

Material Safety Data Sheet

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

KETOCONAZOLUM

EN

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

1.1 Product identifier

Product name: Ketoconazole
Ketoconazolum
Ketoconazol
Kétoconazole
Ketoconazol

N° CAS: 65277-42-1

N° EC: 265-667-4

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: 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. 3	H301
Repr. 1B	H360F
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger
Harmful, Toxic, Harmful to the environment

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Hazard statements:

H301	Toxic if swallowed.
H360F	May damage fertility.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statements:

P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P281	Use personal protective equipment as required.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P501	Dispose of this substance and its container to a special or hazardous waste collection point in accordance with local, regional, national and/or international regulations.

Additional applicable label elements:	Not applicable.
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2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Ketoconazole
IUPAC name:	(±)-cis-1-Acetyl-4-(4-[(2-[2,4-dichlorophenyl]-2-[1H-imidazol-1-ylmethyl]-1,3-dioxolan-4-yl)-methoxy]phenyl)piperazine
Synonyms:	Kuric (2R,4S)-ketoconazole (+)-Ketoconazole
N° CAS:	65277-42-1
N° EC:	265-667-4
Molecular Formula:	C ₂₆ H ₂₈ Cl ₂ N ₄ O ₄
Content:	99.0 per cent to 101.0 per cent (dried substance)

3.2 Mixtures

It contains no other components or impurities that may influence the classification of the product.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.

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After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

Ingestion of even a small amount of this product can produce a serious health risk. May impair fertility. May cause damage to organs.

4.3 Indication of any immediate medical attention and special treatment needed

Do not administer anything by mouth to an unconscious person.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam, dry powder, carbon dioxide, sand, water mist. Neighbouring fires (containers exposed to fire): Water spray or fog.
Unsuitable extinguishing media:	Direct water jet.

5.2 Special hazards arising from the substance/mixture

In case of fire, fumes harmful to health may be produced.

5.3 Advice for firefighters

Surrounding fires:	Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.
Protection against fire:	Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a face mask with full face shield covering the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

For exposure control and personal protective measures, see section 8.
Avoid breathing vapours. Ensure adequate ventilation.

For emergency responders

For exposure control and personal protective measures, see section 8.
Avoid breathing vapours. Ensure adequate ventilation.

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6.2 Environmental precautions

Prevent release to the environment. Prevent entry into sewers and watercourses. If product enters drains or public waterways, notify authorities.

6.3 Methods and material for containment and cleaning up

Store away from other materials. If on the ground, sweep or scoop (shovel or similar) into suitable containers. Limit dust production.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Ask for special instructions before use. Do not eat, drink or smoke while handling this product. Avoid breathing dust, fumes, smoke, gas, mist, vapours or aerosol.
Personal protection:	Not available.
Technical protective measures:	Ensure good ventilation of the processing area to avoid vapour formation.
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 cool place. Keep container tightly closed in a dry, well-ventilated place. Keep container closed when not in use.
Storage – away from:	Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN166.

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Skin protection:	Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.
Hand protection:	Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.
Respiratory protection:	Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental 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:	Characteristic.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	148 °C to 152 °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:	Freely soluble in methylene chloride, soluble in methanol, sparingly soluble in ethanol (96 per cent).
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	LogPow 4.35
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

Molecular weight: 531.43 g/mol

Density (20 °C): 0.394 g/ml

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions.

Stable under the recommended handling and storage conditions (see section 7).

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to avoid

Direct sunlight. Extremely high or extremely low temperatures.

10.5 Incompatible materials

Strong bases. Strong acids. Sources of ignition.

10.6 Hazardous decomposition products

Toxic fumes of carbon oxides (CO_x).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity: Toxic if swallowed.
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	May impair fertility.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	May cause damage to organs through prolonged or repeated exposure.
Aspiration Hazard:	Not available.
Other:	N° RTECS: TK7912300

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.

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Ingestion: Toxic if swallowed.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Very toxic to aquatic life with long lasting effects.

12.2 Persistence and degradability

May cause long-term adverse effects in the environment.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

The substance does not meet the criteria to be identified as a PBT or vPvB according to Annex XIII of the REACH Regulation.

12.6 Other adverse effects

Avoid release to the environment. Use in accordance with good working practices, avoiding dispersal of the product into the environment. Notify the competent authorities if the product has reached watercourses or if it has contaminated soil or vegetation.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: 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) : ADR/RID, IMDG, IATA: 2811
ADR - tunnel code: E

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : ADR/RID: TOXIC SOLID, ORGANIC, N.O.S. (KETOCONAZOLE)
IMDG: TOXIC SOLID, ORGANIC, N.O.S. (KETOCONAZOLE)
IATA: TOXIC SOLID, ORGANIC, N.O.S. (KETOCONAZOLE)

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : 6.1

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14.4 Packing group

ADR/ RID(Land),IMDG(Sea), III
IATA/ICAO (Air) :

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), ADR/RID: Dangerous for the environment
IATA/ICAO (Air) : IMDG: Marine pollutant
IATA: Dangerous for the environment

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

Hazard symbol:



Harmful Toxic Harmful to the environment

Risk phrases:

R25 Toxic if swallowed.
R48 Danger of serious damage to health by prolonged exposure.
R60 May impair fertility.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

S23 Do not breathe dust/fume/gas/mist/vapours/spray.
S46 If swallowed, seek medical advice immediately and show this container or label.
S56 Dispose of this material and its container at hazardous or special waste collection point.

15.2 Chemical safety assessment

A chemical safety assessment of the product 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)

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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.

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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