Technical Data Sheet

Product Name: L-Ergothioneine 99%

1.Technical Data Sheet		
Chemical Name	L-Ergothioneine	
CAS Number	497-30-3	
Molecular Weight	229.3 g/mol	
Molecular Formula	$C_9H_{15}N_3O_2S$	
Compliance (Food / Pharmacopoeia / FCC / Feed)	Food	
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**	**Analysis Method**
Appearance	White to off-white powder	Visual
Identification	Positive	TLC/HPLC
Odor &Taste	Characteristic	Organoleptic
Assay	99.0%	HPLC
Ash Content	≤0.2%	Eur.Ph. <2.4.16>
Loss on Drying	≤0.5%	Eur.Ph.7.0 [2.8.17]
Heavy metals		
Total Heavy Metals	≤10 ppm	USP <233>
Lead	≤1.0 ppm	USP <233>
Arsenic	≤2.0 ppm	USP <233>
Cadmium	≤0.3 ppm	USP <233>
Mercury	≤0.1 ppm	USP <233>
Microorganism		
Total plate count	≤1000 cfu/g	USP <61>
Molds & Yeasts	≤100 cfu/g	USP <61>
E. coli	Negative/10g	USP <62>
Salmonella	Negative/10g	USP <62>
Staphylococcus	Negative/10g	USP <62>
Storage & Shelf Life		
Package	25kg/drum	
Shelf Life	The shelf life for the product is 24 months from date of production. Use it as soon as possible once it is opened.	
Storage	Store in unopened original package under clean and dry condition, away from sunlight.	

2.Origin & Ingredient			
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 3rd 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/18292003 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		N		N		N		N

thereof								
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 SO2		N		N		N		N
Lupines and products thereof		N		N		N		N
Mollusc and product thereof		N		N		N		N
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; Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine. 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. Except when used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages, lactitol. Almond (Amygdalus communis L.) hazelnuts (Corylus avellana), walnut (Juglans regia), cashew (Anacardium occidentale), pecan nuts (Carya illinaiesis), Brazil nut (Bertholletia excelsa), pistachio nut (Pistacia vera), macadamia nut and Queensland nut (Macadamia terniflora) 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 (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 (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 Residual (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	☐YES

by or under quarantine for Transmitting Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE).	☒NO ☐NA
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. Contaminants 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 *and dried spices*: 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

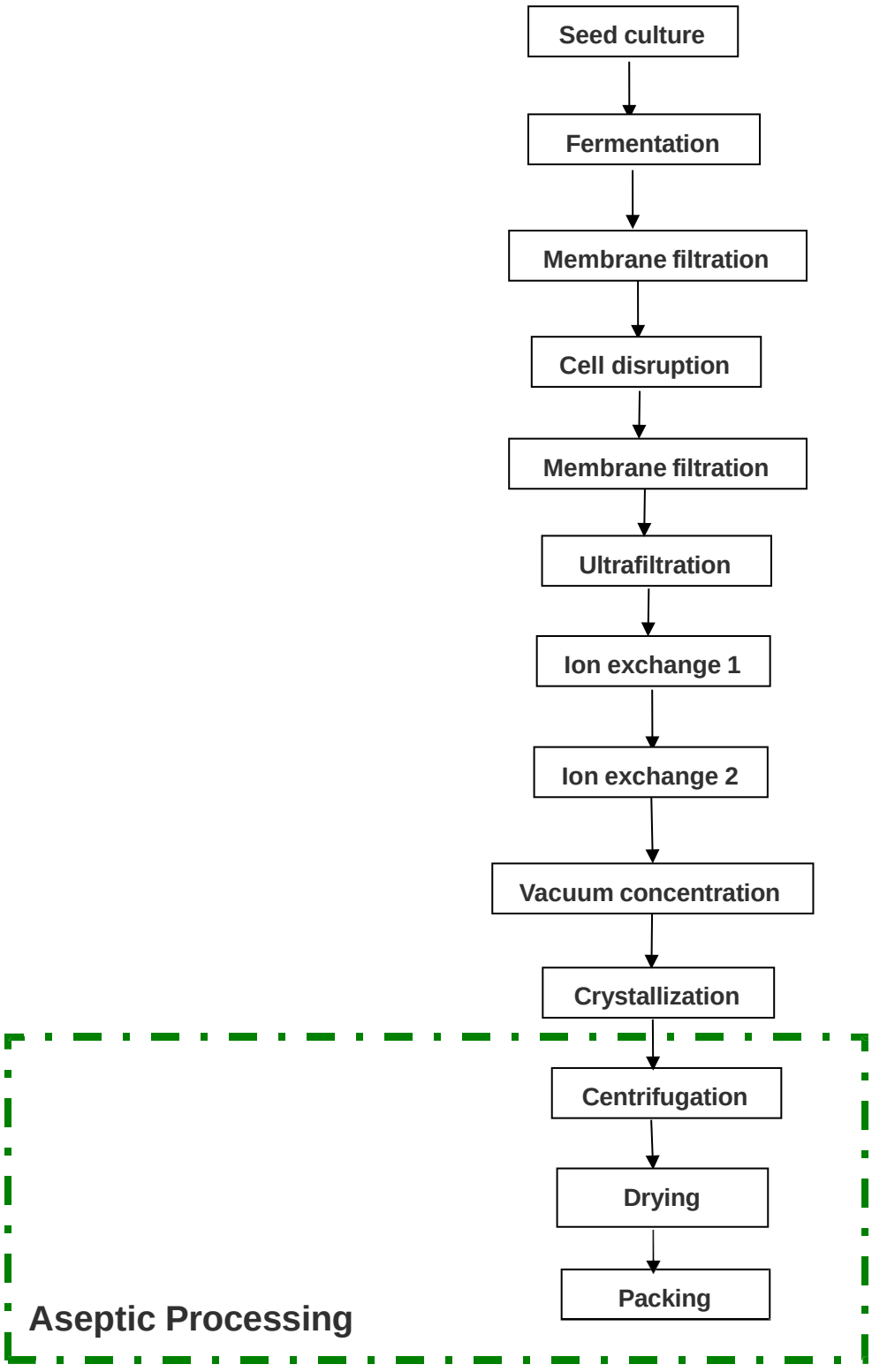
We confirm this product complies with NO.1881/2006 and NO.629/2008 and keep compliance statement available	☒YES

