Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

CARBOCISTEINUM

Publication: 21/09/2022
Revision: XX/XX/XXXX
Version: 00

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Carbocisteine Carbocisteinum Carbocisteïne Carbocistéine Carbocistein
N° CAS:	638-23-3
N° EC:	211-327-5

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:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts 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)
Web page:	www.antigifcentrum.be	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 elements:	Not applicable.

2.3 Other hazards

Other hazards not contributing to the classification: Dust may form explosive mixture in air.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Carbocisteine
IUPAC name:	(2R)-2-amino-3-[(carboxymethyl)sulfanyl]propanoic acid
Synonyms:	Carbocysteine Bronchokod Mucolase Siroxyl
N° CAS:	638-23-3
N° EC:	211-327-5
Molecular Formula:	$C_5H_9NO_4S$
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:	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor. Specific treatment. If you feel unwell, seek medical advice (show the label where possible). Never give anything by mouth to an unconscious person.
After inhalation:	Allow breathing of fresh air. Allow the victim to rest. Remove person to fresh air and keep comfortable for breathing.
After skin contact:	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
After eye contact:	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
After ingestion:	Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Not expected to present a significant hazard under anticipated conditions of normal use.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media:	Do not use a heavy water stream.

5.2 Special hazards arising from the substance/mixture

Fire hazard: Dust may form explosive mixture in air.

Hazardous decomposition products in case of fire:

Nitrogen oxides. Carbon monoxide. Carbon dioxide. Sulphur oxides.

5.3 Advice for firefighters

Surrounding fires:	Use water spray or fog for cooling exposed containers. Be careful when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection against fire:	Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove ignition sources. Evacuate unnecessary personnel. Measures in case of dust release: Dust formation: dust mask.

For emergency responders

Remove ignition sources. Equip clean-up crew with proper protection. Emergency procedures: Ventilate area.

6.2 Environmental precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

For containment: Collect spillage.

Methods for cleaning up: On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

Other information : Dispose of materials or solid residues at an authorized site.

6.4 Reference to other sections

See section 8 for exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Do not eat, drink or smoke when using this product.
Personal protection:	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.
Technical protective measures:	Provide good ventilation in process area to prevent formation of vapours.
Handling:	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Separate working clothes from town clothes. Launder separately.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in original container. Keep container closed when not in use.
Conditions for safe storage, including any incompatibilities:	Provide local exhaust or general room ventilation. Comply with applicable regulations. Store at ambient temperature. Store in a well-ventilated place.

Storage – away from:	Store protected from light. Keep away from ignition sources. Incompatible products: Strong bases, strong acids.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

MOEHS OCCUPATIONAL EXPOSURE BAND OEL (8 hours ref) (mg/m^3): 1 (1mg/m^3 – 10 mg/m^3).

8.2 Exposure controls

Appropriate engineering control

Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Dust extraction (suction).

Individual protection measures

Eye/face protection:	Chemical goggles or safety glasses.
Skin protection:	Not available.
Hand protection:	Wear protective gloves. Type: disposable gloves. Material: Polyvinylalcohol (PVA), Butyl rubber, Natural rubber, Polyvinylchloride (PVC), Latex, Vinyl. Standard: EN 374.
Respiratory protection:	Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Dust production: dust mask with filter type P3. Standard: EN 143.
Thermal hazards:	Not available.

Environmental exposure control

Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Characteristic.
Odour threshold:	Not available.
pH:	2.8 to 3.0
Melting/freezing point:	192 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	206 °C (Estimated by ACDLABS)
Evaporation rate:	Not available.
Flammability (solid/gas):	Dust may form explosive mixture in air.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.

Vapour density:	≈ 0.5 g/cm^3
Relative density:	Not available.
Solubility:	Practically insoluble in alcohol. It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	≈ -2.7 Predicted by ALOGPS
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Dust may form explosive mixture in air.
Oxidising properties:	Not available.

9.2 Other information

Minimum ignition energy: 200 mJ

Additional information:
Dust Cloud minimum Flammability Temperature: 360.
Layer Minimum flammability Temperature Melt - Funde
Explosivity Pmax: 7.1
Explosion Severity Factor Kmax (bar m/s): 148
Explosion Class: St1

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable under use and storage conditions as recommended in section 7.

10.2 Chemical stability

The product is stable at normal handling and storage conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5 Incompatible materials

Strong acids. Strong bases.

10.6 Hazardous decomposition products

Fume. Carbon monoxide. Carbon dioxide. Sulphur oxides. Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): 15 000 mg/kg Oral LD50 (mouse): 8 400 mg/kg
Skin corrosion/irritation:	Based on available data, the classification criteria are not met. pH: 2.8 – 3.0

Serious eye damage/irritation:	Based on available data, the classification criteria are not met. pH: 2.8 – 3.0
Respiratory/skin sensitisation:	Based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Carcinogenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.
STOT-single exposure:	Based on available data, the classification criteria are not met.
STOT-repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration Hazard:	Based on available data, the classification criteria are not met.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology - general: The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

12.2 Persistence and degradability

Readily biodegradable. Not established.

12.3 Bioaccumulative potential

Bioconcentration factor (BCF REACH): ≈ 3.162 (logBCF = 0.5; estimated by BCFWIN 2.17)

Log Pow: ≈ -2.7 Predicted by ALOGPS

Bioaccumulative potential: Not established.

12.4 Mobility in soil

Log Koc: ≈ 1.426 Estimated by PCKOCWIN v.1.17)

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Additional information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Regional legislation (waste): Disposal must be done according to official regulations.

Waste treatment methods: Dispose of contents/container in accordance with licensed collector's sorting instructions.

Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

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

Not available.

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 Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	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)

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
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