

# **Scientific Documentation**

ET107, Dehydrated Alcohol, 200 Proof, Undenatured, USP

Not appropriate for regulatory submission. Please visit <a href="www.spectrumchemical.com">www.spectrumchemical.com</a> 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

#### ET107, Dehydrated Alcohol, 200 Proof, Undenatured, USP

## Table of Contents

- Product Specification
- Certificate of Analysis Sample(s)
- Safety Data Sheet (SDS)
- Certification of Current Good Manufacturing Practices (cGMP)
- Manufacturing Process Flowchart
- Source Statement
- BSE/TSE Statement
- Allergen Statement
- EU Fragrance Allergen Statement
- GMO Statement
- Melamine Statement
- Nitrosamine Statement
- Animal Testing Statement
- Organic Compliance Statement
- Shelf Life Statement
- Other Chemicals Statement
- Elemental Impurities Statement
- Residual Solvents Statement
- General Label Information Sample Label

- General Lot Numbering System Guidance
- Kosher Certificate

# Spectrum<sup>®</sup>



## Specification for Dehydrated Alcohol, 200 Proof, Undenatured, USP (ET107)

Item Number	ET107
Item	Dehydrated Alcohol, 200 Proof, Undenatured, USP
CAS Number	64-17-5
Molecular Formula	C <sub>2</sub> H <sub>5</sub> OH
Molecular Weight	46.07
MDL Number	
Synonyms	Absolute Ethyl Alcohol; Anhydrous Ethanol; Ethanol; Grain Derived Alcohol

Test	Specification			
	Min	Max		
ASSAY (by VOLUME)	99.5 %			
CLARITY OF SOLUTION	NOT MORE OPALESENT THAN STANDARD			
COLOR OF SOLUTION	NOT MORE INTENSE THAN STANDARD			
ACIDITY OR ALKALINITY	SOLUTION IS PINK			
SPECIFIC GRAVITY @ 15.56°C		0.7962		
UV ABSORPTION:				
240 nm		0.40		
250 - 260 nm		0.30		
270 - 340 nm		0.10		
ORGANIC IMPURITIES:				
METHANOL		200 μL/L		
ACETALDEHYDE AND ACETAL		10 μL/L		
BENZENE		2 μL/L		
SUM OF ALL OTHER IMPURITIES		300 μL/L		
LIMIT OF NONVOLATILE RESIDUE		2.5 mg		
ELEMENTAL IMPURITIES	AS REPORTED			
IDENTIFICATION A		0.7962		
IDENTIFICATION B	SPECTRUM MATCHES REFERENCE			
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				



# **Certificate Of Analysis**

Item Number	ET107	Lot Number	2JG0107
Item	Dehydrated Alcohol, 200 Proof, Undenatured, USP		
CAS Number	64-17-5		
Molecular Formula	C <sub>2</sub> H <sub>5</sub> OH	Molecular Weight	46.07

Test	Specif	ication	Result
	min	max	
ASSAY (by VOLUME)	99.5 %		99.98 %
CLARITY OF SOLUTION	NOT MORE OPALESENT THAN STANDARD		NOT MORE OPALESENT THAN STANDARD
COLOR OF SOLUTION	NOT MORE INTENSE THAN STANDARD		NOT MORE INTENSE THAN STANDARD
ACIDITY OR ALKALINITY	SOLUTION IS PINK		SOLUTION IS PINK
SPECIFIC GRAVITY @ 15.56°C		0.7962	0.7937
UV ABSORPTION:			
240 nm		0.40	0.2482
250 - 260 nm		0.30	0.0976
270 - 340 nm		0.10	0.0111
ORGANIC IMPURITIES:			
METHANOL		200 μL/L	< 200 μL/L
ACETALDEHYDE AND ACETAL		10 μL/L	< 10 μL/L
BENZENE		2 μL/L	< 2 μL/L
SUM OF ALL OTHER IMPURITIES		300 μL/L	< 300 μL/L
LIMIT OF NONVOLATILE RESIDUE		2.5 mg	0.0 mg
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION A		0.7962	0.7937
IDENTIFICATION B	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
CERTIFIED KOSHER			CERTIFIED KOSHER
APPEARANCE			CLEAR LIQUID
EXPIRATION DATE			07-JUL-2023
DATE OF MANUFACTURE			07-JUL-2020
RESIDUAL SOLVENTS	AS REPORTED		
CLASS 3 (solvent) / 1-PROPANOL			<300 ppm
CLASS 3 (solvent) / 2-PROPANOL			<300 ppm
MONOGRAPH EDITION			USP 42

