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

· **Informations to product No. 4730**

· **Product name:**

Xylometazolinhydrochlorid, API
Xylometazolini 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:** Danger

· **H-Phrases:**

H301 Toxic if swallowed

· **P-Phrases:**

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

P301 IF SWALLOWED:

P310 Immediately call a POISON CENTER or doctor/physician


Acute Tox. 3

3 Composition / information on ingredients

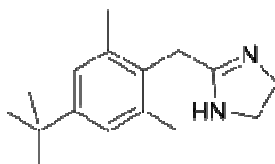
· **Chemical characterization:**

CAS-No. Substance name

1218-35-5 Xylometazolin-Hydrochlorid

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- **EINECS-Nr.:** 214-936-4
- **REACH Reg. No.:** (pre-registered)
- **INCI-Name:** -



* HCl

4 First aid measures

- **General advices:** Take off contaminated clothes immediately.
- **after inhalation:** Fresh air. Assure medical help immediately.
- **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, even if no immediate symptoms are observed.
- **after swallowing:** Rinse mouth, 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 In case of fire dangerous vapours/gases can be generated: 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.

6 Accidental release measures

- **Personal protective measures:** Avoid contact with substance, Wear protective equipment. Good ventilation of working place.
- **Environmental protective measures:** Prevent from entering into drains. If product is entering drainage ditch or surface waters inform responsible authorities.
- **Methods for cleaning:** Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water, Avoid dust formation.

7 Handling and storage

- **Handling:** Avoid dust formation.
- **Advice on safe handling:** Ensure good ventilation/exhaustion at the workplace. Handling corresponding to laboratory safety guidelines.
- **Informations to fire or explosion protection:** Avoid dust formation.
- **Storage:**

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- **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:** TRGS 514 "Storage of toxic and very toxic substances ..."
- **Additional informations to storage conditions:** Keep container tightly closed.

8 Exposure controls / personal protective equipment

- **Personal protective equipment:**
- **General protective and hygiene measures:**
Keep away from food, beverages and animal food.
Take off contaminated clothes immediately.
Wash hands before breaks and after work.
- **Respiratory protection:** Dust protection mask.
- **Hand protection:** Protection gloves of rubber.
- **Eye protection:** Safety glasses

9 Physical and chemical properties


- **Form:** solid
- **Colour:** white - creme colour
- **Odour:** nearly odourless
- **Melting point / melting range:** 327 - 329 °C
- **Boiling point / boiling range:** not determined (Decomposition)
- **Explosion hazard:** not explosive.
- **Bulk density:** ca. 600 kg/m³
- **Solubility in / Miscibility with**
- **Water:** (20 °C) ca. 100 g/l
- **pH-range:** (100 g/l, 20 °C) 5,0 - 6,6

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:** No decomposition during appropriate use.
- **Materials to avoid:** Strong oxidizers, strong acids and bases.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** none

11 Toxicological information

- **Acute toxicity:**
LD50 (oral rat): 122 mg/kg
LC50 (inhal. rat): 0,47 - 1,08 mg/l/4h
- **Primary irritant effect:**
- **on skin:** Not irritant.
- **on eyes:** Irritant effect with danger of serious eye damage.
- **Sensitization:** no sensitizing effect known.
- **Additional information:** In the majority of test systems (micro organisms) the substance did not reveal genotoxic effects. In animal tests also no genotoxic effects were found and no indicators of teratogenicity or damage of fertility.

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12 Ecological information

- **Aquatic toxicity:**

Fish toxicity: OECD-Guideline 203 static:

Brachydanio rerio/LC50 (96 h): 71 mg/l

Aquatic invertebrates: OECD- Guideline 202, Teil 1 static:

Daphnia magna/EC50 (48 h): 5,63 mg/l

Water plants: OECD- Guideline 201 static:

Desmodium subspicatus/EC50 (72 h): 0,91 mg/l

Micro organisms/Effect on activated sludge: OECD- Guideline 209 aerob:

Activated sludge/EC20 (0,5 h): ca. 90 mg/l

Very high acute toxicity for water organisms.

- **log p(O/W):** 2,84

- **Information about elimination (persistence and degradability):**

Method: OECD 301 A (new version) (aerob), activated sludge

Method: DOC-reduction

Elimination: < 10 % (28 d)

Bewertung: Not readily biodegradable. (according to OECD-criteria).

Bioaccumulation potential: An accumulation in organisms is not likely.

- **Water hazard class:** 3 (VwVwS): very 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:**

- **Proper shipping name:** Toxic solids, organic, n.o.s., Xylometazolinhydrochlorid

- **Class:** 6.1

- **UN-number:** 2811

- **Packing group:** III

- **Classification code:** T2

- **Limited quantities (Table 3.4.6. ADR):** 5 kg

- **Hazard classification number:** 60

- **Special provisions (Chapter 3.3 ADR):** 274, 614

- **Additional informations for sea transport IMDG:**


- **EMS-No.:** F-A, S-A

- **Properties:** -

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.

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• **Hazard symbols:** GHS06

• **Signal word:** Danger

• **H-Phrases:**

H301 Toxic if swallowed

• **P-Phraes:**

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

P301 IF SWALLOWED:

P310 Immediately call a POISON CENTER or doctor/physician

• **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.