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

· **Informations to product No. 5732**

· **Product name:**

Ropivacainhydrochlorid-Monohydrat, API Ropivacaini hydrochloridum monohydricum

· **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:** Danger

· **H-Phrases:**

H318 Causes serious eye damage

· **P-Phrases:**

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

P305 IF IN EYES:

P351 Rinse continuously with water for several minutes


Eye Dam. 1

3 Composition / information on ingredients

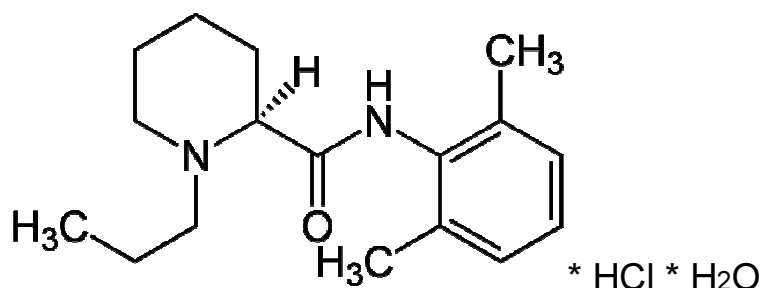
· **Chemical characterization:**

CAS-No. Substance name

132112-35-7 Ropivacaine hydrochloride monohydrate

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- **EINECS-No.:** 663-286-1
- **REACH Reg. No.:** (not registered)
- **INCI-Name:** -



4 First aid measures

- **General advices:** Take off contaminated clothes immediately.
- **after inhalation:** Fresh air. Assure medical help immediately.
- **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. Call in ophthalmologist, even if no immediate symptoms are observed.
- **after swallowing:** Rinse mouth, 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: Hydrogen chloride.
- **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.

6 Accidental release measures

- **Personal protective measures:** Avoid contact with substance, Wear protective equipment. Good ventilation of working place.
- **Environmental protective measures:** Prevent from entering into drains.
- **Methods for cleaning:** Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water, Avoid dust formation.

7 Handling and storage

- **Handling:** Avoid dust formation.
- **Advice on safe handling:** Ensure good ventilation/exhaustion at the workplace. Handling corresponding to laboratory safety guidelines.

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- **Informations to fire or explosion protection:** Avoid dust formation.
- **Storage:**
- **Requirements for storage areas and containers:** Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).
- **Advices on common storage:** None.
- **Additional informations to storage conditions:** Keep container tightly closed.

8 Exposure controls / personal protective equipment

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

9 Physical and chemical properties


- **Form:** solid
- **Colour:** white
- **Odour:** nearly odourless
- **Melting point / melting range:** ca. 270 °C
- **Boiling point / boiling range:** not determined (Decomposition)
- **Explosion hazard:** not explosive.
- **Solubility in / Miscibility with**
- **Water:** (20 °C) soluble
- **pH-range:** Not determined (slightly acid)

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:** No decomposition during appropriate use.
- **Materials to avoid:** Strong oxidizers, strong acids and bases.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** none

11 Toxicological information

- **Acute toxicity:**
Quantitative toxicological data for this product are not available.
- **Primary irritant effect:**
- **on skin:** slightly irritant with local anaesthetic effect.
- **on eyes:** Irritant effect with danger of serious eye damage.
- **Sensitization:** no sensitizing effect known.

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12 Ecological information

- **Aquatic toxicity:**

Quantitative ecotoxicological data for this product are not available.
Not acute harmful for water organisms.

- **log p(O/W):** 3,169

- **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:** GHS05

- **Signal word:** Danger

- **H-Phrases:**

H318 Causes serious eye damage

- **P-Phraes:**

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

P305 IF IN EYES:

P351 Rinse continuously with water for several minutes

- **National regulations (Germany):**

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

• **Storage class TRGS 510:** 8A

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.