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

- **Informations to product No. 5675**
- **Product name:**

### **Naloxonhydrochlorid-Dihydrat, API** Naloxoni hydrochloridum dihydricum

- **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:**

H315 Causes skin irritation  
H319 Causes serious eye irritation  
H335 May cause respiratory irritation


- **P-Phrases:**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray  
P305 IF IN EYES:  
P351 Rinse continuously with water for several minutes

**Skin Irrit. 2**

**Eye Irrit. 2**

**STOT SE 3**

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### 3 Composition / information on ingredients

**CAS-No. Substance name**

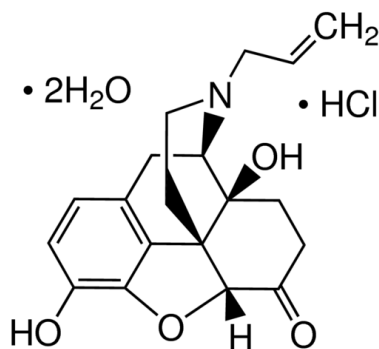
51481-60-8 Naloxonhydrochlorid-Dihydrat

• **EINECS-No.:** 206-611-0

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

• **INCI-Name:** -

• **Chemical characterization:**



### 4 First aid measures


- **after inhalation:** Fresh air or oxygen. If feeling unwell continuously seek medical advice.
- **after skin contact:** Take off contaminated clothes and shoes, wash immediately with plenty of water and soap. If irritation continues seek medical advice immediately.
- **After eye contact:** Rinse out with plenty of water with the eyelid wide open. Call in ophthalmologist.
- **after swallowing:** Drink water. Induce vomiting. Seek medical advice.

### 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: 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:** Good ventilation of working place. Avoid inhalation of dust. Avoid contact with substance. Do not smoke. Protective equipment: Protection gloves of Latex or PVC
- **Environmental protective measures:** Prevent substance from entering into drainage ditch, surface waters, ground water and flowing waters.

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- **Methods for cleaning:** Take up dry. Avoid contact with substance.

## 7 Handling and storage

- **Handling:**

- **Precautions for safe handling**

Ensure good ventilation / exhaustion at the workplace. Avoid formation of dust. Dust / smoke / mist not breathe, protect from heat, sparks and open flames. Avoid contact with skin and eyes. Put on breathing apparatus. Work only in fume cupboard.

- **Informations to fire or explosion protection:** Protect from heat. Eliminate all sources of ignition. In empty containers may form explosive mixtures. The product is combustible

- **Storage:**

- **Requirements for storage areas and containers:** Tightly closed. Store at a dry place. At room temperature ( +15°C to +25°C ).

- **Additional informations to storage conditions:** Keep container tightly closed. Protect from light.

## 8 Exposure controls / personal protective equipment

- **Personal protective equipment:**

- **General protective and hygiene measures:**

Wash hands before breaks and after work. Avoid inhalation of dust. Avoid contact with eyes and skin.

- **Respiratory protection:** Dust protection mask.

- **Hand protection:** Protection gloves of latex or PVC.

- **Eye protection:** Safety glasses.

## 9 Physical and chemical properties

- **Form:** solid

- **Colour:** white

- **Odour:** odourless

- **Melting point / melting range:** ca. 125 °C

- **Boiling point / boiling range:** not determined.

- **Explosion hazard:** The product is not explosive, but explosive dust-air-mixtures can be formed.

- **Density:** not determined

- **Solubility in / Miscibility with**

- **Water:** readily soluble

- **Ethanol:** soluble


- **pH-range:** neutral

## 10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:** No decomposition during appropriate use.

- **Hazardous reactions:** Reactions with strong oxidants and acids.

- **Hazardous decomposition products:** In case of fire: Carbon monoxide und Carbon dioxide, sulphur oxides.

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## 11 Toxicological information

- **Acute toxicity:**  
Oral, Rat: LD50: 660 mg/kg
- **Primary irritant effect:**
- **on skin:** Irritant
- **on eyes:** strong irritations
- **on respiratory organs:** irritations of respiratory organs.

## 12 Ecological information

- **Information about elimination (persistence and degradability):**  
Quantitative data are not available.
- **log p(O/W):** 3,46. Bioaccumulation is not likely.
- **Ecotoxicological effects:**  
Daphnia Magna, LC 50: 90 mg/l/48h
- **Water hazard class:** 2 (Self classification): hazardous for water.
- **Additional information:** Prevent from entering into environmental waters, waste water or soil.

## 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:**  
H315 Causes skin irritation  
H319 Causes serious eye irritation  
H335 May cause respiratory irritation
- **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.