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. 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

Flow Chart of L-Ergothioneine



Material Safety Data Sheet

SECTION 1: Chemical product and company identification

Product Name: L-(+)-Ergothioneine

CAS number: 497-30-3

SECTION 2: Composition/information on ingredients

Molecular formula: $C_9H_{15}N_3O_2S$

Molecular weight: 229.3

Chemical name	Weight%	CAS NO.	EINECS NO.
L-(+)-Ergothioneine	100%	497-30-3	207-843-5

SECTION 3: Hazards summarizing

Classification of the substance or mixture

Skin irritation, Category 2

Eye irritation, Category 2

Specific target organ toxicity - single exposure, Category 3

Hazard statement(s): H315 Causes skin irritation; H319 Causes serious eye irritation; H335 May cause respiratory irritation.

Precautionary statement(s) Prevention: P264 Wash … thoroughly after handling.; P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/..; P261 Avoid breathing dust/fume/gas/mist/ vapors/ spray.; P271 Use only outdoors or in a well-ventilated area

Storage: P403+P233 Store in a well-ventilated place. Keep container tightly closed.; P405 Store locked up.

Disposal: P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

SECTION 4: First-aid measures

Description of first-aid measures if inhaled.

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

Following ingestion

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

SECTION 5: Fire-fighting measures

Suitable extinguishing media

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

Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing mist, gas or vapours. Avoid contacting with skin and eye. Use personal protective equipment. Wear chemical impermeable gloves. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

Environmental precautions

Prevent further spillage or leakage if it is safe to do so. Do not let the chemical enter drains. Discharge into the environment must be avoided.

Methods and materials for containment and cleaning up

Collect and arrange disposal. Keep the chemical in suitable and closed containers for disposal. Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

SECTION 7: Handling and storage

Precautions for safe handling

Handling in a well-ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

Conditions for safe storage, including any incompatibilities.

Keep dry and away from oxidizing agent, long term storage at 2°C to 8°C, avoid direct sunshine.

SECTION 8: Exposure controls/personal protection

Appropriate engineering controls

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

Skin protection

Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

SECTION 9: Physical and chemical proper ties

Physical state	White to off-white powder
Colour	White

Odor	no data available
Melting point	265-267°C (dee.)
Boiling point or initial boiling point and boiling range	no data available
Flammability	no data available
Lower and upper explosion limit/flammability limit	no data available
Flashpoint	no data available
Auto-ignition temperature	no data available
Decomposition temperature	no data available
pH	no data available
Kinematic viscosity	no data available
Solubility	no data available
Partition coefficient n-octanol/water	no data available
Vapour pressure	no data available
Density	0.65-0.85g/cm3
Relative vapour density	no data available
Particle characteristics	no data available

SECTION 10: Stability and reactivity

Reactivity	no data available
Chemical stability	no data available
Possibility of hazardous reactions	no data available
Conditions to avoid	no data available
Incompatible materials	no data available
Hazardous decomposition products	no data available

SECTION 11: Toxicological information

Acute toxicity

Oral: no data available

Inhalation: no data available

Dermal: no data available

SECTIO N 12: Ecological information

Toxicity

Toxicity to fish: no data available

Toxicity to daphnia and other aquatic invertebrates: no data available

Toxicity to algae: no data available

Toxicity to microorganisms: no data available

SECTI ON 13: Disposal

Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

SECTIO N 14: Transport information

UN Number

ADR/RUD: no data available IMDG: no data available IATA: no data available

UN Proper Shipping Name

ADR/RUD: no data available IMDG: no data available IATA: no data available

Transport hazard class(es)

ADR/RUD: no data available IMDG: no data available IATA: no data available

Packing group, if applicable

ADR/RUD: no data available IMDG: no data available IATA: no data available

Environmental hazards

ADR/RUD: no data available IMDG: no data available IATA: no data available

Special precautions for user

no data available

Transport in bulk according to IMO instruments

no data available

SECTION 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

European Inventory of Existing Commercial Chemical Substances (EINECS)

Listed. EC Inventory

Listed.

United States Toxic Substances Control Act (TSCA) Inventory Not

Listed. China Catalog of Hazardous chemicals 2015 Not

Listed.

New Zealand Inventory of Chemicals (NZioC) Listed.

Philippines Inventory of Chemicals and Chemical Substances (PICCS) Not Listed. Vietnam National Chemical Inventory Listed.

Chinese Chemical Inventory of Existing Chemical Substances (China IECSC) Not Listed.

Korea Existing Chemicals List (KECL) Not Listed.

SECTION 16: Other Information

Further Information

We shall not be held liable for any damage resulting from handling or from contact with the above product. This material must only be handled by suitably qualified experienced scientists in appropriately equipped and authorized facilities. The above information is believed to be correct but does not purport to be all inclusive and should be used as a guide only for experienced personnel. Always consult your safety advisor and follow appropriate local and national safety legislature. The absence of warning must not, under any circumstance, be taken to mean that no hazard exists.