CARBOCYSTEINE LYSINE SALT

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Reference number: 71450
Issue date: 2/25/2016 Revision date: 4/8/2024 Supersedes version of: 5/11/2020 Version: 8.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	:	Substance
Trade name	:	CARBOCYSTEINE LYSINE SALT
Chemical name	:	S-(Carboxymethyl)-L-cysteine (1:1) L-Lysine monohidrate
IUPAC name	:	(2R)-2-Amino-3-[(carboxymethyl)sulfanyl]propanoic acid;(2S)-2,6-diaminohexanoic acid; hydrate
EC-No.	:	256-425-9
CAS-No.	:	151756-26-2
Product code	:	71450
Type of product	:	Active Ingredient for Medicinal / Pharmaceutical Use
Formula	:	C6H14N2O2.C5H9NO4S
Synonyms	:	Lisica; L-Lysine S-(carboxymethyl)-L-cysteine (1:1) ; (2R)-2-amino-3-(carboxymethyl(sulfanyl))propanoic acid
Other means of identification	:	(C(O)(C(N)CSCC(O)=O)=O).NCCCCC(N)C(O)=O

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

1.2.1. Relevant identified uses

Main use category	:	API,Industrial use,Professional use,Medicinal use
Industrial/Professional use spec	:	Active Ingredient for Medicinal / Pharmaceutical Use Industrial For professional use only
Use of the substance/mixture	:	Mucolytic, Bronchosecretolytic, antibronchospastic

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

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hse@moehs.es - www.moehs.com

1.4. Emergency telephone number

Emergency number	:	+34 93 586 05 20 (9:00 - 17:00)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

May ignite spontaneously if exposed to air. To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

Other hazards which do not result in classification : Dust may form explosive mixture in air.

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
CARBOCYSTEINE LYSINE SALT	CAS-No.: 151756-26-2 EC-No.: 256-425-9	≈ 100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Allow affected person to breathe fresh air. Allow the victim to rest. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after inhalation : None under normal use.

Symptoms/effects after skin contact : Repeated exposure may cause skin dryness or cracking.

Symptoms/effects after eye contact : mild eye irritation.

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

Never give anything by mouth to an unconscious person.

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 or mixture

Fire hazard : May ignite spontaneously if exposed to air.

Hazardous decomposition products in case of fire : Carbon monoxide. Carbon dioxide. Nitrogen oxides.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Isolate from fire, if possible, without unnecessary risk. Remove ignition sources. No flames, no sparks. Eliminate all sources of ignition.

6.1.1. For non-emergency personnel

Protective equipment : Breathing equipment.

Emergency procedures : Evacuate unnecessary personnel. Avoid breathing dust, mist or spray.

Measures in case of dust release : Dust formation: dust mask.

6.1.2. For emergency responders

Protective equipment : Use personal protective equipment as required. Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area. Stop leak if safe to do so. Shovel or sweep up and put in a closed container for disposal.

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. Minimise generation of dust. Store away from other materials.

6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Avoid breathing dust.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Remove contaminated clothes. Separate working clothes from town clothes. Launder separately.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at room temperature. Keep only in the original container in a cool, well ventilated place away from : Direct sunlight, Heat sources. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container closed when not in use.

Incompatible products : Strong bases. Strong acids. Oxidizing agent.

Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

Active Ingredient for Medicinal/Pharmaceutical Use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 1 (> 1 mg/m3)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:
Local exhaust or breathing protection. Dust extraction (suction). 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. Breathing equipment.

8.2.2. Personal protection equipment

Personal protective equipment:
Avoid all unnecessary exposure.

Personal protective equipment symbol(s):

8.2.2.1. Eye and face protection

Eye protection:
Chemical goggles or safety glasses

Eye protection		
Type	**Field of application**	**Standard**
Safety glasses	Dust	EN 166

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Skin and body protection	
Type	**Standard**
Disposable gowns, Reusable gowns, Tyvek® Gown/Coveralls	EN 13034, EN 1149-1

Other skin protection Materials for protective clothing		
Condition	**Material**	**Standard**
Good resistance:	Tyvek®, Polyethylene, Synthetic material	EN 13034, EN ISO 13982-1

8.2.2.3. Respiratory protection

Respiratory protection:
Where exposure through inhalation may occur from use, respiratory protection equipment is recommended

Respiratory protection			
Device	**Filter type**	**Condition**	**Standard**
Dust mask, Full face mask	Type P3	High dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

