

Technical Data Sheet

Product Name: Ergexis™ L-Ergothioneine 99%

Product Code: EZ891314a

1. Technical Data Sheet

Chemical Name	L-Ergothioneine
CAS Number	497-30-3
Molecular Weight	229.3 g/mol
Molecular Formula	C ₉ H ₁₅ N ₃ O ₂ S
Compliance (Food / Pharmacopoeia / FCC / Feed)	Food
Manufacturer	Enzymolab
Address	Chengnan Road, Huaxi Subdistrict, Changxing County, Huzhou City, Zhejiang Province, 313100, China

Brief Introduction:

L-Ergothioneine (L-ET) is a naturally occurring amino acid derivative, found primarily in mushrooms and certain bacteria. It is synthesized by fungi and mycobacteria and accumulates in human tissues via a specific transporter (OCTN1), suggesting its essential physiological roles.

Item	Standard	Results	Analysis Method
Appearance	White powder;	Conforms	Visual
Identification	Compliant with structure	Conforms	¹ H-NMR
Elemental analysis	C 47.14 ± 0.4% H 6.59 ± 0.4% N 18.32 ± 0.4%	C:47.03% H:6.49% N:18.30%	¹ H-NMR; elemental analysis
Chemical purity (HPLC)	≥99.5%	99.99%	HPLC [Eur. Ph. 2.2.29]
Chemical purity (¹ H-NMR)	≥99.0%	99.99%	¹ H-NMR
Optical rotation	[α] _D ≥ (+)122° (c = 1, H ₂ O);	+124.5°	Polarimetry
Loss on drying	<0.5%	0.04%	Eur. Ph. 01/2008:20232
Total residual solvents	Methanol, ethyl acetate, isopropanol and ethanol: <1,000 ppm;	84.24 ppm	Gas chromatography

Item	Standard	Results	Analysis Method
Impurities	<0.8%	Not Detected	HPLC/GPC or 1H-NMR
Lead	<3.0 ppm	Not Detected	ICP/AES
Cadmium	<1.0 ppm	Not Detected	ICP/AES
Mercury	<0.1 ppm	Not Detected	Atomic fluorescence
Total viable aerobic count (TVAC)	$\leq 1 \times 10^3$ CFU/g	<10 CFU/g	Eur. Ph. 01/2011:50104
Total yeast and mould count (TYMC)	$\leq 1 \times 10^2$ CFU/g	<10 CFU/g	Eur. Ph. 01/2011:50104
Escherichia coli	Absence in 1 g	Not Detected	Eur. Ph. 01/2011:50104
Storage & Shelf Life			
Package	Sterile inner bag(s) inside aluminum foil bag(s)		
Shelf Life	24 months from the date of production		
Storage	Keep sealed in a cool and dry place; protect from sunlight and moisture.		

2. Origin & Ingredients			
Country of origin of the product: China		Origin statement: available ☒	
This product is a pure material ☒		This product is a compound material ☐	
Animal origin	☐ bovine	Specific Source: /	
	☐ porcine	Specific Source: /	
	☐ ovine	Specific Source: /	
	☐ others:	Specific Source: /	
Synthetic	☐	Starting material:	Origin:
Biotechnological processing	☐ Catalysis By Enzymes	Name of Enzyme: / Sources of Enzymes: /	
	☐ Fermentation	Source of Medium: / Strain: /	
Botanical Origin	Botanical Name:	/	
	Part:	/	
	Wild or Cultivated:	/	
	Country of Origin:	/	
	Solvent Used:	/	

3. Nutrition Data	
Nutritional Composition	☒ Per 100g ☐ Per Serving
☐ Energy (KJ) ☒ Energy (Kcal)	0kcal
Fat (g)	0
Carbohydrates (g)	0
Protein (g)	0
Sodium (mg)	0
Remarks: Nutrition Data Are Obtained By 3 rd Party Lab; Tested on A Yearly Basis	

4. Non-GMO Declaration	YES	NO (Means Not Contain)
The product does not contain or consist of GMO	☐	☒
The product is not produced from GMO or not contain ingredients produced from GMO (irrespective of whether there is NDA or protein of GM origin in the final production)	☐	☒
This product is not produced by means of GM microorganism including precursor substances, e.g., with GMOs or Genetically Modified microorganisms processing aids (bacteria, yeast,).	☐	☒
This product is not produced with the help of enzymes, which were obtained from GMOs	☐	☒
Does the product contain any ingredients from animal?	☐	☒
If yes, are genetically modified crops contained in the feed for the animal?	☐	☒
We confirm that this product complies with regulations EC/1829/2003 and EC1830/2003 and keep non-GMO statement available.	☒	☐