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Certified by:

Himanshu Patel
Quality Control Manager
Spectrum Chemicals & Laboratory Products

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

Preparation Date: 9/27/2013 Revision date 8/26/2019 Revision Number: G10

#### 1. IDENTIFICATION

**Product identifier** 

Product code: ET107

Product Name: DEHYDRATED ALCOHOL, 200 PROOF, USP

Other means of identification

**Synonyms:** Absolute ethanol

Alcohol

Alcohol dehydrated Alcohol, anhydrous Alcool ethylique (French) Absolute Ethanol 200 proof

Ethanol

Ethyl alcohol anhydrous

Ethyl hydrate Ethyl hydroxide Fermentation alcohol Dehydrated Alcohol

Ethanol, undenatured 200 proof

Ethanol 200 proof Ethyl alcohol

Alcohol etílico (Spanish)

CAS #: 64-17-5
RTECS # KQ6300000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Solvent. Perfuming agent. In pharmaceuticals. Inks. In organic synthesis. In

beverages.

Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp

14422 South San Pedro St. Gardena, CA 90248

(310) 516-8000

Order Online At: <a href="https://www.spectrumchemical.com">https://www.spectrumchemical.com</a>

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person:Tom Tyner (USA - West Coast)Contact Person:Ibad Tirmiz (USA - East Coast)

#### 2. HAZARDS IDENTIFICATION

#### Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Product code: ET107 Product name: DEHYDRATED Page 1/14

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

#### 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



#### Hazards not otherwise classified (HNOC)

Not Applicable

#### Other hazards

Can burn with an invisible flame

Causes mild skin irritation

#### **Precautionary Statements - Prevention**

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wash face, hands and any exposed skin thoroughly after handling

Do not breathe mist or vapors

Do not eat, drink or smoke when using this product

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

Use only outdoors or in a well-ventilated area

Keep away from heat/sparks/open flames/hot surfaces. — No smoking

Keep container tightly closed

Ground container and receiving equipment

Use explosion-proof equipment

Use only non-sparking tools

Take precautionary measures against static discharge

Keep cool

#### **Precautionary Statements - Response**

IF exposed or concerned: Get medical attention

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

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 skin irritation occurs: Get medical attention

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.

#### **Precautionary Statements - Storage**

Store locked up

Store in a well-ventilated place. Keep container tightly closed

Product code: ET107 Product name: DEHYDRATED Page 2 / 14

#### **Precautionary Statements - Disposal**

Dispose of contents and container to an approved waste disposal plant in accordance with local, regional, national and international regulations as applicable

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Ethyl Alcohol 200 proof	64-17-5	100

#### 4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you

have a poison emergency and need to talk to a poison specialist. Call

1-800-222-1222.

**Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothing and

shoes. Get medical attention. If skin irritation persists, call a physician.

**Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention.

Inhalation: Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial

respiration. Get medical attention.

**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an

unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms Causes eye irritation

May cause skin irritation

May cause irritation of respiratory tract

Dyspnea (Difficulty breathing and shortness of breath)

Central nervous system effects

Dizziness Drowsiness Headache Ataxia

Staggering gait Nausea Vomiting

May cause cardiovascular effects

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

**Protection of first-aiders** 

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

#### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media** 

Suitable Extinguishing Media: Carbon dioxide (CO2). Dry chemical. Alcohol-resistant foam. Water spray.

Product code: ET107 Product name: DEHYDRATED Page 3 / 14

Unsuitable Extinguishing Media: Do not use a solid (straight) water stream as it may scatter

and spread fire.

