

SAFETY DATA SHEET

1. Identification

Product Identifier: Dehydrated Alcohol Injection, USP

Synonyms: Ethyl alcohol; Ethanol

National Drug Code (NDC): 17478-503-05

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Flammable liquid Category 2


Health Hazards: Skin irritation Category 2

Eye irritation Category 2B

Reproductive toxicity Category 1A

Specific target organ toxicity – repeated exposure Category 1

Specific target organ toxicity – single exposure (respiratory tract irritation) Category 3

Symbol(s):   

Signal Word: Danger.

Hazard Statement(s): H225 Highly flammable liquid and vapor.

H315 Causes skin irritation.

H320 Causes eye irritation.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

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Precautionary Statement(s):

- H360 May damage fertility or the unborn child.
- H370 Causes damage to organs (central nervous system, heart, liver) through prolonged or repeated exposure.
- P201 Obtain special instruction before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P210 Keep away from heat/sparks/open flames/hot surfaces. No Smoking.
- P233 Keep container tightly closed.
- P403 Store in a well-ventilated place. Keep cool.
+
P235
- P405 Store locked up.
- P240 Ground/bond container and receiving equipment.
- P241 Use explosion-proof electrical, ventilating, and lighting equipment.
- P242 Use only non-sparking tools.
- P243 Take precautionary measures against static discharge.
- P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
- P264 Wash potentially exposed skin after handling.
- P270 Do not eat, drink, or smoke when using this product.
- P271 Use only in a well-ventilated area.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P303 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
+
P361
+
P353
- P332 If skin irritation occurs: Get medical
+
P313

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- P305 IF IN EYES: Rinse cautiously with water
+
P351 for several minutes. Remove contact lenses, if
+
P338 present and easy to do. Continue rinsing. Seek
medical attention.
- P337 If eye irritation persists: Get medical attention.
+
P313
- P304 IF INHALED: Remove person to fresh air and
+
P340 keep comfortable for breathing.
- P308 If exposed or concerned: Call a POISON
+
P312 CENTER/doctor/physician if you feel unwell.
- P321 Specific treatment (see Section 4).
- P362 Take off contaminated clothing and wash it
+
P364 before reuse.
- P370 In case of fire: Use dry sand, dry chemical or
+
P378 alcohol-resistant foam to extinguish.
- P501 Dispose of contents/container in accordance
with local/provincial/federal regulations.

Hazards Not Otherwise Classified: Not classifiable.
Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Ethyl Alcohol	64-17-5	Ethanol; Dehydrated Alcohol	C ₂ H ₆ O	46.07	≥ 98

4. First Aid Measures

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

Signs and Symptoms:

Central nervous system depression; liver injury; nausea; vomiting; diarrhea; flushing; depression; drowsiness; impaired perception; incoordination; stupor; narcosis.

Medical Conditions Aggravated by Exposure:

Epilepsy; alcohol addiction; fluid/electrolyte imbalance; pregnancy. Pre-existing ailments in the following organs: Central nervous system; cardiovascular system; hematopoietic system; respiratory system; hepatic system.

Notes to Physician:

Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:

Carbon dioxide (CO₂); dry chemical; alcohol-resistant foam; water spray. (Use extinguishing media for type of surrounding fire).

Unsuitable Extinguishing Media:

Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:

These products include carbon oxides.

Other Specific Hazards:

Closed containers may explode from the heat of fire. Highly flammable. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

Special Protective Equipment/Precautions for Firefighters:

Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions:

Do not inhale vapors, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment:

For personal protection see section 8.

Methods for Cleaning Up:

Highly flammable liquid. Eliminate all sources of ignition. All equipment used when handling this product must be grounded. A vapor suppressing foam may be used to reduce vapors. Do not touch or walk through spilled material. Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions:

Highly flammable liquid. 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). Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections:

Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling:

Keep open containers away from flames and other potential sources of ignition. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities:

Store according to label and/or product insert information. Keep open containers away from flames and other potential sources of ignition. Store away from oxidizers, acids and bases.

Specific End Use:

Pharmaceuticals.

8. **Exposure Controls/Personal Protection**

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Ethanol	OSHA PEL: 1000 ppm (1900 mg/m ³), 8 Hour TWA ACGIH TLV: 1000 ppm (1900 mg/m ³), 8 Hour TWA

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Protective laboratory coat, apron, or disposable garment.

