



Safety data sheet according to 1907/2006/EC, Article 31

Printing date 08.10.2021

Version number 1.00

Revision: 05.10.2021

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

- **Product identifier**
- **Trade name:** Ketoconazole, API
- **Article number:** 5270
- **CAS Number:**
65277-42-1
- **EC number:**
265-667-4
- **Index number:**
613-283-00-6
- **Registration number** The substance is exempt from REACH-registration.
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture**
Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.
- **Uses advised against** No relevant information available.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
CAELO
Caesar & Loretz GmbH
Herderstr. 31
D-40721 Hilden
GERMANY
- **Further information obtainable from:**
E-mail: info@caelo.de
Tel.: +49210349940 (during regular opening hours)
- **Emergency telephone number:**
Poison Information Center Bonn
Venusberg-Campus 1, 53127 Bonn
Tel: +49 (0) 228-192400

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**

Acute Tox. 3	H301	Toxic if swallowed.
Repr. 1B	H360F	May damage fertility.
STOT RE 2	H373	May cause damage to organs through prolonged or repeated exposure.
Aquatic Acute 1	H400	Very toxic to aquatic life.
Aquatic Chronic 1	H410	Very toxic to aquatic life with long lasting effects.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.

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Hazard pictograms

GHS06



GHS08



GHS09

Signal word Danger**Hazard statements**

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.

Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

P321 Specific treatment (see on this label).

P330 Rinse mouth.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards**Results of PBT and vPvB assessment****PBT:** Not applicable.**vPvB:** Not applicable.

3 Composition/information on ingredients

Chemical characterisation: Substances**CAS No. Description**

65277-42-1 ketoconazole

Identification number(s)**EC number:** 265-667-4**Index number:** 613-283-00-6

4 First aid measures

Description of first aid measures**General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

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.

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- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
 - **After swallowing:** Drink plenty of water and provide fresh air. Call for a doctor immediately.
 - **Information for doctor:**
 - **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.
-

5 Firefighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents:**
All regular extinguishing media can be used.
Use fire extinguishing methods suitable to surrounding conditions.
 - **Special hazards arising from the substance or mixture**
Combustible but not oxidising. In case of fire dangerous vapours/gases can be generated: Smoke gases.
 - **Advice for firefighters**
 - **Protective equipment:** In case of fire wear suitable protective clothes and respiratory protection.
 - **Additional information**
Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.
-

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
Avoid contact with the substance.
 - **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Inform respective authorities in case of seepage into water course or sewage system.
 - **Methods and material for containment and cleaning up:**
Take up dry. Clean up with water.
Dispose contaminated material as waste according to item 13.
 - **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
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7 Handling and storage

- **Handling:**
 - **Precautions for safe handling** Thorough dedusting.
 - **Information about fire - and explosion protection:** Protect against electrostatic charges.
 - **Conditions for safe storage, including any incompatibilities**
 - **Storage:**
 - **Requirements to be met by storerooms and receptacles:**
Store in a cool location.
Tightly closed.
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- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store receptacle in a well ventilated area.
- **Storage class:** TRHS 510: 6.1 C Combustible acutely toxic or chronic substances
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Store protective clothing separately.
- **Respiratory protection:** Dust protection mask.
- **Protection of hands:** Protective gloves
- **Material of gloves**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses
- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

· Form:	Crystalline powder
· Colour:	White
· Odour:	Odourless
· Odour threshold:	Not determined.
· pH-value:	Not applicable.
- **Change in condition**

· Melting point/freezing point:	146 °C
· Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.

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- **Flammability (solid, gas):** Product is not flammable.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Not determined.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
 - Lower: Not determined.
 - Upper: Not determined.
- **Vapour pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with water:** Not determined.
- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
 - Dynamic: Not applicable.
 - Kinematic: Not applicable.
- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions**
 - Reacts with oxidising agents.
 - Reacts with strong acids.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**
 - Carbon monoxide and carbon dioxide
 - Hydrogen chloride (HCl)

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
 - Toxic if swallowed.
- **LD/LC50 values relevant for classification:**
 - Oral LD50 166 mg/kg (rat)

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- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**
May damage fertility.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**
May cause damage to organs through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Very toxic for fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
Also poisonous for fish and plankton in water bodies.
Very toxic for aquatic organisms
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to local regulations.

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14 Transport information

· UN-Number	UN2811
· ADR, IMDG, IATA	
· UN proper shipping name	
· ADR	3288 TOXIC SOLID, INORGANIC, N.O.S. (ketoconazole), ENVIRONMENTALLY HAZARDOUS
· IMDG	TOXIC SOLID, ORGANIC, N.O.S. (ketoconazole)
· IATA	Toxic solid, organic, n.o.s. (ketoconazole)
· Transport hazard class(es)	
· ADR, IMDG, IATA	
· Class	6.1 Toxic substances.
· Label	6.1
· Packing group	
· ADR, IMDG, IATA	III
· Environmental hazards:	Environmentally hazardous substance, solid
· Special marking (ADR):	Symbol (fish and tree)
· Special precautions for user	Warning: Toxic substances.
· Hazard identification number (Kemler code):	60
· EMS Number:	F-A,S-A
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5 kg
· Transport category	2
· Tunnel restriction code	E
· IMDG	
· Limited quantities (LQ)	5 kg

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV) Not listed
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 30
- National regulations:
- Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)
TRHS 510: 6.1 C Combustible acutely toxic or chronic substances
- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.

- Reasons for alterations This version replaces all old versions.

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Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity – Category 3

Repr. 1B: Reproductive toxicity – Category 1B

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1