Specific hazards arising from the chemical

Hazardous combustion products Carbon Monoxide, Carbon Dioxide.

**Specific hazards** Flammable. May be ignited by heat, sparks or flames.

Material can burn with invisible flame. Vapor may travel considerable distance to source of ignition and flash back. Vapors may form explosive mixtures with air. Most vapors are heavier than air. They will spread along the ground and collect in low or confined areas (sewers, basements, tanks). Container explosion may occur under fire conditions or when heated. Fire may produce irritating,

corrosive and/or toxic gases.

**Special Protective Actions for Firefighters** 

Specific Methods: No information available

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus

pressure-demand, MSHA/NIOSH (approved or equivalent)

and full protective gear

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid

contact with skin, eyes and clothing. Use personal protective equipment. Remove all sources of ignition. Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Use spark-proof tools and explosion-proof equipment. In case of large spill, water spray or vapor suppressing foam may be used to reduce vapors, but may not prevent ignition in closed

spaces.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent entry into waterways,

sewers, basements or confined areas.

Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Absorb spill with inert material (e.g.

vermiculite, dry sand or earth). In case of large spill, dike if needed. Dike far

ahead of liquid spill for later disposal.

**Methods for cleaning up**Use appropriate tools to put the spilled material in a suitable chemical waste

disposal container. Use only non-sparking tools. Clean contaminated surface

thoroughly.

#### 7. HANDLING AND STORAGE

#### Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Remove all sources of ignition. To avoid ignition of vapors by static electricity discharge, all metal parts of the equipment must be grounded. Keep away from incompatible materials.

Product code: ET107 Product name: DEHYDRATED Page 4 / 14
ALCOHOL. 200 PROOF. USP

#### Safe Handling Advice:

Wear personal protective equipment. Use only in well-ventilated areas. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not breathe vapors or spray mist. Do not ingest. When using do not smoke. Handle in accordance with good industrial hygiene and safety practice.

#### Conditions for safe storage, including any incompatibilities

#### **Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Sensitive to light. Store in light-resistant containers. Keep away from heat and sources of ignition. Store in a segregated and approved area. Store away from incompatible materials.

#### **Incompatible Materials:**

Oxidizing agents

Acids

Alkali Metals

Halogens

Caustics

isocyanates

Metals

**Bases** 

Acid anhydrides

Acid chlorides

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Control parameters

#### National occupational exposure limits

#### **United States**

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Ethyl Alcohol 200 proof	64-17-5	1000 ppm TWA	1000 ppm TWA	1000 ppm STEL	None
		1900 mg/m³ TWA	1900 mg/m³ TWA		

#### Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Ethyl Alcohol 200 proof	64-17-5	1000 ppm TWA 1880 mg/m³ TWA	1000 ppm STEL	1000 ppm STEL	1000 ppm TWAEV 1880 mg/m³ TWAEV

#### **Australia and Mexico**

Component	CAS No	Australia	Mexico
Ethyl Alcohol 200 proof	64-17-5	1000 ppm TWA	1000 ppm STEL
. ,		1880 mg/m <sup>3</sup> TWA	

#### Appropriate engineering controls

**Engineering measures to reduce exposure:** 

Ensure adequate ventilation. Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors and mist below their respective

threshold limit value.

Individual protection measures, such as personal protective equipment

Product code: ET107 Product name: DEHYDRATED Page 5 / 14

#### **Personal Protective Equipment**

Eye protection: Goggles Safety glasses with side-shields.

Chemical resistant apron Skin and body protection:

Long sleeved clothing

Gloves

Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Respiratory protection:

Hygiene measures: Avoid contact with skin, eyes and clothing. When using, do not eat, drink or

smoke. Wash hands before breaks and immediately after handling the product

3.3%

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Appearance: Color:

Liquid No information available. Clear, Colorless.

Odor: Taste **Formula** Mild. Pleasant. Alcoholic. Like wine or Pungent. Burning. CH3CH2OH

whiskey. Ethereal.

