

L-Lysine hcl

Product SPECIFICATION

Product Name	L-Lysine hcl
INCI Name	lysine hydrochloride
EINECS Number	211-519-9
CAS Code	657-27-2

The product meets OR exceeds:
EP USP AJI

EP5	
Characters	A white, crystalline powder or colorless crystals.
Identification	As per EP5 (Chemical examine & Infrared Absorption)
Appearance of solution	Clear and not more intensely coloured than reference solution.
Specific rotation	+21.0° to +22.5°
Ninhydrin-positive substances	Examine by thin-layer chromatography
Sulphates	Not more than 300 ppm
Ammonium	Not more than 200 ppm
Iron (Fe)	Not more than 30 ppm
Heavy metals (Pb)	Not more than 10 ppm
Loss on drying	Not more than 0.5%
Sulphated ash	not more than 0.1%
Assay	98.5% ~ 101.0%
Special Specification (EU)	
Arsenic	Less than 2 ppm
Lead	Less than 3 ppm
Mercury	Less than 0.1 ppm
Cadmium	Less than 1 ppm
Microbiology	
Total plate count	≤10.000 cfu/g
Yeast/moulds count	≤1.000 cfu/g
Escherichia coli	1g/Absent
Salmonella	25g/Absent
Staphylococcus aureus	Absent
USP29	
Identification	Infrared Absorption
Appearance	Fresh materials, free flowing, odourless, white color and no black spec
Specific rotation	+20.4° to +21.4°
Loss on drying	Not more than 0.4%
Residue on ignition	Not more than 0.1%

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Sulfate	Nor more than 0.03%
Iron	Not more than 0.003%
Heavy metals	Not more than 0.0015%
Chromatographic purity	As per USP29 (By TLC)
Individual impurity	≤ 0.5%
Total impurity	≤ 2.0%
Organic volatile impurities	Meets the requirements
Content of chloride	19.0% ~ 19.6%
Residual solvents	Meets the requirements
Assay	98.5 to 101.5%
Special Specification (EU)	
Arsenic	Less than 2 ppm
Lead	Less than 3 ppm
Mercury	Less than 0.1 ppm
Cadmium	Less than 1 ppm
Microbiology	
Total plate count	≤10.000 cfu/g
Yeast/moulds count	≤1.000 cfu/g
Escherichia coli	1g/Absent
Salmonella	25g/Absent
Staphylococcus aureus	Absent
AJ197	
Identification	Infrared Absorption
Specific rotation [α] 20 D	+20.8° to +21.5°
State of solution (Transmittance)	Clear and colorless not less than 98.0%
Chloride (Cl)	19.12 to 19.51%
Ammonium (NH4)	Not more than 0.02%
Sulfate (SO4)	Not more than 0.02%
Iron (Fe)	Not more than 10 ppm
Heavy metals (Pb)	Not more than 10 ppm
Other amino acids	Conforms
Loss on drying	Not more than 0.40%
Residue on ignition	Not more than 0.10%
Assay	98.5 to 101.0%
pH	5.0 to 6.0

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GENERAL PRODUCT INFORMATION

Mesh of the product	>=70% through mesh 20
Taped density	<=0.80g/ml
Bulk density	>=0.45g/ml
Water solubility	Freely soluble in water (63g/100g at 20°C) and in formic acid, very slightly in soluble in ethanol, practically insoluble in ether.
Origin (Synthetic, Fermentation)	Fermentation
Origin (Animal, Vegetal, etc.)	Vegetable origin
Is the product and their ingredients FREE of GLUTEN?	Yes
Product is suitable for Vegans	Yes
Product is suitable for Vegetarians	Yes
Product is free of fructose	Yes
Is this product suitable for food?	Yes
Can be the product used in baby food (According to Directive 2006/141/CE)?	No
Pharmacopoeias that product meets	USP
Country of the raw material/s	China
Storage conditions (In the warehouse)	Preserve in well-closed containers, drying place and avoid from light.

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TECHNICAL PRODUCT INFORMATION

Name of the product	L-Lysine HCL
Molecular Formula	C6H14N2O2.HCL
Molecular mass	182.65
Frequency of analysis of each contaminant?	Every batch
Frequency of analysis of microbiology?	Every batch, Every batch
Frequency of analysis of each heavy metals?	Every batch, Every batch

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FOREIGN BODIES

Explanation about control of the foreign bodies during the manufacturing process:

Metal detector	Yes
Sieve	Yes
Filter	Yes
X-Ray	No

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INGREDIENTS

In accordance with the Directive 2003/89/EC We confirm this is the ingredients and their content in %

L-Lysine hcl 98.5 to 101.0%

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BSE/TSE

The product does not contain and is not derived from Specified Risk Material as defined in Commission Directive European and it is conform to the EU legislation relating to the risk of Transmission of Spongiform Encephalopathy (TSE).

GMO

Following EU regulations have been published in the Official Journal of the European Union:

- Regulation (EC) No.1829/2003 of the European Parliament and the Council of 22nd September 2003 on genetically modified food and feed
- Regulation (EC) No.1830/2003 of the European Parliament and the Council of 22nd September 2003 concerning tractability and labeling on genetically modified organisms and tractability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

This product has not been genetically modified so there is no obligation of GMO labeling as defined by the above mentioned regulations.

