

## Chemical Safety Data Sheet MSDS / SDS

## Ketoconazole SDS

Revision Date:2024-04-25 Revision Number:1

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

Product name: Ketoconazole  
CAS: 65277-42-1

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

Relevant identified uses: For R&D use only. Not for medicinal, household or other use.  
Uses advised against: none

**Company Identification**

Company: Chemicalbook.in  
Address: 5 vasavi Layout Basaveswara Nilayam Pragathi Nagar Hyderabad, India -500090  
Telephone: +91 9550333722

**SECTION 2: Hazards identification****Classification of the substance or mixture**

Acute toxicity - Category 3, Oral  
Specific target organ toxicity - repeated exposure, Category 2

Hazardous to the aquatic environment, short-term (Acute) - Category Acute 1  
Hazardous to the aquatic environment, long-term (Chronic) - Category Chronic 1  
Reproductive toxicity, Category 1B

### GHS label elements, including precautionary statements

Pictogram(s)



Signal word

Danger

### Hazard statement(s)

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

### Precautionary statement(s)

### Prevention

P264 Wash ... thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P260 Do not breathe dust/fume/gas/mist/vapours/spray.  
P273 Avoid release to the environment.  
P203 Obtain, read and follow all safety instructions before use.  
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

### Response

P301+P316 IF SWALLOWED: Get emergency medical help immediately.  
P321 Specific treatment (see ... on this label).  
P330 Rinse mouth.  
P319 Get medical help if you feel unwell.  
P391 Collect spillage.  
P318 IF exposed or concerned, get medical advice.

### Storage

P405 Store locked up.

### Disposal

P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

**Other hazards which do not result in classification**

no data available

**SECTION 3: Composition/information on ingredients**

**Substance**

Chemical name: Ketoconazole

Common names and synonyms: Ketoconazole

CAS number: 65277-42-1

EC number: 265-667-4

Concentration: 100%

**SECTION 4: First aid measures**

**Description of necessary first-aid measures**

**If inhaled**

Fresh air, rest.

**Following skin contact**

Rinse and then wash skin with water and soap.

**Following eye contact**

Rinse with plenty of water (remove contact lenses if easily possible).

**Following ingestion**

Rinse mouth. Give a slurry of activated charcoal in water to drink. Refer immediately for medical attention.

**Most important symptoms/effects, acute and delayed**

no data available

#### **Indication of immediate medical attention and special treatment needed, if necessary**

Immediate first aid: Ensure that adequate decontamination has been carried out. If patient is not breathing, start artificial respiration, preferably with a demand valve resuscitator, bag-valve-mask device, or pocket mask, as trained. Perform CPR if necessary. Immediately flush contaminated eyes with gently flowing water. Do not induce vomiting. If vomiting occurs, lean patient forward or place on the left side (head-down position, if possible) to maintain an open airway and prevent aspiration. Keep patient quiet and maintain normal body temperature. Obtain medical attention. Poisons A and B

### **SECTION 5: Firefighting measures**

#### **Suitable extinguishing media**

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

#### **Specific hazards arising from the chemical**

Not combustible.

#### **Special protective actions for fire-fighters**

In case of fire in the surroundings, use appropriate extinguishing media.

### **SECTION 6: Accidental release measures**

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

Personal protection: filter respirator for organic gases and particulates adapted to the airborne concentration of the substance. Do NOT let this chemical enter the environment. Sweep spilled substance into covered containers. If appropriate, moisten first to prevent dusting. Carefully collect remainder. Then store and dispose of according to local regulations.

#### **Environmental precautions**

Personal protection: filter respirator for organic gases and particulates adapted to the airborne concentration of the substance. Do NOT let this chemical enter the environment. Sweep spilled substance into covered containers. If appropriate, moisten first to prevent dusting. Carefully collect remainder. Then store and dispose of according to local regulations.

#### **Methods and materials for containment and cleaning up**

Accidental Release Measures. Personal precautions, protective equipment and emergency procedures: Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided. Methods and materials for containment and cleaning up: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

## **SECTION 7: Handling and storage**

### **Precautions for safe handling**

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

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

Provision to contain effluent from fire extinguishing. Well closed. Separated from food and feedstuffs. Store in an area without drain or sewer access. Store at controlled room temperature 15 deg - 25 deg C (59 deg - 77 deg F). Protect from moisture.

## **SECTION 8: Exposure controls/personal protection**

### **Control parameters**

#### **Occupational Exposure limit values**

no data available

#### **Biological limit values**

no data available

### **Appropriate engineering controls**

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

### **Individual protection measures, such as personal protective equipment (PPE)**

#### **Eye/face protection**

Wear safety goggles.

**Skin protection**

Protective gloves.

**Respiratory protection**

Use local exhaust or breathing protection.

