



Shanghai Kyowa Amino Acid CO.,Ltd.

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

Phone: 86-21-5970-1998

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CERTIFICATE OF ANALYSIS

Commodity: L-SERINE  
Lot No.: 16010606  
Manufacturing date: Jan-15-2016  
Analysis date: Jan-15-2016  
Retest date: Jan-15-2019

SPECIFICATION	ACCEPTANCE CRITERIA	RESULT
APPEARANCE	WHITE CRYSTALS OR CRYSTALLINE POWDER	WHITE CRYSTALS
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)	+14.4 ~ +15.5°	+15.2°
(AT 25°C)	+14.0 ~ +15.6°	+14.8°
AMMONIUM (NH <sub>4</sub> )	NOT MORE THAN 0.020%	NOT MORE THAN 0.020%
CHLORIDE (Cl)	NOT MORE THAN 0.020%	NOT MORE THAN 0.020%
SULFATE (SO <sub>4</sub> )	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 <sub>2</sub> O <sub>3</sub> )	NOT MORE THAN 1ppm	NOT MORE THAN 1ppm
LOSS ON DRYING	NOT MORE THAN 0.20%	0.07%
RESIDUE ON IGNITION	NOT MORE THAN 0.10%	0.01%
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%	100.2%

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: May-03-2016

QA Manager

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

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

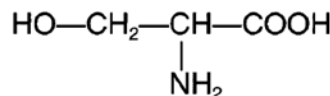
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**Specification of L-SERINE** CAS No.: 56-45-1

Edition date: 01.05.2015

Revision index: 3

**MOLECULAR  
STRUCTURE  
AND FORMULA**

$\text{C}_3\text{H}_7\text{NO}_3$  : 105.09  
N : 13.33%

**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)	+14.4 ~ +15.5°	CP
AMMONIUM (NH <sub>4</sub> )	NOT MORE THAN 0.020%	CP
CHLORIDE (Cl)	NOT MORE THAN 0.020%	CP
SULFATE (SO <sub>4</sub> )	NOT MORE THAN 0.020%	CP
IRON (Fe)	NOT MORE THAN 10ppm	CP
HEAVY METALS (as Pb)*	NOT MORE THAN 10ppm	CP
ARSENIC (As <sub>2</sub> O <sub>3</sub> )	NOT MORE THAN 1ppm	CP
RELATED SUBSTANCES: UNSPECIFIED IMPURITY TOTAL IMPURITIES	NOT MORE THAN 0.2% NOT MORE THAN 0.5%	In-house
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

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### Section 1: Identification

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#### Product identifier used on the label;

**Product name:** L-Serine

#### Other means of identification;

No information

#### Recommended use of the chemical and restrictions on use;

**Recommended use:** Pharmaceutical bulk, food additive, intermediate for synthesis, etc.

**Restrictions on use:** No information

#### Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party;

**Name:** Shanghai Kyowa Amino Acid Co., Ltd.  
**Department in Charge:** QUALITY UNIT  
**Address:** No. 158 Xintuan Road, Qingpu Industrial Zone,  
Shanghai 201707, China  
**Telephone number:** +86-021-59701998  
**Fax number:** +86-021-59701135  
**e-mail address:** -

**Name:** Kyowa Hakko Europe GmbH  
**Department in Charge:** -  
**Address:** Am Wehrhahn 50, 40211 Dusseldorf, Germany  
**Telephone number:** +49-211-17545-0  
**Fax number:** +49-211-17545-441  
**e-mail address:** [bio-chemicals@kyowa.de](mailto:bio-chemicals@kyowa.de)

#### Emergency phone number

+49-211-17545-0 (Kyowa Hakko Europe GmbH)  
(9:00- 17:00 CET)

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### Section 2: Hazard(s) identification

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#### Classification of the chemical in accordance with paragraph (d) of §1910.1200;

##### Physical Hazards

Not classified

##### Health Hazards

Not classified

##### Environmental Hazards

Not classified

**Other Hazards**

No information

**Signal word, hazard statement(s), symbol(s) and precautionary statement(s) in accordance with paragraph (f) of §1910.1200;**

