

BioKyowa Inc.PO Box 1550
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**CERTIFICATE OF ANALYSIS**

PRODUCT: **L-GLUTAMINE**
LOT NUMBER: **GM-PL-16393**
DATE OF MANUFACTURE: **Dec-16-2016**
DATE OF ANALYSIS: **Dec-27-2016**
RETEST DATE: **Dec-16-2019**

TEST	METHOD*	SPECIFICATION	RESULT
APPEARANCE	Visual	White crystalline powder	White Crystalline Powder
IDENTIFICATION	USP	Conforms	CONFORMS
STATE OF SOLUTION	%T430nm	NLT 98.0%	99.2%
pH	USP	4.0 - 6.0	5.1
SPECIFIC ROTATION (AT 20°C)	USP	+6.3 to +7.3°	+7.0
CHLORIDE	USP	NMT 0.020%	NMT 0.020%
SULFATE	USP	NMT 0.020%	NMT 0.020%
IRON	USP	NMT 10 PPM	NMT 10 PPM
HEAVY METALS	USP	NMT 5 PPM	NMT 5 PPM
LEAD	USP	NMT 5 PPM	NMT 5 PPM
ARSENIC	JP	NMT 1 PPM	NMT 1 PPM
FOREIGN AMINO ACIDS**	USP	NMT 0.5%	NMT 0.5%
LOSS ON DRYING	USP	NMT 0.20%	0.00%
RESIDUE ON IGNITION	USP	NMT 0.10%	0.01%
ASSAY (DRIED BASIS)	USP	99.0 - 101.0%	99.8%
TOTAL COUNT (CFU)	USP	NMT 1,000/g	NMT 1,000/g
YEASTS AND MOLDS (CFU)	USP	NMT 100/g	NMT 100/g
COLIFORM	USP	NEG	NEG
INSOLUBLE FOREIGN MATTER	FCC	CONFORMS	CONFORMS

We hereby certify that the commodity described above meets the monograph requirements of the current USP, JP, and FCC; and meets the requirements of residual solvents in those pharmacopoeias. *METHOD-USP and FCC include cross validation with internal method. ** Foreign Amino Acids Testing - Meets requirements for Related Compounds as required by USP, and Ninhydrin-positive substances as required by EP. Made in USA by fermentation using a non-pathogenic microbe, and without animal origin raw materials.

ORIGINAL

ANALYSIS APPROVED BY / DATE:

30330-00/01, 30350-00

Linda Withrow, Quality Assurance

Dec-29-2016



BioKyowa Inc.

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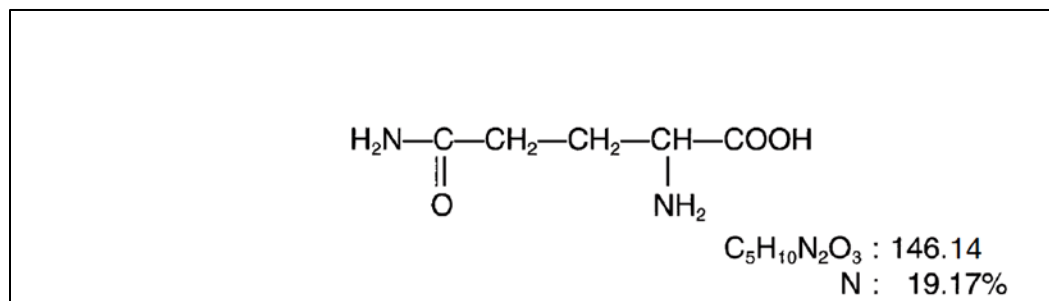
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Specification of L-GLUTAMINE CAS No.: 56-85-9

Edition date: 01.05.2015

Revision index: 4

MOLECULAR STRUCTURE AND FORMULA



DESCRIPTION

White crystalline powder
Odorless
Slightly characteristic taste

SPECIFICATION AND PROCEDURE

Test Item	Acceptance Criteria	Methods
APPEARANCE	WHITE CRYSTALLINE POWDER	Visual
IDENTIFICATION	PASS TEST	USP
STATE OF SOLUTION (T%)	NOT LESS THAN 98.0%	In-house
pH	4.0 ~ 6.0	USP
SPECIFIC ROTATION (AT 20°C)	+6.3 ~ +7.3°	USP
CHLORIDE (Cl)	NOT MORE THAN 0.020%	USP
SULFATE (SO ₄)	NOT MORE THAN 0.020%	USP
IRON (Fe)	NOT MORE THAN 10ppm	USP
HEAVY METALS (as Pb)	NOT MORE THAN 5ppm	USP
LEAD	NOT MORE THAN 5ppm	USP
ARSENIC (As ₂ O ₃)	NOT MORE THAN 1ppm	JP
FOREIGN AMINO ACIDS	NOT MORE THAN 0.5%	USP
LOSS ON DRYING	NOT MORE THAN 0.20%	USP
RESIDUE ON IGNITION	NOT MORE THAN 0.10%	USP
INSOLUBLE FOREIGN MATTER	PASS TEST	FCC
ASSAY(DRY BASIS)	99.0 ~ 101.0%	USP
TOTAL COUNT (CFU)	NOT MORE THAN 1,000 /g	USP
YEAST AND MOLDS (CFU)	NOT MORE THAN 100 /g	USP
COLIFORM	NEGATIVE/g	USP

STATEMENT

We hereby certify that the commodity above meets the monograph requirements of the current USP and FCC and meets the requirement of residual solvents of the current USP.

Foreign amino acids: Meets requirement of Related Compounds in current USP.

Made in USA by fermentation using a non-pathogenic microbe, and without animal origin raw materials.

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-Glutamine

Other means of identification;

No information

Recommended use of the chemical and restrictions on use;

Recommended use: 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: BioKyowa Inc.

Department in Charge:

Address: 5469 Nash Road, Cape Girardeau, MO 63702, U.S.A.

Telephone number: +1-573-335-4849

Fax number: +1-573-335-1466

e-mail address: info@biokyowa.com

Name: KYOWA HAKKO U.S.A., INC.

Department in Charge:

Address: 600 Third Avenue, 19th Floor, New York, NY 10016, U.S.A.

Telephone number: +1-212-319-5353

Fax number: +1-212-421-1283

Emergency phone number

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-Glutamine
CAS No.:	56-85-9
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	4.0-6.0 at 20 g/1000 mL of water
Melting point/freezing point	185°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)	4.8 g/100 g of water at 30°C and practically insoluble in methanol, ethanol, ether, benzene, acetone, ethyl acetate.
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-Glutamine 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: June 2, 2015

References:

Information of KYOWA HAKKO BIO 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.