

**Safety Data Sheet**  
according to Regulation (EC) No. 1907/2006 (REACH)

**FIPHARMA**

**Trade name :** Ketoconazole micro  
**Revision date :** 16-08-2019  
**Print date :** 21-11-2019

**Version (Revision) :** 1.1.0 (1.0.1)

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

**1.1 Product identifier**

Ketoconazole micro (1965)  
Ketoconazole ; CAS No. : 65277-42-1

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

**Relevant identified uses**

**Product Categories [PC]**

PC 29 - Pharmaceuticals

**Uses advised against**

This product should not be used for purposes other than the applications referred to above.

**1.3 Details of the supplier of the safety data sheet**

**Supplier (manufacturer/importer/only representative/downstream user/distributor)**

Ofipharma B.V.

**Street :** Heembadweg 5

**Postal code/city :** 9561 CZ Ter Apel

**Telephone :** +31 599 745 390

**Telefax :** +31 599 582 734

**1.4 Emergency telephone number**

+31 599 583 433

Telefoon voor professionele hulpverleners: NVIC + (0)30 - 274 88 88. Uitsluitend bestemd om professionele hulpverleners te informeren bij acute vergiftigingen.

**SECTION 2: Hazards identification**

**2.1 Classification of the substance or mixture**

**Classification according to Regulation (EC) No 1272/2008 [CLP]**

Acute Tox. 3 ; H301 - Acute toxicity (oral) : Category 3 ; Toxic if swallowed.

Repr. 1B ; H360 - Reproductive toxicity : Category 1B ; May damage fertility or the unborn child.

Aquatic Acute 1 ; H400 - Hazardous to the aquatic environment : Acute 1 ; Very toxic to aquatic life.

Aquatic Chronic 1 ; H410 - Hazardous to the aquatic environment : Chronic 1 ; Very toxic to aquatic life with long lasting effects.

**2.2 Label elements**

**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

**Hazard pictograms**



Skull and crossbones (GHS06) · Health hazard (GHS08) · Environment (GHS09)

**Signal word**

Danger

**Hazard statements**

H301 Toxic if swallowed.

H360 May damage fertility or the unborn child.

H410 Very toxic to aquatic life with long lasting effects.

**Precautionary statements**

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P201	Obtain special instructions before use.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/....
P308+P313	IF exposed or concerned: Get medical advice/attention.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations

## 2.3 Other hazards

None

## 2.4 Additional information

This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

**Substance name :** Ketoconazole

**CAS No. :** 65277-42-1

**Purity :** 100 % [mass]

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information

When in doubt or if symptoms are observed, get medical advice.

#### Following inhalation

No special measures are necessary.

#### In case of skin contact

Wash immediately with: Water and soap Change contaminated, saturated clothing. Wash contaminated clothing prior to re-use.

#### After eye contact

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

#### After ingestion

Call a physician in any case! Do NOT induce vomiting. If major quantity of dust is swallowed or inhaled, immediately drink: Water

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

The following symptoms may occur: No known symptoms to date. Repeated exposure may cause skin dryness or cracking.

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

None

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

None

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

None

### 5.3 Advice for firefighters

None

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#### 5.4 Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

### SECTION 6: Accidental release measures

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

##### For non-emergency personnel

##### Protective equipment

Avoid contact with skin, eyes and clothes. Use personal protection equipment.

#### 6.2 Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Make sure spills can be contained, e.g. in sump pallets or kerbed areas. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

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

##### For containment

Collect in closed and suitable containers for disposal. Treat the recovered material as prescribed in the section on waste disposal.

##### For cleaning up

Suitable material for taking up: Sand Absorbing material, organic

#### 6.4 Reference to other sections

See protective measures under point 7 and 8.

### SECTION 7: Handling and storage



#### 7.1 Precautions for safe handling

None

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

##### Technical measures and storage conditions

Keep/Store only in original container. Suitable container/equipment material: Stainless steel Polyethylene (PE)  
Unsuitable container/equipment material: Butyl caoutchouc (butyl rubber)

##### Hints on joint storage

Storage class (TRGS 510) : 6.1D

#### 7.3 Specific end use(s)

None

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

None

#### 8.2 Exposure controls

##### Personal protection equipment



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## Eye/face protection

Eye glasses with side protection

## Skin protection

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. DIN-/EN-Norms EN ISO 374 DIN EN 420 Suitable material NBR (Nitrile rubber) PVA (Polyvinyl alcohol) PVC (polyvinyl chloride)

## Hand protection

**Breakthrough time (maximum wearing time) :** > 60 m.

**Thickness of the glove material :** > 0,5 mm

## Respiratory protection

If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn. Suitable respiratory protection apparatus Full-/half-/quarter-face masks (DIN EN 136/140) Filtering device (full mask or mouthpiece) with filter: ABEK-P3

## General health and safety measures

Immediately remove any contaminated clothing, shoes or stockings. Wash contaminated clothing prior to re-use.

