

Product: **KETOCONAZOL (EUR. PH.)**

Product code: 1165

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Emission date: 23/07/2026

Version: 1165_MSDS_ENG_0126

**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****1.1. Product identifier**

Product name: **KETOCONAZOL (EUR. PH.)**
Product code: 1165
Nº CAS: 65277-42-1
Nº EC: 265-667-4

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

Relevant identified uses: Active pharmaceutical ingredient

1.3. Details of the supplier of the safety data sheet

Company: **METAPHARMACEUTICAL INDUSTRIAL SLU**
JOSEP PLA 163 2º 5ª
08020 BARCELONA
SPAIN
Phone number: (0034) 933 089 976
Contact e-mail: info@metaph.es
Web page: www.metaph.com

1.4. Emergency telephone number

National Institute of Toxicology of Madrid: (0034) 915 620 420

2. HAZARDS IDENTIFICATION**2.1. Classification of the substance or mixture**

The product is classified as dangerous according to the provisions of Regulation (EC) 1272/2008 (CLP).

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

2.2. Label Elements

Signal word (CLP): DANGER

Hazard statements:

H301: Toxic if swallowed
H360F: May damage fertility or the unborn child
H373: May cause damage to organs
H400: Very toxic to aquatic life
H410: Very toxic to aquatic life with long lasting effects

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Precautionary statements:

P260:	Do not breathe dust/fume/gas/mist/vapours/spray
P264:	Wash ... thoroughly after handling
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 to...

2.3. Other hazards

No additional information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS**3.1. Substances**

Product name:	KETOCONAZOL
Synonyms:	KETOCONAZOL, KETOCONAZOL
IUPAC name:	(±)-cis-1-Acetyl-4-(4-[(2-[2,4-dichlorophenyl]-2-[1H-imidazol-1-ylmethyl]-1,3-dioxolan-4-yl)-methoxy]phenyl)piperazine
Nº CAS:	65277-42-1
Nº EC:	265-667-4
Molecular formula:	C ₂₆ H ₂₈ Cl ₂ N ₄ O ₄

3.2. Mixtures

Not applicable.

4. FIRST AID MEASURES**4.1. Description of first aid measures**

General advises:	Consult a doctor. Show the safety data sheet to the doctor on duty.
Inhalation:	Take outdoors. If breathing is irregular, call a doctor immediately. Only apply artificial respiration if breathing stops or under medical supervision.
Skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists.
Eye contact:	Remove contact lenses and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
Ingestion:	If conscious, give 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 poses a serious health risk. It may damage fertility. It causes damage to organs.

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

In case of doubt, or if symptoms of discomfort persist, seek medical attention.

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5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing methods: Foam, dry chemical powder, carbon dioxide, sand, water spray/mist

Unsuitable extinguishing methods: Direct water jet.

Neighboring fires (containers exposed to fire): Water spray or water mist.

5.2. Special hazards arising from the substance or mixture

In the event of fire, hazardous combustion gases or vapors may be generated.

5.3. Advice for firefighters

General information: Cool containers with water to prevent product decomposition and development of potential health hazards. Always use full fire protection. Collect the water that should not enter the sewer. Eliminate the contaminated water used to extinguish and the remains of the second current regulations.

Equipment: Helmet with visor, flame retardant clothing (jacket and trousers with braces around the arms, legs and waist, EN 469), gloves (fire and dielectric proof, EN 659), a mask with a full-face mask. operator's face or car (protective car) in the case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

For exposure controls and personal protection measures, see Section 8.
Provide cleanup personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

6.2. Environmental precautions

Prevent release into the environment. Avoid entry into sewers and waterways. If the product reaches drains or public watercourses, notify the relevant authorities.

6.3. Methods and material for containment and cleaning up

Store away from other materials. If spilled on the ground, sweep up or collect using a shovel or similar tool and place in suitable containers. Minimize dust generation.

6.4. Reference to other sections

For exposure controls and personal protective measures, see Section 8.
For disposal recommendations, see Section 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Obtain special instructions before use. Wash thoroughly after handling. Do not eat, drink, or smoke when using this product.
Ensure good ventilation of the processing area to prevent the formation of vapors.
Avoid breathing dust, fumes, gas, mist, vapors, or spray.

7.2. Conditions for safe storage, including any incompatibilities

Store in a cool place. Keep the container tightly closed in a dry, well-ventilated area. Keep the container closed when not in use.

7.3. Specific end use(s)

No additional information available beyond that provided in Section 1

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure controls/personal protection

No data available.

8.2. Exposure controls

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation in the workplace by means of effective local suction. When choosing personal protective equipment, ask your chemical suppliers if necessary. Personal protective equipment must bear the CE marking that certifies compliance with the applicable regulations. Arrange an emergency shower with a visco-elastic tray.



Eye and face protection:

Protection masks and safety glasses according to EN 165, EN 166, EN 167, EN 168.

Hands protection:

Handle with gloves. The selected protective gloves must comply with the specifications of the EU Directive 89/686/EEC and the standards EN 374-1, EN 374-2, EN 374-3, EN 420 derived from it.

