

BioKyowa Inc.
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CERTIFICATE OF ANALYSIS

PRODUCT: L-ARGININE
LOT NUMBER: ARF-PL-16498
DATE OF MANUFACTURE: Sep-04-2016
DATE OF ANALYSIS: Dec-06-2016
RETEST DATE: Sep-04-2019

TEST	SPECIFICATION	RESULT
APPEARANCE	White crystal or crystalline powder	White crystal or crystalline powder
IDENTIFICATION	CONFORMS	CONFORMS
STATE OF SOLUTION	NLT 98.0%	99.7%
pH	10.5 - 12.0	11.2
SPECIFIC ROTATION (AT 20°C)	+26.9 to +27.9°	+27.7
SPECIFIC ROTATION (AT 25°C)	+26.3 to +27.7°	+27.5
AMMONIUM	NMT 0.02%	NMT 0.02%
CHLORIDE	NMT 0.020%	NMT 0.020%
SULFATE	NMT 0.020%	NMT 0.020%
IRON	NMT 10 PPM	NMT 10 PPM
HEAVY METALS	NMT 5 PPM	NMT 5 PPM
LEAD	NMT 5 PPM	NMT 5 PPM
ARSENIC	NMT 1 PPM	NMT 1 PPM
FOREIGN AMINO ACIDS(Total)	NMT 0.5%	NMT 0.05%
FOREIGN AMINO ACIDS(Each)	NMT 0.2%	NMT 0.05%
LOSS ON DRYING	NMT 0.50%	0.19%
RESIDUE ON IGNITION	NMT 0.10%	0.04%
ASSAY (DRIED BASIS)	99.0 - 101.0%	100.3%
TOTAL COUNT (CFU)	NMT 1,000/g	NMT 1,000/g
YEASTS AND MOLDS (CFU)	NMT 100/g	NMT 100/g
COLIFORM	NEG	NEG

This specification meets the quality requirements of the current USP and EP product monographs. No organic solvents are used throughout the manufacturing process. No animal origin raw materials/additives are used throughout the manufacturing process. Made in U.S.A.

ANALYSIS APPROVED BY / DATE:

Linda Withrow

ORIGINAL

Dec-19-2016

30210-09

Linda Withrow, Quality Assurance

L-Arginine

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1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : L-Arginine
Chemical Name : L-Arginine
CAS-No. : 74-79-3
EC-No. : 200-811-1
Registration number : 01-2119963927-19-0000

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Intermediate, Additive, Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company : BioKyowa Inc.
5469 Nash Road, Cape Girardeau,
MO 63702
U.S.A.

Telephone : +1-573-335-4849

E-mail address : info@biokyowa.com

1.4 Emergency telephone number

1-212-319-5353 (Kyowa Hakko U.S.A. Inc.)

49-211-17545-0 (Kyowa Hakko Europe GmbH)

2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not classified.

Classification (67/548/EEC, 1999/45/EC)

Not classified.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms : Not applicable.

2.3 Other hazards

no data available

3. Composition/information on ingredients

3.1 Substances

The product is a chemical substance within the meaning of the REACH Regulation (1907/2006/EC).

The following table contains the main constituent at the top.

Further dangerous ingredients are mentioned when it is necessary in accordance with Appendix II No.

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3.1 of the REACH Regulation.

Chemical Name	CAS-No.	EC-No.	Index-No.
		Registration number	
L-Arginine	74-79-3	200-811-1	
		01-2119963927-19-0000	

4. First aid measures

4.1 Description of first aid measures

- General advice : If you feel unwell, seek medical advice (show the label where possible).
Move out of dangerous area. Take off contaminated clothing and shoes immediately. Never give anything by mouth to an unconscious person.
First aider needs to protect himself.
- If inhaled : If breathed in, move person into fresh air. If symptoms persist, call a physician. Keep patient warm and at rest. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Do NOT use solvents or thinners. If skin irritation persists, call a physician.
- In case of eye contact : Protect unharmed eye. If easy to do, remove contact lens, if worn. In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- If swallowed : If swallowed, DO NOT induce vomiting. If a person vomits when lying on his back, place him in the recovery position. If swallowed, seek medical advice immediately and show this container or label.

4.2 Most important symptoms and effects, both acute and delayed

no data available

4.3 Indication of any immediate medical attention and special treatment needed

no data available

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire fighting : Do not use a solid water stream as it may scatter and spread fire. Exposure to decomposition products may be a hazard to health.
Hazardous decomposition products may be formed under fire

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conditions (see section 10).

5.3 Advice for firefighters

Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Further information : Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. In the event of fire and/or explosion do not breathe fumes. Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation, especially in confined areas. Avoid contact with skin and eyes.

6.2 Environmental precautions

Do not flush into surface water or sanitary sewer system. If the product contaminates rivers and lakes or drains inform respective authorities.

6.3 Methods and materials for containment and cleaning up

Use mechanical handling equipment. Keep in suitable, closed containers for disposal. Clean contaminated surface thoroughly.