9. **Physical and Chemical Properties**

Physical State/Color: Liquid/Colorless.
Odor: Alcoholic.
Odor Threshold: 5-10 ppm (recognition); 84 ppm (tolerance).
pH: 8.3 – 9.8.
Melting Point: -114°C (-173.2°F).
Freezing Point: 0.797 at 25°C.
Boiling Point: 79°C (174.2°F).
Flash Point: 13°C (53.6°F).
Evaporation Rate: 1.4.
Flammability (solid, gas): No data available.
Flammability Limit - Lower: 3.3%.
Flammability Limit - Upper: 19%.
Vapor Pressure: 43 mm Hg at 23°C.
Vapor Density: 1.59.
Relative Density: No data available.
Solubility(ies): Miscible in water, methanol, ether, acetone.
Partition Coefficient (n-octanol/water): -0.31.

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Auto-Ignition Temperature: No data available.
Decomposition Temperature: 363°C (685.4°F).
Viscosity: No data available.

10. Stability and Reactivity

Reactivity: No data available.
Chemical Stability: Stable under recommended storage conditions.
Possibility of Hazardous Reactions: No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration): Heat, sparks, flames or other ignition sources.
Incompatible Materials: Oxidizers, acids and bases.
Hazardous Decomposition Products: No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May cause irritation.
Ingestion: May be fatal if swallowed.
Skin Contact: May be fatal if absorbed through the skin. May cause skin irritation.
Eye Contact: May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

Drowsiness; impaired perception; incoordination; stupor; narcosis; hepatotoxicity; liver cirrhosis; hypoglycemia; ketoacidosis; peripheral neuropathy; Wernicke-Korsakoff Syndrome; pancreatitis; hepatitis; myopathy; portal hypertension; myelosuppression; cardiac arrhythmia; withdrawal, delirium tremens.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Ethanol	Rat	Oral	LD ₅₀	7,060 mg/kg
Ethanol	Rat	Inhalation	LD ₅₀	20,000 ppm (10 Hours)

Acute Toxicity – Dermal: No data available.
Corrosivity: No data available.

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Dermal Irritation:

Compound	Species	Study Type	Severity
Ethanol	Rabbit	Skin irritation, Draize test (24 Hours)	Irritant

Eye Irritation:

Compound	Species	Study Type	Severity
Ethanol	Rabbit	Eye irritation, Draize test (24 Hours)	Moderate

Sensitization:

No data available.

Toxicokinetics/Metabolism:

Modulate neural transmission; prolong/enhance neural transmission; overload metabolic enzyme.

Target Organ Effects:

May affect the central nervous system; liver; fetus.

Reproductive Effects:

Ethanol has been shown to produce fetotoxicity in the embryo or fetus of laboratory animals. Chronic prenatal exposure has been associated with a distinct pattern of congenital malformations ("fetal alcohol syndrome").

Carcinogenicity:

No data available.

National Toxicology Program (NTP):

Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC):

Group 1 - Carcinogenic to humans (ethanol in alcoholic beverages).

Occupational Safety and Health Administration (OSHA):

Not considered to be a carcinogen.

Mutagenicity:

May affect genetic material. Experiments with bacteria and/or yeast have shown mutagenic effects.

Aspiration Hazard:

No data available.

12. Ecological Information

Ecotoxicity

Aquatic:

Compound	Species	Test Type	Dose
Ethanol	Rainbow trout	LC ₅₀	12,900 – 15,300 mg/mL (96 Hours)
Ethanol	Daphnia magna	LC ₅₀	9,268 – 14,221 mg/mL (48 Hours)

Terrestrial:

No data available.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Soil:

No data available.

Mobility in Environment:

No data available.

Other Adverse Effects:

No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	UN1170.
UN Proper Shipping Name:	Ethanol.
Transport Hazard Class(es):	3.
Packing Group:	II.
Department of Transportation:	Regulated as a hazardous material.
International Air Transport Association (IATA):	Regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA):	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
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CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
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SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

Massachusetts:	Ethanol.
New Jersey:	Ethanol.
Pennsylvania:	Ethanol.
Minnesota Hazardous Substance List:	Ethanol.
Louisiana RQ List:	Volatile Organic Compound.
California Proposition 65:	Ethanol (when in alcoholic beverages).

16. Other Information

Not made with natural rubber latex.

NFPA Rating:		HMIS Classification:	
Health: 2		Health: 2	
Flammability: 3		Flammability: 3	
Reactivity: 0		Physical Hazard: 0	



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