Molecular/Formula weight (g/mole): Flammability (solid, gas) Flashpoint (°C/°F):

46.07 no data available 12-14 °C/53.6-57.2 °F 15.8-18 °C/60.44-64.4 °F

Flash Point Tested according to: Autoignition Temperature (°C/°F): **Lower Explosion Limit (%):** 

363-426 °C/685.4-798.8 °F Closed cup

Open cup

**Upper Explosion Limit (%):** Melting point/range(°C/°F): Decomposition temperature(°C/°F):

-114.1-117.3 °C/-173.38-179.14 °F No information available 19%

Boiling point/range(°C/°F): Bulk density: Density (g/cm3):

78-79 °C/172.4-174.2 °F No information available No information available

Vapor pressure @ 20°C (kPa): Specific gravity: рΗ

0.789 @ 20 °C No information available 5.7-5.866

**Evaporation rate:** Vapor density: VOC content (q/L):

No information available 1.59 789

Odor threshold (ppm): Partition coefficient Viscosity:

5-10 (recognition) No information available (n-octanol/water):

84 (tolerance) -0.31

Miscibility: Solubility:

Miscible with water Very soluble in water Miscible with Acetone Soluble in Benzene Miscible with Ether

Miscible with Benzene Miscible with glacial Acetic Acid Miscible with many organic solvents

#### 10. STABILITY AND REACTIVITY

#### Reactivity

When Ethanol comes in contact with Sodium, it liberates flammable hydrogen gas

It can react vigorously or explosively with acid hydrides or acid chlorides

It reacts with alkali metals to liberate flammable hydrogen gas

It reacts with acetyl bromide to evolve hydrogen bromide

It reacts with ammonia + silver nitrate to form silver nitride and silver fulminate

Product code: ET107 Product name: DEHYDRATED Page 6 / 14

Ethyl alcohol can react with freshly cut/etched/scratched aluminum with the evolution of heat and release of hydrogen gas. The Ethyl alcohol has to be on the aluminum surface as it is being cut/scratched/etched

Ethyl Alcohol reacts vigorously with acetyl chloride.

Ethyl alcohol reacts with silver (I) oxide + ammonia or hydrazine to form silver nitride and silver fulminate

Ethanol ignites and then explodes on contact with the following compounds: acetic anhydride + sodium hydrosulfate, disulfuric acid + nitric acid, phosphorus (III) oxide, platinum, potassium tert-butoxide + acids

Ethanol rapidly absorbs moisture from the air. Can react vigorously/explosively with oxidizers. Ethanol can react vigorously/explosively with the following: ammonium hydroxide & silver oxide, chlorine or chlorine oxides, perchlorates (barium perchlorate, chloryl perchlorate, magnesium perchlorate (forms ethyl perchlorate), nitrosyl perchlorate, potassium perchlorate, silver perchlorate, uranyl perchlorate), acetic anhydride, acetyl bromide (evolves hydrogen bromide), acetyl chloride, aluminum sesquibromide ethylate, bromine pentafluoride, calcium hypochlorite, chromic anhydride, , chromium trioxide, chromyl chloride, cyanuric acid + water, dichloromethane + sulfuric acid + nitrate (or) nitrite, manganese perchlorate + 2,2-dimethoxy propane, dioxygen difluoride, disulfuryl difluoride, fluorine nitrate, hydrogen peroxide, iodine heptafluoride, manganese heptoxide, iodine + methanol + mercuric oxide, iodine + Phosphorus (forms ethane iodide), mercuric nitrate, nitric acid, perchloric acid, permanganic acid, peroxodisulfuric acid, platinum black, potassium dioxide, potassium permanganate, potassium superoxide, potassium tert-butoxide, ruthenium(VIII) oxide, silver +nitric acid (forms silver fulminate), silver nitrate (forms ethyl nitrate), silver peroxide, sodium hydrazide, hydrogen peroxide + sulfuric acid, sulfuric acid + permanganates, uranium hexafluoride, sulfuric acid + sodium dichromate, tetrachlorisilane + water, silver & nitric acid, tetraphosphorus hexaoxide

**Chemical stability** 

**Stability:** Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

<u>Conditions to avoid:</u> Heat. Ignition sources. Incompatible materials.

