

GLYCINE - G1062500 Manuf. code: 35HHCX**PRODUCT SPECIFICATION**

Product Name	INCI Name	EINECS Number	CAS Code
GLYCINE	glycine	200-272-2	56-40-6

The product meets OR exceeds: **EP11 / USP31**

Appearance	White crystalline powder
Identification	Infrared Absorption
Appearance of solution	Clear and colorless
Assay (C ₂ H ₅ NO ₂)%	98.5 ~ 101.5
Ph value (5% in water)	5.9 ~ 6.4
Heavy metals (as Pb)%	≤ 0.001
Lead (as Pb), mg/kg	≤ 3
Chloride (as Cl)%	≤ 0.007
Loss on drying%	≤ 0.2
Sulphate (as SO ₄)%	≤ 0.0065
Arsenic (As) mg/kg	≤ 1
Mercury (Hg) mg/kg	≤ 0.1
Cadmium (Cd) mg/kg	≤ 1
Hydrolyzable substances	Meets the requirements
Residue on ignition %	≤ 0.1
Ethylene oxide and 2-chloro-ethanol, ppm / MRL	≤ 0.01
Organic volatile impurities	Meets the requirements
Total Plate Count, cfu/g	≤1000
Mould, cfu/g	≤100
Yeast, cfu/g	≤100

Technical package

Dossier Técnico
20/11/2023

GLYCINE - G1062500

Manuf. code: 35HHCX

PRODUCT SPECIFICATION

E-Coil, cfu/10g	Absence
Salmonella, cfu/g	Absence
Ninhydrin-positive substances	Meets the requirements

Reference standard: EP11/USP31

Package: 25kgs/bag

Shelf life: three years

GLYCINE - G1062500 Manuf. code: 35HHCX**GENERAL PRODUCT INFORMATION**

Mesh of the product	20-80
Tapped density	0.7998 g/ml
Bulk density	0.942 g/ml
Water solubility	25 g/100ml at 25 Deg C
Type of Manufacturing process (Synthesis, Fermentation, Extraction, etc.)	Synthetic
Is the product FREE of GLUTEN?	Yes
Is the product suitable for vegans?	Yes
Is the product suitable for vegetarians?	Yes
Is the product free of fructose?	Yes
Is this product suitable for food?	Yes
Is this product suitable for feed of animals?	Yes
Pharmacopoeias that the product meets	USP/EP
Drug indication	amino acid
Melting point	232-236 Deg C
Country of origin of the raw material/s of the product	China
Storage conditions (in the warehouse)	Cool and shaded

GLYCINE - G1062500 Manuf. code: 35HHCX

GENERAL PRODUCT INFORMATION

Additional information about the product:

- The product does not contain isoflavones.
- The used of plastic packaging respects the rules of regulation 10/2022EC and compliance has been checked through migration testing.
- The product packagings are free from bisphenol A and phtalates.
- The packaging used comply with the regulation 1895/2005EC of 18 November 2005 on the restriction of the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs
- Products meet radioactivity thresholds established by European Regulation 733 / 2008EC and its subsequent amendments.
- Additives, colours and flavourings implemented comply with new regulations FIAP 1332-1333-1334/2008EC and subsequent amendments including the n°1129/2011 on the maximum limits usable according to food.
- The product complies with European Regulation No 767/2009 (Feed).
- REACH registration number: 01-2119864796-18-0024

ELEMENTAL IMPURITIES - ICH Q3D

- Each individual class 1 and class 2a element stated in the ICH Q3D guideline is integrated in the specification.
- Class 2B or class 3 elements are not intentionally added during the manufacture of the product.

Complies with E640 of Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008

GLYCINE - G1062500 Manuf. code: 35HHCX**TECHNICAL PRODUCT INFORMATION**

Name of the product	Glycine
INCI Name	
IUPAC name	2-aminoacetic acid
EINECS	200-272-2
Molecular Formula	C ₂ H ₅ NO ₂
Molecular mass	75.06
Country of the factory (Manufacturing site)	China
Raw materials used for the manufacture of this product and their function	Tech grade glycine
Frequency of analysis of each contaminant?	Every batch
Frequency of analysis of microbiology?	Heavy metals: Every batch, Microbiology: On request
Frequency of analysis of each heavy metal?	Heavy metals: Every batch, Microbiology: On request

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Explanation of actions taken during the manufacturing process of this product to reduce the risk of appearance of foreign material:

Metal detector	Yes	Before packing procedure
Sieve	Yes	Before packing procedure
Filter	Yes	During purify procedure
X-Ray	No	
Other	No	

GLYCINE - G1062500

Manuf. code: 35HHCX

INGREDIENTS

In accordance with the EU Regulation 1169/2011, amending EU Regulation 1924/2006 and EU Regulation 1925/2006, the following ones are the ingredients and their content (in %) in this product.

Glycine	100%
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GLYCINE - G1062500 Manuf. code: 35HHCX

BSE/TSE

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

GMO

The following EU regulations have been published in the Official Journal of the European Union in this subject:

- Regulation (EC) No.1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed.

