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

· **Informations to product No. 4885**

· **Product name:**

Midazolamhydrochlorid, 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

H336 May cause drowsiness or dizziness

H361 Suspected of damaging fertility or the unborn child

H362 May cause harm to breast-fed children

· **P-Phrases:**

P301 IF SWALLOWED:

P313 Get medical advice/attention

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


P202 Do not handle until all safety precautions have been read and understood

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3 Composition / information on ingredients

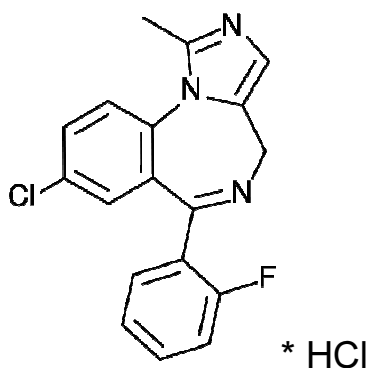
CAS-No. Substance name

59467-96-8 Midazolam hydrochloride (8-Chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5a][1,4]benzodiazepine hydrochloride)

CAS-No. Substance name

59467-96-8 Midazolamhydrochlorid

- REACH Reg. No.: (pre-registered)
- INCI-Name: -
- Chemical characterization:



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, organic halogen compounds.
- **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 dust formation and contact with substance.
- **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.

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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:** Powder
- **Colour:** white – light yellow
- **Odour:** odourless
- **Melting point / melting range:** 148 – 151 °C
- **Boiling point / boiling range:** not determined
- **Solubility in / Miscibility with**
- **Water:** nearly not soluble.
Soluble in organic solvents (examples: methanol, ethanol)
- **pH-range:** not determined

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:**
LD50: (oral, Rat): 1600 mg/kg (Midazolam)
- **Primary irritant effect:**
- **on skin:** Slightly irritant
- **on eyes:** Slightly irritant
- **Additional toxicological informations:**
Causes depression of the central nervous system, irritations of skin and eyes, can be harmful for pregnant or breast-feeding women.

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12 Ecological information

- **Ecotoxicological 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:** Warning
- **H-Phrases:**
H302 Harmful if swallowed
H336 May cause drowsiness or dizziness
H361 Suspected of damaging fertility or the unborn child
H362 May cause harm to breast-fed children
- **P-Phrases:**
P301 IF SWALLOWED:
P313 Get medical advice/attention
P280 Wear protective gloves/protective clothing/eye protection/face protection
P202 Do not handle until all safety precautions have been read and understood
- **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.

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