

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

93289-Capsules 0 white

Version 1 Date of compilation: 21/12/2022

Version 3 (replaces version 2)

Revision date: 27/05/2025

Page 1 of 7

Print date: 27/05/2025



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: Capsules 0 white
Product Code: 93289

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

pharmaceutical use

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **GUINAMA S.L**
Address: C/ Oslo Nº3
City: 46185 - La Pobla de Vallbona
Province: Valencia
Telephone: +34961869090 / 902119816
Fax: +34961850352
E-mail: ventas@guinama.com
Web: www.guinama.com

1.4 Emergency telephone number: +34961869090 / 902119816 (Only available during office hours; Monday-Friday; 08:00-18:00)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

The product is not classified as hazardous within the meaning of Regulation (EC) No 1272/2008.

2.2 Label elements.

Este producto no está clasificado como peligroso según el Reglamento CE 1272/2008.

2.3 Other hazards.

The mixture does not contain substances classified as PBT.
The mixture does not contain substances classified as vPvB.
The mixture does not contain any endocrine disrupting properties substances.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

Hazardous ingredient

None of the ingredients of this material meet the definition of "hazardous chemical".

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

Composition

- Gelatin type B (Nº CAS 9000-7-8)
- Water (Nº CAS 7732-18-5)
- Dyes or pigments (if they are required). Check pigments detail sheet.

3.1 Substances.

Not applicable.

3.2 Mixtures.

This mixture does not contain substances at a concentration higher than the values established in Annex II of Regulation (EC) 1907/2006 and its subsequent modifications, which represent a danger to health or the environment, neither have a limit of Community exposure in the workplace, neither are classified as PBT / vPvB, neither are they on the candidate list.

SECTION 4: FIRST AID MEASURES.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

93289-Capsules 0 white

Version 1 Date of compilation: 21/12/2022

Version 3 (replaces version 2)

Revision date: 27/05/2025



Page 2 of 7

Print date: 27/05/2025

4.1 Description of first aid measures.

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Inhalation.

If breathing stops, seek emergency medical attention. Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

Skin contact.

Remove contaminated clothing.

Ingestion.

Keep calm. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed.

No known acute or delayed effects from exposure to the product.

4.3 Indication of any immediate medical attention and special treatment needed.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: FIREFIGHTING MEASURES.

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture.

Special risks.

Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

-Continued on next page.-

SAFETY DATA SHEET

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93289-Capsules 0 white

Version 1 Date of compilation: 21/12/2022

Version 3 (replaces version 2)

Revision date: 27/05/2025



Page 3 of 7

Print date: 27/05/2025

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

The product does not require special handling measures, the following general measures are recommended:

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

The product does not require special storage measures. As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided.

Keep away from oxidising agents and from highly acidic or alkaline materials.

Store the containers between 15 and 25 °C, in a dry and well-ventilated place.

Store according to local legislation. Observe indications on the label. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls.

Measures of a technical nature:

Concentration:	100 %
Uses:	pharmaceutical use
Breathing protection:	
If the recommended technical measures are observed, no individual protection equipment is necessary.	
Hand protection:	
If the product is handled correctly, no individual protection equipment is necessary.	
Eye protection:	
If the product is handled correctly, no individual protection equipment is necessary.	
Skin protection:	
PPE:	Work footwear.
Characteristics:	«CE» marking, category II.
CEN standards:	EN ISO 13287, EN 20347
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Not applicable/Not available due to the nature/properties of the product

Colour: According to customers' specifications.

Odour: Odorless

Odour threshold: Not applicable/Not available due to the nature/properties of the product

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

93289-Capsules 0 white



Version 1 Date of compilation: 21/12/2022

Version 3 (replaces version 2)

