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

- **Informations to product No. 4820**
- **Product name:**

Buprenorphinhydrochlorid, API

- **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
H361 Suspected of damaging fertility or the unborn child

- **P-Phrases:**

P202 Do not handle until all safety precautions have been read and understood
P301 IF SWALLOWED
P313 Get medical advice/attention

Acute Tox. 4

Repr. 2

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3 Composition / information on ingredients

· **Chemical characterization:**

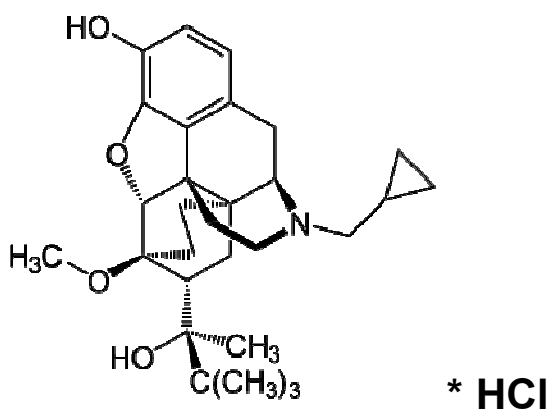
CAS-No. Substance name

53152-21-9 Buprenorphinhydrochlorid

· **EINECS-No.:** 258-396-8

· **REACH Reg. No.:** (pre-registered)

· **INCI-Name:** -



4 First aid measures


- **after inhalation:** Bring the person out of the contaminated area to fresh air, Seek medical help immediately. Show product-label or this MSDS.
- **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.
- **after swallowing:** Drink plenty of water. Induce vomiting. 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.
- **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:** Exhaustion of dust.
- **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.

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7 Handling and storage

- **Handling:**
- **Advice on safe handling:** Wear protective equipment (See chapter 8).
- **Storage:**
- **Requirements for storage areas and containers:** Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C). Protect from light.
- **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 latex or rubber.
- **Eye protection:** Safety glasses.

9 Physical and chemical properties


- **Form:** solid
- **Colour:** white crystalline powder
- **Odour:** Odourless
- **Melting point / melting range:** 268 °C
- **Boiling point / boiling range:** not determined
- **Solubility in / Miscibility with**
- **Water:** (20 °C) ca. 20 g/l
- **pH-range:** (10 g/l, 20 °C) 4 - 6

10 Stability and reactivity

- **Hazardous decomposition products:**
At high temperatures irritant or harmful vapours are released.

11 Toxicological information

- **Acute toxicity:**
- LD/LD50-data relevant for hazard classification:**
- TDLO: (oral, Mensch): 2,86 mg/kg
- LD50: (oral, Rat): >1000 mg/kg
- LD50: (s.c., Rat): >1000 mg/kg
- LD50: (i.v., Rat): 62 mg/kg
- LD50: (i.m., Rat): > 600 mg/kg
- LD50: (oral, Mouse): 800 mg/kg
- LD50: (i.m., Mouse): > 600 mg/kg
- LD50: (s.c., Mouse): >1000 mg/kg

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LD50: (i.v., Mouse): 72 mg/kg

- **Primary irritant effect:**
- **on skin:** Slightly irritant.
- **on eyes:** Slightly irritant.
- **Additional toxicological informations:** Systemic effects: Illness, Respiratory insufficiency. Führt zu Fatigue, Dizziness, Inconsciousness. No indications of carcinogene effect known. Can be reproduction toxic. The product is not completely examined.

12 Ecological information

- **Ecotoxic effects:**
Quantitative ecotoxicological data for this product are not available.
- **General advices:** Prevent from leaking into ground water, environment waters or drainage.
- **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:** GHS08, GHS07
- **Signal word:** Danger
- **H-Phrases:**
H302 Harmful if swallowed
H361 Suspected of damaging fertility or the unborn child
- **P-Phrases:**
P202 Do not handle until all safety precautions have been read and understood
P301 IF SWALLOWED
P313 Get medical advice/attention
- **National regulations (Germany):**
- **Water hazard class:** see chapter 12
- **Storage class TRGS 510:** 6.1C

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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.