Respiratory protection:

Where risk assessment shows that air purifying respirators are appropriate, use type N95 (USA) or type P1 (EN 149) dust mask. Use respirators and components tested and approved under the appropriate government standards such as NIOSH (USA) or CEN (EU).

Skin protection:

Choose body protection based on the amount and concentration of the dangerous substance in the workplace.

Hygiene measures:

Handle with adequate industrial hygiene precautions, and respect safety practices. Wash your hands before breaks and after finishing the workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Aspect:	Solid
Color:	White or almost white
Odor:	Characteristic
Molecular weight (g/mol):	531.43
Density (20 °C):	0.394 g/mL
Melting point (°C):	148 – 152
Water solubility (20 °C):	Insoluble
n-Octanol/Water Partition Coefficient (20 °C):	LogPow -4.35

9.2. Other information

Dissociation constant (20 °C):	4.65
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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 the recommended handling and storage conditions (see Section 7).

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Direct sunlight, moisture, and extremely high temperatures.

10.5. Incompatible materials

Strong bases, strong acids and ignition sources.

10.6. Hazardous decomposition products

Toxic fumes of carbon oxides (COx).

11. TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity (LD50, rat):	Toxic if swallow
Skin corrosion/irritation:	No additional information available (Lack of data)
Serious eye damage/eye irritation:	No additional information available (Lack of data)
Skin or respiratory sensitization:	No additional information available (Lack of data)
Germ cell mutagenicity:	No additional information available (Lack of data)
Carcinogenicity:	No additional information available (Lack of data)
Reproductive toxicity:	May damage fertility
STOT – single exposure:	No additional information available (Lack of data)
STOT – repeated exposure:	ay cause damage to organs through prolonged or repeated exposure
Aspiration Hazard:	No additional information available (Lack of data)
Potential Health Effects	
Inhalation:	No additional information available (Lack of data)
Ingestion:	No additional information available (Lack of data)
Skin:	No additional information available (Lack of data)
Eyes:	No additional information available (Lack of data)
Signs and Symptoms of Exposure:	No additional information available (Lack of data)

11.2. Information on other hazards

Nº RTECS: TK7912300

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12. ECOLOGICAL INFORMATION

Use in accordance with good work practices, avoiding dispersing the product in the environment. Notify the competent authorities if the product has reached water courses or if it has contaminated the soil or vegetation.

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

No data available.

12.4. Results of PBT and vPvB assessment

This substance does not meet the criteria for identification as a PBT or vPvB substance in accordance with Annex XIII of the REACH Regulation.

12.5. Endocrine disrupting properties

No data available.

12.6. Other adverse effects

Avoid release to the environment.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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

Contaminated packaging: Dispose of as unused product.

14. INFORMACIÓN RELATIVA AL TRANSPORTE

The product is classified by the conventions of dangerous substances.

14.1. UN Number

ADR/RID, IMDG, IATA: 2811

ADR – tunne code: E

14.2. UN proper shipping name

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)

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**14.3. Transport hazard class(es)**

	Class	Label	Pictogram
ADR / RID:	6.1	6.1	
IMDG:	6.1	6.1	
IATA:	6.1	6.1	

14.4. Packing group

ADR/RID, IMDG, IATA: III

14.5. Environmental hazards

ADR / RID:	Hazardous to the environment	
IMDG:	Marine Pollutant	
IATA:	Hazardous to the environment	

14.6. Special precautions for user

No data available.

14.7. Maritime transport in bulk according to IMO instruments

No data available.

15. REGULATORY INFORMATION**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

The Safety Data Sheet complies with the requirements of Regulation (EU) 2020/878 of the Commission of June 18, 2020, by which Annex II of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council is modified, relating to the registration, evaluation, authorization and restriction of chemical substances and mixtures (REACH).

15.2. Chemical safety assessment

No additional information available.

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16. OTHER INFORMATION

Abbreviations and acronyms:

PBT: Persistent, bioaccumulative and toxic

mPmB: Very persistent and very bioaccumulative

REACH: Registration, Evaluation, Authorization and Restriction of Chemicals

Data sources used:

Regulation (CE) No. 1272/2008 of the European Parliament and of the Council, of December 16, 2008, on the classification, labeling and packaging of substances and mixtures, and by which Directives 67/548/CEE and 1999 are modified and repealed /45/CE and modifies Regulation (CE) No. 1907/2006.

Regulation (EU) 2020/878 of the Commission of June 18, 2020, by which Annex II of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council, regarding registration, evaluation, authorization and the restriction of chemical substances and mixtures (REACH)

Safety Data Sheet according to Annex II of REACH Regulation (EU) 2020/878

Department issuing the Safety Data Sheet:

Technical Department

The information in this Product Safety Data Sheet is based on current knowledge and current EC and national laws, as far as the working conditions of users are beyond our knowledge and control. The product must not be used for purposes other than those specified, without first having a written instruction on its handling. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established in the legislation.