## Environmental exposure controls

See section 7. No additional measures necessary.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

**Appearance :** solid

**Colour :** white

**Odour :** No data available

### Safety relevant basis data

<b>Freezing point :</b>	( 1013 hPa )	No data available
<b>Initial boiling point and boiling range :</b>	( 1013 hPa )	No data available
<b>Flash point :</b>		No data available
<b>Ignition temperature :</b>		No data available
<b>Lower explosion limit :</b>		No data available
<b>Upper explosion limit :</b>		No data available
<b>Vapour pressure :</b>	( 50 °C )	No data available
<b>Relative density :</b>	( 20 °C )	No data available
<b>Water solubility :</b>	( 20 °C )	No data available
<b>pH :</b>		not determined
<b>log P O/W :</b>		No data available
<b>Cinematic viscosity :</b>	( 40 °C )	No data available
<b>Relative vapour density :</b>	( 20 °C )	No data available
<b>Evaporation rate :</b>		No data available
<b>Flammable solids :</b>	No data available.	
<b>Oxidising solids :</b>	No data available.	

### 9.2 Other information

None

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

not applicable

### 10.2 Chemical stability

Stable under normal conditions of use

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**10.3 Possibility of hazardous reactions**

No information available.

**10.4 Conditions to avoid**

No information available.

**10.5 Incompatible materials**

Strong oxidizers

**10.6 Hazardous decomposition products**

No information available.

**SECTION 11: Toxicological information**

**11.1 Information on toxicological effects**

**Irritant and corrosive effects**

**Primary irritation to the skin**

Not an irritant.

**Irritation to eyes**

Not an irritant.

**Irritation to respiratory tract**

No data available

**CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

**Carcinogenicity**

This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.

**Germ cell mutagenicity**

No indications of human germ cell mutagenicity exist.

**Reproductive toxicity**

This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.

**STOT-single exposure**

not applicable

**STOT-repeated exposure**

Prolonged or repeated contact with skin or mucous membrane result in irritation symptoms such as redness, blistering, dermatitis, etc.

**SECTION 12: Ecological information**

**12.1 Toxicity**

harmless to aquatic organisms up to the tested concentration

**12.2 Persistence and degradability**

Biodegradable.

**12.3 Bioaccumulative potential**

No indication of bioaccumulation potential.

**12.4 Mobility in soil**

No information available.

**12.5 Results of PBT and vPvB assessment**

This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

**12.6 Other adverse effects**

None

**12.7 Additional ecotoxicological information**

None

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Delivery to an approved waste disposal company. Contaminated packages must be completely emptied and can be re-used following proper cleaning. Handle contaminated packages in the same way as the substance itself.

## SECTION 14: Transport information

### 14.1 UN number

UN 2811

### 14.2 UN proper shipping name

#### Land transport (ADR/RID)

TOXIC SOLID, ORGANIC, N.O.S. ( Ketoconazole )

#### Sea transport (IMDG)

TOXIC SOLID, ORGANIC, N.O.S. ( Ketoconazole )

#### Air transport (ICAO-TI / IATA-DGR)

TOXIC SOLID, ORGANIC, N.O.S. ( Ketoconazole )

### 14.3 Transport hazard class(es)

#### Land transport (ADR/RID)

Class(es) : 6.1  
Classification code : T2  
Hazard identification number (Kemler No.) : 60  
Tunnel restriction code : E  
Special provisions : LQ 5 kg · E 1  
Hazard label(s) : 6.1 / N

#### Sea transport (IMDG)

Class(es) : 6.1  
EmS-No. : F-A / S-A  
Special provisions : LQ 5 kg · E 1  
Hazard label(s) : 6.1 / N

#### Air transport (ICAO-TI / IATA-DGR)

Class(es) : 6.1  
Special provisions : E 1  
Hazard label(s) : 6.1

### 14.4 Packing group

III

### 14.5 Environmental hazards

Land transport (ADR/RID) : Yes  
Sea transport (IMDG) : Yes (P)  
Air transport (ICAO-TI / IATA-DGR) : Yes

### 14.6 Special precautions for user

None

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

not applicable

## SECTION 15: Regulatory information

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

EU legislation

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## Authorisations and/or restrictions on use

### Restrictions on use

Use restriction according to REACH annex XVII, no. : 3

### National regulations

#### Water hazard class (WGK)

Class : nwg (Non-hazardous to water)

## 15.2 Chemical safety assessment

Chemical safety assessments for substances in this preparation were not carried out.