<b>Symbol(s)</b>	Not applicable
<b>Signal word</b>	Not applicable
<b>Hazard Statement(s)</b>	Not applicable
<b>Precautionary Statement(s)</b>	Not applicable

**Description of any hazards not otherwise classified;**

No information

**Ingredient with unknown acute toxicity in the mixture**

Not applicable

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**Section 3: Composition/information on ingredients**

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<b>Chemical name:</b>	L-Serine
<b>CAS No.:</b>	56-45-1
<b>Purity:</b>	100 wt%

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**Section 4: First-aid measures**

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**Necessary first-aid measures by relevant routes of exposure;**

IF INHALED	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If symptoms continue, call a doctor/physician.
IF ON SKIN	Rinse with plenty of water. If symptoms continue, call a doctor/physician.
IF IN EYES	Immediately rinse cautiously with water for 15 - 20 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If symptoms continue, call a doctor/physician.
IF SWALLOWED	Rinse mouth. Immediately get medical advice/attention.

**Most important symptoms/effects, acute and delayed;**

Not applicable

**Indication of immediate medical attention and special treatment needed, if necessary;**

No information

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**Section 5: Fire-fighting measures**

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**Suitable (and unsuitable) extinguishing media;**

**Suitable extinguishing media:**

Use water mist, dry chemical powder, fire foam or carbon dioxide.

#### **Unsuitable extinguishing media**

Applying direct water may be dangerous because fire may expand to surroundings.

#### **Specific hazards arising from the chemical;**

General caution; powdered materials may cause dust explosions under certain conditions.

#### **Special protective equipment and precautions for fire-fighters;**

Cut off any ignition sources and extinguish with an appropriate agent.

Cool the surrounding tank and the buildings with direct water jet to avoid risk of fire spreading.

Take action from windward.

Keep out except responsible personnel.

Move container to a safe area if it can be done without risk.

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### **Section 6: Accidental release measures**

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#### **Personal precautions, protective equipment, and emergency procedures;**

Keep out except responsible personnel.

Wear suitable protective equipment described in "SECTION 8: Exposure controls/personal protection".

Avoid release into the environment because product may cause local effects.

#### **Methods and materials for containment and cleaning up;**

Sweep up scattered materials or vacuum them using a vacuum cleaner so as not to cause dust then collect them into an empty container.

Do not eat or drink near handling and storage locations.

Eliminate all ignition sources (no smoking, flares, sparks or flames in immediate area).

Prevent to flowing into drains, sewers, basements or closed areas.

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### **Section 7: Handling and storage**

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#### **Precautions for safe handling**

##### **Protective measures:**

Install appropriate equipment and wear suitable protective apparatus described in "SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION".

Do not eat, drink or smoke when using this product.

Avoid the generation of dust.

##### **Advice on general occupational hygiene:**

Wash hands thoroughly after handling.

#### **Conditions for safe storage, including any incompatibilities**

##### **Technical measures:**

In the storage area, install adequate light and ventilation systems to handle hazardous materials.

Take precautionary measures against static discharge.

**Incompatible materials:**

Oxidizing agents

**Conditions for safe storage:**

Controlled room temperature in tight container.

**Packing material:**

Use a sealed container without damage or leakage.

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**Section 8: Exposure controls/personal protection**

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**Occupational Exposure Limits;**

OSHA PEL	Not applicable
ACGIH TLV-TWA (2014)	Not applicable
ACGIH TLV-STEL (2014)	Not applicable

**Appropriate engineering controls;**

In a work place where dusts generate, ensure to use sealed instrument or local ventilation.

**Individual protection measures, such as personal protective equipment;**

Respiratory protection	In case of dust generation, wear appropriate protective mask or air aspirator as required.
Hand protection	If hand contact is possible, wear protective gloves.
Eye protection	Wear safety glasses or goggles if in eyes.
Skin and body protection	Wear protective clothing and apron if necessary.

