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

- Informations to product No. 5059
- Product name:

Ambroxolhydrochlorid, API Ambroxoli 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:**

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

- **P-Phrases:**

P305 IF IN EYES:
P351 Rinse continuously with water for several minutes
P280 Wear protective gloves/protective clothing/eye protection/face protection

Skin Irrit. 2
Eye Irrit. 2
STOT SE 3

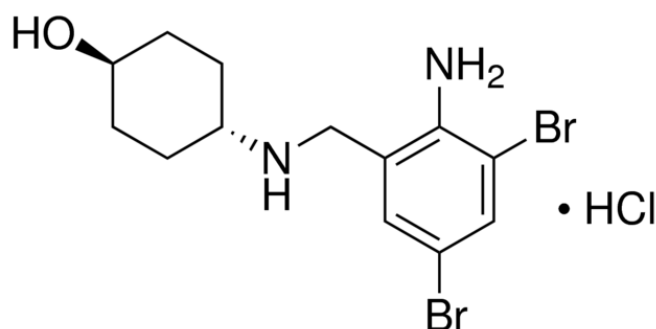
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3 Composition / information on ingredients

CAS-No. Substance name

23828-92-4 Ambroxolhydrochlorid

- EINECS-No.: 248-111-5
- REACH Reg. No.: (pre-registered)
- INCI-Name: -
- Chemical characterization:



4 First aid measures


- **General advices:** If feeling unwell after exposition seek medical advice
- **after inhalation:** Fresh air
- **after skin contact:** Wash off with water
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open.
- **after swallowing:** Induce vomiting. If feeling unwell 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 vapours/gases can be generated: Hydrogen halogenides.
- **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.
- **Environmental protective measures:** No special measures required.
- **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:**

Containers might contain Silica - Gel as drying agent in the inner plastic bag. To avoid mixing with the product don't damage Silica - Gel - bag.

Store cool, dry and tightly closed. Protect from light. Keep away from solvents.

- **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:**

Do not store in metal containers. Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).

- **Advices on common storage:** Not required.

8 Exposure controls / personal protective equipment

- **Personal protective equipment:**

- **Respiratory protection:** Required if dusts are generated.

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

- **Eye protection:** Safety glasses.

9 Physical and chemical properties

- **Form:** solid

- **Colour:** white

- **Odour:** odourless.

- **Melting point / melting range:** 233 – 234 °C (decomposition)

- **Flammability (solid, vapours):** The product is not flammable.

- **Explosion hazard:** The product is not hazardous for explosion.

- **Density:** Not determined.

- **Solubility in / Miscibility with**

- **Water:** (20 °C) not readily soluble

- **pH-range:** (50g/l, 25 °C) ca. 4

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:**

No decomposition during appropriate use.

- **Hazardous reactions:** No hazardous reactions known.


- **Hazardous decomposition products:** none.

- **Additional information:** Sensitive against light and air. Reducing agent.

11 Toxicological information

- **Acute toxicity:**

LD/LD50-data relevant for hazard classification:

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LD50 (oral, Rat): 4203 mg/kg

- **Chronic toxicity:** Not cancerogene in animal experiments.
- **Additional toxicological informations:** In case of appropriate handling and usage the product does not cause harmful effects.

12 Ecological information

- **Information about elimination (persistence and degradability):**
Biodegradable.
- **Ecotoxic effects:**
Quantitative informations are not available.
- **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:**
H315 Causes skin irritation
H319 Causes serious eye irritation
H335 May cause respiratory irritation
- **P-Phrases:**
P305 IF IN EYES:
P351 Rinse continuously with water for several minutes
P280 Wear protective gloves/protective clothing/eye protection/face protection
- **National regulations (Germany):**
- **Water hazard class:** see chapter 12
- **Storage class TRGS 510:** 11

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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.