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

- Informations to product No. 5270
- Product name:

Ketoconazol, 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: Danger


- H-Phrases:

H301 Toxic if swallowed
H360F May damage fertility
H373 May cause damage to organs through prolonged or repeated exposure
H410 Very toxic to aquatic life with long lasting effects

- P-Phrases:

P264 Wash thoroughly after handling
P280 Wear protective gloves/protective clothing/eye protection/face protection
P301 IF SWALLOWED:
P310 Immediately call a POISON CENTER or doctor/physician
P273 Avoid release to the environment

Acute Tox. 3
Repr. 1B
STOT RE 2

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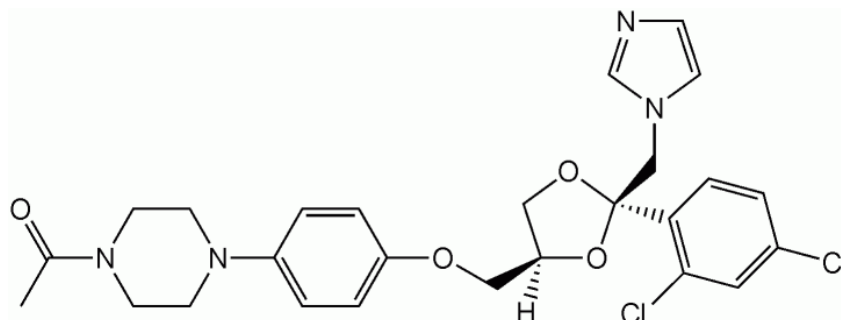
Aquatic Acute 1
Aquatic Chronic 1

3 Composition / information on ingredients

CAS-No. Substance name

65277-42-1 Ketoconazol

- **EINECS-No.:** 265-667-4
- **REACH Reg. No.:** (pre-registered)
- **INCI-Name:** -
- **Chemical characterization:**



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.
- **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.
- **Medical advice:** Long-termed or repeated exposition can cause sensitization.

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.

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- **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.

7 Handling and storage

- **Handling:**
- **Advice on safe handling:** The usual precaution measures during handling of chemicals should be observed.
- **Informations to fire or explosion protection:** Take measures to prevent electrostatic charging.
- **Storage:**
- **Requirements for storage areas and containers:** Store at a good ventilated place. Keep container cool, dry and tightly closed.

8 Exposure controls / 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 rubber.
- **Eye protection:** Safety glasses

9 Physical and chemical properties


- **Form:** Crystalline powder
- **Colour:** colourless
- **Odour:** odourless
- **Melting point / melting range:** 148 - 152 °C
- **Boiling point / boiling range:** - (Decomposition)
- **Solubility in / Miscibility with**
- **Water:** not soluble

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:** Carbon monoxide, nitrogen oxides and Hydrogen chloride.

11 Toxicological information

- **Acute toxicity:**
LD/LD50-data relevant for hazard classification:
65277-42-1 Ketoconazol
Oral: LD50: 166 mg/kg (rat)

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Oral: LD50: 618 mg/kg (mouse)

- **Sensitization:** Sensitizing effect possible..
- **Sub-acute / chronic toxicity:** Intoxication after swallowing can cause liver damages. Irritant effect on eyes and respiratory ways.
- **Additional toxicological informations:** Fungicide effect, therapeutically used.

12 Ecological information

- **Aquatic toxicity:** Toxic for water organisms.
- **Information about elimination (persistence and degradability):** Quantitative data about ecological effects of this product are not available.
- **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:**
- **Proper shipping name:** Toxic solids, organic, n.o.s., Ketoconazol
- **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):** -
- **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.

- **Hazard symbols:** GHS06, GHS08, GHS09
- **Signal word:** Danger
- **H-Phrases:**
H301 Toxic if swallowed
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H373 May cause damage to organs through prolonged or repeated exposure
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• **P-Phrases:**

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• **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.