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

· **Informations to product No. 5190**

· **Product name:**

Clotrimazol, mikronisiert, API
Clotrimazolum

· **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

H315 Causes skin irritation

H319 Causes serious eye irritation.

· **P-Phrases:**

P301 IF SWALLOWED:


P313 Get medical advice/attention

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

Acute Tox. 4

Skin Irrit. 2

Eye Irrit. 2

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3 Composition / information on ingredients

• **Chemical characterization:**

CAS-No. Substance name: 23593-75-1 Clotrimazol

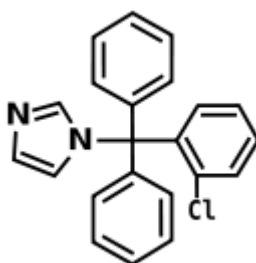
• **EINECS-Nr.:** 245-764-8

• **REACH Reg. No.:** (pre-registered)

• **INCI-Name:** Clotrimazol

• **Chemical characterization**

1-((2-Chlorphenyl)diphenylmethyl)-1-(o-chlor-alpha-alpha- diphenylbenzyl)imidazol



4 First aid measures


- **after inhalation:** Fresh air or oxygen. If feeling unwell continuously seek medical advice.
- **after skin contact:** Wash away with plenty of water.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open.
- **after swallowing:** Drink water. Induce vomiting. Seek medical advice.

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.

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7 Handling and storage

- **Handling:** No special requirements.
- **Advice on safe handling:** Good ventilation / exhaustion of working place
- **Informations to fire or explosion protection:** Avoid dust formation.
- **Storage:**
- **Requirements for storage areas and containers:** Tightly closed. Store in cool, dry, ventilated place and closed containers. At room temperature (+15°C to +25°C). Protect from light.
- **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.
- **Respiratory protection:** Dust protection mask.
- **Hand protection:** Protection gloves of rubber or latex
- **Eye protection:** Safety glasses

9 Physical and chemical properties


- **Form:** solid
- **Colour:** white
- **Odour:** nearly odourless
- **Melting point / melting range:** 141 - 145 °C
- **Boiling point / boiling range:** not determined
- **Flash point:** not determined
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** not readily soluble
- **pH-range:** not determined

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:**
No decomposition during appropriate use.
- **Materials to avoid:** Strong oxidizers
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** Hydrogen chloride und nitrogen oxides.

11 Toxicological information

- **Acute toxicity:**
LD 50 (Oral, cat): >1000 mg/kg
(Oral, Dog): >2000 mg/kg
(Oral, mouse): 761 mg/kg

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(Oral, rat): 708 mg/kg
(Oral, rabbit): >1000 mg/kg

- **Primary irritant effect:**
- **on skin:** Irritant.
- **on eyes:** Irritant.
- **on respiratory organs:** can be harmful by inhalation
- **If swallowed:** Harmful if swallowed
- **Sensitization:** May cause sensitization by skin contact

12 Ecological information

- **Aquatic toxicity:**
EC100/48 h 0.1 mg / l (Daphnia magna)
EC50/48h 0.02 mg / l (Crustacean)
EC50/72h 0.098 mg / l (algae)
LC50/96> 0.29 ppm (fish)
- **Persistence and degradability biodegradable:** biodegradable.
- **Additional ecological information:**
Dangerous in the long term degradation products are possible. The products of degradation are more toxic. Do not release into ground water, surface water or soil.
- **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 information

- **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
- **Signal word:** Warning
- **H-Phrases:**
H302 Harmful if swallowed
H315 Causes skin irritation
H319 Causes serious eye irritation.
- **P-Phrases:**
P301 IF SWALLOWED:
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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.