

SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME ALPHA LIPOIC ACID, USP

PRODUCT CODE 2535

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SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION Acute Toxicity - Oral (Category 4)

PICTOGRAM

SIGNAL WORD Warning

HAZARD STATEMENT(S) Harmful if swallowed.

ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS Repeated exposure may cause skin dryness or cracking.

PRECAUTIONARY STATEMENT(S)

Prevention Wash thoroughly after handling
Do not eat, drink or smoke when using this product.

Response IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.

Storage Not applicable

Disposal Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION Health Hazard 1 Flammability

Reactivity

0

Personal Protection

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME 1, 2-Dithiolane-3-pentanoic acid; 1,2-dithiolane-3-valeric acid

BOTANICAL NAME Not applicable

SYNONYM CHEMICAL Thioctic acid; DL-alpha-Lipoic acid

FORMULACAS NUMBER C₈H₁₄O₂S₂

ALTERNATE CAS NUMBER 1077-28-7

Not applicable

MOLECULAR WEIGHT 206.329

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
ALPHA LIPOIC ACID	1077-28-7	214-071-2	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES Chemical family: Dithiol.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT IF Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

SWALLOWED Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

IF INHALED Not expected to present a significant hazard under anticipated conditions of normal use.

SYMPTOMS AND EFFECTS

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL Not applicable

FLAMMABLE PROPERTIES HAZARDOUS May be combustible at high temperature

COMBUSTION PRODUCTS Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA **Small fire:** dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture. Preserve in well-closed containers. Protect from light.

SPECIFIC END USE(S)

See Section 1

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: ALPHA LIPOIC ACID CAS #: 1077-28-7

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH AIHA	N/L	N/L	N/L	N/L	N/L	-
WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSISHSE	N/L	N/L	N/L	-	-	-
GESTIS	N/L	N/L	N/L	-	-	-
	N/L	N/L	N/L	-	-	-

N/L = Not Listed **EXPOSURE**

GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

SPECIFIC ENGINEERING CONTROLS

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	Solid				
DESCRIPTION	Slightly yellow crystalline powder. Is almost odorless.				
SOLUBILITY ODOR	Very slightly soluble in water, very soluble in dimethyl formamide, freely soluble in methanol.				
FLAMMABILITY	Almost odorless				
	May be combustible at high temperature				
AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	(160-165)°C, (320-329)°F	DECOMPOSITION TEMPERATURE	Not available
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	3.4	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(60-62)°C, (140-143.6)°F
ODOR THRESHOLD	Not available	OXIDIZING PROPERTY	Not available	pH	Not available
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	0.4	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY(AIR = 1)	Not available	VAPOR PRESSURE	0.1265 kPa (25°C)	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY CHEMICAL	Not established
STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidizing agents
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, sulfur oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 1130 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	Due to lack of data the classification is not possible.
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible.
CARCINOGENICITY	<p>OSHA ALPHA LIPOIC ACID is not listed.</p> <p>NTP ALPHA LIPOIC ACID is not listed.</p> <p>IARC ALPHA LIPOIC ACID is not listed.</p> <p>California Proposition 65 This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</p>
ADDITIONAL CARCINOGENICITY INFORMATION	Based on available data, the classification criteria are not met. 20 - 180 mg/kg/day Carcinogenicity study, administered orally. Result: Not carcinogenic; Species: Rat; Test Duration: 2 years
REPRODUCTIVE TOXICITY	Based on available data, the classification criteria are not met. This material has not caused birth defects in animal studies.
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Based on available data, the classification criteria are not met.
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	Based on available data, the classification criteria are not met.
ASPIRATION HAZARDS	Based on available data, the classification criteria are not met.
SIGNS AND SYMPTOMS OF EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.
	Symptoms related to the physical, chemical, and toxicological characteristics Nausea. Vomiting. Dizziness. Skin rash.
	Delayed and immediate effects of exposure Anemia. Thrombocytopenia. Decrease in blood sugar levels.
	Medical conditions aggravated by exposure Hypoglycemia.
POTENTIAL HEALTH EFFECTS	<p>Inhalation May be harmful if inhaled. May cause respiratory tract irritation.</p> <p>Ingestion Harmful if swallowed.</p> <p>Skin Eyes May be harmful if absorbed through skin. May cause skin irritation</p> <p>May cause eye irritation.</p>

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	Not available
BIOACCUMULATIVE POTENTIAL MOBILITY	LogPow: 3.4
IN SOIL	Water Solubility: 127mg/L (25°C) Henry's Law Constant: 1.64E-08 atm-m ³ /mole (25°C)

OTHER ADVERSE EFFECTS	Not available
	This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAMEUN	Not dangerous good
NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable
AUSTRALIAHAZCHEM	
EU	Not Applicable
TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not listed
ENVIRONMENTAL HAZARDS SPECIAL SHIPPING INFORMATION	Not available
	Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS								
Chemical Name& CAS	CERCLA 40 CFR Part 302.4	SARA (Title III)40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know New Jersey	Massachusetts	CaliforniaProp 65
ALPHA LIPOIC ACID 1077-28-7	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS			
Chemical Name& CAS	Poisons and Therapeutic Goods Regulation	Therapeutic GoodsAct	Code of Practices - Illicit Drug Precursors
ALPHA LIPOIC ACID 1077-28-7	N/L	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name& CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	EC 649/2012	EC 2012/118
ALPHA LIPOIC ACID 1077-28-7	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SECTION 16: OTHER INFORMATION

REFERENCES

ABBREVIATIONS AND ACRONYMS

Available upon request

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

07/2019

SUPERSEDES

03/2016

For a list of changes to the SDS since the last version, please communicate with Rawpharma Biz Private Limited

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Rawpharma Biz Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.