

MICONAZOLUM

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Miconazole
Miconazolum
Miconazol
Miconazole
Miconazol

N° CAS: 22916-47-8

N° EC: 245-324-5

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: Magis-Pharma NV
Neerlandweg 24
2610 Wilrijk
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

1.4 Emergency telephone number

| | | |
|----------------------------|-------------------------|--------------------------|
| Public utility foundation: | Belgisch Antigifcentrum | Centre Antipoisons Belge |
| Telephone: | (+32) (0)70 245 245 | (Service 24/7) |
| Web page: | www.antigifcentrum.be | www.centreantipoisons.be |

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

| | |
|-------------------|------|
| Acute Tox. 4 | H302 |
| Aquatic Chronic 4 | H413 |

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

| | |
|------|---|
| H302 | Harmful if swallowed (warning: acute toxicity, oral) |
| H413 | May cause long lasting harmful effects to aquatic life [Hazardous to the aquatic environment, long-term hazard] |

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Precautionary statements:

| | |
|---------------------------------------|---|
| P264 | Wash hands [and ...] thoroughly after handling. |
| P270 | Do not eat, drink or smoke when using this product. |
| P273 | Avoid release to the environment. |
| P301 + P317 | IF SWALLOWED: Get medical help. |
| P330 | Rinse mouth. |
| P391 | Collect spillage. |
| P501 | Dispose of contents/container to ... |
| Additional applicable label elements: | Not applicable |

2.3 Other hazards

For additional information on toxicity, please refer to Section 11.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

| | |
|--------------------|--|
| Product name: | Miconazole |
| IUPAC name: | 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-1H-imidazole |
| Synonyms: | Monistat Minostat |
| N° CAS: | 22916-47-8 |
| N° EC: | 245-324-5 |
| Molecular Formula: | C ₁₈ H ₁₄ Cl ₄ N ₂ O |
| Content: | 100% |

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

| | |
|---------------------|---|
| After inhalation: | Remove from exposure and move to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid. |
| After skin contact: | Get medical aid. Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. |
| After eye contact: | Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid. |
| After ingestion: | Never give anything by mouth to an unconscious person. Get medical aid. Do NOT induce vomiting. If conscious and alert, rinse mouth and drink 2-4 cupfuls of milk or water. |

4.2 Most important symptoms and effects, both acute and delayed



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Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician: Treat symptomatically and supportively.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use agent most appropriate to extinguish fire. Use water spray, dry chemical, carbon dioxide, or appropriate foam.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

NFPA Rating: (estimated) Health: 1; Flammability: 0; Instability: 0

5.3 Advice for firefighters

Surrounding fires: During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.

Protection against fire: As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Use proper personal protective equipment as indicated in Section 8.

For emergency responders

Use proper personal protective equipment as indicated in Section 8.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Vacuum or sweep up material and place into a suitable disposal container. Clean up spills immediately, observing precautions in the Protective Equipment section. Avoid generating dusty conditions. Provide ventilation.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Avoid contact with eyes, skin, and clothing. Keep container tightly closed. Avoid ingestion and inhalation. Wash thoroughly after handling.

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|--------------------------------|---|
| Personal protection: | Not available. |
| Technical protective measures: | Use with adequate ventilation. Minimize dust generation and accumulation. |
| Handling: | Wash thoroughly after handling. |

7.2 Conditions for safe storage, including any incompatibilities

| | |
|---|--|
| Storage: | Not available. |
| Conditions for safe storage, including any incompatibilities: | Store in a tightly closed container. Store in a cool, dry, well-ventilated area. |
| Storage – away from: | Store away from incompatible substances. |

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Exposure limits

| Chemical name | ACGIH | NIOSH | OSHA - Final PELs |
|---------------|--------------|--------------|-------------------|
| Miconazole | None listed. | None listed. | None listed. |

OSHA Vacated PELs: Miconazole: No OSHA Vacated PELs are listed for this chemical.

