



GONMISOL
FINE INGREDIENTS

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www.gonmisol.com

Productos Químicos Gonmisol S.A.
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Camí de la Verneda 47-49
Sant Adrià de Besòs 08930
Barcelona - Spain (EU)

Technical package

Dossier Técnico
25/11/2022

R-ALPHA LIPOIC ACID

PRODUCT SPECIFICATION

Product Name	INCI Name	EINECS Number	CAS Code
R-ALPHA LIPOIC ACID	N/A	N/A	1200-22-2

Description	A pale yellow crystal with a characteristic odor, tasteless
Identification	Meets the requirements
Melting point	48 ~ 51° C
Specific optical Rotation (C=1, Ethanol)	+115° - +125°
Loss on drying	0.5% Max.
Residue on ignition	0.1% Max.
Residual Solvents	
- Cyclohexane	0.388% Max.
- Ethyl Acetate	0.500% Max.
- Toluene	0.089% Max.
Heavy metals	10 ppm Max.
Lead	2 ppm Max.
Arsenic	1 ppm Max.
Cadmium	1 ppm Max.
Mercury	0.1 ppm Max.
Total Plate Count	1,000 per/g Max.
Moulds and Yeasts	100 per/g Max.
Escherichia coli	Negative/g
Salmonella	Negative/10g
Particle Size	100% Through 40 mesh



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PRODUCT SPECIFICATION

Loose Bulk Density	0.25 ~ 0.35 g/ml
Assay	99.00% Min.

Keep it below 25°, do not be insolated.



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GENERAL PRODUCT INFORMATION

Mesh of the product	20-80
Tapped density	0.4-0.5 g/ml
Bulk density	0.25-0.35 g/ml
Water solubility	Very soluble in cold water
Type of Manufacturing process (Synthesis, Fermentation, Extraction, etc.)	synthetic
Specific Origin of the product (Animal, Vegetal, etc.)	chemical
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
Can the product be used in baby food (according to Regulation (EU) N° 609/2013, Commission Delegated Regulation (EU) 2016/127, Commission Delegated Regulation (EU) 2021/572 and amendments)?	No
Pharmacopoeias that the product meets	In-house
Melting point	48-52°C
Country of origin of the raw material/s of the product	Raw material from China
Storage conditions (in the warehouse)	Seal and store away from light



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TECHNICAL PRODUCT INFORMATION

Name of the product	R-Alpha Lipoic Acid
Molecular Formula	C ₈ H ₁₄ O ₂ S ₂
Molecular mass	206.33
Country of the factory (Manufacturing site)	China
Raw materials used for the manufacture of this product and their function	Vitamins medicine, has better effect than Alpha Lipoic Acid
Frequency of analysis of each contaminant?	Every batch
Frequency of analysis of microbiology?	Heavy metals: Every batch, Microbiology: Every batch
Frequency of analysis of each heavy metal?	Heavy metals: Every batch, Microbiology: Every batch



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FOREIGN MATERIAL

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

Metal detector	Yes	12000 gauss
Sieve	No	
Filter	No	
X-Ray	No	



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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.

R(+)-Alpha-Lipoic acid	100%
------------------------	------



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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.



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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 2012 of the World Anti-Doping Agency, the ingredient is not a doping substance or 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 or 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 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.

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.



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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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ALBA LIST (ALLERGENS)

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	-

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.



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NUTRITIONAL INFORMATION

Approximative Nutritional Information of this product is as follows:

Nutrition Information per 100 grams

Calories 0

Calories from Fat 0

Total Fat 0

-monounsaturated 0

-polyunsaturated 0

-saturated 0

-trans fat 0

Cholesterol 0

Total Carbohydrate 0

-dietary fiber 0

-sugar 0

-sugar alcohols 0

-other carbohydrates 0

Protein 0

Vitamin A (as) 0

Vitamin D (as) 0

Vitamin E (as) 0

Vitamin K 0

Thiamin (vitamin B-1)(as) 0

Riboflavin (as) 0

Niacin (as) 0

Vitamin B-6 (as) 0

Vitamin B-6 (as) 0

Folate, Folic Acid or Folacin 0

Vitamin B-12 (as) 0

Biotin (as) 0

Pantothenic Acid (as) 0

Calcium (as) 0

Phosphorus (as) 0

Iodine (as) 0

Magnesium (as) 0

Zinc (as) 0

Selenium (as) 0

Copper (as) 0

Manganese (as) 0

Molybdenum (as) 0

Chromium (as) 0

Molybdenum (as) 0

Chloride (as) 0



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NUTRITIONAL INFORMATION

Sodium (as) 0
Potassium (as) 0



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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.