6.4 Reference to other sections

see chapter: 7, 8, 11, 12 and 13

7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : For personal protection see section 8. Avoid creating dust.
Avoid contact with skin and eyes. Do not breathe dust.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Dust explosion class : no data available

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Store in original container. Keep containers tightly closed in a dry, well-ventilated place at room temperature.

Advice on common storage : Incompatible with oxidizing agents.

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Keep away from food, drink and animal feedingstuffs. Incompatible with acids.

Other data : No decomposition if stored and applied as directed.

7.3 Specific end uses

no data available

8. Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

Other information on limit values: see chapter 16

8.2 Exposure controls

Engineering measures

Provide sufficient air exchange and/or exhaust in work rooms.

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.

Hand protection

Remarks : Wear suitable gloves. Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer.

Eye protection : Tightly fitting safety goggles

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.
General industrial hygiene practice.
Do not breathe dust.
Avoid contact with skin, eyes and clothing.
When using do not eat, drink or smoke.
Wash hands before breaks and at the end of workday.
Wash contaminated clothing before re-use.
Follow the skin protection plan.

Environmental exposure controls

General advice : Do not flush into surface water or sanitary sewer system.
If the product contaminates rivers and lakes or drains inform respective

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authorities.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: solid
Colour	: white
Odour	: odourless
Odour Threshold	: no data available
Flash point	: not applicable
Ignition temperature	: no data available
Thermal decomposition	: 244 °C
Lower explosion limit	: not applicable
Upper explosion limit	: not applicable
Explosive properties	: Not explosive
Flammability (solid, gas)	: no data available
Oxidizing properties	: No oxidizing effect
Auto-ignition temperature	: no data available
Burning number	: no data available
Molecular Weight	: 174.20
pH	: 10,5 - 12,0 Concentration: 100,00g/l
Melting point/range	: 244 °C
Boiling point/boiling range	: not applicable
Vapour pressure	: not applicable
Density	: no data available
Bulk density	: no data available
Water solubility	: completely soluble
Partition coefficient: n-octanol/water	: no data available
Solubility in other solvents	: partly soluble Medium: Alcohol

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Viscosity, dynamic	: not applicable
Viscosity, kinematic	: not applicable
Flow time	: no data available
Impact Sensitivity	: no data available
Relative vapour density	: not applicable
Surface tension	: no data available
Evaporation rate	: no data available
Minimum ignition energy	: no data available
Acid number	: no data available
Refraction index	: no data available
Miscibility in water	: no data available
Solvent separation test	: no data available

9.2 Other information

None known.

10. Stability and reactivity

10.1 Reactivity

no data available

10.2 Chemical stability

The product is chemically stable.

10.3 Possibility of hazardous reactions

Stability : No decomposition if stored and applied as directed.

Dust can form an explosive mixture in air.

10.4 Conditions to avoid

Heat. Exposure to moisture. Exposure to light.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Acids

10.6 Hazardous decomposition products

Hazardous decomposition products : In case of fire hazardous decomposition products may be produced such as:

Carbon dioxide (CO₂), carbon monoxide (CO), oxides of nitrogen (NO_x), dense black smoke.

Thermal decomposition : 244 °C

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11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Acute oral toxicity:

L-Arginine : LD50 (rat): > 5.110 mg/kg

Acute inhalation toxicity:

no data available

Acute dermal toxicity:

no data available

Acute toxicity (other routes of administration):

no data available

Skin corrosion/irritation

no data available

Serious eye damage/eye irritation

L-Arginine : Species: rabbit

Non-irritating to eyes

Respiratory or skin sensitization

Sensitisation:

no data available

Germ cell mutagenicity

Genotoxicity in vitro:

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

Teratogenicity

no data available

STOT - single exposure

no data available

STOT - repeated exposure

no data available

Aspiration hazard

Aspiration toxicity

no data available

Neurological effects

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no data available

Toxicology Assessment

Toxicology, Metabolism, Distribution

no data available

Acute effects

no data available

12. Ecological information

12.1 Toxicity

no data available

12.2 Persistence and degradability

Biodegradability

: Result: Readily biodegradable.

Method: OECD Test Guideline 301C

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

no data available

12.6 Other adverse effects

Additional ecological information : The product should not be allowed to enter drains, water courses or the soil.

13. Disposal considerations

13.1 Waste treatment methods

Advice on disposal and packaging : Disposal:

In accordance with local and national regulations. This material and its container must be disposed of as hazardous waste.

Do not dispose of together with household waste.

Waste codes should be assigned by the user based on the application for which the product was used.

14. Transport information

ADR

Not dangerous goods

RID

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Not dangerous goods

IATA

Not dangerous goods

IMDG

Not dangerous goods

Special precautions for user

see chapter: 6, 7 and 8

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

VOC : not applicable

Directive 96/82/EC : Update: 2003

Directive 96/82/EC does not apply

Further information : Reserved for industrial and professional use.

15.2 Chemical Safety Assessment

no data available

16. Other information

Full text of R-phrases referred to under sections 2 and 3

Not applicable.

Full text of H-Statements referred to under sections 2 and 3.

Not applicable.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.