

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

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## MICONAZOLI NITRAS

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

#### 1.1 Product identifier

Product name:	Miconazole nitrate Miconazoli nitras Miconazolenitraat Miconazole (nitrate de) Miconazolnitrat
N° CAS:	22832-87-7
N° EC:	245-256-6

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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#### 1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts 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
Skin Sens. 1	H317
Aquatic Chronic 1	H410

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

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H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements:	
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P273	Avoid release to the environment.
P321	Specific treatment (see on this label).
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P501	Dispose of contents/container in accordance with local/regional/national/international regulation.
Additional applicable label elements:	Not applicable.

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Miconazole nitrate
IUPAC name:	1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]imidazole;nitric acid
Synonyms:	Andergin Albistat
N° CAS:	22832-87-7
N° EC:	245-256-6
Molecular Formula:	C <sub>18</sub> H <sub>15</sub> Cl <sub>4</sub> N <sub>3</sub> O <sub>4</sub>
Content:	99.0 per cent to 101.0 per cent (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.
After inhalation:	If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Consult a physician.
After skin contact:	In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. Call a physician.
After eye contact:	

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After ingestion:

In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.

If swallowed, wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Call a physician.

### 4.2 Most important symptoms and effects, both acute and delayed

Not available.

### 4.3 Indication of any immediate medical attention and special treatment needed

Not available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media:

Not available.

### 5.2 Special hazards arising from the substance/mixture

Emits toxic fumes under fire conditions.

Hazardous decomposition products formed under fire conditions: Carbon oxides, nitrogen oxides (NO<sub>x</sub>), hydrogen chloride gas.

### 5.3 Advice for firefighters

Surrounding fires:

Not available.

Protection against fire:

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Hazardous combustion products:

Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Use personal protective equipment. Avoid breathing dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

#### For emergency responders

Use personal protective equipment. Avoid breathing dust. Evacuate personnel to safe areas.

### 6.2 Environmental precautions

Do not let product enter drains.

### 6.3 Methods and material for containment and cleaning up

Soak up with inert absorbent material, vacuum or sweep up material and keep in suitable, closed containers for disposal. Avoid generating dusty conditions. Ventilate area and wash spill site after material pickup is complete.

### 6.4 Reference to other sections

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Not available.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:	Normal measures for preventive fire protection.
Personal protection:	Avoid contact with skin and eyes. Avoid inhalation of dust, vapour or mist. Avoid prolonged or repeated exposure.
Technical protective measures:	Not available.
Handling:	Not available.

#### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Storage – away from:	Protected from light.

#### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Contains no substances with occupational exposure limit values.

#### 8.2 Exposure controls

##### Appropriate engineering control

Safety shower and eye bath. Mechanical exhaust required.

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

##### Individual protection measures

Eye/face protection:	Tightly fitting safety goggles. Face shield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin protection:	Complete suit protecting against chemicals, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Hand protection:	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product.

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### Respiratory protection:

Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator.

Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

### Thermal hazards:

Not determined.

### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance:	White or almost white powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	178 °C to 184 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not applicable.
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:	Sparingly soluble in methanol, slightly soluble in ethanol (96 per cent).
Solubility in water:	Very slightly soluble in water.
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.

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### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Strong oxidising agents.

### 10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions: Carbon oxides, nitrogen oxides (NO<sub>x</sub>), hydrogen chloride gas.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:

Oral LD<sub>50</sub> (rat): 920 mg/kg

Intraperitoneal LD<sub>50</sub> (rat): 1 060 mg/kg

Subcutaneous LD<sub>50</sub> (rat): > 5 g/kg; Remarks: Sense organs and special senses (nose, eye, ear, and taste): eye: lacrimation. Behavioural: Ataxia. Gastrointestinal: Ulceration or bleeding from stomach.

Intravenous LD<sub>50</sub> (rat): 14 700 µg/kg

Oral LD<sub>50</sub> (mouse): 578 mg/kg; Remarks: Sense organs and special senses (nose, eye, ear, and taste): Eye: Lacrimation. Behavioural: Ataxia. Gastrointestinal: Ulceration or bleeding from stomach.

Intraperitoneal LD<sub>50</sub> (mouse): 480 mg/kg

Subcutaneous LD<sub>50</sub> (mouse): > 5 g/kg; Remarks: Sense organs and special senses (nose, eye, ear, and taste): eye: lacrimation. Behavioural: Ataxia. Gastrointestinal: Ulceration or bleeding from stomach.

Intravenous LD<sub>50</sub> (mouse): 28 mg/kg

Oral LD<sub>50</sub> (dog): > 160 mg/kg

Oral LD<sub>50</sub> (guinea pig): 276 mg/kg

Skin corrosion/irritation:

Not available.

Serious eye damage/irritation:

Not available.

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Respiratory/skin sensitisation:	May cause allergic skin reaction.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity:	<p>Overexposure may cause reproductive disorder(s) based on tests with laboratory animals.</p> <p>Species: Rat Dose: 330 mg/kg Route of Application: Oral Exposure Time: (7-17D PREG) Result: Maternal Effects: Parturition.</p> <p>Species: Rat Dose: 810 mg/kg Route of Application: Oral Exposure Time: (17-22D PREG/21D POST) Result: Effects on Newborn: Stillbirth. Effects on Newborn: Growth statistics (e.g., reduced weight gain).</p> <p>Species: Rat Dose: 270 mg/kg Route of Application: Oral Exposure Time: (17-22D PREG/21D POST) Result: Effects on Newborn: Behavioral.</p> <p>Species: Rabbit Dose: 1 300 mg/kg Route of Application: Oral Exposure Time: (6-18D PREG) Result: Effects on Fertility: Post-implantation mortality (e.g., dead and/or resorbed implants per total number of implants).</p>
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Signs and symptoms of exposure: To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Causes eye irritation.

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Skin contact:	May be harmful if absorbed through skin. Causes skin irritation.
Inhalation:	May be harmful if inhaled. Causes respiratory tract irritation.
Ingestion:	May be harmful if swallowed.
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

Not available.

#### 12.6 Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.  
Very toxic to aquatic life.

### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Product: Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging: Dispose of as unused product.

### SECTION 14: TRANSPORT INFORMATION

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

##### 14.1 UN Number

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

##### 14.2 UN proper shipping name

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

##### 14.3 Transport hazard class(es)

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



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### 14.4 Packing group

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

### 14.5 Environmental hazards

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

### 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 hazardous material as defined by the transport regulations.

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Harmful to the environment  
Harmful

Risk phrases:

R22 Harmful if swallowed  
R43 May cause sensitization by skin contact.  
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

S36/37/39 Wear suitable protective clothing and gloves.

### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

## 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

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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

### 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

Quality Department

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