5. Allergen Declaration								
We have carefully reviewed this product according to EU Regulation 1169/2011 and modifications and confirm the following:								
Direct incorporation as a base raw material or in a derivative form (don't forget the carriers, the additives, and the processing aids)			CROSS CONTAMINATION					
			Presence on the production line		Presence on the production workshop		Presence on the production factory	
Yes (Precise nature)	No		Yes (precise the nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No

Cereals containing gluten (1) and products thereof		N		N		N		N
Crustaceans and products thereof		N		N		N		N
Eggs and products thereof		N		N		N		N
Fish and products thereof (2)		N		N		N		N
Peanuts and products thereof		N		N		N		N
Soybeans and products thereof (3)		N		N		N		N
Milk and products thereof (including lactose) (4)		N		N		N		N
Nuts (5) or products thereof		N		N		N		N
Celery and products thereof		N		N		N		N
Mustard and products thereof		N		N		N		N
Sesame seeds and product thereof		N		N		N		N
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO ₂		N		N		N		N
Lupines and products thereof		N		N		N		N
Mollusc and product thereof		N		N		N		N
1. Cereals which contain gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) except: wheat-based glucose syrups including dextrose, wheat-based maltodextrins, glucose syrups based on barley, cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages; 2. Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine. 3. Except fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources. 4. Except when used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages, lactitol. 5. Almond (<i>Amygdalus communis</i> L.) hazelnuts (<i>Corylus avellana</i>), walnut (<i>Juglans regia</i>), cashew (<i>Anacardium occidentale</i>), pecan nuts (<i>Carya illinoensis</i>), Brazil nut (<i>Bertholletia excelsa</i>), pistachio nut (<i>Pistacia vera</i>), macadamia nut and Queensland nut (<i>Macadamia terniflora</i>) and products thereof, except nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;								

6. Non-Irradiation Statement

(According to EU directive 1999/2/EC & 1999/3/EC)

This product has not been treated with ionising radiation	☐ YES	☒ NO, not treated
None of the raw materials we used for this product have been treated with ionising radiation.	☐ YES	☒ NO, not treated
We confirm above non-Irradiation statement is available	☒ YES	

7. Nanomaterial Statement

(According to EU Regulation (EU) No. 1363/2013)

This product does not contain any nanomaterials as defined in EU food legislation	☐ YES	☒ NO, does not contain
This product has not been made with nanotechnology	☐ YES	☒ NO, is not made with nanotechnology
We confirm above non-Nanomaterial statement is available	☒ YES	

8. Residual Solvents

(According to UE Directive 2009/32 modified by (UE)2010/59; EP5.4; USP476; ICH Q3C(R7))

For this product following solvents are used during production process: Solvent A: max residual level:	☒ solvent used. ☐ solvent not used
We confirm solvent residual of this product complies with:	☒ EP 7.0 ☒ USP <476> ☒ ICH Q3C(R7) ☒ Directive 2010/59/EU ☐ NA
We confirm Solvent residual statement is available	☒ YES

9. Pesticide Residues

(According to EC 396/2005; EP07; USP <561>)

This product is of vegetable origin	☒ YES ☐ NO
We confirm pesticide residual of this product complies with:	☒ EC 396/2005 ☒ EP 07/2008 ☒ USP<561> ☐ N/A
Pesticide residual statement available	☒ YES

10. BSE/TSE Information

(According to EU No. 2019/319; EP general chapter 5.2.8)

Cattle, sheep, goats, and other animals naturally susceptible to infection with transmissible spongiform encephalopathy (TSE) agents, or those susceptible to infection through the oral route (excluding humans and non-human primates), are defined as "BSE-relevant animal species." Pigs and birds, however, are not naturally susceptible to infection via the oral route and, therefore, are not considered TSE-relevant species. Similarly, dogs, rabbits, and fish are also not classified as TSE-relevant animal species.	
The product contains no ingredients of ruminant origin and no materials derived from or exposed to ruminants affected by or under quarantine for Transmitting Transmissible Spongiform	☐ YES ☒ NO ☐ NA

Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE).	
In the manufacturing of this product, there is not any raw or source material and /or reagent used that is of animal origin i.e., bovine, serum-albumin, enzymes, culture broths including those used to prepare working or master cell tanks.	☐ YES ☒ NO
Equipment/systems/tools use for processing or storage of the material do not come into contact at any time with materials of animal origin (e.g., components of media filler used to check such system).	☐ YES ☒ NO
The material is not purified by using solvents, chromatographic media or buffers that contain components of animal origin.	☐ YES ☒ NO
We confirm this product complies with:	☒ EU legislation 999/2001 & ☒ EP general chapter 5.2.8
We confirm BSE/TSE statement is available	☒ YES

11. Contaminant Information

(According to UE regulation NO.1881/2006 and NO.629/2008 as regards maximum levels for certain contaminants in foodstuff)

Aflatoxin B1 <5ppb Aflatoxins B1 + B2 + G1 + G2 <10ppb Ochratoxin A <15ppb	☒ YES ☐ NO ☐ NA
Melamine Free	☒ YES
Dioxins, Furans, Polychlorinated Biphenyls Free	☒ YES
For polycyclic aromatic hydrocarbons, in cocoa fiber, banana chips, food supplements and their preparations, dried herbs <i>and dried spices</i> . Maximum level of 10 µg/kg of benzo(a)pyrene 50 µg/kg for the sum of PAH4 (PAH4; benzo[a]pyrene, chrysene, Benz[a]anthracene and benzo[b]fluoranthene) in food supplements	☒ YES ☐ NO ☐ NA
We confirm this product complies with NO.1881/2006 and NO.629/2008 and keep compliance statement available	☒ YES

12. WADA Statement

We confirm that none of the products manufactured or stored within our facility contain any prohormones, stimulants, steroids, or other substances listed on the current WADA (World Anti-Doping Agency) list.

13. Ethylene Oxide (ETO)-Free Statement

We hereby confirm that ethylene oxide (ETO), 2-chloroethanol, or any other chemical sterilizing agents are not used during the manufacturing, storage, or transportation of our products.

14. Other Statements

We confirm Nitrates of this product complies with EU No 1258/2011	☒ YES ☐ NO ☐ NA
We confirm Mycotoxins / Aflatoxins of this product complies with EU No 165/2010	☒ YES ☐ NO ☐ NA
We confirm 3-MCPD of this product complies with EU No. 2020/1322	☒ YES ☐ NO ☐ NA
We confirm Pyrrolizidine alkaloids of this product complies with Regulation (EU) 2020/2040	☒ YES ☐ NO ☐ NA

Safety Data Sheet

SECTION 1: Identification of The Substance/Mixture And of The Company

1.1 Product Identifiers

Product name: L-Ergothioneine

CAS-No.: 497-30-3

1.2 Details of The Supplier of The Safety Data Sheet

Manufacturer: Enzymolab

Address: Chengnan Road, Huaxi Subdistrict, Changxing County, Huzhou City, Zhejiang Province, 313100, China

1.3 Relevant Identified Uses of The Substance or Mixture

Identified uses: Various uses that have been identified. Not for pharmaceutical use.

SECTION 2: Hazards Identification

Summary of Emergency

White if breathed in, move person into fresh air. If not breathing, give artificial respiration. Wash off with soap and plenty of water. Flush eyes with water as a precaution. Never give anything by mouth to an unconscious person. Rinse mouth with water.

2.1 GHS Classification

Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).

2.2 GHS Label Elements

Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).

2.3 Physical And Chemical Hazards

Referring to current information, no physical or chemical hazard.

2.4 Health Hazards

Referring to current information, no health hazard.

2.5 Environmental Hazards

Referring to current information, no environmental hazard.

2.6 Other Hazards - none

SECTION 3: Composition/Information on Ingredients

Substance/Mixture: Substance

3.1 Substances

Synonyms: (S)-[1-carboxy-2-(2-mercaptoimidazol-4-yl)ethyl]trimethylammonium
hydroxide; 2-MERCAPTOHISTIDINE BETAINE

Formula: C₉H₁₅N₃O₂S

Molecular weight: 229.30

CAS-No.: 497-30-3

EC-No.: 207-843-5

No components need to be disclosed according to the applicable regulations.

