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### Section 1 - Identification


- (a) **Product Identifier:** Dehydrated Alcohol Injection, USP
- (b) **Product Code:** 83634-306-41 and 83634-306-05
- Common/Trade Name:** Ablysinol, Ethanol
- Chemical Name:** Ethyl Alcohol
- Chemical Family:** Alcohols
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901
- (e) **Emergency Telephone:** 855-283-6229

### Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** Flammable Liquid Category 2  
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


#### (b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):

<b>GHS Signal Word:</b>	Danger
<b>GHS Hazard Statement:</b>	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. H360: May damage fertility or the unborn child. H370: Causes damage to organs (central nervous)
<b>GHS Symbols:</b>	  

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<b>GHS Precautionary Statements:</b>	<p>P203 - Obtain, read and follow all safety instructions before use.</p> <p>P210 – Keep away from heat, hot surface, sparks, open flames and other ignition sources. No smoking.</p> <p>P233 – Keep container tightly closed.</p> <p>P240 – Ground/bond container and receiving equipment.</p> <p>P241 – Use explosion-proof electrical, ventilating, and lighting equipment.</p> <p>P242 – Use only non-sparking tools.</p> <p>P243 – Take precautionary measures against static discharge.</p> <p>P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.</p> <p>P264 - Wash potentially exposed skin thoroughly after handling.</p> <p>P264+P265 - Wash potentially exposed skin thoroughly after handling. Do not touch eyes.</p> <p>P270: Do not eat, drink, or smoke when using this product.</p> <p>P271 - Use only outdoors or in a well-ventilated area.</p> <p>P280 – Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.</p> <p>P302+P352 - IF ON SKIN: wash with plenty of water.</p> <p>P303+P361+P353 - IF ON SKIN (or hair): Take off Immediately all contaminated clothing. Rinse SKIN with water or shower.</p> <p>P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.</p> <p>P308+P316 - IF exposed or concerned: Get emergency medical help immediately.</p> <p>P318 - If exposed or concerned, get medical advice.</p> <p>P319 - Get medical help if you feel unwell.</p> <p>P321 – Specific treatment (see Section 4).</p> <p>P332+P317 - If skin irritation occurs: Get medical help.</p> <p>P333+P317 - If skin irritation or rash occurs: Get medical help.</p> <p>P362+P364 - Take off contaminated clothing and wash it before reuse.</p> <p>P370+P378 - In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.</p> <p>P403+P233 - Store in a well-ventilated place. Keep container tightly closed.</p> <p>P403+P235 - Store in a well-ventilated place. Keep cool.</p> <p>P405 - Store locked up.</p> <p>P501 - Dispose of contents/container per local/national regulations.</p>
<b>Other Hazards:</b>	Not applicable.

**(d) Unknown Acute Toxicity** N/A


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### Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Dehydrated Alcohol	Ethanol	>99% by volume	64-17-5	N/A

### Section 4 – First Aid Measures

<b>Eye Exposure:</b>	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. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Skin Exposure:</b>	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.
<b>Ingestion:</b>	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.
<b>Inhalation:</b>	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.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see Section 8).
<b>Signs and Symptoms:</b>	Central nervous system depression; liver injury; nausea; vomiting; diarrhea; flushing; depression; drowsiness; impaired perception; incoordination; stupor; narcosis.
<b>Medical Conditions Aggravated by Exposure:</b>	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.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

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## Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media:** Carbon dioxide (CO<sub>2</sub>); dry chemical; alcohol-resistant foam; water spray. (Use extinguishing media for type of surrounding fire).
- (b) **Hazardous Combustion Products:** These products include carbon oxides.
- (c) **Special Protective Equipment / Precautions:** Wear self-contained breathing apparatus and full and protective gear.
- (d) **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.

## Section 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.

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.

