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

· **Informations to product No. 2555**

· **Product name:**

Promethazinhydrochlorid, API Promethazini hydrochloridum

· **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

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation

H332 Harmful if inhaled

H335 May cause respiratory irritation

H411 Toxic to aquatic life with long lasting effects.

· **P-Phrases:**


P260 Do not breathe dust/fume/gas/mist/vapours/spray

P305 IF IN EYES:

P351 Rinse continuously with water for several minutes

P313 Get medical advice/attention

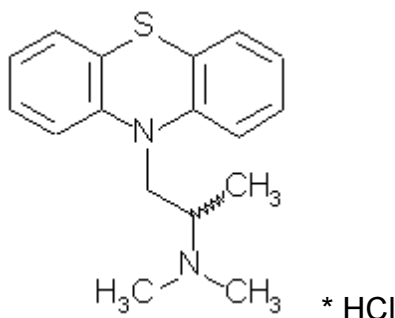
P273 Avoid release to the environment

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Acute Tox. 4
Skin Irrit. 2
Eye Irrit. 2
Skin Sens. 1
STOT SE: 3
Aquatic Chronic: 2

3 Composition / information on ingredients

• **Chemical characterization:**



CAS-No. Substance name

58-33-3 (+-)-Promethazinhydrochlorid


- **EINECS-No.:** 200-275-2
- **REACH Reg. No.:** (pre-registered)
- **INCI-Name:** -

4 First aid measures

- **after inhalation:** Fresh air. If feeling unwell continuously 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 , seek medical advice.
- **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 but not flammable. In case of fire dangerous gases / vapours can be released: Smoke gases, 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.

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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.
- **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:** Not required.
- **Additional informations to storage conditions:** Keep container tightly closed.

8 Exposure controls / personal protective equipment


- **Personal protective equipment:**
- **General protective and hygiene measures:**
Take off contaminated clothes immediately.
Wash hands before breaks and after work.
- **Respiratory protection:** Dust protection mask.
- **Hand protection:** Protection gloves.
- **Eye protection:** Safety glasses.

9 Physical and chemical properties

- **Form:** solid
- **Colour:** white
- **Odour:** odourless
- **Melting point / melting range:** 230 - 232 °C
- **Boiling point / boiling range:** not determined
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** readily soluble

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:**
No decomposition during appropriate use.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** Hydrogen chloride.

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11 Toxicological information

- **Acute toxicity:**
LD50 (oral, Mouse): 255 mg/kg
LD50 (oral, Rat): 765 mg/kg
- **Primary irritating effect:**
- **on skin:** Strong irritations.
- **on eyes:** Irritant effect.

12 Ecological information

- **Ecotoxicological data:**
EC50 Fische: 2 mg/l/96h
EC50 (Daphnia magna, 48h): 1,5 mg/l
- **Biodegradation:** (28d) 2%, not readily biodegradable.
- **Water hazard class (german regulation):** WGK 2 (Self classification): hazardous for water.
- **General advices:** Prevent from leaking into ground water, environment waters or drainage.

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, GHS09
- **Signal word:** Warning
- **H-Phrases:**
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P273 Avoid release to the environment

• **National regulations (Germany):**

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

• **Storage class TRGS 510:** 6.1C

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.