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FACTORY ACCREDITATIONS/CERTIFICATIONS

ISO 9001	Yes
ISO 22000	Yes
GMP	No
FAMI QS	No



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NON ANIMAL TESTING

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



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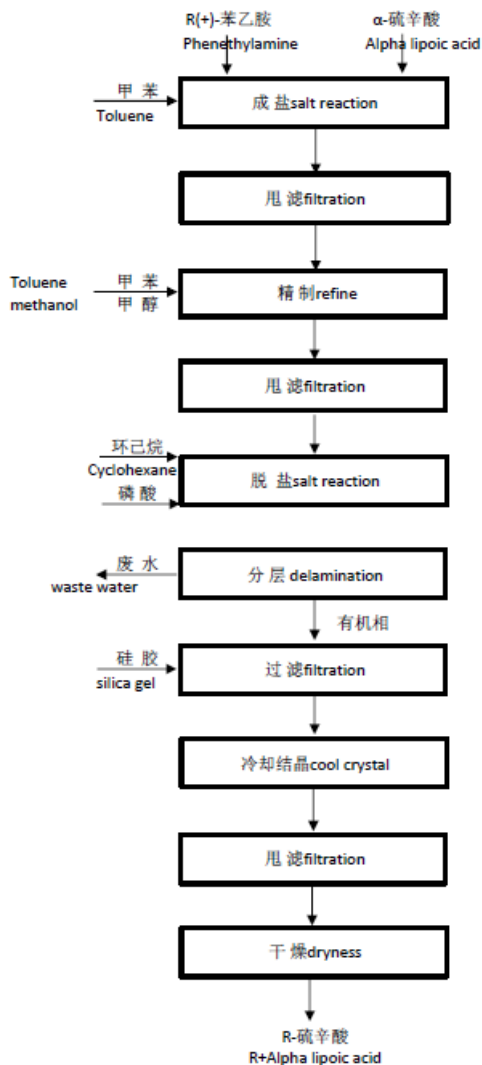
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Flow Chart





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**Material Safety Data
Sheet**

**Documento MSDS
26/05/2022**

R-ALPHA LIPOIC ACID

MSDS (Material Safety Data Sheet)

1. CHEMICAL PRODUCT IDENTIFICATION

Product Name: R-ALPHA LIPOIC ACID
CAS Number: 1200-22-2

Supplier Information:

Productos Químicos Gonmisol S.A.
Camino de la Verneda 47-49
08930 - San Adrian del Besos
Barcelona - Spain
Phone +34 933136118
Fax +34 933147427
www.gonmisol.com

2. HAZARD IDENTIFICATION

Product not subject to compulsory markings
Take the usual cautionary measures for chemical material handling

3. INFORMATION ON COMPOSITION

Name : R+ alpha lipoic acid
Chemical Formula : C₈H₁₄O₂S₂
Molecular Weight : 206.33 CAS No.: 1200-22-2
Assay: NLT99%

4. FIRST AID MEASURES

General Instruction : The product is neither dangerous nor hazardous .
Availability of the usual first aid means is requested.
Eye contact : In case of contact ,immediately flush eyes with copious amounts of water for at least 15 minutes . Assure adequate flushing by separating the eyelids with fingers; call a physician .
Skin contact : in case of contact , immediately wash skin with soap and copious amounts of water .
Ingestion : if swallowed , wash out mouth with water provided person is conscious, call a physician.
Inhalation : if inhaled , remove to fresh air , if not breathing give artificial respiration. If breathing is difficult , Give oxygen
Notes to physicians : Treat symptomatically.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media : water spray , dry chemical powder , carbon dioxide .
Unusal fire and explosions : Emits toxic flumes under fire conditions.
Special protective equipment : wear a self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.



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**Material Safety Data
Sheet**

**Documento MSDS
26/05/2022**

R-ALPHA LIPOIC ACID

MSDS (Material Safety Data Sheet)

6. ACCIDENTAL SPILLING MEASURES

Antidust mask , chemical safety goggles, rubber boots and heavy rubber gloves .
Sweep up, place in a bag and hold for waste disposal ; avoid raising dust .
Ventilate area and wash spill site after material pickup is complete .

7. STORAGE AND HANDLING

Handling : usual protective equipment against chemical powder.
Storage : Stored in dry , dark and cool place .

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

General measures : Normal cautions for chemical materials.
Personal protection and hygiene : General guidelines of good industrial hygiene
Respiratory protection : antidust mask
Hands protection: gloves
Eyes protection: goggles
Skin protection: protective clothing
Technical facility measures : Efficient exhaustion system

9. STABILITY AND REACTIVITY

General features : stable in dry and cool palce
Condition to avoid : warning , contact with acidic mediums
Materials to avoid : Oxidizers , mineral acids

10. PHYSICAL AND CHEMICAL PROPERTIES

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

11. TOXICOLOGICAL INFORMATION:

N/P

12. ECOLOGICAL INFORMATION:

N/P



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**Material Safety Data
Sheet**

**Documento MSDS
26/05/2022**

R-ALPHA LIPOIC ACID

MSDS (Material Safety Data Sheet)

13. DISPOSAL CONSIDERATION:

Waste disposal methods:

Dispose of in a manner consistent with federal, state and local regulations.

Not listed as a material banned from land disposal according to rcra.

14. TRANSPORT INFORMATION:

N/P

15. REGULATORY INFORMATION

SARA Title III information:

N/P

Federal regulatory information:

N/P

State regulatory information:

N/P

16. OTHER INFORMATION

Other information: N/P