



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-LEUCINE
Lot No.: 16040635
Manufacturing date: May-09-2016
Analysis date: May-09-2016
Retest date: May-09-2019

| 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 | 5.5 ~ 6.5 | 6.0 |
| SPECIFIC ROTATION (AT 20°C) | +14.9 ~ +16.0° | +15.5° |
| (AT 25°C) | +14.9 ~ +17.3° | +15.8° |
| 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% | 0.02% |
| RESIDUE ON IGNITION | NOT MORE THAN 0.10% | 0.03% |
| RELATED SUBSTANCES | | |
| ISOLEUCINE | NOT MORE THAN 0.8% | NOT DETECTED |
| UNSPECIFIED IMPURITY | NOT MORE THAN 0.2% | 0.1% |
| TOTAL IMPURITIES | NOT MORE THAN 1.0% | 0.1% |
| ASSAY (DRY BASIS) | 99.0 ~ 101.0% | 100.3% |

We hereby certify that the commodity described above is tested in accordance with CP, however, meets quality requirements of the current JP, EP and USP 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

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

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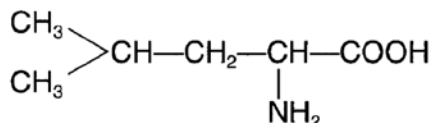
Phone: +86-21-5970-1998

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Specification of L-LEUCINE CAS No.: 61-90-5

Edition date: 01.05.2015

Revision index: 3

**MOLECULAR
STRUCTURE
AND FORMULA**

$$\text{C}_6\text{H}_{13}\text{NO}_2 : 131.17$$

$$\text{N} : 10.68\%$$
DESCRIPTION

White crystals or crystalline powder
Odorless
Slightly bitter 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 | 5.5 ~ 6.5 | CP |
| SPECIFIC ROTATION (AT 20°C) | +14.9 ~ +16.0° | 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: ISOLEUCINE UNSPECIFIED IMPURITY TOTAL IMPURITIES | NOT MORE THAN 0.8% NOT MORE THAN 0.2% NOT MORE THAN 1.0% | 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. The FCC-certified grade (Insoluble Foreign Matter: Pass Test) will be supplied on request.

STORAGE

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

RETEST DATE

3 years from manufacturing date

SAFETY DATA SHEET

Section 1: Identification

Product identifier used on the label;

Product name: L-Leucine

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

Emergency phone number

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

Section 2: Hazard(s) identification

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;

| | |
|-----------------------------------|----------------|
| Symbol(s) | Not applicable |
| Signal word | Not applicable |
| Hazard Statement(s) | Not applicable |
| Precautionary Statement(s) | Not applicable |

Description of any hazards not otherwise classified;

No information

Ingredient with unknown acute toxicity in the mixture

Not applicable

Section 3: Composition/information on ingredients

| | |
|-----------------------|-----------|
| Chemical name: | L-Leucine |
| CAS No.: | 61-90-5 |
| Purity: | 100 wt% |

Section 4: First-aid measures

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

Section 5: Fire-fighting measures

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.

Section 6: Accidental release measures

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.

Section 7: Handling and storage

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.

Section 8: Exposure controls/personal protection

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. |

Section 9: Physical and chemical properties

| | |
|--|---|
| Appearance (physical state, color, etc.) | Solid (20°C), white |
| Odor | Odorless |
| Odor threshold | No information |
| pH | 5.5-6.5 at 1 g/100 mL of water |
| Melting point/freezing point | 292-295°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) | Sparingly soluble in water, practically insoluble in alcohol. |
| 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

Section 10: Stability and reactivity

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.

Section 11: Toxicological information

Symptoms related to the physical, chemical and toxicological characteristics;

Acute toxicity (oral): Rat LD₅₀ > 16,000 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

Section 12: Ecological information

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-Leucine 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.

Section 13: Disposal considerations

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.

Section 14: Transport information

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.

Section 15: Regulatory information

OSHA: Not listed

TSCA inventory: Listed on the TSCA Inventory.

TSCA SNUR: Not listed

SARA Title III: Section 302 (Extremely Hazardous Substances): Not listed

Section 304 (Hazardous Substances): Not listed

Section 313 (TRI Chemicals): Not listed

CERCLA Reportable Quantity: 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.

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

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.