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| <p>Page 1 of 5</p> <p>Print Date 28.11.2018</p> | <p>Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Diltiazemhydrochlorid, API</p> |  <p>Revision Date 28.11.2018</p> |
|---|---|---|

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

- Informations to product No. 5219
- Product name:

Diltiazemhydrochlorid, API Dilitazemi 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

- P-Phrases:

P301 IF SWALLOWED:

P311 Call a POISON CENTER or doctor/physician


Acute Tox. 4

3 Composition / information on ingredients

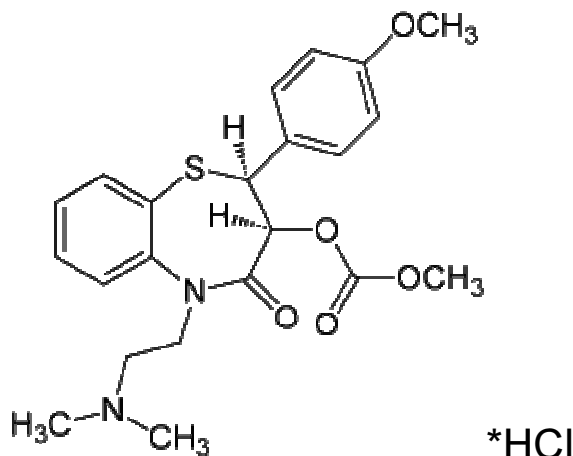
- Chemical characterization:

CAS-No. Substance name

33286-22-5 Diltiazemhydrochlorid

| | | |
|---|---|---|
| <p>Page 2 of 5</p> <p>Print Date 28.11.2018</p> | <p>Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Diltiazemhydrochlorid, API</p> |  <p>Revision Date 28.11.2018</p> |
|---|---|---|

- **EINECS-No.:** 251-443-3
- **REACH Reg. No.:** (pre-registered)
- **INCI-Name:** -



4 First aid measures


- **After inhalation:** Fresh air. If irritation of respiratory ways continues, 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.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open.
- **after swallowing:** 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 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:** 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.

| | | |
|---|---|---|
| <p>Page 3 of 5</p> <p>Print Date 28.11.2018</p> | <p>Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Diltiazemhydrochlorid, API</p> |  <p>Revision Date 28.11.2018</p> |
|---|---|---|

7 Handling and storage

- **Handling:**
- **Advice on safe handling:** No special measures required
- **Informations to fire or explosion protection:** No special measures required
- **Storage:**
- **Requirements for storage areas and containers:** keep container cool, dry and good ventilated.
Protect from direct sunlight.
- **Advices on common storage:**
- **Additional informations to storage conditions:** Keep container tightly closed.

8 Exposure controls / personal protective equipment

Components with limit values that require monitoring at the workplace: none

- **General information:**
- **Personal protective equipment:** The usual precaution measures during handling of chemicals should be observed.
- **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 rubber.
- **Eye protection:** Safety glasses.

9 Physical and chemical properties


- **Form:** crystalline powder
- **Colour:** white
- **Odour:** odourless
- **Melting point / melting range:** 213 °C (Decomposition)
- **Boiling point / boiling range:** -
- **Ignition temperature:** Not flammable
- **Explosion hazard:** The product is not explosive.
- **Solubility in / Miscibility with**
- **Water:** readily soluble
- **pH-range:** 4,3 - 5,3

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:** No decomposition during appropriate use.
- **Hazardous reactions:** Reactions with oxidants, strong bases and acids..
- **Hazardous decomposition products:** none.

11 Toxicological information

- **Acute toxicity:**
- LD/LD50-data relevant for hazard classification:**
Oral: LD50: Rat: 560 mg/kg

| | | |
|---|---|---|
| <p>Page 4 of 5</p> <p>Print Date 28.11.2018</p> | <p>Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Diltiazemhydrochlorid, API</p> |  <p>Revision Date 28.11.2018</p> |
|---|---|---|

- **Primary irritant effect:**
- **on eyes:** slightly irritant
- **on respiratory organs:** slightly irritant
- **Sensitization:**
- **Sub-acute / chronic toxicity:** Mutagenity: not mutangene.
- **Additional toxicological informations:** Symptoms after swallowing:: Bradycardia, drop in blood pressure, hyperglycaemia. Chronical intoxication: Illness, Vomiting, weakness and vertigo.

12 Ecological information

- **Ecotoxicical effects:**
Quantitative ecotoxicological data for this product are not available.
- **General advices:** Prevent from entering sewage water or drainage ditch undiluted or unneutralized.
- **Water hazard class:** 1 (self classification): slightly 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:** GHS07
- **Signal word:** Warning
- **H-Phrases:**
H302 Harmful if swallowed
- **P-Phrases:**
P301 IF SWALLOWED:
P311 Call a POISON CENTER or doctor/physician
- **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.

| | | |
|---|---|---|
| <p>Page 5 of 5</p> <p>Print Date 28.11.2018</p> | <p>Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Diltiazemhydrochlorid, API</p> |  <p>Revision Date 28.11.2018</p> |
|---|---|---|

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