- Regulation (EC) No.1830/2003 of the European Parliament and the Council of 22 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 that this product is not made from irradiated/ionized raw materials and that this product was not irradiated/ionized.

GLYCINE - G1062500 Manuf. code: 35HHCX**PESTICIDES**

To our actual knowledge of the production process, of the raw materials and of the equipment used, the potential pesticide residues in this product comply with the European legislation on pesticide residues (esp. Regulation (EC) No. 396/2005 and amendments). However, we do not 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 (EU) No. 2023/915 setting maximum levels for certain contaminants in foodstuffs.

PCBS AND MELAMINE

This product is in accordance and meets with the Commission Regulation (EU) No. 2023/915 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 2024 of the World Anti-Doping Agency (WADA), this product is not a doping substance or a combination of doping substances. This product is not manufactured from a doping substance.

NANOMATERIALS

According to the definition of 'Nanomaterials' of the UE Regulation No 1169/2011 of the European Parliament and of the Council of 25th of October 2011 (amending Commission Regulation (EC) 1924/2006 and Commission Regulation (EC) 1925/2006) on the provision of food information to consumers, we hereby attest that no nanomaterials are used in the manufacture, in the formulation nor in the packaging materials of this product.

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PACKING

We confirm that the packing used for this product is in compliance with:

- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27th of 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.
- Commission Regulation (EU) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

ETHYLENE OXIDE (ETO) & 2-CHLORO-ETHANOL

Ethylene Oxide (& 2-Chloroethanol) is not used in any phases of the process of manufacture or storage of this product. This product does not enter in contact with Ethylene Oxide (& 2-Chloroethanol) in any phases of the process of manufacture or of storage. Therefore, this product is compliant with the limit established in Commission Regulation (EC) No. 396/2005.

GLYCINE - G1062500 Manuf. code: 35HHCX**ALLERGENS**

In accordance with Regulation (EU) No. 1169/2011, amending Commission Regulation (EC) No. 1924/2006 and Commission Regulation (EC) No. 1925/2006, we confirm the following information:

Does this product contain or is derived from or could be cross-contaminated by any of the following allergens?

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 (with exceptions established in Annex II)	No
Milk and products thereof (including lactose) (with exceptions established in Annex II)	No
Nuts (i.e. almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut) and products thereof (with exceptions established in Annex II)	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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Note: 'Yes' means that there is contamination from

- 1) recipe contents,
- 2) other products handled on the same production line or
- 3) other products 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	-

GLYCINE - G1062500 Manuf. code: 35HHCX

NUTRITIONAL INFORMATION

Approximative Nutritional Information of this product is as follows:

Nutritional values: 100g:

Calorific value 1987kJ

Calorific value 468kcal

Protein 116,9g

Carbohydrate 0g

thereof sugar g

thereof dextrose g

thereof lactose g

thereof saccharose g

thereof polyvalent alcohols g

thereof starch g Vitamin B12 0g

Fat 0g Biotin 0mg

thereof saturated fatty acids g

thereof monounsaturated fatty acids g

thereof polyunsaturated fatty acids g

Cholesterol 0g

Dietary fiber 0g

Sodium 0g

Salt 0g

Ethylalcohol 0g

Organic acids 0g

Vitamins and minerals content 100g:

Vitamin A 0g

Vitamin D 0g

Vitamin E 0mg

Vitamin C 0mg

Thiamin (Vitamin B1) 0mg

Riboflavin (Vitamin B2) 0mg

Niacin 0mg

Vitamin B6 0mg

Folic acid 0g

Vitamin B5 0mg

Calcium 0mg

Phosphor 0mg

Iron 0mg

Magnesium 0mg

Zinc 0mg

Jodine 0g

Potassium 0mg

Copper 0mg

Technical package

Dossier Técnico
20/11/2023

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NUTRITIONAL INFORMATION

Selenium 0ig
Manganese 0mg
Chrom - chrome 0ig
BE – bread unit

GLYCINE - G1062500 Manuf. code: 35HHCX

RESIDUE LIMITS (GELATIN, COLLAGEN)

We herewith certify that this product in compliance with: Commission Regulation (EU) No. 2016/355 of 11st of March 2016, amending Annex III to Commission 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

We herewith certify that this product complies with Commission Regulation (EC) No. 852/2004 of the European Parliament on the hygiene of foodstuffs and all its amendments.

FULL TRACEABILITY

This product complies with the full traceability criteria as mentioned in Commission Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28th of 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.

Technical package

Dossier Técnico
20/11/2023

GLYCINE - G1062500

Manuf. code: 35HHCX

FACTORY ACCREDITATIONS/CERTIFICATIONS

ISO 9001	Yes
ISO 22000	Yes
HACCP	Yes
GMP	Yes
FAMI QS	Yes
BRC	Yes
Other accreditations/certifications	FSCC 22000

Technical package

Dossier Técnico
20/11/2023

GLYCINE - G1062500 Manuf. code: 35HHCX

NON ANIMAL TESTING

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

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Flow Chart

