADR

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

ADN

UN/ID No	UN1170
Proper shipping name	Ethanol
Transport hazard class(es)	3
Packing Group	II
Classification code	F1
Special Provisions	144, 601
Description	UN1170, Ethanol, 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/NDL	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/NDL - 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			
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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 -

HMIS

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

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) (AEL(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 23-May-2022

Revision Note No information available.

Disclaimer

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

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

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

Catalog Number	Product Name
E1068	Dehydrated Alcohol, 200 Proof, USP, EP, BP

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

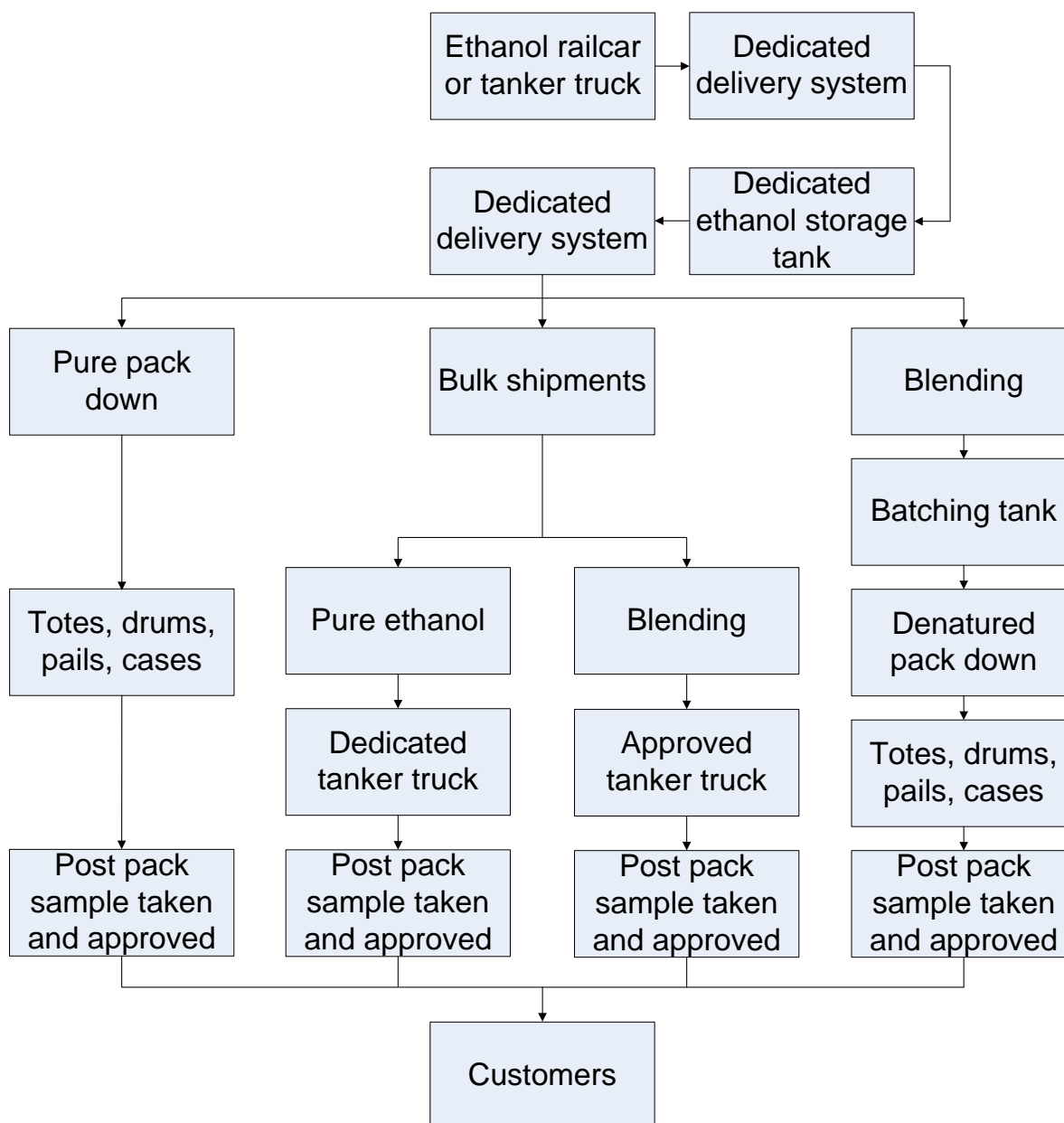
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Dehydrated Alcohol, 200 Proof, USP, EP, BP - E1068



Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

E1068, Dehydrated Alcohol, 200 Proof, USP, EP, BP

Source Statement

The above mentioned catalog item is manufactured from plant origin (Corn). 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
- Peanuts
- Sulfites > 10 ppm
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Soy
- Latex

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 above mentioned catalog item and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured with the use of genetically modified organisms and is therefore not 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 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 | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Dehydrated Alcohol, 200 Proof, USP, EP, BP (Cat# E1068)

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 - Dehydrated Alcohol, 200 Proof, USP, EP, BP (Cat# E1068)

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	< 5000 ppm
2-Propanol	3	< 5000 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.

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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**

C **Highly flammable liquid and vapor • Can burn with an invisible flame • Causes serious eye irritation • May cause respiratory irritation • May cause drowsiness or dizziness • May damage fertility or the unborn child • Causes damage to organs through prolonged or repeated exposure.**

B **Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • 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 • Do not eat, drink or smoke when using this product • 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 • Keep container tightly closed.**

FIRST AID: 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 attention. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell. IN CASE OF FIRE: Use dry chemical, water spray, alcohol-resistant foam or CO₂ to extinguish.

L **KEEP FROM CHILDREN**

spectrum®
CHEMICAL MFG CORP

E1068 **D** **4 L** **F**

Dehydrated Alcohol

(Grain Derived Alcohol; Anhydrous Ethanol; Ethanol; Ethyl Alcohol)

E **200 Proof**
USP, EP, BP

G **CAS 64-17-5**

H **CAUTION:** For manufacturing and processing for non-beverage purposes. For industrial use.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

DOT: UN1170, Ethanol, 3, PG II

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

K **C₂H₅OH** **F.W. 46.07**

For specifications see Certificate of Analysis.

BOTTLED BY:
SPECTRUM LABORATORY PRODUCTS, INC.
GARDENA, CALIFORNIA

WARNING: Cancer and Reproductive Harm
www.P65Warnings.ca.gov

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.

I **Lot No. 062233** **M**

J **Exp. Date: 03-31-2030**

SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901

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

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

Corporate Headquarters:

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