

**Shanghai Kyowa Amino Acid CO.,Ltd.**

No. 158 Xintuan Road, Qingpu Industrial Zone, Shanghai 201707 China

Phone: 86-21-5970-1998

Fax: 86-21-5970-1135

CERTIFICATE OF ANALYSIS

Commodity: L-THREONINE
Lot No.: 16090301
Manufacturing date: Sep-28-2016
Analysis date: Sep-28-2016
Retest date: Sep-28-2019

SPECIFICATION	ACCEPTANCE CRITERIA	RESULT
APPEARANCE	WHITE CRYSTALS OR CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER
IDENTIFICATION BY IR	PASS TEST	PASS TEST
STATE OF SOLUTION (T%)	NOT LESS THAN 98.0%	NOT LESS THAN 98.0%
pH	5.2 ~ 6.2	5.8
SPECIFIC ROTATION (AT 20°C)	-27.6 ~ -29.0°	-28.4°
(AT 25°C)	-26.7 ~ -29.1°	-28.2°
AMMONIUM (NH ₄)	NOT MORE THAN 0.020%	NOT MORE THAN 0.020%
CHLORIDE (Cl)	NOT MORE THAN 0.020%	NOT MORE THAN 0.020%
SULFATE (SO ₄)	NOT MORE THAN 0.020%	NOT MORE THAN 0.020%
IRON (Fe)	NOT MORE THAN 10ppm	NOT MORE THAN 10ppm
HEAVY METALS (as Pb)	NOT MORE THAN 5ppm	NOT MORE THAN 5ppm
ARSENIC (As ₂ O ₃)	NOT MORE THAN 1ppm	NOT MORE THAN 1ppm
LOSS ON DRYING	NOT MORE THAN 0.20%	0.05%
RESIDUE ON IGNITION	NOT MORE THAN 0.10%	0.02%
RELATED SUBSTANCES		
UNSPECIFIED IMPURITY	NOT MORE THAN 0.2%	NOT DETECTED
TOTAL IMPURITIES	NOT MORE THAN 0.5%	NOT DETECTED
ASSAY (DRY BASIS)	99.0 ~ 101.0%	99.9%

We hereby certify that the commodity described above is tested in according with CP, however, meets quality requirements of the current JP, EP, USP and FCC monographs, including EP and USP requirements for residual solvent and microbiology (non-sterile substance for pharmaceutical use).

No animal origin raw materials/additives are used throughout the manufacturing process.

Made in China.

The undersigned affirms that contents mentioned above are truly reported in accordance with the analysis by Quality Control Department.

Lu Yazhou

Date of issue: Nov-29-2016

QA Manager

**Shanghai Kyowa Amino Acid Co., Ltd.**

No. 158 Xintuan Road, Qingpu Industrial Zone, Shanghai 201707 China

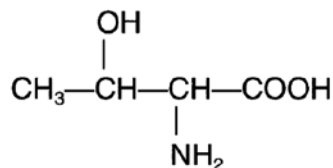
Phone: +86-21-5970-1998

Fax: +86-21-5970-1135

Specification of L-THREONINE CAS No.: 72-19-5

Edition date: 01.05.2015

Revision index: 3

**MOLECULAR
STRUCTURE
AND FORMULA** $\text{C}_4\text{H}_9\text{NO}_3 : 119.12$
 $\text{N} : 11.76\%$ **DESCRIPTION**

White crystals or crystalline powder
Odorless
Slightly sweet taste

**SPECIFICATION
AND PROCEDURE**

Test Item	Acceptance Criteria	Methods
APPEARANCE	WHITE CRYSTALS OR CRYSTALLINE POWDER	Visual
IDENTIFICATION	PASS TEST	IR
STATE OF SOLUTION (T%)	NOT LESS THAN 98.0%	In-house
pH	5.2 ~ 6.2	CP
SPECIFIC ROTATION (AT 20°C)	-27.6 ~ -29.0°	CP
AMMONIUM (NH ₄)	NOT MORE THAN 0.020%	CP
CHLORIDE (Cl)	NOT MORE THAN 0.020%	CP
SULFATE (SO ₄)	NOT MORE THAN 0.020%	CP
IRON (Fe)	NOT MORE THAN 10ppm	CP
HEAVY METALS (as Pb)*	NOT MORE THAN 10ppm	CP
ARSENIC (As ₂ O ₃)	NOT MORE THAN 1ppm	CP
RELATED SUBSTANCES: UNSPECIFIED IMPURITY	NOT MORE THAN 0.2%	In-house
TOTAL IMPURITIES	NOT MORE THAN 0.5%	
LOSS ON DRYING	NOT MORE THAN 0.20%	CP
RESIDUE ON IGNITION	NOT MORE THAN 0.10%	CP
ENDOTOXIN**	LESS THAN 6.0 EU/g	CP
ASSAY(DRY BASIS)	99.0 ~ 101.0%	CP
TOTAL COUNT (CFU)***	NOT MORE THAN 1,000 /g	CP
YEAST AND MOLDS (CFU)***	NOT MORE THAN 100 /g	CP
E. COLI***	NEGATIVE /g	CP

* Heavy Metals (Pb): "Not more than 5ppm" will be supplied on request.

** The endotoxin-certified grade will be supplied on request.

*** The microbiological parameters are tested and confirmed for every lot although they are not indicated on the Certificate of Analysis.