## SECTION 16: Other information

### 16.1 Indication of changes

02. Labelling according to Regulation (EC) No. 1272/2008 [CLP] · 15. Restrictions on use · 15. Water hazard class (WGK)

### 16.2 Abbreviations and acronyms

a.i. = Active ingredient  
ACGIH = American Conference of Governmental Industrial Hygienists (US)  
ADR = European Agreement concerning the International Carriage of Dangerous Goods by Road  
AFFF = Aqueous Film Forming Foam  
AISE = International Association for Soaps, Detergents and Maintenance Products (joint project of AISE and CEFIC)  
AOAC = AOAC International (formerly Association of Official Analytical Chemists)  
aq. = Aqueous  
ASTM = American Society of Testing and Materials (US)  
atm = Atmosphere(s)  
B.V. = Beperkt Vennootschap (Limited)  
BCF = Bioconcentration Factor  
bp = Boiling point at stated pressure  
bw = Body weight  
ca = (Circa) about  
CAS No = Chemical Abstracts Service Number (see ACS - American Chemical Society)  
CEFIC = European Chemical Industry Council (established 1972)  
CIPAC = Collaborative International Pesticides Analytical Council  
CLP = REGULATION (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.  
Conc = Concentration  
cP = CentiPoise  
cSt = Centistokes  
d = Day(s)  
DIN = Deutsches Institut für Normung e.V.  
DNEL = Derived No-Effect Level  
DT50 = Time for 50% loss; half-life  
EbC50 = Median effective concentration (biomass, e.g. of algae)  
EC = European Community; European Commission  
EC50 = Median effective concentration  
EINECS = European Inventory of Existing Commercial Chemical Substances (EU, outdated, now replaced by EC Number)  
ELINCS = European List of Notified (New) Chemicals (see Tab 7, Background - Guide)  
ErC50 = Median effective concentration (growth rate, e.g. of algae)  
EU = European Union  
EWC = European Waste Catalogue  
FAO = Food and Agriculture Organization (United Nations)  
GIFAP = Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now CropLife International)  
h = Hour(s)  
hPa = HectoPascal (unit of pressure)  
IARC = International Agency for Research on Cancer  
IATA = International Air Transport Association  
IC50 = Concentration that produces 50% inhibition  
IMDG Code = International Maritime Dangerous Goods Code

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IMO = International Maritime Organization  
ISO = International Organization for Standardization  
IUCLID = International Uniform Chemical Information Database  
IUPAC = International Union of Pure and Applied Chemistry  
kg = Kilogram  
Kow = Distribution coefficient between n-octanol and water  
kPa = KiloPascal (unit of pressure)  
LC50 = Concentration required to kill 50% of test organisms  
LD50 = Dose required to kill 50% of test organisms  
LEL = Lower Explosive Limit/Lower Explosion Limit  
LOAEL = Lowest observed adverse effect level  
mg = Milligram  
min = Minute(s)  
ml = Milliliter  
mmHg = Pressure equivalent to 1 mm of mercury (133.3 Pa)  
mp = Melting point  
MRL = Maximum Residue Limit  
MSDS = Material Safety Data Sheet  
n.o.s. = Not Otherwise Specified  
NIOSH = National Institute for Occupational Safety and Health (US)  
NOAEL = No Observed Adverse Effect Level  
NOEC = No observed effect concentration  
NOEL = No Observable Effect Level  
NOx = Oxides of Nitrogen  
OECD = Organization for Economic Cooperation and Development  
OEL = Occupational Exposure Limits  
Pa = Pascal (unit of pressure)  
PBT = Persistent, Bioaccumulative or Toxic  
pH = -log<sub>10</sub> hydrogen ion concentration  
pKa = -log<sub>10</sub> acid dissociation constant  
PNEC = Previsible Non Effect Concentration  
POPs = Persistent Organic Pollutants  
ppb = Parts per billion  
PPE = Personal Protection Equipment  
ppm = Parts per million  
ppt = Parts per trillion  
PVC = Polyvinyl Chloride  
QSAR = Quantitative Structure-Activity Relationship  
REACH = Registration, Evaluation and Authorization of Chemicals (EU, see NCP)  
SI = International System of Units  
STEL = Short-Term Exposure Limit  
tech. = Technical grade  
TSCA = Toxic Substances Control Act (US)  
TWA = Time-Weighted Average  
vPvB = Very Persistent and Very Bioaccumulative  
WHO = World Health Organization = OMS  
y = Year(s)

### 16.3 Key literature references and sources for data

None

### 16.4 Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

No information available.

### 16.4 Relevant H- and EUH-phrases (Number and full text)

None

### 16.5 Training advice

None

### 16.6 Additional information

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None

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The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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