

Trade name: Clotrimazolium micronisiert

Substance number: 842770

Version: 1 / CH

Date revised: 01.03.2019

Replaces Version: - / CH

Print date: 01.03.19

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

1.1. Product identifier

Clotrimazolium micronisiert

Item No. 84277003

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/preparation

Active pharmaceutical substance, Manufacture of pharmaceutical products

1.3. Details of the supplier of the safety data sheet

Address/Manufacturer

Hänseler AG

Industriestrasse 35

9101 Herisau

Telephone no. 0041 (0)71 353 58 58

E-mail address of sdb@haenseler.ch

person responsible

for this SDS

1.4. Emergency telephone number

Switzerland :145 / Abroad +41 (0)44 251 51 51

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

Classification (Regulation (EC) No. 1272/2008)

Acute Tox. 4 H302

Skin Irrit. 2 H315

Eye Irrit. 2 H319

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008

For explanation of abbreviations see section 16.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard pictograms



Signal word

Warning

Hazard statements

H302

Harmful if swallowed.

H315

Causes skin irritation.

H319

Causes serious eye irritation.

Precautionary statements

P264.1

Wash hands thoroughly after handling.

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P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P301+P312 IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P330 Rinse mouth.
 P501.3 Disposal in compliance with local and national regulations.

Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)

contains Clotrimazole

SECTION 3: Composition/information on ingredients**Hazardous ingredients****Clotrimazole**

CAS No.	23593-75-1		
EINECS no.	245-764-8		
Registration no.	PRE-REGISTERED		
Concentration	>= 50		%
Classification (Regulation (EC) No. 1272/2008)			
	Acute Tox. 4		H302
	Skin Irrit. 2		H315
	Eye Irrit. 2		H319

SECTION 4: First aid measures**4.1. Description of first aid measures****After inhalation**

Ensure supply of fresh air. If necessary, give oxygen. In the event of symptoms take medical treatment.

After skin contact

Wash skin thoroughly with water (15 min.).

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.).

After ingestion

If swallowed, rinse mouth with water (only if the person is conscious). Let plenty of water be drunk in small gulps. Induce vomiting, seek medical advice.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Extinguishing measures to suit surroundings

Non suitable extinguishing media

not applicable

5.2. Special hazards arising from the substance or mixture

The product is combustible. In case of combustion evolution of dangerous gases possible.

5.3. Advice for firefighters**Special protective equipment for fire-fighting**

Use personal protective clothing. Use self-contained breathing apparatus.

Other information

Fire residues and contaminated fire-fighting water must be disposed of in accordance with the local

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regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Don't touch

6.2. Environmental precautions

Do not empty into drains, caverns and basements.

6.3. Methods and material for containment and cleaning up

To pick up dry. When picked up, treat material as prescribed under Section 13 "Disposal". Clean up affected area.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Provide good ventilation of working area (local exhaust ventilation if necessary).

Advice on protection against fire and explosion

Avoid dust formation.

7.2. Conditions for safe storage, including any incompatibilities

Storage classes

Storage class according to TRGS 510	13	Non- combustible solids
Storage category (Switzerland)	11/13	Other solid hazardous substances with hazardous classification/labelling

Further information on storage conditions

Keep containers tightly closed in a dry, cool and well-ventilated place.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

General protective and hygiene measures

Keep away from food-stuffs, beverages and feed-stocks. Wash hands before breaks and after work.

Respiratory protection

Dust mask

Hand protection

necessary

Appropriate Material rubber

Eye protection

Safety glasses

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form	solid		
Colour	white		
Odour	almost odourless		
Melting point			
Value	141	to	145 °C

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Flash point

Value	°C
Remarks	Not applicable

Vapour pressure

Remarks	Not applicable
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Density

Remarks	not determined
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Solubility in water

Remarks	Difficult to dissolve
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SECTION 10: Stability and reactivity**10.1. Reactivity**

No decomposition if stored and applied as directed.

10.2. Chemical stability

No decomposition if stored and applied as directed.

10.3. Possibility of hazardous reactions

No decomposition if stored and applied as directed.

10.4. Conditions to avoid

Oxidising agents

10.5. Incompatible materials

Oxidising agents

10.6. Hazardous decomposition products

Hydrogen chloride (HCl), Nitrous gases

SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute oral toxicity**

ATE	708	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)	

Acute oral toxicity (Components)**Clotrimazole**

Species	cat		
LD50	>	1000	mg/kg

Clotrimazole

Species	dog		
LD50	>	2000	mg/kg

Clotrimazole

Species	mouse		
LD50		761	mg/kg

Clotrimazole

Species	rat		
LD50		708	mg/kg

Clotrimazole

Species	rabbit		
LD50	>	1000	mg/kg

Skin corrosion/irritation (Components)

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Clotrimazole
evaluation irritant

Serious eye damage/irritation (Components)

Clotrimazole
evaluation irritant

Sensitization (Components)

Clotrimazole
evaluation May cause sensitization by skin contact.

SECTION 12: Ecological information**12.1. Toxicity****Fish toxicity (Components)**

Clotrimazole
LC50 > 0.29 ppm(V)
Duration of exposure 96 h

Daphnia toxicity (Components)

Clotrimazole
Species Daphnia magna
EC100 0.1 mg/l
Duration of exposure 48 h

Algae toxicity (Components)

Clotrimazole
EC50 0.098 mg/l
Duration of exposure 72 h

12.2. Persistence and degradability**Biodegradability (Components)**

Clotrimazole
evaluation biodegradable

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations for the product**

EWC waste code 07 05 wastes from the MFSU of pharmaceuticals

Disposal recommendations for packaging

Disposal in compliance with local and national regulations.

SECTION 14: Transport information

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number	Non-dangerous goods	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

SECTION 15: Regulatory information

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15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**Water Hazard Class (Germany)**

Water Hazard Class (Germany) WGK 2

Remarks Derivation of WGK according to Annex 1 No. 5.2 AwSV

SECTION 16: Other information**Hazard statements listed in Chapter 3**

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

CLP categories listed in Chapter 3

Acute Tox. 4	Acute toxicity, Category 4
Eye Irrit. 2	Eye irritation, Category 2
Skin Irrit. 2	Skin irritation, Category 2

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: ***
This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.