

# Productos Quimicos Gonmisol S.A. Tel 34 933 136 118 Camino de la Verneda 47-49 Fax 34 933 147427 08930 - San Adrian del Besos Barcelona - Spain

www.gonmisol.com

# L-Phenylalanine

| <b>Product Name</b>  | L-Phenylalanine    |  |
|----------------------|--------------------|--|
| INCI Name            | 3-phenyl-L-alanine |  |
| <b>EINECS Number</b> | 200-568-1          |  |
| CAS Code             | 63-91-2            |  |

| The product meets OR exceeds: FCC6 |  |
|------------------------------------|--|
| Description                        |  |
| Identification (IR)                |  |

| Description              | White crystals or crystalline powder   |
|--------------------------|--|
| Identification (IR)      | Concordant with the reference spectrum |
| Specific rotation [α]D20 | -33.2º ~ -35.2º                        |
| Assay                    | 98.5 ~ 101.5%                          |
| Loss on drying           | ≤ 0.20%                                |
| Residue on ignition      | ≤ 0.10%                                |
| PH                       | 5.4~6.0                                |
| Chloride                 | ≤0.021                                 |
| Heavy Metals(Pb)         | ≤15ppm                                 |
| Lead                     | ≤ 3 ppm                                |
| Arsenic (As)             | ≤ 1 ppm                                |
| Mercury                  | ≤ 0.1 ppm                              |
| Cadmium                  | ≤ 1 ppm                                |
| <b>Total Plate Count</b> | ≤ 10000 cfu/g                          |
| Yeast&Mold               | ≤ 1000 cfu/g                           |
| Salmonella               | Absent/10g                             |
| Enterobacteries          | Absent/g                               |
| Staphylococcus aureus    | Absent/g                               |
| E.Coli                   | Absent/g                               |

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| Mesh of the product  | 20                       |
|--|--------------------------|
| Taped denisty  | -                        |
| Bulk density   | -                        |
| Water solubility   | 2.74 (H2O, g/100g, 20°C) |
| Origin (Synthetis, Fermentation)   | Fermentation             |
| Origin (Animal, Vegetal, etc.)   | Glucose                  |
| Is the product and their ingredients FREE of GLUTEN?                       | Yes                      |
| Product is suitable for Vegans   | Yes                      |
| Product is suitable for Vegatarians  | 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                    | FCC, USP, EP       |
|--|--------------------|
| Drug indication                                      | Not applicable     |
| Melting Point  | 270-275ºC          |
| Country of the raw material/s                        | South Korea        |
| Storage conditions (In the warehouse)                | Ambient conditions |
| Storage conditions (During the transport-Short term) | Ambient conditions |

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#### TECHNICAL PRODUCT INFORMATION

| IUPAC name                                 | (S)-2-Amino-3-phenylpropanoic acid                            |  |
|--|---|--|
| ATC Code                                   | Not applicable  |  |
| Molecular Formula                          | C9H11NO2  |  |
| Stereochemistry                            | https://en.wikipedia.org/wiki/Phenylalanine                   |  |
| Molecular mass                             | 165.192 g/mol   |  |
| Raw materials used and their function      | Glucose for starting raw material. Not present in the product |  |
|  |   |  |
| Frequency of analysis of each contaminant? | Every lot   |  |
| Frequency of analysis of each              | Every lot   |  |

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

| Metal detector | Yes |
|----------------|-----|
| Sieve          | Yes |
| Filter         | Yes |
| X-Ray          | No  |
| Other          | Yes |

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

L-Phenylalanine 100

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### BSE/TSI

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).

#### **GMC**

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 SO2  | 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 aproximate

ITEM / TEST METHOD / RESULT TEST RESULT: Assay / GB 5009.5-2003 / 99.72g/100g Fat / GB 5009.6-2003 / 0.5g/100g Moisture / GB 5009.3-2003 / 0.09g/100g Ash / GB 5009.4-2003 / 0.05g/100g Protein / GB 5009.5-2003 / 0g/100g CALCULATE RESULT: Carbohydrate / GB 28050-2004 / 0.09g/100g Energy / GB 28050-2004 / 1315KJ/100g

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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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| ISO 9001                            | Yes           |
|-------------------------------------|---------------|
| ISO 14001                           | No            |
| ISO 22000                           | Yes           |
| HACCP                               | No            |
| GMP                                 | No            |
| FAMI QS                             | No            |
| BRC                                 | No            |
| Other accreditations/certifications | Halal, Kosher |

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

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# L-Phenylalanine

# 1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY UNDERTAKING

Product Name: L-Phenylalanine

CAS Number: 63-91-2 Supplier Information:

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### 2. HAZARDS IDENTIFICATION