<u>Incompatible Materials:</u> Oxidizing agents

Acids

Alkali Metals Halogens Caustics isocyanates Metals Bases

Acid anhydrides
Acid chlorides

**Hazardous decomposition** 

products:

Carbon monoxide. Carbon dioxide. When heated to decomposition it emits acrid

smoke and irritating fumes.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

#### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

**Principal Routes of Exposure:** Ingestion. Skin. Eyes. Inhalation.

**Acute Toxicity** 

**Component Information** 

Product code: ET107 Product name: DEHYDRATED Page 7 / 14

Ethyl Alcohol 200 proof

CAS No 64-17-5

LD50/oral/rat = 7060 mg/kg Oral LD50 Rat

**LD50/oral/mouse** = 3450 mg/kg Oral LD50 Mouse

**LD50/dermal/rabbit** = No information available

**LD50/dermal/rat** = No information available

LC50/inhalation/rat = 124.7 mg/L Inhalation LC50 Rat 4 h

LC50/inhalation/mouse = 39000 mg/m<sup>3</sup> 4 h

Other LD50 or LC50information = >60000 ppm Inhalation LC50 Mouse 1 h

5900 mg/m³ Inhalation LC50 Rat 6 h 20000 ppm Inhalation LC50 Rat 10 h 5560 mg/kg Oral LD50 Guinea Pig 6300 mg/kg Oral LD50 Rabbit

#### **Product Information**

LD50/oral/rat =

Value - Acute Toxicity = 7060 mg/kg

LD50/oral/mouse =

Value - Acute Tox = 3450 mg/kg

LD50/dermal/rabbit

**Value - Acute Toxicity =** No information available

LD50/dermal/rat

**VALUE - Acute Tox =** No information available

LC50/inhalation/rat

VALUE-Vapor = 124.7 mg/l (4-hr)
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = 39 mg/l (4-hr)

**VALUE - Gas =** No information available

VALUE - Dust/Mist = No information available

**Symptoms** 

**Skin Contact:** Mildly to moderately irritating to the skin.

**Eye Contact:** Causes serious eye irritation. Causes moderate to severe eye irritation.

**Inhalation** May cause irritation of respiratory tract. Symptoms may include coughing and

shortness of breath. May cause nausea and headache. It may affect

behavior/central nervous system (ataxia, general anesthetic, drowsiness). May affect respiration (respiratory depression). Inhalation of high concentrations of vapor may cause anesthetic effects. Inhalation of high concentrations of vapors

may cause dizziness or suffocation. May affect the brain.

**Ingestion** Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May

cause gastritis. May cause loss of appetite. May cause flushed skin. May affect the cardiovascular system (change in heart rate). May affect the cardiovascular system (hypotension or hypertension, tachycardia, dysrhythmias). It may affect behavior/central nervous system (excitation, mild euphoria, excessive talking, fatigue, headache, dizziness, drowsiness, staggaring gait, ataxia, hallucinations,

Product code: ET107 Product name: DEHYDRATED Page 8 / 14

slurred speech, amnesia, confusion, release of inhibitions, agressive behavior, convulsions, coma). May affect respiration (dyspnea, respiratory depression). It may affect the brain. May affect liver. May affect the blood. May affect the endocrine system. It may affect the spleen. May affect urinary system (kidneys).

**Aspiration hazard** 

No information available.

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

**Chronic Toxicity** Prolonged or repeated skin contact may cause dermatitis, and dryness and

cracking of the skin. Prolonged or repeated ingestion may affect behavior/central nervous system. Prolonged or repeated ingestion may affect metabolism (cause anorexia, weight loss). Prolonged or repeated ingestion may affect the liver (fatty liver degeneration, cirrhosis of the liver. Prolonged or repeated ingestion may affect the cardiovascular system. Prolonged or repeated inhalation may affect the

liver.