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**Section 9: Physical and chemical properties**

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Appearance (physical state, color, etc.)	Solid (20°C), white
Odor	Odorless
Odor threshold	No information
pH	5.2-6.2 at 10 g/100 mL of water
Melting point/freezing point	228°C (decomposition)
Initial boiling point and boiling range	Not applicable
Flash point	Not applicable
Evaporation rate	Not applicable
Flammability (solid, gas)	No information
Upper/lower flammability or explosive limits	Not applicable
Vapor pressure	Not applicable
Vapor density	Not applicable
Relative density	No information
Solubility (ies)	Soluble in water, practically insoluble in alcohol and ether
Partition coefficient: <i>n</i> -octanol/water	No information

Auto-ignition temperature	No information
Decomposition temperature	No information
Viscosity	Not applicable

#### **Other information**

Explosive properties: No

Oxidising properties: No

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### **Section 10: Stability and reactivity**

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#### **Reactivity**

Stable under normal handling condition.

#### **Chemical stability**

Stable under normal handling condition.

#### **Possibility of hazardous reactions**

No hazardous reaction expected under normal handling.

#### **Conditions to avoid**

Avoid high temperature, high humidity or light.

#### **Incompatible materials**

Oxidizing agents

#### **Hazardous decomposition products**

In case of fire, toxic decomposition products may be generated.

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### **Section 11: Toxicological information**

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#### **Symptoms related to the physical, chemical and toxicological characteristics;**

Acute toxicity (oral): Rat LD<sub>50</sub> 14,000 mg/kg

#### **Delayed and immediate effects and also chronic effects from short- and long-term exposure;**

Not applicable

#### **Numerical measures of toxicity (such as acute toxicity estimates);**

Not applicable

#### **Whether the chemical is listed in the NTP Report on Carcinogens or has been found to be a potential carcinogen in the IARC Monographs, or by OSHA;**

IARC: Not listed

NTP Report: Not listed

OSHA: Not listed

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## Section 12: Ecological information

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### Ecotoxicity:

Aquatic acute toxicity: No information  
Aquatic chronic toxicity: No information

### Persistence and degradability:

No information

### Bioaccumulative potential:

No information

### Mobility in soil:

No information

### Other adverse effects:

L-Serine 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.

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## Section 13: Disposal considerations

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### Waste treatment methods

Dispose of waste in accordance with applicable local, regional and international regulations and standards.

When disposing, consult to a certificated waste trader or local offices if they deal with the waste.

Used container should be recycled after cleaning or dispose of in compliance with related laws and local regulations.

Contents should be removed completely when dispose of empty containers.

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## Section 14: Transport information

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**UN number** Not applicable

**UN proper shipping name** Not applicable

**Transport hazard class(es)** Not applicable

**Packing group** Not applicable

**Environmental hazards** Not applicable

**Transport in bulk according to Annex II of MARPOL 73/78 and IBC code**

Not applicable

### Special precautions for user

When transporting, avoid direct sunlight. Confirm no leakage to containers. When loading, prevent containers from falling, dropping off or damaging. Take preventive measures of collapse.

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## Section 15: Regulatory information

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**OSHA:** Not listed

**TSCA inventory:** Listed on the TSCA Inventory

**TSCA SNUR:** Not listed

**SARA Title III:** Not listed



**CERCLA Reportable Quantity:**

Section 302 (Extremely Hazardous Substances): Not listed

Section 304 (Hazardous Substances): Not listed

Section 313 (TRI Chemicals): Not listed

**Clean Air Act:**

This product does not contain any substances regulated as hazardous air pollutants under Section 112 of the Clean Air Act.

**Clean Water Act:**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act.

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**Section 16: Other information, including date of preparation or last revision**

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**Update history:**

Date of issue: 29th May, 2015

**References:**

Information of SHANGHAI KYOWA AMINO ACID CO., LTD.

**[Disclaimer]**

This SDS has been prepared based on the best available information however, it may not be sufficient in some cases. It is user's responsibility to modify or update any contents in this SDS regarding information on hazardous properties and/or instruction for safe handling of the product when they become available. Precautionary measures in this SDS are only applicable for normal handling conditions and it is necessary to take appropriate additional measures to ensure safe handling which depend on your specific use conditions or situations.