

SAFETY DATA SHEET

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

94201-Cystine-L

Version 1 Date of compilation: 3/12/2015

Version 7 (replaces version 6)

Revision date: 29/04/2024

Page 1 of 8

Print date: 29/04/2024



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

1.1 Product identifier.

Product Name: Cystine-L
Product Code: 94201

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

Excipient pharmaceutical use
Oral 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 esta 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.
The substance does not meet the criteria for identification as PBT or vPvB in accordance with Annex XIII of REACH.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Not applicable.

3.2 Mixtures.

Substances posing a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, assigned a Community exposure limit in the workplace, and classified as PBT/vPvB or included in the Candidate List:

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 56-89-3 EC No: 200-296-3 Registration No: 01-2119959856-16-XXXX	Cystine	90.0%	-	-

-Continued on next page.-

SAFETY DATA SHEET

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

94201-Cystine-L

Version 1 Date of compilation: 3/12/2015

Version 7 (replaces version 6)

Revision date: 29/04/2024



Page 2 of 8

Print date: 29/04/2024

(*) The complete text of the H phrases is given in section 16 of this Safety Data Sheet.

SECTION 4: FIRST AID MEASURES.

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.

-Continued on next page.-

SAFETY DATA SHEET

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

94201-Cystine-L



Version 1 Date of compilation: 3/12/2015

Version 7 (replaces version 6)

Revision date: 29/04/2024

Page 3 of 8

Print date: 29/04/2024

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.

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.

Respiratory protection is necessary for: dust formation. Filter type: P1 (DIN EN 149)

Hand protection: wear suitable gloves

Fitting Material: NBR (Nitrile Rubber)

Material thickness: 0.11mm

Drilling time: >480 min

Eye protection: Tightly sealed goggles.

Skin and body protection: Wear suitable protective clothing.

General protection and hygiene measures: Change soaked clothing immediately. Before handling the product, apply protective skin cream. Before taking breaks and finishing work, wash your hands and face well, and shower if necessary.

Information on environmental regulations: Do not pour waste down the drain.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Solid

Colour: White

Odour: Characteristic

Odour threshold: Not available

Melting point: Decomposes before melting °C

Freezing point: Not applicable

-Continued on next page.-

SAFETY DATA SHEET

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

94201-Cystine-L

Version 1 Date of compilation: 3/12/2015

Version 7 (replaces version 6)

Revision date: 29/04/2024



Page 4 of 8

Print date: 29/04/2024

Boiling point or initial boiling point and boiling range: Not applicable
Flammability: Not available
Lower explosion limit: Not available
Upper explosion limit: Not available
Flash point: Not available
Auto-ignition temperature: Not available
Decomposition temperature: >210 °C
pH: Not applicable/Not available due to the nature/properties of the product
Kinematic viscosity: Not available
Solubility: Not available
Hydrosolubility: 0,12 kg/m³
Liposolubility: Not available
Partition coefficient n-octanol/water (log value): -4.34
Vapour pressure: Not available
Absolute density: Not available
Relative density: 1.66
Relative vapour density: Not available
Particle characteristics: Not available

9.2 Other information

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

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

Decomposition begins at temperatures of: 210°C

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.

It does not decompose if it is put to its intended uses. Hazardous decomposition products: Nitrogen oxides, carbon monoxide, carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION.

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

Toxicological information about the substances present in the composition.

Name	Acute toxicity			
	Type	Test	Kind	Value
Cystine	Oral	LD50	rat male/female	> 25000 mg/kg bw (72 h) [1] [1] Acute toxicity test of Cystenosine and its constituent ingredients inosine and cystine in rats, 1978. OECD Guideline 401 (Acute Oral Toxicity)
	Dermal	LD50	rat male/female	> 2 000 mg/kg bw (24 h) [1]

-Continued on next page.-

SAFETY DATA SHEET

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

94201-Cystine-L



Version 1 Date of compilation: 3/12/2015

Version 7 (replaces version 6)

Revision date: 29/04/2024

Page 5 of 8

Print date: 29/04/2024

CAS No: 56-89-3 EC No: 200-296-3		[1] study report, 2012. OECD Guideline 402 (Acute Dermal Toxicity)
	Inhalation	

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;

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.

Name	Ecotoxicity			
	Type	Test	Kind	Value
Cystine	Fish	LC50	Danio rerio	> 100 mg/L (96 h) [1]
		[1] study report, 2012. OECD Guideline 203 (Fish, Acute Toxicity Test)		
	Aquatic invertebrates	EC50	Daphnia magna	> 100 mg/L (48 h) [1]
CAS No: 56-89-3 EC No: 200-296-3	Aquatic plants	EC50 Pseudokirchneriella subcapitata		> 100 mg/L (72 h) [1]
		[1] study report, 2011. OECD Guideline 201 (Alga, Growth Inhibition Test)		

12.2 Persistence and degradability.

-Continued on next page.-

SAFETY DATA SHEET

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

94201-Cystine-L

Version 1 Date of compilation: 3/12/2015

Version 7 (replaces version 6)

Revision date: 29/04/2024



Page 6 of 8

Print date: 29/04/2024

Easily biodegradable

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.

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.

-Continued on next page.-

SAFETY DATA SHEET

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

94201-Cystine-L

Version 1 Date of compilation: 3/12/2015

Version 7 (replaces version 6)

Revision date: 29/04/2024



Page 7 of 8

Print date: 29/04/2024

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).
- Changes in the composition of the product (SECTION 3.2).

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

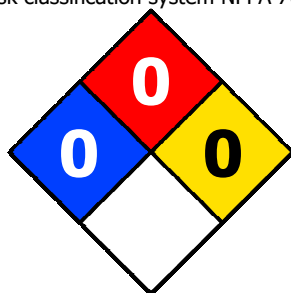
Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

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

Information on the TSCA Inventory (Toxic Substances Control Act) USA:

CAS No	Name	State
56-89-3	Cystine	Registered

Risk classification system NFPA 704:



Health hazard: 0 (Normal Material)

Flammability: 0 (Will not burn)

Reactivity: 0 (Stable)

Abbreviations and acronyms used:

CEN: European Committee for Standardization.
EC50: Half maximal effective concentration.
PPE: Personal protection equipment.
LC50: Lethal concentration, 50%.
LD50: Lethal dose, 50%.

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.

-Continued on next page.-

SAFETY DATA SHEET

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

94201-Cystine-L

Version 1 **Date of compilation: 3/12/2015**

Version 7 (replaces version 6)

Revision date: 29/04/2024

Page 8 of 8

Print date: 29/04/2024



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.