# U.S. Pharmacopeial Convention

# SAFETY DATA SHEET

#### 1. Identification

Product identifier Alpha Lipoic Acid

Other means of identification

Catalog number1368201CAS number1077-28-7SynonymsThioctic acid

Chemical name 1,2-Dithiolane-3-valeric acid

**Recommended use** Specified quality tests and assay use only.

**Recommended restrictions** Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway

Rockville MD 20852-1790 United States

**Telephone** RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

# 2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 4

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement Harmful if swallowed.

**Precautionary statement** 

**Prevention** Wash thoroughly after handling.

**Response** If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth.

Storage Not available.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information None.

## 3. Composition/information on ingredients

Substance

Chemical nameCommon name and synonymsCAS number%Alpha Lipoic AcidThioctic acid1077-28-7100

4. First-aid measures

**Inhalation** Move to fresh air. Call a physician if symptoms develop or persist.

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Rinse skin with water/shower. Get medical attention if irritation develops and persists. Skin contact

Rinse with water. Get medical attention if irritation develops and persists. Eye contact

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Ingestion

Most important

symptoms/effects, acute and

delayed

None known.

Indication of immediate medical attention and special

treatment needed

**General information** 

Provide general supportive measures and treat symptomatically.

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

## 5. Fire-fighting measures

Suitable extinguishing media Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire fighting

equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials. General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

**Environmental precautions** 

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

#### 8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

**Biological limit values** 

Appropriate engineering controls

No biological exposure limits noted for the ingredient(s).

For laboratory operations, use good technique and limit open handling. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

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**Respiratory protection** Respirators are generally not required for laboratory operations. Chose respiratory protection

appropriate to the task and the level of existing engineering controls.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards.

Procedures for any other uses or quantities should be determined after an appropriate

assessment.

# 9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.

Form Crystalline powder.

ColorYellow.OdorFaint odor.Odor thresholdNot available.pHNot available.

Melting point/freezing point  $140 - 143.6 \,^{\circ}\text{F} \, (60 - 62 \,^{\circ}\text{C})$ Initial boiling point and boiling  $320 - 329 \,^{\circ}\text{F} \, (160 - 165 \,^{\circ}\text{C})$ 

range

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower

er

(%)

Flammability limit - upper

(%)

Not available.

Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure 0.13 kPa at 25 °C

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Practically insoluble.

**Solubility (other)** Alkaline solutions: Soluble.

Alcohol: Insoluble.

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Chemical familyDithiol.Molecular formulaC8H14O2S2Molecular weight206.33Specific gravity0.4

#### 10. Stability and reactivity

**Reactivity**The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. SOx.

#### 11. Toxicological information

Information on likely routes of exposure

**Inhalation** Knowledge about health hazard is incomplete.

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Knowledge about health hazard is incomplete. Skin contact Knowledge about health hazard is incomplete. Eye contact

Harmful if swallowed. Ingestion

Symptoms related to the physical, chemical, and

toxicological characteristics Skin rash. Gastrointestinal disturbances. Dizziness.

#### Information on toxicological effects

Harmful if swallowed. Acute toxicity

**Product** Species **Test Results** 

Alpha Lipoic Acid (CAS 1077-28-7)

**Acute** Oral

LD50 Mouse 502 mg/kg Rat 1130 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete. Serious eye damage/eye Knowledge about health hazard is incomplete.

irritation

Respiratory or skin sensitization

Knowledge about health hazard is incomplete. Respiratory sensitization Knowledge about health hazard is incomplete. Skin sensitization Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

> Mutagenicity Ames test Result: Negative.

Based on available data, the classification criteria are not met. Carcinogenicity

20 - 180 mg/kg/day Carcinogenicity, administered orally.

Result: Negative. Species: Rat Test Duration: 2 years

IARC Monographs. Overall Evaluation of Carcinogenicity

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed

Knowledge about health hazard is incomplete. Reproductive toxicity

Specific target organ toxicity single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

Based on available data, the classification criteria are not met. **Aspiration hazard** 

#### 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

No data is available on the degradability of this product. Persistence and degradability

No data available.

Bioaccumulative potential Mobility in soil No data available

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

#### 13. Disposal considerations

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the **Disposal instructions** 

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

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Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

#### 14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to

Annex II of MARPOL 73/78 and

the IBC Code

**General information** It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

Not applicable.

## 15. Regulatory information

**US federal regulations** 

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)** 

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Immediate Hazard - Yes **Hazard categories** 

> Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Yes

chemical

SARA 313 (TRI reporting)

Not regulated.

#### Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA) **US state regulations** 

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material

is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes

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Country(s) or region Inventory name On inventory (yes/no)\*

Philippines Philippine Inventory of Chemicals and Chemical Substances

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

 Issue date
 09-10-2008

 Revision date
 03-21-2018

Version # 03

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herein.

Material name: Alpha Lipoic Acid USP SDS US