



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

Printing date 31.03.2023

Version number 1.00

Revision: 31.03.2023

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

- **Product identifier**
- **Trade name:** Miconazole nitrate, API
- **Article number:** 4422
- **CAS Number:**
22832-87-7
- **EC number:**
245-256-6
- **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. 4 H302 Harmful if swallowed.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07



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- **Signal word** Warning
- **Hazard statements**
 - H302 Harmful if swallowed.
 - H317 May cause an allergic skin reaction.
- **Precautionary statements**
 - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 - P280 Wear protective gloves.
 - P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
 - P330 Rinse mouth.
 - P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 - 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: 22832-87-7 Miconazole nitrate
- **Identification number(s)**
- **EC number:** 245-256-6

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.
- **After eye contact:**
 - Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** If symptoms persist consult 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.

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· Special hazards arising from the substance or mixture

Flammable.

Formation of toxic gases is possible during heating or in case of fire.

· 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.**· 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.

7 Handling and storage

· Precautions for safe handling No special precautions are necessary if used correctly.**· Information about fire - and explosion protection:** No special measures required.**· Conditions for safe storage, including any incompatibilities****· Storage:****· Requirements to be met by storerooms and receptacles:**

Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).

· Information about storage in one common storage facility: Not required.**· Further information about storage conditions:** No further information**· Storage class:** TRHS 510: 11 Combustible solids**· 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 item 7.**· Individual protection measures, such as personal protective equipment****· General protective and hygienic measures:**

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

· Respiratory protection: Dust protection mask.**· Hand protection** Protective gloves

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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

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:

Undetermined.

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.

Ignition temperature:

350 °C

Decomposition temperature:

Not determined.

pH

Not applicable.

Viscosity:**Kinematic viscosity**

Not applicable.

Dynamic:

Not applicable.

Solubility**water:**

Not determined.

Partition coefficient n-octanol/water (log value)

Not determined.

Vapour pressure:

Not applicable.

Density and/or relative density**Density:**

Not determined.

Relative density

Not determined.

Vapour density

Not applicable.

Particle characteristics

Not determined

Other information**Appearance:****Form:**

Solid

Important information on protection of health and environment, and on safety.**Auto-ignition temperature:**

Not determined.

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· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not applicable.
· Information with regard to physical hazard classes	
· Explosives	Void
	Void
· Flammable gases	Void
	Void
· Aerosols	Void
	Void
· Oxidising gases	Void
	Void
· Gases under pressure	Void
	Void
· Flammable liquids	Void
	Void
· Flammable solids	Void
	Void
· Self-reactive substances and mixtures	Void
	Void
· Pyrophoric liquids	Void
	Void
· Pyrophoric solids	Void
	Void
· Self-heating substances and mixtures	Void
	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
	Void
· Oxidising liquids	Void
	Void
· Oxidising solids	Void
	Void
· Organic peroxides	Void
	Void
· Corrosive to metals	Void
	Void
· Desensitised explosives	Void
	Void

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** No dangerous reactions known.

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- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:**
 - alkali metals
 - Strong reducing agents
- **Hazardous decomposition products:**
 - Chlorine
 - Hydrogen chloride (HCl)
 - Nitrogen oxides
 - No dangerous decomposition products known.

11 Toxicological information

- **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Harmful if swallowed.
- **LD/LC50 values relevant for classification:**
 - Oral LD50 920 mg/kg (rat)
 - LD50 (i.p.) 1,060 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** May cause an allergic skin reaction.
- **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** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **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.

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**· Additional ecological information:****· General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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

Not subject to transport regulations.

· ADR, IMDG, IATA

not regulated

· UN proper shipping name**· ADR, IMDG, IATA**

not regulated

· Transport hazard class(es)**· ADR, ADN, IMDG, IATA****· Class**

not regulated

· Packing group**· ADR, IMDG, IATA**

not regulated

· Environmental hazards:

Not applicable.

· Special precautions for user

Not applicable.

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

Not applicable.

· UN "Model Regulation":

not regulated

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 Not listed

· 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 nonstationary vessels (TRGS 510) (Germany)

TRHS 510: 11 Combustible solids

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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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.

· **Date of previous version:** 31.03.2023

· **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. 4: Acute toxicity – Category 4

Skin Sens. 1: Skin sensitisation – Category 1

· * **Data compared to the previous version altered.**