**Sensitization:** No information available.

Mutagenic Effects: May affect genetic material based on animal test data

Mutations in microorganisms

Experiments with bacteria and/or yeast have shown mutagenic effects

Cytogenic analysis - hamster ovary Cytogenic Analysis (Hamster embryo) Cytogenic analysis - human leukocyte Cytogenic Analysis: human lymphocyte Sister Chromatid Exchange - Hamster ovary Sister Chromatid Exchange (human lymphocyte)

Carcinogenic effects:

Equivocal tumorigenic agent by Registry of Toxic Effects of Chemical Substances (RTECS) criteria. Confirmed Animal Carcinogen with Unknown Relevance to Humans.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Ethyl Alcohol 200 proof		Monograph 100E [2012] in alcoholic	A3 Confirmed Animal Carcinogen with Unknown Relevance to Humans	Not listed	Present	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

A3 - Animal Carcinogen

IARC (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans

(In alcoholic beverages)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

**Reproductive toxicity** May damage fertility or the unborn child

**Reproductive Effects:**Causes adverse reproductive effects **Developmental Effects:**May cause harm to the unborn child

May cause adverse developmental effects

Product code: ET107 Product name: DEHYDRATED Page 9 / 14

**Teratogenic Effects:** Causes birth defects (teratogenic effects)

**Specific Target Organ Toxicity** 

STOT - single exposure

STOT - repeated exposure

**Target Organs:** 

respiratory system. central nervous system.

Causes damage to organs through prolonged or repeated exposure. Skin. Liver. Central nervous system. Nervous system. Heart. Reproductive

System.

#### 12. ECOLOGICAL INFORMATION

#### **Ecotoxicity**

**Ecotoxicity effects:** Aquatic environment.

Ethyl Alcohol 200 proof - 64-17-5

Fish

LC50: 12.0 - 16.0mL/L (96h, Oncorhynchus mykiss) LC50: >100mg/L (96h, Pimephales promelas) LC50: 13400 - 15100mg/L (96h, Pimephales promelas)

LC50: 9268 - 14221mg/L (48h, Daphnia magna) EC50: =2mg/L (48h, Daphnia Crustacea

magna) EC50: =10800mg/L (24h, Daphnia magna)

No information available Persistence and degradability:

Bioaccumulative potential: No information available.

No information available Mobility in soil Other adverse effects No information available.

#### 13. DISPOSAL CONSIDERATIONS

#### **Disposal Methods**

#### Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

#### Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Ethyl Alcohol 200 proof	64-17-5	None	None	None	None

#### 14. TRANSPORT INFORMATION

DOT

UN1170 UN-No: Ethanol **Proper Shipping Name: Hazard Class** 

No information available **Subsidiary Class** 

Packing group: **Emergency Response Guide** 127

Number

**Marine Pollutant** No data available DOT RQ (lbs): No information available

**Special Provisions** 24, IB2, T4, TP1

Product code: ET107 Product name: DEHYDRATED Page 10 / 14

Symbol(s): No information available UN1170, Ethanol, 3, II

TDG (Canada)

UN-No: UN1170
Proper Shipping Name: Ethanol

Hazard Class 3

Subsidiary Risk: No information available

Packing Group:

Marine PollutantNo Information availableDescription:UN1170, Ethanol, 3, II

ADR

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

Subsidiary Risk: No information available

Special Provisions 144, 601

**Description:** UN1170, Ethanol, 3, II

**IMDG** 

UN-No: UN1170
Proper Shipping Name: Ethanol
Hazard Class: 3

Subsidiary Risk: No information available

Packing Group:

Marine Pollutant No information available

EMS: F-E Special Provisions 144

**Description** UN1170, Ethanol, 3, II

**RID** 

UN Number UN1170
Proper Shipping Name: Ethanol
Transport hazard class(es) 3
Subsidiary Risk: 3
Packing group II

Special Provisions 144, 601

**Description:** UN1170, Ethanol, 3, II

ICAO (air)

UN-No: UN1170
Proper Shipping Name: Ethanol

Hazard Class 3

Subsidiary Risk: No information available

Packing Group:

**Description:** UN1170, Ethanol, 3, II

Special Provisions A58, A180, A3

**IATA** 

UN Number UN1170
Proper Shipping Name: Ethanol

Transport hazard class(es) 3

Subsidiary Risk: No information available

Response

Product code: ET107 Product name: DEHYDRATED Page 11 / 14
ALCOHOL, 200 PROOF, USP

Special Provisions Description:

No information available UN1170, Ethanol, 3, II

#### 15. REGULATORY INFORMATION

#### **International Inventories**

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
Ethyl Alcohol 200 proof	64-17-5	Present(ACTI VE)	KE-13217	Present	(2)-202	Present	Present	Present 200-578-6

#### **U.S. Regulations**

Ethyl Alcohol 200 proof

Massachusetts RTK: Present

New Jersey RTK Hazardous Substance List: 0844

Pennsylvania RTK: Present

Minnesota - Hazardous Substance List: Present

Louisana Reportable Quantity List for Pollutants: Present (listed as Volatile Organic Compounds)

California Directors List of Hazardous Substances: Present

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1293

FDA - 21 CFR - Total Food Additives 169.175, 169.176, 169.177, 169.181, 172.340, 172.560, 172.580, 175.105, 176.180,

- List Sourced from EAFUS 176.200, 177.1200, 177.1650, 178.1010, 184.1293, 73.30, 73.345, 73.615

#### California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

#### Chemicals Known to the State of California to Cause Cancer:

△WARNING: This product can expose you to chemicals including (see table below) which is (are) known to the State of California to cause cancer. For more information go to www.p65warnings.ca.gov.

#### Chemicals Known to the State of California to Cause Reproductive Toxicity:

<u>MARNING</u>: This product can expose you to chemicals including (see table below) which is (are) known to the State of California to cause birth defects or other reproductive harm. For more information go to www.p65warnings.ca.gov.

Component	CAS No	Carcinogen		Female Reproductive Toxicity:
Ethyl Alcohol 200 proof	64-17-5	(Ethanol in	developmental toxicity (Ethyl alcohol in alcoholic beverages)	 Not Listed

#### **CERCLA/SARA**

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Ethyl Alcohol 200 proof	64-17-5	None	None	None	None	None

#### U.S. TSCA

Component		TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Ethyl Alcohol 200 proof	64-17-5	Not Applicable	Not Applicable

#### Canada

Product code: ET107 Product name: DEHYDRATED Page 12 / 14

#### WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

Component Ethyl Alcohol 200 proof 64-17-5 ( 100 )

WHMIS 2015 Hazard Classification Flammable liquids - Category 2: H225 Highly flammable liquid and vapour.; Serious Eye Damage/Eye Irritation - Category 2B: H320 Causes eye irritation.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

#### DSL/NDSL

	CAS No	Canada (DSL)	Canada (NDSL)
Ethyl Alcohol 200 proof	64-17-5	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Ethyl Alcohol 200 proof	64-17-5	Not listed
Component		CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Ethyl Alcohol 200 proof	64-17-5	Not listed

#### **EU Classification**

#### EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Ethyl Alcohol 200 proof	64-17-5	Flammable liquids - Flam. Liq. 2: H225
		Highly flammable liquid and
		vapour.603-002-00-5

EU - CLP (1272/2008)

#### R-phrase(s)

R11 - Highly flammable

<u>S -phrase(s)</u> S 7 - Keep container tightly closed.

S16 - Keep away from sources of ignition - No smoking

Component	CAS No		Concentration Limits:	Safety Phrases
Ethyl Alcohol 200 proof	64-17-5	F; R11	No information	S(2) S7 S16

The product is classified in accordance with Annex VI to Directive 67/548/EEC

#### Indication of danger:

F - Highly flammable

Product code: ET107 Product name: DEHYDRATED Page 13 / 14



#### **16. OTHER INFORMATION**

Preparation Date: 9/27/2013
Revision date 8/26/2019
Prepared by: Sonia Owen

**Disclaimer:** All chemicals may pose unknown hazards and should be used with caution. This

Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the

completeness or accuracy of the information contained herein.