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## Section 7 - Handling and Storage

**General 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.

**Storage Conditions:** 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.

## Section 8 - Exposure Controls / Personal Protection

### (a) Exposure Limits –

Ethanol – OSHA PEL: 1,000 ppm (1,900 mg/m<sup>3</sup>), 8 hour TWA  
ACGIH TLV: 1,000 ppm (1,900 mg/m<sup>3</sup>), 8 hour TWA

### (b) Engineering Controls


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

### (c) Individual Protection Measures

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

## Section 9 - Physical and Chemical Properties

(a)	<b>Appearance</b>	Clear, colorless
(b)	<b>Odor</b>	Alcoholic
(c)	<b>Odor Threshold</b>	Not available

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(d)	<b>pH</b>	8.3 to 9.8
(e)	<b>Melting Point:</b>	Not available
(f)	<b>Initial Boiling Point:</b>	Not available
(g)	<b>Flash Point</b>	Not available
(h)	<b>Evaporation Rate:</b>	Not available
(i)	<b>Flammability</b>	Not available
(j)	<b>Upper Lower Flammability or Explosion Limits</b>	Not available
(k)	<b>Vapor Pressure:</b>	43 mm Hg at 23°C
(l)	<b>Vapor Density:</b>	Not available
(m)	<b>Relative Density</b>	0.790 to 0.793
(n)	<b>Solubility(ies)</b>	Miscible in water and with practically all organic solvents
(o)	<b>Partition Coefficient: n-octanol/water</b>	Not available
(p)	<b>Auto-ignition Temperature</b>	Not available
(q)	<b>Decomposition Temperature</b>	Not available
(r)	<b>Viscosity</b>	Not available

#### Section 10 - Stability and Reactivity

(a)	<b>Reactivity</b>	No data available.
(b)	<b>Chemical Stability</b>	Stable under standard use and storage conditions.
(c)	<b>Conditions to Avoid</b>	Heat, flames, sparks and other ignition sources.
(d)	<b>Incompatible Materials</b>	Oxidizers, acids, and bases.
(e)	<b>Hazardous Decomposition Products</b>	No data available.

#### Section 11 - Toxicological Information

(a)	<b>Likely Routes of Exposure</b>	Eye/skin contact, inhalation or ingestion
(b)	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	May cause eye irritation. May be fatal if absorbed through the skin. May cause skin irritation. May cause respiratory irritation. May be fatal if swallowed.
(c)	<b>Symptoms Related to the Physical, Chemical and Toxicological Characteristics:</b>	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

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<b>(d)</b>	<b>Delayed and Immediate Effects of Exposure:</b>	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.
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**(e) Acute Toxicity**

Component	Type	Route	Species	Dosage
Ethanol	LD <sub>50</sub>	Oral	Rat	7,060 mg/kg
Ethanol	LD <sub>50</sub>	Inhalation	Rat	20,000 ppm (10 hours)

**Dermal:** No data available.

**Corrosivity:** No data available.

**Dermal Irritation:**

Component	Study Type	Species	Dosage
Ethanol	Skin irritation, Draize test (24 hours)	Rabbit	Irritant

**Eye Irritation:**

Component	Study Type	Species	Dosage
Ethanol	Eye irritation, Draize test (24 hours)	Rabbit	Moderate

**Sensitization:** No data available.

**Toxicokinetic/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.



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

**Aspiration Hazard:** No data available.

## Section 12 - Ecological Information

(a)	<b>Ecotoxicity</b>	Rainbow Trout, LC <sub>50</sub> – 12,900 to 15,300 mg/mL (96 hours) Daphnia Magna LC <sub>50</sub> – 9,268 to 14,221 mg/mL (48 hours)
(b)	<b>Persistence and degradability</b>	No data available.
(c)	<b>Bioaccumulative potential</b>	No data available.
(d)	<b>Mobility in soil</b>	No data available.
(e)	<b>Other Adverse Effects</b>	No data available.

## Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water.

## Section 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

## Section 15 - Regulatory Information


Below is selected regulatory information chosen primarily for possible Avenacy usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

### U.S. Federal Regulations:

**TSCA** – This product is a drug regulated by the Food and Drug Administration (FDA) and is not regulated by TSCA.

**CERCLA** – Not listed.



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SARA 302 – Not listed.

SARA 313 – 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)

**NFPA Rating:**

Health: 2  
Flammability: 3  
Reactivity: 0

**HMIS Classification:**

Health: 2  
Flammability: 3  
Physical Hazard: 0

**Section 16 - Other Information**


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Avenacy  
10 N. Martingale Road, Suite 225  
Schaumburg, IL 60173  
847-773-4901

**Glossary:** This glossary contains definitions of general terms used in Safety Data Sheets (SDS). Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute

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CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System