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

· **Informations to product No. 4422**

· **Product name:**

### **Miconazolnitrat, API** Miconazoli nitras

· **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:**

H302 Harmful if swallowed

H317 May cause an allergic skin reaction

· **P-Phrases:**

P264 Wash thoroughly after handling

P280 Wear protective gloves/protective clothing/eye protection/face protection

**Acute Tox. 4**


**Skin Sens. 1**

## 3 Composition / information on ingredients

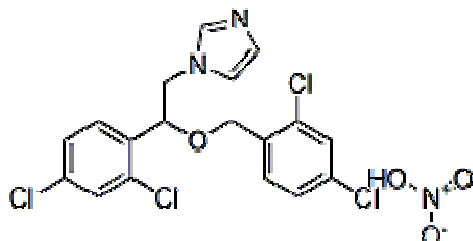
**CAS-No. Substance name**

22832-87-7 Miconazolnitrat

· **EINECS-No.:** 245-256-6

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- **REACH Reg. No.:** 01-2120767452-51-0000
- **INCI-Name:** -
- **Chemical characterization:**



#### 4 First aid measures

- **after inhalation:** Fresh air, 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. If irritation continues, call in ophthalmologist..
- **after swallowing:** Drink plenty of water, Induce vomiting. If feeling unwell continuously seek medical advice.
- **Medical advice:** Used as antimycoticum.

#### 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, organic halogen compounds.
- **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.
- **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:** Avoid dust formation, Do not inhale dust.
- **Informations to fire or explosion protection:** No special measures required.
- **Storage:**
- **Requirements for storage areas and containers:**  
Tightly closed. Store at a dry place. At room temperature ( +15°C to +25°C ).

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- **Advices on common storage:** Not required.
- **Additional informations to storage conditions:** Keep container tightly closed.

## 8 Exposure controls / personal protective equipment

- **Personal protective equipment:**
- **General protective and hygiene measures:**  
Keep away from food, beverages and animal food.  
Wash hands before breaks and after work.  
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:** solid
- **Colour:** white
- **Odour:** odourless
- **Melting point / melting range:** 178 – 184 °C
- **Flash point:** not determined
- **Ignition temperature:** 350 °C
- **Density:** not determined.
- **Solubility in / Miscibility with**
- **Water:** not readily soluble

## 10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:** No decomposition during appropriate use.
- **Materials to avoid:** Alkali metals, strong reductants.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** Chlorine, Hydrogen chloride, nitrogen oxides.

## 11 Toxicological information

- **Acute toxicity:**  
LD50 (oral,Rat): 920 mg/kg  
LD50 (i.p.,Rat): 1060 mg/kg  
LD50 (i.v.,Rat): 14700 mg/kg
- **Primary irritant effect:**
- **on skin:** Strong irritations.
- **on eyes:** Irritant effect.
- **on respiratory organs:** Allergic reactions possible.
- **after swallowing:** Vomiting, Diarrhea, Cramps, Cardiovascular disorders.
- **Sensitization:** Sensitization by skin contact possible.

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## 12 Ecological information

- **Ecotoxical effects:**

Quantitative ecotoxicological data for this product 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

- **H-Phrases:**

H302 Harmful if swallowed

H317 May cause an allergic skin reaction

- **P-Phrases:**

P264 Wash thoroughly after handling

P280 Wear protective gloves/protective clothing/eye protection/face protection

- **National regulations (Germany):**

- **Water hazard class:** see chapter 12

- **Storage class TRGS 510:** 11

## 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.