Revision date: 27/05/2025

Page 4 of 7

Print date: 27/05/2025

Melting point: Not applicable/Not available due to the nature/properties of the product
Freezing point: Not applicable/Not available due to the nature/properties of the product
Boiling point or initial boiling point and boiling range: Not applicable/Not available due to the nature/properties of the product
Flammability: Not applicable/Not available due to the nature/properties of the product
Lower explosion limit: Not applicable/Not available due to the nature/properties of the product
Upper explosion limit: Not applicable/Not available due to the nature/properties of the product
Flash point: Not applicable/Not available due to the nature/properties of the product
Auto-ignition temperature: Not applicable/Not available due to the nature/properties of the product
Decomposition temperature: Not applicable/Not available due to the nature/properties of the product
pH: Not applicable/Not available due to the nature/properties of the product
Kinematic viscosity: Not applicable/Not available due to the nature/properties of the product
Solubility: Solubility in water (20°C): sparingly soluble. Solubility in ethanol (20°C): practically soluble.
Hydrosolubility: Not applicable/Not available due to the nature/properties of the product
Liposolubility: Not applicable/Not available due to the nature/properties of the product
Partition coefficient n-octanol/water (log value): Not applicable/Not available due to the nature/properties of the product
Vapour pressure: Not applicable/Not available due to the nature/properties of the product
Absolute density: Not applicable/Not available due to the nature/properties of the product
Relative density: Not applicable/Not available due to the nature/properties of the product
Relative vapour density: Not applicable/Not available due to the nature/properties of the product
Particle characteristics: Not applicable/Not available due to the nature/properties of the product
Appearance: The capsule shape is a pair of cylinders, each with one end closed, which can be overlapped one on the other.
Elastic.

9.2 Other information

Not applicable/Not available due to the nature/properties of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on hazard classes as defined in Regulation (EC) N° 1272/2008.

There are no tested data available on the product.

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

Not conclusive data for classification.

c) serious eye damage/irritation;

Not conclusive data for classification.

d) respiratory or skin sensitisation;

Not conclusive data for classification.

e) germ cell mutagenicity;

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

93289-Capsules 0 white

Version 1 Date of compilation: 21/12/2022

Version 3 (replaces version 2)

Revision date: 27/05/2025



Page 5 of 7

Print date: 27/05/2025

Not conclusive data for classification.

f) carcinogenicity;

Not conclusive data for classification.

g) reproductive toxicity;

Not conclusive data for classification.

h) STOT-single exposure;

Not conclusive data for classification.

i) STOT-repeated exposure;

Not conclusive data for classification.

j) aspiration hazard;

Not conclusive data for classification.

11.2 Information on other hazards.

Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

There is no information available on other adverse health effects.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

No information is available regarding the ecotoxicity of the substances present.

12.2 Persistence and degradability.

No information is available regarding the biodegradability of the substances present.

No information is available on the degradability of the substances present.

No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation of the substances present.

12.4 Mobility in soil.

No information is available about the mobility in soil.

The product must not be allowed to go into sewers or waterways.

Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects.

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

No information is available about other adverse effects for the environment.

SECTION 13: DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

93289-Capsules 0 white

Version 1 Date of compilation: 21/12/2022

Version 3 (replaces version 2)

Revision date: 27/05/2025



Page 6 of 7

Print date: 27/05/2025

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

14.1 UN number or ID number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR/RID: Not classified as hazardous for transport.

IMDG: Not classified as hazardous for transport.

ICAO/IATA: Not classified as hazardous for transport.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): Not applicable.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Maritime transport in bulk according to IMO instruments.

Not classified as hazardous for transport.

SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

Changes regarding to the previous version:

- Changes in the information of the supplier (SECTION 1.3).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards On basis of test data

Health hazards Calculation method

Environmental hazards Calculation method

It is recommended that the product only be employed for the purposes advised.

Risk classification system NFPA 704:

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93289-Capsules 0 white

Version 1 Date of compilation: 21/12/2022

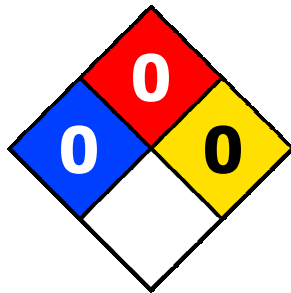
Version 3 (replaces version 2)

Revision date: 27/05/2025



Page 7 of 7

Print date: 27/05/2025



Health hazard: 0 (Normal Material)

Flammability: 0 (Will not burn)

Reactivity: 0 (Stable)

Abbreviations and acronyms used:

CEN: European Committee for Standardization.

PPE: Personal protection equipment.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2020/878.

Regulation (EC) No 1907/2006.

Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.