STATEMENT

The specification meets or exceeds the current USP and EP product monographs and residual solvents requirements of USP and EP. Made in China by fermentation using non-pathogenic microbe, without using any animal origin raw material.

STORAGE

Keep containers tightly closed in a dry, well-ventilated place at room temperature

RETEST DATE

3 years from manufacturing date

SAFETY DATA SHEET ACCORDING TO 2001/58/EC

ISSUED DATE: July 30, 2006

Page 1 of 3

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

- 1.1. Identification of the substance or preparation : L-Threonine
- 1.2. Use of the substance/preparation
: pharmaceutical bulk, food additive, intermediate for synthesis, etc.
- 1.3. Company/undertaking identification
Company : Shanghai Kyowa Amino Acid Co., Ltd.
Department for information : Quality Assurance Dept.
Address : 158, Xin Turn Road, Qingpu Industrial Zone, Shanghai, China, 201700
TEL-No. : 86-21-59701998 FAX-No. : 86-21-59701135
- 1.4. Emergency contact : Shanghai Kyowa Amino Acid Co., Ltd.
TEL-No. : 86-21-59701998 FAX-No. : 86-21-59701135

2. COMPOSITION/INFORMATION ON INGREDIENTS

- 2.1 The product is highly purified substance.
L-THREONINE ($C_4H_9NO_3$ = 119.12)
- 2.2 The product is not and does not include dangerous substances classified according to Directive 1999/45/EC.
- CAS-Number of the product : 72-19-5
EP-Number of the product : 200-774-1

3. HAZARD IDENTIFICATION

The product is not dangerous and hazards to man and the environment according to classification rules in Directives 67/548/EEC or 1999/45/EC. Skin or eye irritant is not expected.

4. FIRST AID MEASURES

General Instructions : Avoid direct contact with the product.

Eye contact : Wash thoroughly with water. If irritation occurs, consult a physician.

Skin contact : Wash thoroughly with water. If irritation occurs, consult a physician.

Ingestion : Rinse out with water. If any symptoms appear, consult a physician.

Inhalation : If irritation occurs, consult a physician.

Notes to the physician : There is no special information available. Treat symptomatically.

Information given above is to the best of our knowledge and is only related to the product as delivered in order to give a complete review of safety aspects accurate as of the date indicated. All data given are never meant to guarantee product properties.

5. FIRE FIGHTING MEASURES

- Suitable extinguishing media : water, Form, CO₂, Dry chemical
- Extinguishing media which must not be used for safety reasons : none
- Special exposure hazards arising from substance or preparation itself, combustion products, resulting gases : This product is decomposed to CO₂ and H₂O by burning.
- Special protective equipment required for fire-fighting
: In case of fire, wear a self-containing breathing apparatus and full protective clothing.

6. ACCIDENTAL RELEASE MEASURES

Wear protective equipment (see chapter 8.2).

The product is solid at room temperature. Use solid waste clean-up procedures.

7. STORAGE AND HANDLING

7.1. Handling : Wear protective equipment (see chapter 8.2).

7.2. Storage : Controlled room temperature in tight container.

7.3. Specific use : not applicable

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Exposure limit values : Exposure limit value for health hazard is not determined.

8.2. Exposure controls

8.2.1. Occupational exposure control

Follow the general guidelines of good industrial hygiene. Do not breathe product dusts. Change contaminated clothing and thoroughly clean before re-use.

- Respiratory : Mask is recommended to use.
- Hand protection : Gloves is recommended to use.
- Eye protection : Goggles is recommended to use.
- Skin protection : Head cover, coverall or laboratory coat buttoned to neck, long sleeves is recommended to use.

8.2.2. Environmental exposure control

- Facility design : It is recommended to install an efficient exhaustion system.
- Components with exposure limits
: The product does not contain any components with exposure limits.

9. PHYSICAL AND CHEMICAL PROPERTIES**9.1 General information**

Appearance : Solid (at 20°C), white Odor : Odorless

9.2. Important health, safety and environmental information

- pH : 5.2 - 6.2 at 1 g per 100 ml of water
- Boiling point : Not applicable
- Flash point : Not applicable
- Flammability : See Section 16.
- Explosive properties : No
- Oxidizing properties : No
- Vapor pressure : Not applicable
- Relative density : No data
- Solubility : 90g per 100 g of water at 20°C. Practically insoluble in ethanol or ether
- Partition coefficient (n-octanol/water) : No data
- Viscosity : Not applicable
- Vapor density : Not applicable
- Evaporation rate : Not applicable

9.3. Other information

- Melting point : 265 - 270°C

10. STABILITY AND REACTIVITY

This product is stable under controlled room temperature in tight container.

- Conditions to avoid : High temperature, high humidity or light
- Materials to avoid : Oxidizers
- Hazardous decomposition products : None

11. TOXICOLOGICAL INFORMATION

LD 50 : More than 16 g/kg (rat, oral), Skin or eye irritant is not expected.

12. ECOLOGICAL INFORMATION

L-Threonine is one of common substances (amino acids) composing animal or plant body and is degraded by oxidation and hydrolysis. No serious influence to environment is expected.

13. DISPOSAL CONSIDERATIONS

Waste disposal method : With chemical wastes.

14. TRANSPORT INFORMATION

The product is not covered by transport regulations.

15. REGULATORY INFORMATION

The product is not dangerous nor hazardous.

16. OTHER INFORMATION

As with most organic solids, dust from this material may pose an explosion of fire hazard, if suspended in air and there is a source of ignition.