Other information:
Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	white.
Appearance	:	white to slightly yellow.
Molecular mass	:	≈ 343.4 g/mol
Odour	:	characteristic.
Odour threshold	:	Not available
Melting point	:	177 – 181 °C
Freezing point	:	Not available
Boiling point	:	≈ 417.3 °C at 760mmHg, anhydrous form
Flammability	:	May ignite spontaneously if exposed to air
Explosive properties	:	May ignite spontaneously if exposed to air.
Explosive limits	:	Not applicable
Lower explosion limit	:	≈ 30 g/m³
Upper explosion limit	:	Not applicable
Flash point	:	≈ 206.2 °C
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
pH	:	Not available
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Water: completely soluble Ethanol: Etanol. Practically insoluble
Partition coefficient n-octanol/water (Log Kow)	:	≈ 3.05 Predicted, Lysine Free base
Partition coefficient n-octanol/water (Log Pow)	:	≈ 2.7 Predicted, S-Carboxymethyl-L-cysteine
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not applicable
Particle size	:	Not available
Particle size distribution	:	Not available
Particle shape	:	Not available
Particle aspect ratio	:	Not available
Particle aggregation state	:	Not available
Particle agglomeration state	:	Not available
Particle specific surface area	:	Not available
Particle dustiness	:	Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Minimum ignition energy : ≈ 840 mJ
Additional information : Layer Minimum flammability Temperature : Melt - funde.
Dust Cloud minimum Flammability Temperature :400 º C.
Explosivity Pmax : 7.7 bar.g.
Explosion Severity Factor Kmax (bar.m/s) :108.
Explosion Class : St1

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

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. Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

CARBOCYSTEINE LYSINE SALT (151756-26-2)	
LD50 oral rat	≈ 15000 mg/kg S-Carboxymethyl-L-cysteine, CAS nº 638-23-3 [Scifinder, October 2020]
LD50 Intraperitoneal rat	≈ 7800 mg/kg S-Carboxymethyl-L-cystine, CAS nº 638-23-3, [Scifinder, October 2020]
LD50, subcutaneous, rat	= 10600 mg/kg S-Carboxymethyl-L-cystine (CAS nº 638-23-3, Scifinder, October 2020)
LD50, intraperitoneal, mouse	= 5000 mg/kg S-Carboxymethyl-L-cystine (CAS nº 638-23-3, Scifinder, October 2020)
LD50, oral, mouse	= 8400 mg/kg S-Carboxymethyl-L-cystine (CAS nº 638-23-3, ChemIDplus)
LD50, subcutaneous, mouse	= 9000 mg/kg S-Carboxymethyl-L-cystine (CAS nº 638-23-3, ChemIDplus)

Skin corrosion/irritation : Not classified
Additional information : Based on available data, the classification criteria are not met
Serious eye damage/irritation : Not classified
Additional information : Based on available data, the classification criteria are not met
Respiratory or skin sensitisation : Not classified
Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified
Additional information : Based on available data, the classification criteria are not met
Carcinogenicity : Not classified
Additional information : Based on available data, the classification criteria are not met
Reproductive toxicity : Not classified
Additional information : Based on available data, the classification criteria are not met
STOT-single exposure : Not classified
Additional information : Based on available data, the classification criteria are not met
STOT-repeated exposure : Not classified
Additional information : Based on available data, the classification criteria are not met
Aspiration hazard : Not classified
Additional information : Based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

11.2.2. Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute) : Not classified
Hazardous to the aquatic environment, long–term (chronic) : Not classified

12.2. Persistence and degradability

CARBOCYSTEINE LYSINE SALT (151756-26-2)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

CARBOCYSTEINE LYSINE SALT (151756-26-2)	
Partition coefficient n-octanol/water (Log Pow)	≈ 2.7 Predicted, S-Carboxymethyl-L-cysteine
Partition coefficient n-octanol/water (Log Kow)	≈ 3.05 Predicted, Lysine Free base
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging 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

In accordance with

14.1. UN number or ID number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

Dangerous for the environment : No

Other information : No supplementary information available

14.6. Special precautions for user

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : Conform to current legislation, regulations and orders.

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Water hazard class (WGK)	:	Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	The substance is not listed
SZW-lijst van mutagene stoffen	:	The substance is not listed
SZW-lijst van reprotoxische stoffen – Borstvoeding	:	The substance is not listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid	:	The substance is not listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling	:	The substance is not listed

Denmark

Classification remarks	:	Emergency management guidelines for the storage of flammable liquids must be followed

Switzerland

Storage class (LK)	:	NG - Non-hazardous

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
	non-classified PBT substance
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
IARC	International Agency for Research on Cancer
	NOEL
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
LD50	Median lethal dose
LC50	Median lethal concentration

Data sources	:	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Other information	:	None.

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.