



## Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 06.06.2024

Version number 1.00

Revision: 06.06.2024

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

- **Product identifier**
- **Trade name:** Ketoconazole
- **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



#### · 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.

· **Determination of endocrine-disrupting properties** Not applicable.

### 3 Composition/information on ingredients

#### · Substances

#### · CAS No. Description

CAS: 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.
  - **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 section 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.
- 

### 7 Handling and storage

- **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.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store receptacle in a well ventilated area.

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- **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

- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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.
- **Hand protection** 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/face protection** Safety glasses
- **Body protection:** Protective work clothing

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **Colour:** White
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** 146 °C
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Product is not flammable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Decomposition temperature:** Not determined.
- **pH** Not applicable.

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· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not applicable.
· <b>Dynamic:</b>	Not applicable.
· <b>Solubility</b>	
· <b>water:</b>	Not determined.
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density and/or relative density</b>	
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Particle characteristics</b>	Not determined
· <b>Other information</b>	
· <b>Appearance:</b>	
· <b>Form:</b>	Crystalline powder
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Ignition temperature:</b>	Not determined.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not applicable.
· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

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## 10 Stability and reactivity

- **Reactivity** No further relevant information available.

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- **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 hazard classes as defined in Regulation (EC) No 1272/2008**
  - **Acute toxicity** Toxic if swallowed.
  - **LD/LC50 values relevant for classification:**  
Oral LD50 166 mg/kg (rat)
  - **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.
  - **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.
  - **Information on other hazards**
  - **Endocrine disrupting properties**  
On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.
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### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Endocrine disrupting properties**  
Based on the available data, the substance does not meet the criteria for the identification of substances with properties affecting the endocrine system according to Article 59(1) of the REACH Regulation and the criteria of the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.

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The product does not contain substances with endocrine disrupting properties.

**Other adverse 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

### 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.

### 14 Transport information

**UN number or ID number****ADR, IMDG, IATA**

UN2811

**UN proper shipping name****ADR**2811 TOXIC SOLID, ORGANIC, 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

**Marine pollutant:**

Symbol (fish and tree)

**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

**Maritime transport in bulk according to IMO instruments**

Not applicable.

**Transport/Additional information:****ADR****Limited quantities (LQ)**

5 kg

**Transport category**

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· <b>Tunnel restriction code</b>	E
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	5 kg
· <b>UN "Model Regulation":</b>	UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (KETOCONAZOLE), 6.1, III, ENVIRONMENTALLY HAZARDOUS

### 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, 75
- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**  
Substance is not listed.
- **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.
- **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 Arbejdshygienisk 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