

Material Safety Data Sheet

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

CELIPROLOLI HYDROCHLORIDUM

EN

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Publication: 11/09/2022

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Version: 01



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

1.1 Product identifier

Product name: Celiprolol hydrochloride
Celiprololi hydrochloridum
Celiprolol hydrochloride
Céliprolol (chlorhydrate de)
Celiprololhydrochlorid

N° CAS: 57470-78-7

N° EC: 260-752-2

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)
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

Aquatic Chronic 3 H412

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable.

Signal word(s): Not applicable.

Hazard statements:

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P233 Keep container tightly closed.

P262 Do not get in eyes, on skin, or on clothing.

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P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P273	Avoid release to the environment.
P280	Wear protective gloves, eye protection, face protection.
P314	Get medical advice/attention if you feel unwell.
P501	Dispose of contents/container in a safe manner in accordance with local/national regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Other hazards not contributing to the classification: None under normal conditions.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Celiprolol hydrochloride
IUPAC name:	3-[3-acetyl-4-[3-(<i>tert</i> -butylamino)-2-hydroxypropoxy]phenyl]-1,1-diethylurea hydrochloride
Synonyms:	Celiprolol HCl Selectol
N° CAS:	57470-78-7
N° EC:	260-752-2
Molecular Formula:	C ₂₀ H ₃₄ ClN ₃ O ₄
Content:	99.0 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:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
After inhalation:	Allow affected person to breathe fresh air. Allow the victim to rest.
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. If you feel unwell, seek medical advice.

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

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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: Carbon dioxide. fume. Carbon monoxide. Nitrogen oxides.

5.3 Advice for firefighters

Surrounding fires: 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 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

Evacuate unnecessary personnel.

For emergency responders

Equip cleanup crew with proper protection. Ventilate area.

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and 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.

Personal protection: Not available.

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Technical protective measures:

Not available.

Handling:

Do not eat, drink or smoke when using this product. Wash contaminated clothing before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Keep only in the original container in a cool, well-ventilated place. Store at room temperature. Keep container closed when not in use.

Storage – away from:

Protected from light.

Incompatible products: Strong bases. Strong acids.

Incompatible materials: Sources of ignition. Direct sunlight.

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: 2 (0.1-1 mg/m³)

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Avoid all unnecessary exposure.

Eye/face protection:

Chemical goggles or safety glasses.

Skin protection:

Not determined.

Hand protection:

Type: disposable gloves.

Material: Nitrile rubber (NBR), Polyvinylalcohol (PVA), Butyl rubber, Natural rubber, Polyvinylchloride (PVC), Latex.

Standard: EN 374

Respiratory protection:

Device: dust mask

Filter type: type P3

Standard: EN 134

Thermal hazards:

Not determined.

Environmental exposure control

Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:

White or very slightly yellow, crystalline powder.

Odour:

Characteristic.

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Odour threshold:	Not available.
pH:	6 - 8 (15% in water)
Melting/freezing point:	197 - 200 °C [Scifinder]
Initial boiling point:	586.5 °C (at 760mmHg)
Boiling range:	Not available.
Flash point:	308.5 °C
Evaporation rate:	Not available.
Flammability (solid/gas):	May form combustible dust concentrations in air.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	1.114 g/cm ³
Relative density:	Not available.
Solubility:	Freely soluble in methanol, soluble in ethanol (96%), very slightly soluble in methylene chloride. Etanol: 1.61 (at 25 °C in g/mL) Chloroform: 0.42 (at 25 °C in g/mL) Methanol: 18.2 (at 25 °C in g/mL)
Solubility in water:	Freely soluble in water. 15.1 g/100ml (at 25 °C)
Partition coefficient (n-octanol/water):	Log Pow: 0.8 [37 °C; Mazzo, D.J. et al., 1991]
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 mass:	416 g/mol
Layer Minimum flammability Temperature:	Melt.
Dust Cloud minimum Flammability Temperature:	460 °C
Minimum ignition energy:	26 mJ
Explosion Class:	St2
Minimum Explosive Concentration:	30 g/m ³
Explosivity Pmax:	8.3 bar·g

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Explosion Severity Factor 254
Kmax (bar.m/s):

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

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

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.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute toxicity (oral):	Not classified.
	Acute toxicity (dermal):	Not classified.
	Acute toxicity (inhalation):	Not classified.
	LD ₅₀ oral rat	3826 mg/kg [Scifinder]
	LD ₅₀ oral	1834 mg/kg [Mouse; Scifinder]
	LD ₅₀ , intravenous, rat	68.3 mg/kg [Scifinder]
	LD ₅₀ , intravenous, mouse	56.2 mg/kg [Scifinder]
Skin corrosion/irritation:	LD ₅₀ , subcutaneous, rat	754 mg/kg [ChemIDplus]
	Not classified	
	pH: 6 - 8 (15% in water)	
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.	
	Not classified	
	pH: 6 - 8 (15% in water)	
Respiratory/skin sensitisation:	Based on available data, the classification criteria are not met.	
	Not classified.	
	Based on available data, the classification criteria are not met.	
Germ cell mutagenicity:	Not classified.	
	Based on available data, the classification criteria are not met	
	Genetic Toxicity: (Study Type, Cell Type/Organism, Result)	

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	Bacterial Mutagenicity (Ames) Negative Mammalian Cell Mutagenicity Negative
Carcinogenicity:	Not classified. Based on available data, the classification criteria are not met.
Reproductive toxicity:	Not classified. Based on available data, the classification criteria are not met <u>Repeated Dose Toxicity</u> 12 Month(s) Dog Oral 10 mg/kg/day NOAEL Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s)) Reproductive & Fertility Rat 320 mg/kg/day NOAEL Fertility Embryo / Fetal Development Rat 320 mg/kg/day NOAEL Fetotoxicity, Not <u>Teratogenic</u> Embryo / Fetal Development Rat Oral 600 mg/kg/day LOAEL Maternal Toxicity Embryo / Fetal Development Rabbit Oral 54
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not classified. Based on available data, the classification criteria are not met.
STOT-repeated exposure:	Not classified. Based on available data, the classification criteria are not met.
Aspiration Hazard:	Not classified. Based on available data, the classification criteria are not met.
Other:	Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met. Overexposure may cause headache, cold extremities and fatigue. This product is rapidly absorbed from the gastrointestinal tract.

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

Acute aquatic toxicity: Not classified. Chronic aquatic toxicity: Not classified.

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Log Pow: 0.8 [37°C; Mazzo, D.J. et al., 1991]

Bioaccumulative potential: weak

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12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Other adverse effects: WGK Germany: 1 - Low hazard to waters.

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

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

14.1 UN Number

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

ADR/ Dangerous for the environment: No.
RID(Land),IMDG(Sea), Marine pollutant: No.
IATA/ICAO (Air) :

14.6 Special precautions for user

Not applicable.

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

Not applicable.

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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: R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases: S7 Keep container tightly closed.
S20/21 When using do not eat, drink or smoke.
S24/25 Avoid contact with skin and eyes.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
S51 Use only in well-ventilated areas.
S61 Avoid release to the environment. Refer to special instructions/safety data sheet.

15.2 Chemical safety assessment

No chemical safety assessment has 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 Bioaccumulative

16.3 Key literature references/sources for data

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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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