**End of Safety Data Sheet** 

Product code: ET107 Product name: DEHYDRATED Page 14 / 14



October 16, 2020

#### 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
ET107	Dehydrated Alcohol, 200 Proof
	Undenatured, 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,

Oralia Chavez

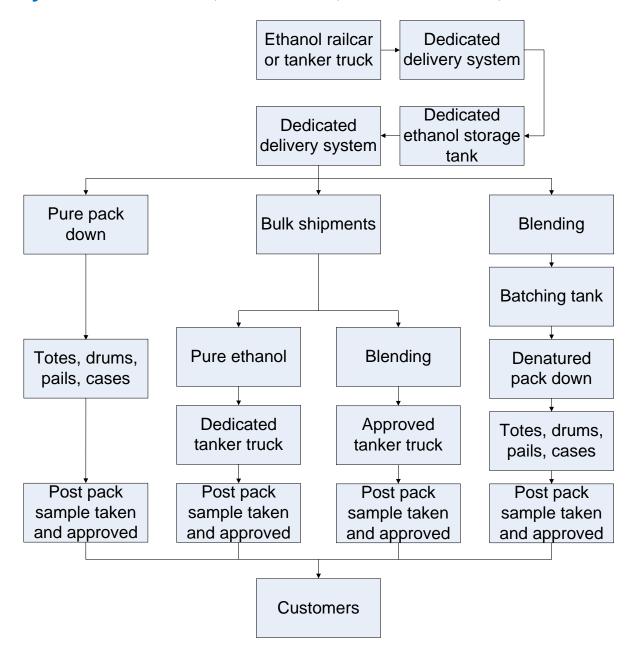
Order Chanz

Quality Assurance Specialist



## **Manufacturing Process Flowchart**

## Dehydrated Alcohol, 200 Proof, Undenatured, USP - ET107



#### 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



# **ET107**, Dehydrated Alcohol, 200 Proof, Undenatured, USP

#### **Source Statement**

The above mentioned catalog item is derived from plant derived material, Corn, and fermentation derived material, Enzymes and Yeast. 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
- Sov

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- 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 with the use of genetically modified organisms and might contain GMO's, but no detectable levels of GMO's 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 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



# RE: Elemental Impurities - Dehydrated Alcohol, 200 Proof, Undenatured, USP (Cat# ET107)

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, Undenatured, USP (Cat# ET107)

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.

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



### **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 Bar Code
- GHS Hazard Pictograms
- Warning, Safety Data and Precautionary Information
- Product Catalog Number
- Item Name, Form, Grade
- Storage Color Band

- Size/Quantity
- Chemical Abstracts Service (CAS) Registry Number
- Caution Information
- DOT Shipping Information
- Toll-Free 24-Hour Chemical **Emergency Telephone Number**
- Empirical Formula, Formula Weight and Technical Specifications Panel
- Expiration Information
- Lot Number
- Kosher Certified by Kosher Supervision of America (KSA).

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:

769 Jersey Ave. New Brunswick, NJ 08901 West Coast Facility:

14422 S. San Pedro St. Gardena, CA 90248

732.214.1300

310.516.8000



May 28, 2020

#### **RE: Lot Numbering System**

**Dear Valued Customer:** 

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

**Example**: Zl0928 = The 928<sup>th</sup> material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility
- 4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

**Example**: 2AA0706 = The 706<sup>th</sup> material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at quality\_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,

**Quality Assurance Specialist** 

Ordu Anny

CORPORATEHEADQUARTERS

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



The following product(s) prepared by the named company are certified kosher with the stated requirements:

## **Spectrum Laboratory Products, Inc.**

S-0032

14422 S. San Pedro Street Gardena CA 90248 **USA** 

**Product Name** ET107, Ethyl Alcohol, 200 Proof, USP

**Brand Spectrum** 

**UKD-ID** KSAV3-I5V5F9

P D/P/M

**Symbol Required KSA** 

**Special Conditions** This certificate expires on

Feb 01, 2021

Rabbi Binyomin Lisbon **Kashrus Administrator** 

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.