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

· **Informations to product No. 5540**

· **Product name:**

Prilocainhydrochlorid, API

Prilocaini hydrochloridum

Prilocaine hydrochloride

· **Supplier of the Product / responsible Company:**

Caesar & Loretz GmbH

Herderstr. 31

40721 Hilden

Tel.: 02103/4994-0

Fax: 02103/32360

e-mail: info@caelo.de

· **Emergency telephone:**

Giftinformationszentrum Mainz

Langenbeckstr. 1, 55131 Mainz

Tel.: 06131/19240

· **Relevant identified uses of the substance or mixture and uses advised against:**

No further relevant information available.

· **Application of the substance / mixture:**

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

2 Hazards identification

· **GHS-Labeling Elements:**



· **Signal word:** Warning

· **H-Phrases:**

H302 Harmful if swallowed.

H315 Causes skin irritation

H319 Causes serious eye irritation.

H412 Harmful to aquatic life with long lasting effects.

· **P-Phrases:**

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P273 Avoid release to the environment

P305 IF IN EYES:


P351 Rinse continuously with water for several minutes

P301 IF SWALLOWED:

P312 Call a POISON CENTER or doctor/physician if you feel unwell

Acute Tox.: 4

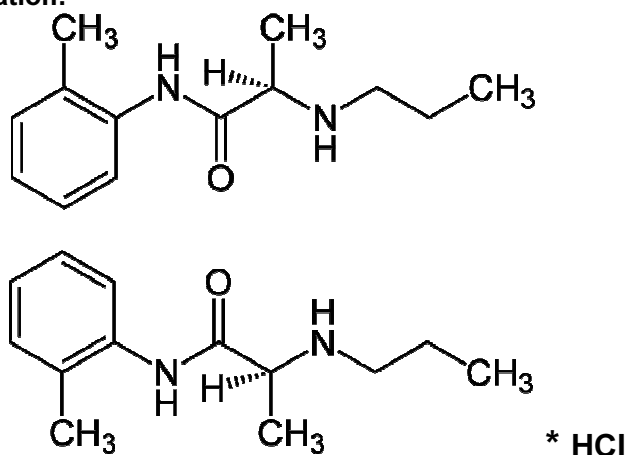
Skin Irrit. 2

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Eye Irrit.: 2
Aquatic Chronic: 3

3 Composition / information on ingredients

• **Chemical characterization:**




CAS-No. Substance name
 1786-81-8 Prilocaine hydrochloride
 • **EINECS-No.:** 217-244-0
 • **REACH Reg. No.:** -
 • **INCI-Name:** -

4 First aid measures

- **after inhalation:** Fresh air. Seek medical advice.
- **after skin contact:** Take off contaminated clothes and shoes, wash immediately with plenty of water and soap.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open.
- **after swallowing:** Seek medical advice immediately

5 Fire-fighting measures

- **Suitable extinguishing media:** . All regular extinguishing media can be used. Select fire fighting measures suitable to surrounding environment.
- **Specific hazards during fire fighting:** Combustible. In case of fire dangerous vapours/gases can be generated: Nitrogen oxides.
- **Special protective equipment for fire-fighters:** Suitable protective clothes and respiratory protection.
- **Additional information:** Prevent fire extinguishing water from contaminating surface water, the ground water system or soil. Residues must be deposited according to local regulations.

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6 Accidental release measures

- **Personal protective measures:** Avoid contact with substance.
- **Environmental protective measures:** Prevent from entering into surface water, the ground water system or soil.
- **Methods for cleaning:** Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water.

7 Handling and storage

- **Handling:** No special requirements.
- **Advice on safe handling:** Ensure good ventilation/exhaustion at the workplace. Handling corresponding to laboratory safety guidelines.
- **Informations to fire or explosion protection:** No special measures required.
- **Storage:**
- **Requirements for storage areas and containers:** Tightly closed. Store at a dry place.
- **Advices on common storage:** Not required.

8 Exposure controls / personal protective equipment


- **Personal protective equipment:**
- **General protective and hygiene measures:**
Keep away from food, beverages and animal food.
Wash hands before breaks and after work.
- **Respiratory protection:** Dust protection mask.
- **Hand protection:** Protection gloves of rubber or latex
- **Eye protection:** Safety glasses

9 Physical and chemical properties

- **Form:** solid
- **Colour:** white – light yellow
- **Odour:** nearly odourless
- **Melting point / melting range:** 167 - 169 °C
- **Boiling point / boiling range:** not determined
- **Flash point:** not determined
- **Flammability (solid, vapours):** The product is not flammable.
- **Solubility in / Miscibility with**
- **Water:** (20 °C) ca. 200 g/l
- **pH-value:** (1%, 20 °C) 4,7

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:** Avoid strong heating.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** None.

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11 Toxicological information

- **Acute toxicity:**

LD/LD50-data relevant for hazard classification:

LD50 (oral, rat): 300-2000 mg/kg (OECD 423)

Primary irritant effect:

Skin irritation: Irritant

Serious eye irritation

12 Ecological information

- **Ecotoxicity:** Acute harmful for water organisms.

Toxicity for fishes: No quantitative data available.

- **Persistence and degradability**

Not readily biodegradable: >60%.

- **Bioaccumulative potential**

Bioaccumulation in organisms is not likely.

- **Log pOW:** 2,12 (25 °C)

• **Water hazard class:** 2 (self classification): hazardous for water.

13 Disposal considerations

- **Product:**

• **Recommendation:** Disposal according to local regulations as pharmaceutical waste.

- **Empty contaminated packaging:**

• **Recommendation:** Disposal according to the local regulations.

14 Transport informations

- **Land transport according to ADR:**

Not classified as dangerous in the meaning of transport regulations.

15 Regulatory information

- **Labelling according to actual legislation (GHS, Globally Harmonized System of Classification and Labelling of Chemicals):**

The product is classified and labelled according to GHS-regulations.

- **Hazard symbols:** GHS07

- **Signal word:** Warning

- **H-Phrases:**

H302 Harmful if swallowed.

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H412 Harmful to aquatic life with long lasting effects.

- **P-Phrases:**

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• **National regulations (Germany):**

• **Water hazard class:** see chapter 12

• **Storage class TRGS 510:** 11

16 Other Information

The information provided in this MSDS is correct to the best of our knowledge at the date of edition.

• **Reason for last revision:** Adjustment to regulation (EC) 1907/2006 (REACH) and GHS-labelling system.