

Prilocaine

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Revision date: 08/12/2023 Supersedes version of: 03/04/2023 Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Prilocaine
Chemical name : Prilocaine
Product code : 201600752

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

1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.
Use of the substance/mixture : For professional use only
Function or use category : Laboratory chemicals

1.2.2. Uses advised against

Restrictions on use : Do not use : Ingestion, Inhalation, Dermal

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe 7, Allée Kastner, CS30026
F- 67081 Strasbourg
France
T +33(0)388412035 - F +33(0)388412771
sds@edqm.eu - www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Acute toxicity (oral), Category 4	H302
Serious eye damage/eye irritation, Category 1	H318
Specific target organ toxicity – Single exposure, Category 3, Narcosis	H336
Hazardous to the aquatic environment – Chronic Hazard, Category 3	H412

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS05

GHS07

Signal word (CLP) : Danger
Hazard statements (CLP) : H302 - Harmful if swallowed.
H318 - Causes serious eye damage.
H336 - May cause drowsiness or dizziness.
H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements (CLP) : P261 - Avoid breathing dust.
P264 - Wash hands, forearms and face thoroughly after handling.

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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/protective clothing/eye protection/face protection/hearing protection.
P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER or doctor.
P312 - Call a POISON CENTRE or doctor if you feel unwell.
P330 - Rinse mouth.
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

Hazard pictograms (CLP) :



GHS05

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Prilocaine	-	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Dam. 1, H318 STOT SE 3, H336 Aquatic Chronic 3, H412

Full text of H- and EUH-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Immediately flush the contact area with plenty of water.
First-aid measures after inhalation : Move to fresh air. Allow affected person to breathe fresh air. Immediate medical attention and special treatment, if necessary.
First-aid measures after skin contact : Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent. Flush with lukewarm water for 15 minutes. Get medical advice if skin irritation persists.
First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation persists, consult an eye specialist.
First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Specific medical surveillance.

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

Symptoms/effects	: Causes burns.
Symptoms/effects after inhalation	: Insufficient data available. May cause shortness of breath, tightness of the chest, a sore throat and cough.
Symptoms/effects after skin contact	: Insufficient data available. Redness, pain.
Symptoms/effects after eye contact	: Insufficient data available. Redness, pain.
Symptoms/effects after ingestion	: Burns to the gastric/intestinal mucosa. Symptoms may include dizziness, headache, nausea and loss of coordination.

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

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active substance. Pharmaceutical.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Extinguishing blanket.

5.2. Special hazards arising from the substance or mixture

Fire hazard : See Heading 2.2. Beware, risk of formation of toxic and corrosive gases.

5.3. Advice for firefighters

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

Protective equipment : See Section 8.

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Ensure waste is collected and contained. Clean thoroughly. Material should be handled with caution. In aqueous medium : Corrosive to eyes, respiratory system and skin.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended. In aqueous medium : Corrosive to eyes, respiratory system and skin.
Precautions for safe handling	: Material should be handled with caution. Avoid any direct contact with the product.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety procedures.

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7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.
Storage conditions : Store locked up.

7.3. Specific end use(s)

See Heading 1.

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

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Safety glasses. DIN EN 166

8.2.2.2. Skin protection

Skin and body protection:

Use chemically protective clothing. DIN EN 13034

Hand protection:

Chemically resistant protective gloves. ISO 374-1

8.2.2.3. Respiratory protection

Respiratory protection:

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

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Colour	: Not available
Appearance	: Powder.
Odour	: Not applicable.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 1 – 10 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
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

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

None under normal use. See Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Harmful if swallowed.

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Acute toxicity (dermal) : Not classified (Lack of data)
Acute toxicity (inhalation) : Not classified (Lack of data)

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LD50 oral rat	> 300 – ≤ 2000 mg/kg (estimated value)
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Skin corrosion/irritation : Not classified (Lack of data)
Serious eye damage/irritation : Causes serious eye damage.
Respiratory or skin sensitisation : Not classified (Lack of data)
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity : Not classified (Inconclusive data)
Reproductive toxicity : Not classified (Inconclusive data)
STOT-single exposure : May cause drowsiness or dizziness.
STOT-repeated exposure : Not classified (Lack of data)
Aspiration hazard : Not classified (Technical impossibility to obtain the data)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Hazardous waste. Use suitable disposal containers.
Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic) : Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

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

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional waste regulation : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

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ADR	IMDG	IATA
14.1. UN number or ID number		
Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name		
Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)		
Not applicable	Not applicable	Not applicable
14.4. Packing group		
Not applicable	Not applicable	Not applicable
14.5. Environmental hazards		
Not applicable	Not applicable	Not applicable
No supplementary information available		

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

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

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 applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

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)

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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

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Reason for no classification	Added	
	Supersedes version of	Added	
	Revision date	Added	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Precautionary statements (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	
2.2	Signal word (CLP)	Modified	
2.2	Hazard pictograms (CLP)	Modified	
4.1	First-aid measures general	Added	
4.1	First-aid measures after inhalation	Added	
4.1	First-aid measures after ingestion	Added	
4.1	First-aid measures after skin contact	Modified	
4.1	First-aid measures after eye contact	Modified	
4.2	Symptoms/effects after ingestion	Added	
4.2	Symptoms/effects	Added	
4.2	Symptoms/effects after eye contact	Added	
4.2	Symptoms/effects after inhalation	Added	
4.2	Symptoms/effects after skin contact	Added	
4.3	Other medical advice or treatment	Added	
5.2	Fire hazard	Modified	
6.1	Protective equipment	Added	
6.1	General measures	Added	
6.3	Methods for cleaning up	Added	
7.1	Additional hazards when processed	Added	
7.1	Precautions for safe handling	Added	
7.1	Hygiene measures	Added	
7.2	Technical measures	Added	
7.2	Storage conditions	Added	
8.2	Respiratory protection	Added	

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Indication of changes			
Section	Changed item	Change	Comments
8.2	Eye protection	Added	
8.2	Hand protection	Modified	
8.2	Appropriate engineering controls	Modified	
8.2	Skin and body protection	Modified	
9.1	Odour	Added	
11.1	Reason for no classification	Added	
11.1	LD50 oral rat	Added	
11.1	Reason for no classification	Added	
11.1	ATE CLP (oral)	Added	
12.1	Ecology - general	Modified	
13.1	Regional waste regulation	Added	

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H302	Harmful if swallowed.
H318	Causes serious eye damage.
H336	May cause drowsiness or dizziness.
H412	Harmful to aquatic life with long lasting effects.
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.