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

1.1 Product identifier

Product name: L-Cystine

> L-Cystinum L-Cystine L-Cystine L-Cystin

N° CAS: 56-89-3 200-296-3 N° EC:

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: Magis-Pharma NV

> Neerlandweg 24 2610 Wilrijk Belgium

Telephone: (+32) (0)3 457 11 76 Email: info@magis-pharma.be Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation: Belgisch Antigifcentrum Centre Antipoisons Belge

Telephone: (+32) (0)70 245 245 (Service 24/7)

www.antigifcentrum.be Web page: www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Not classified.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable. Signal word(s): Not applicable. Hazard statements: Not applicable. Precautionary statements: Not applicable. Additional applicable label Not applicable.

elements:

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2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: L-Cystine

IUPAC name: 2-amino-3-[(2-amino-2-carboxyethyl)disulfanyl]propanoic acid

Synonyms: Cystine

L-Dicysteine

 N° CAS:
 56-89-3

 N° EC:
 200-296-3

 Molecular Formula:
 $C_6H_{12}N_2O_4S_2$

Content: 98.5 per cent to 101.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Consult a doctor. Show the safety data sheet to the doctor in attendance.

After inhalation: Take outdoors. If breathing is irregular, call a doctor immediately. Only apply

artificial respiration if breathing stops or under medical supervision.

After skin contact: Wash immediately with plenty of soap and water for at least 15 minutes. Take off all

contaminated clothing immediately. Get medical attention if irritation develops and

persists.

After eye contact:

Remove contact lenses and rinse immediately with plenty of water, including under

the eyelids, for at least 15 minutes. Get medical attention.

After ingestion:

If conscious, give the victim plenty of water to drink. Never give anything by mouth

After ingestion:

to an unconscious person. DO NOT induce vomiting. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

There are no known acute or delayed effects from exposure to the product. Treat symptomatically.

4.3 Indication of any immediate medical attention and special treatment needed

If in doubt, or if symptoms of discomfort persist, seek medical attention.

Never give anything by mouth to people who are unconscious.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water mist.

Neighbouring fires (containers exposed to fire): Water spray or fog.

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Unsuitable extinguishing media: Direct water jet.

5.2 Special hazards arising from the substance/mixture

Avoid breathing combustion products (carbon dioxide, nitrous gases, cyanides).

5.3 Advice for firefighters

Surrounding fires: Cool containers with water to avoid decomposition of the product

and the development of potential health hazards. Always wear full fire protection. Collect the water that should not enter the sewer. Eliminate the contaminated water used to extinguish and the

remains of the second current regulations.

Protection against fire: Helmet with visor, flame retardant clothing (jacket and trousers with

straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

If vapours or dust are released when breathing, wear respiratory protection. These indications are valid for both workers and emergency workers.

For emergency responders

If vapours or dust are released when breathing, wear respiratory protection. These indications are valid for both workers and emergency workers.

6.2 Environmental precautions

Do not allow product to enter sewers, surface and/or ground water.

6.3 Methods and material for containment and cleaning up

Contain spillage with earth or inert material. Collect most of the material and remove the residue with water jets. Disposal of contaminated material must be carried out in accordance with section 13.

6.4 Reference to other sections

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

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Do not inhale dust. Avoid contact with eyes, skin and clothing.

Personal protection: Do not inhale dust. Avoid contact with eyes, skin and clothing.

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Technical protective measures: Not available. Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any

incompatibilities:

Keep the container tightly closed in a dry and well-ventilated place.

Storage – away from: Store protected from light. Away from strong oxidizing agents.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection: Protective masks and safety glasses according to EN166.

Skin protection: Choose body protection according to the quantity and concentration of the

hazardous substance in the workplace.

Hand protection: Handle with gloves. The selected protective gloves must comply with the

specifications of the EU Directive 89/686/EEC and the standard EN 374 derived from

it. Wash hands before breaks and after finishing work.

Respiratory protection: Where risk assessment shows that air purifying respirators are appropriate, wear

type N95 (USA) or type P1 (EN 143) dust mask. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US)

or CEN (EU).

Thermal hazards: Not determined.

Environmental exposure control

Use in accordance with good working practices, avoiding dispersal of the product into the environment. Notify the competent authorities if the product reaches water courses, sewers, soil or vegetation.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

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Appearance: White or almost white, crystalline powder.

Odour: Odourless
Odour threshold: Not available.

pH: Not available.

Melting/freezing point: > 240 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: > 60 °C

Evaporation rate: Not available. Flammability (solid/gas): Not available. Upper/lower flammability or Not available.

explosive limits:

NOL available

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: Not available.

Solubility: Practically insoluble in ethanol (96 per cent). It dissolves in dilute solutions of alkali

hydroxides.

Solubility in water: Practically insoluble in water.

Partition coefficient Not available.

(n-octanol/water):

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Molecular weight: 240,29 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable if used properly. No special conditions.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Avoid any kind of incorrect handling.

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10.5 Incompatible materials

Keep away from oxidising agents and strongly alkaline or acidic materials to avoid exothermic reactions.

10.6 Hazardous decomposition products

Carbon oxides (Cox).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:

Skin corrosion/irritation:

Not available.

Serious eye damage/irritation:

Respiratory/skin sensitisation:

Not available.

Not available.

Not available.

Not available.

Carcinogenicity: No component of this product is identified as a probable, possible or confirmed

human carcinogen at levels greater than or equal to 0.1%.

Reproductive toxicity: Not available.

Summary of evaluation of the Not available.

CMR properties:

STOT-single exposure: Not available.
STOT-repeated exposure: Not available.
Aspiration Hazard: Not available.
Other: Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:

Skin contact:

Not available.

Inhalation:

Not available.

Not available.

Not available.

Not available.

Not available.

Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Easily biodegradable.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

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Not available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment is not available as chemical safety assessment is not required/has not been performed.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.2 UN proper shipping name

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.5 Environmental hazards

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

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SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.
Risk phrases: Not applicable.
Safety phrases: Not applicable.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR: European Agreement concerning the International Carriage of Dangerous Goods by

Road

CAS: Chemical Abstracts Service (division of the American Chemical Society)

EC (number): European Community (number)

IATA: International Air Transport Association
ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous GoodsIUPAC: International Union of Pure and Applied ChemistryPBT: Persistent, Bioaccumulative and Toxic substance

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

STOT: Specific Target Organ Toxicity
UN (number): United Nations (number)

vPvB: very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.

https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available.

16.7 Notice for user(s)

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The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department FAC SECUNDUM ARTEM NV info@magis-pharma.be