NON IRRADIATION/NON IONIZED

According to directives 1992/2/EC and 1999/3/EC, We confirm is not made from irradiated/ionized raw materials or was irradiated/ionized the product.

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PESTICIDES

To our actual knowledge of production process, raw materials and equipment used potential pesticide residues in the above mentioned product comply with the European legislation on pesticide residues, esp. Regulation (EC)None. 396/2005. However, we do no test for pesticide residues on a routine basis.

RESIDUAL SOLVENTS

The product meets with:

- DIRECTIVE 2009/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients
- DIRECTIVE 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

CONTAMINANTS

The product is in accordance and meets with the commission regulation (EC) No.629/2008 of 2 July 2008 amending regulation (EC) No.1881/2006 setting maximum levels for certain contaminants in foodstuffs.

PCBS and MELAMINE

The product is in accordance and meets with the commission regulation (EU) No.594/2012 of 5 July 2012 amending regulation (EC) No.1881/2006 as regards the maximum levels of the contaminants Ochratoxin a, non dioxin-like PCBS and melamine in foodstuffs.

ANTI-DOPING

As per the list of 2012 of the world anti-doping agency the ingredient is not a doping substance and not a combination of doping substances. The ingredient does not contain any doping substance. The ingredient does not result from a doping substance.

As per the list of 2016 of the world anti-doping agency the ingredient is not a doping substance and not a combination of doping substances. The ingredient does not contain any doping substance. The ingredient does not result from a doping substance.

NANOMATERIALS

According to the the definition of 'nanomaterials' of the UE REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 on the provision of food information to consumers , we hereby attest that no nanomaterials are used in the formulation nor in the packaging materials of our product.

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PACKING

We confirm that the packing used is in compliance with:

- Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs.
- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

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ALLERGENS

In accordance with the Directive 2003/89/EC and Council amending Directive 2000/13/EC and taking Directive 2005/26/EC, Directive 2005/63/EC and Directive 2006/142/EC of 22.12.2006 into consideration. We confirm the following information:

Note: Does the raw material CONTAIN or is it DERIVED from or could it be CROSS-CONTAMINATED by any of the following.

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	No
Crustaceans and products thereof	No
Eggs and products thereof	No
Fish and products thereof	No
Peanuts and products thereof	No
Soybeans and products thereof	No
Milk and products thereof (including lactose)	No
Nuts (i.e. Almond, Hazelnut, Walnut, Cashew, Pecan nut, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut and products thereof)	No
Celery and products thereof	No
Mustard and products thereof	No
Sesame seeds and products thereof	No
Sulphur dioxide and sulphite at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO ₂	No
Lupine and products thereof	No
Molluscs and products thereof	No

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ALBA LIST (ALLERGENS)

When it is written 'No' means that there's no contamination in:

Contain in recipe, Handled on same production line or Handled at same side.

Where: 1) Contain in recipe 2) Handled on same production line 3) Handled at same side.

	Cross contamination (mg/kg)?	Where?
Cow milk protein	No	-
Lactose	No	-
Chicken egg	No	-
Soya protein	No	-
Soya oil	No	-
Gluten	No	-
Wheat	No	-
Rye	No	-
Cattle	No	-
Pork	No	-
Chicken	No	-
Fish	No	-
Shellfish and Crustaceae	No	-
Corn	No	-
Cocoa	No	-
Leguminous plants	No	-
Nuts	No	-
Nut oil	No	-
Peanut	No	-
Peanut oil	No	-
Sesame	No	-
Sesame oil	No	-
Glutamate	No	-
Sulphide (E220 to E228)	No	-
Coriander	No	-
Celery	No	-
Carrot	No	-
Lupines	No	-

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NUTRITIONAL INFORMATION

The values given are approximate

Unit Weight 100 gram
Amount Per Unit
Total Fat 0 gram
Saturated Fat 0 gram
Trans Fat 0 gram
Cholesterol 0 gram
Total Carbohydrate 0 gram
Dietary Fiber 0 gram
Sugars 0 gram
Protein 0 gram
Sodium 0 gram
Calcium 0 gram
Total Calories 0 KJ / 0 Calorie

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RESIDUE LIMITS

For the products/s mentioned above We herewith certify that the ingredient mentioned is in compliance with: commission regulation (EU) 2016/355 of 11 march 2016 amending Annex III to regulation (EC) No. 853/2004 of the European parliament and of the council as regards the specific requirements for gelatine, collagen and highly refined products of animal origin intended for human consumption.

HYGIENE OF FOODSTUFFS

For the products/s mentioned above We herewith certify that the production complies with regulation (EC) No. 852/2004 of the European parliament on the hygiene of foodstuffs and all its amendments.

FULL TRACEABILITY

For the products/s mentioned above We herewith the full traceability as mentioned in regulation (EC) No. 178/2002 of the European parliament and of the council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European food safety authority and laying down procedures in matters of food safety.