SECTION 4: First Aid Measures

4.1 Description of First Aid Measures

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact

Wash off with soap and plenty of water.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 Most Important Symptoms And Effects, Both Acute And Delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of Any Immediate Medical Attention And Special Treatment Needed

No data available

4.4 Notes to Physician

No data available

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special Hazards Arising From The Substance or Mixture

Carbon oxides, Nitrogen oxides (NO_x), Sulphur oxides

5.3 Advice for Firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment And Emergency Procedures

Avoid dust formation. Avoid breathing vapours, mist or gas.

For personal protection see section 8.

6.2 Environmental Precautions

Do not let product enter drains.

6.3 Methods And Materials for Containment And Cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to Other Sections

For disposal see section 13.

SECTION 7: Handling And Storage

7.1 Precautions for Safe Handling

Advice on Protection Against Fire And Explosion

Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene Measures

General industrial hygiene practice.

7.2 Conditions for Safe Storage

Storage Conditions

Store in a cool, dry place at room temperature in a sealed container, away from sunlight and moisture.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

Ingredients with Workplace Control Parameters

We are not aware of any national exposure limit.

8.2 Exposure Controls

Appropriate Engineering Controls

General industrial hygiene practice.

Personal Protective Equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of Environmental Exposure

Do not let product enter drains.

SECTION 9: Physical And Chemical Properties

9.1 Information on Basic Physical And Chemical Properties

A) Appearance	White crystal
B) Odor	Characteristic odor
C) Odor Threshold	No data available
D) pH	5.5-7.5
E) Melting point (Decompose)	270-271°C
F) Initial boiling point and boiling range	No data available
G) Flash point	No data available
H) Evaporation rate	No data available
I) Flammability (solid, gas)	No data available
J) Upper/lower flammability or explosive limits	No data available
K) Vapour pressure	No data available
L) Vapour density	No data available
M) Relative density	No data available
N) Water solubility	No data available
O) Partition coefficient (n-octanol/water)	No data available
P) Auto-ignition temperature	No data available
Q) Decomposition temperature	No data available
R) Viscosity(kinematic/dynamic)	No data available
S) Explosive properties	No data available
T) Oxidizing properties	No data available

9.2 Other Safety Information

No data available

SECTION 10: Stability And Reactivity

10.1 Chemical Stability

Stable under recommended storage conditions.

10.2 Possibility of Hazardous Reactions

No data available

10.3 Conditions to Avoid

Avoid light, heat, and high humidity.

10.4 Incompatible Materials

Strong oxidizing agents.

10.5 Hazardous Decomposition Products

In the event of fire: see Section 5.

SECTION 11: Toxicological Information

11.1 Information on Toxicological Effects

Acute toxicity

Oral: ≥ 1600 mg/kg mouse

Inhalation: no harm of severe acute poisoning

Dermal: no harm of severe acute poisoning

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

At a concentration of 5000 μ g/mL, no mutations were found in the chromosomal aberration test of CHL cells.

Carcinogenicity

No data available

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Additional Information

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

SECTION 12: Ecological Information

12.1 Toxicity

No data available

12.2 Persistence and Degradability

No data available

12.3 Bioaccumulative Potential

No data available

12.4 Mobility in Soil

No data available

12.5 Results of PBT and vPvB Assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other Adverse Effects

No data available

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport Information

14.1 UN Number

ADR/RID: -

IMDG: -

IATA: -

14.2 UN Proper Shipping Name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA-DGR: Not dangerous goods

14.3 Transport Hazard Classes

ADR/RID: - IMDG: - IATA: -

14.4 Packaging Group

ADR/RID: - IMDG: IATA: -

14.5 Environmental Hazards

ADR/RID: No IMDG: No IATA: No

14.6 Special Precautions for User

No data available

14.7 Incompatible Materials

Strong oxidizing agents.

Further Information

Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory Information

15.1 Safety, Health And Environmental Regulations/Legislation Specific for The Substance or Mixture

National Regulatory Information

Downstream users need to comply with the conditions of safe use of the chemical, understand the environmental and health hazard and risk management measures identified on the MSDS as well as the local/national regulations concerning the chemical.

Other Regulations

Please pay attention on the waste treatment should also comply with local regulations requirement.

SECTION 16: Other Information

Copyright: Enzymolab.

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.