8.2 Exposure controls

Appropriate engineering control

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation to keep airborne concentrations low.

Individual protection measures

| | |
|-------------------------|---|
| Eye/face protection: | Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. |
| Skin protection: | Wear appropriate protective clothing to prevent skin exposure. |
| Hand protection: | Wear appropriate protective gloves to prevent skin exposure. |
| Respiratory protection: | Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. |
| Thermal hazards: | Not determined. |

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

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| | |
|---|--------------------------|
| Appearance: | Physical state: solid |
| Odour: | Not available. |
| Odour threshold: | Not available. |
| pH: | Not available. |
| Melting/freezing point: | Melts at about 78°-82°C. |
| Initial boiling point: | Not available. |
| Boiling range: | Not available. |
| Flash point: | Not available. |
| Evaporation rate: | Not available. |
| Flammability (solid/gas): | Not available. |
| Upper/lower flammability or explosive limits: | Not available. |
| Vapour pressure: | Not available. |
| Vapour density: | Not available. |
| Relative density: | Not available. |
| Solubility: | Not available. |
| Solubility in water: | Not available. |
| Partition coefficient (n-octanol/water): | Not available. |
| Auto-ignition temperature: | Not available. |
| Decomposition temperature: | Not available. |
| Viscosity: | Not available. |
| Explosive properties: | Not available. |
| Oxidising properties: | Not available. |

9.2 Other information

Molecular weight: 416 AMU

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable at room temperature in closed containers under normal storage and handling conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerization: Has not been reported.

10.4 Conditions to avoid

Incompatible materials, dust generation, excess heat, strong oxidants.

10.5 Incompatible materials

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Oxidizing agents.

10.6 Hazardous decomposition products

Hydrogen chloride, nitrogen oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide, chlorine.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

| | | |
|--|--|-----------|
| Acute toxicity: | Oral LD ₅₀ (mouse): | 519 mg/kg |
| | Oral LD ₅₀ (rat): | 550 mg/kg |
| Skin corrosion/irritation: | Not available. | |
| Serious eye damage/irritation: | Not available. | |
| Respiratory/skin sensitisation: | Not available. | |
| Germ cell mutagenicity: | Not available. | |
| Carcinogenicity: | Not listed by ACGIH, IARC, NTP, or CA Prop 65. | |
| Reproductive toxicity: | Not available. | |
| Summary of evaluation of the CMR properties: | Not available. | |
| STOT-single exposure: | Not available. | |
| STOT-repeated exposure: | Not available. | |
| Aspiration Hazard: | Not available. | |
| Other: | Not available. | |

11.2 Additional information on potential adverse human health effects and symptoms

| | |
|---------------|----------------|
| Eye contact: | Not available. |
| Skin contact: | Not available. |
| Inhalation: | Not available. |
| Ingestion: | Not available. |
| Aspiration: | Not available. |

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

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Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

RCRA P-Series: None listed.

RCRA U-Series: None listed.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), Not classified.
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Not regulated as a hazardous material.
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), Not classified.
IATA/ICAO (Air) :

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), Not classified.
IATA/ICAO (Air) :

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Not classified.
IATA/ICAO (Air) :

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

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Hazard symbol:



Warning

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

| | |
|--------------|---|
| ADR: | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| CAS: | Chemical Abstracts Service (division of the American Chemical Society) |
| EC (number): | European Community (number) |
| IATA: | International Air Transport Association |
| ICAO: | International Civil Aviation Organization |
| IMDG: | International Maritime Code for Dangerous Goods |
| IUPAC: | International Union of Pure and Applied Chemistry |
| PBT: | Persistent, Bioaccumulative and Toxic substance |
| RID: | Regulations Concerning the International Transport of Dangerous Goods by Rail |
| STOT: | Specific Target Organ Toxicity |
| UN (number): | United Nations (number) |
| vPvB: | very Persistent and very Bioaccumulative |

16.3 Key literature references/sources for data

European Chemicals Agency.
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available



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16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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