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FACTORY ACCREDITATIONS/CERTIFICATIONS

ISO 9001	Yes
ISO 14001	Yes
ISO 22000	No
HACCP	Yes
GMP	Yes
FAMI QS	No

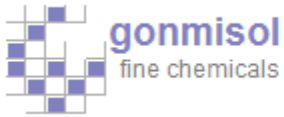
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NON ANIMAL TESTING

We certify that the product has not been tested on animals for cosmetic purposes.

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MSDS (Material Safety Data Sheet)

Section 1 - Chemical Product and Company Identification

Product Name: L-Lysine hcl
CAS Number: 657-27-2
Synonym: L-Lysine monohcl

Supplier Information:

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Section 2 - Composition, Information on Ingredients

CAS# 657-27-2
Chemical Name: L-Lysine hydrochloride
% ca.100
EINECS# 211-519-9
Hazard Symbols: None listed
Risk Phrases: None listed

Section 3 - Hazards Identification

EMERGENCY OVERVIEW

The toxicological properties of this material have not been fully investigated.

Potential Health Effects

Eye: May cause eye irritation.

Skin: May cause skin irritation.

Ingestion: May cause irritation of the digestive tract. The toxicological properties of this substance have not been fully investigated.

Inhalation: May cause respiratory tract irritation. The toxicological properties of this substance have not been fully investigated.

Chronic: No information found.

Section 4 - First Aid Measures

Eyes: Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids.

Get medical aid.

Skin: Get medical aid. Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse.

Ingestion: Never give anything by mouth to an unconscious person. Get medical aid. Do NOT induce vomiting.

If conscious and alert, rinse mouth and drink 2-4 cupfuls of milk or water.

Inhalation: Remove from exposure and move to fresh air immediately. If not breathing, give artificial respiration.

If breathing is difficult, give oxygen. Get medical aid.

Notes to Physician:

Section 5 - Fire Fighting Measures

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MSDS (Material Safety Data Sheet)

General Information: As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. Dusts at sufficient concentrations can form explosive mixtures with air. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.
Extinguishing Media: Use agent most appropriate to extinguish fire. Use water spray, dry chemical, carbon dioxide, or appropriate foam.

Section 6 - Accidental Release Measures

General Information: Use proper personal protective equipment as indicated in Section 8.
Spills/Leaks: Clean up spills immediately, observing precautions in the Protective Equipment section. Sweep up or absorb material, then place into a suitable clean, dry, closed container for disposal. Avoid generating dusty conditions. Provide ventilation.

Section 7 - Handling and Storage

Handling: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Minimize dust generation and accumulation. Avoid contact with eyes, skin, and clothing. Keep container tightly closed. Avoid ingestion and inhalation.
Storage: Store in a tightly closed container. Store in a cool, dry, well-ventilated area away from incompatible substances.

Section 8 - Exposure Controls, Personal Protection

Engineering Controls: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation to keep airborne concentrations low.

Exposure Limits

CAS# 657-27-2:

Personal Protective Equipment

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin: Wear appropriate protective gloves to prevent skin exposure.

Clothing: Wear appropriate protective clothing to prevent skin exposure.

Respirators: A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements or European Standard EN 149 must be followed whenever workplace conditions warrant respirator use.

Section 9 - Physical and Chemical Properties

For this information, please, refer directly to the Certificate of Analysis OR Specifications

Section 10 - Stability and Reactivity

Chemical Stability: Stable. However, may decompose if heated.

Conditions to Avoid: Incompatible materials, dust generation, temperatures above 150.

Incompatibilities with Other Materials: Strong oxidizing agents.

Hazardous Decomposition Products: Hydrogen chloride, nitrogen oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide.

Hazardous Polymerization: Has not been reported.

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MSDS (Material Safety Data Sheet)

Section 11 - Toxicological Information

RTECS#: CAS# 657-27-2: OL5650000

LD50/LC50: RTECS:

CAS# 657-27-2: Oral, rat: LD50 = 10 gm/kg;

Carcinogenicity: L-Lysine hydrochloride - Not listed as a carcinogen by ACGIH, IARC, NTP, or CA Prop 65.

Other: No information found.

Section 12 - Ecological Information

Not available

Section 13 - Disposal Considerations

Products considered hazardous for supply are classified as Special Waste and the disposal of such chemicals is covered by regulations which may vary according to location. Contact a specialist disposal company or the local authority or advice. Empty containers must be decontaminated before returning for recycling.

Section 14 - Transport Information

The goods is not subject to IMO IMDG CODE

Section 15 - Regulatory Information

European/International Regulations

European Labeling in Accordance with EC Directives

Hazard Symbols: Not available

Risk Phrases:

Safety Phrases:

WGK (Water Danger/Protection)

CAS# 657-27-2: 0

Canada

CAS# 657-27-2 is listed on Canada's DSL List

US Federal

TSCA

CAS# 657-27-2 is listed on the TSCA Inventory.

Section 16 - Other Information

MSDS Creation Date: 12/01/2007

Revision #6 Date 9/10/2012

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential, or exemplary damages howsoever arising, even if the company has been advised of the possibility of such damages.

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