Classification of the substance Physical hazards: Not applicable Health hazards: Not applicable

Environmental hazards: Not applicable

Label elements Not applicable Potential effects

May cause eye and skin irritation It will increase the biological oxygen demand (BOD) of water

## 3. COMPOSITION INFORMATION ON INGREDIENTS

Substance

Name of substance: L-Phenylalanine

CAS number: 63-91-2 EC number: 200-568-1 Index number: -Concentration: 100%

## 4. FIRST AID MEASURES

Description of first aid measures

After eye contact: Flush with copious amounts of water for at least 15 minute. Assure adequate flushing by separating

the eyelids with fingers. Call a physician

After skin contact: Immediately wash skin with soap and flush with water

After inhalation: Remove to fresh air. If breathing becomes difficult, call a physician After ingestion: Wash out mouth with water provided person is conscious. Call a physician

Most important symptoms and effects, both acute and delayed

Not determined

Indication of any immediate medical attention and special treatment needed

Not determined

## 5. FIRE FIGHTING MEASURES

Extinguishing media

Water spray, Carbon dioxide, dry chemical powder or appropriate foam

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# L-Phenylalanine

### MSDS (Material Safety Data Sheet)

Special hazards arising from the substance or mixture

Emits toxic fumes under fire conditions

Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes

## 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

See precautions in section 7 and 8. Avoid raising dust. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves

**Environmental precautions** 

None

Methods and material for containment and cleaning up

Sweep up, place in a bag and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete.

Reference to other sections

See precautions in section 7 and 8

## 7. HANDLING AND STORAGE

Precautions for safe handling

Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure.

Conditions for safe storage, including any incompatibilities

Store in a cool and dry place. Recommended storage temperature is 15~30°C. Keep container tightly closed and

inner bag sealed

Specific end use(s)

Not applicable

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Not applicable

Exposure controls

Respiratory protection: NIOSH/MSHA-APPROVED respirator Hand protection: Compatible chemical-resistant gloves

Eye protection: Chemical safety goggles Body protection: Safety shower and eye bath

Hygiene measures: Mechanical exhaust required. Wash thoroughly after handling

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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

## 10. STABILITY AND REACTIVITY

Reactivity

Not determined

Chemical stability

Stable under recommended storage conditions

Possibility of hazardous reactions

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### MSDS (Material Safety Data Sheet)

Hazard polymerization will not occur Conditions to avoid Not determined Incompatible materials Strong oxidizers Hazardous decomposition materials Carbon monoxide, Carbon dioxide, Nitrogen oxides

## 11. TOXICOLOGICAL INFORMATION

Acute toxicity

May be harmful if absorbed through the skin. May be harmful if inhaled. May be harmful if swallowed

Skin corrosion/irritation

May cause skin irritation

Serious eye damage/irritation

May cause eye irritation

Respiratory or skin sensitization

Not determined

Germ cell mutagenicity

Not determined

Carcinogenicity

Not determined

Reproductive toxicity

Not determined

STOT-single exposure

May be irritating to mucous membranes and upper respiratory tract

STOT-repeated exposure

Not determined

Aspiration hazard

Not determined

RTECS No.

AY 7535000

# 12. ECOLOGICAL INFORMATION

**Toxicity** 

Not determined

Persistence and degradability

Not determined

Bioaccumulative potential

Not determined

Mobility in soil

Not determined

Results of PBT and vPvB assessment

Not determined

Other adverse effects

Not determined

## 13. DISPOSAL CONSIDERATIONS

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### Waste treatment methods

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state and local environmental regulations List of CER codes

Allocation of the waste code numbers according EC Directive 91/692/EEC must be realized under considerations of existing sector specifics and processes

## 14. TRANSPORT INFORMATION

**UN Number** 

None

UN proper shipping name

None

Transport hazard classes

None

Packing group

None

**Environmental hazards** 

None

Land transport (ADR/RID)

None

Onland waterway craft (ADN/ADNR)

None

Marine transport (IMDG)

None

Air transport (IATA)

None

Special precautions for user

None

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Not determined

No special requirements for transport according to international regulations.

## 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture **OEL=MAK** 

NOES 1983: HZD X5534; NIS 4; TNF 792; NOS 14; TNE 19901; TFE 14903

EPA TSCA Section 8(B) chemical inventory

Chemical safety assessment

Not applicable.

## 16. OTHER INFORMATION

This information is based on our present knowledge and is provided according to the relevant EC and national regulations. This information is intended as a characterization of the product in order to provide guidance for the relevant safety issues. However, this document does not provide any warranty, expressed or implied, regarding the properties of the product. In no event will we be responsible for damages of any nature whatsoever resulting from the use of or reliance on information.

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