**Thermal hazards**

no data available

**SECTION 9: Physical and chemical properties and safety characteristics**

Physical state:	Solid
Colour:	Crystals from 4-methylpentanone
Odour:	no data available
Melting point/freezing point:	10°C(lit.)
Boiling point or initial boiling point and boiling range:	200°C
Flammability:	Not combustible.
Lower and upper explosion limit/flammability limit:	no data available
Flash point:	178°C(lit.)
Auto-ignition temperature:	no data available
Decomposition temperature:	no data available
pH:	no data available

Kinematic viscosity:	no data available
Solubility:	no data available
Partition coefficient n-octanol/water:	4.35
Vapour pressure:	6.41X10 <sup>-14</sup> mm Hg at 25 deg C (est)
Density and/or relative density:	1.38g/cm <sup>3</sup>
Relative vapour density:	no data available
Particle characteristics:	no data available

## SECTION 10: Stability and reactivity

### Reactivity

no data available

### Chemical stability

no data available

### Possibility of hazardous reactions

Not combustible.

### Conditions to avoid

no data available

### Incompatible materials

Incompatible materials: Strong oxidizing agents.

### **Hazardous decomposition products**

When heated to decomposition it emits toxic fumes of /hydrogen chloride and nitrogen oxides/.

## **SECTION 11: Toxicological information**

### **Acute toxicity**

Oral: LD50 Rats oral 166 mg/kg

Inhalation: no data available

Dermal: no data available

### **Skin corrosion/irritation**

no data available

### **Serious eye damage/irritation**

no data available

### **Respiratory or skin sensitization**

no data available

### **Germ cell mutagenicity**

no data available

### **Carcinogenicity**

no data available

### **Reproductive toxicity**

no data available

### **STOT-single exposure**

no data available



### **STOT-repeated exposure**

The substance may have effects on the endocrine system and liver. Animal tests show that this substance possibly causes toxicity to human reproduction or development.

### **Aspiration hazard**

A harmful concentration of airborne particles can be reached quickly when dispersed, especially if powdered.

## **SECTION 12: Ecological information**

### **Toxicity**

Toxicity to fish: no data available

Toxicity to daphnia and other aquatic invertebrates: EC50; Species: Daphnia magna (Water Flea) age <24 hr neonate; Conditions: freshwater, static, 20 deg C; Concentration: 8100 ug/L for 24 hr (95% confidence interval: 4600-10800 ug/L); Effect: intoxication, immobilization /100% purity

Toxicity to algae: no data available

Toxicity to microorganisms: no data available

### **Persistence and degradability**

AEROBIC: Residue of azole antifungals in the environment is of concern due to the environmental risks and persistence. Distribution, behavior, and fate of frequently used azole antifungal pharmaceuticals were investigated in wastewater at two sewage treatment plants (STPs) in China. Fluconazole, clotrimazole, econazole, ketoconazole, and miconazole were constantly detected at 1-1834 ng/L in the wastewater. The latter four were also ubiquitously detected in sewage sludge. Fluconazole passed through treatment in the STPs and largely remained in the final effluent. On the contrary, biotransformation and sorption to sludge occurred to the other azoles. Ketoconazole was more readily bio-transformed, whereas clotrimazole, econazole, and miconazole were more likely to be adsorbed onto and persisted in sewage sludge. Lipophilicity plays the governing role on adsorption. The highest concentrations in the raw wastewater were observed in winter for the azole pharmaceuticals except for fluconazole. The seasonal difference was smoothed out after treatment in the STPs.

### **Bioaccumulative potential**

An estimated BCF of 340 was calculated in fish for ketoconazole(SRC), using a log Kow of 4.34(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is high(SRC).

### **Mobility in soil**

The Koc of ketoconazole is estimated as 3,000(SRC), using a log Kow of 4.34(1) and a regression-derived equation(2). According to a classification scheme(3), this estimated Koc value suggests that ketoconazole is expected to have slight mobility in soil. The estimated pKa value of 3.96(4) indicates that this compound will exist partially in the cation form in the environment and cations generally adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts(5). Ketoconazole adsorption isotherms (Kd) of  $9.7 \times 10^3$  L/kg and  $8.5 \times 10^3$  L/kg were measured in primary sludge and long-age secondary sludge, respectively. Sludge was obtained from 2 wastewater treatment plants that were representative of plants utilized in industrialized countries(6).

### **Other adverse effects**

no data available

## **SECTION 13: Disposal considerations**

### **Disposal methods**

#### **Product**

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

#### **Contaminated packaging**

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

## **SECTION 14: Transport information**

### **UN Number**

ADR/RID: UN2811 (For reference only, please check.)

IMDG: UN2811 (For reference only, please check.)

IATA: UN2811 (For reference only, please check.)

### **UN Proper Shipping Name**

ADR/RID: TOXIC SOLID, ORGANIC, N.O.S. (For reference only, please check.)

IMDG: TOXIC SOLID, ORGANIC, N.O.S. (For reference only, please check.)  
IATA: TOXIC SOLID, ORGANIC, N.O.S. (For reference only, please check.)

#### **Transport hazard class(es)**

ADR/RID: 6.1 (For reference only, please check.)  
IMDG: 6.1 (For reference only, please check.)  
IATA: 6.1 (For reference only, please check.)

#### **Packing group, if applicable**

ADR/RID: I (For reference only, please check.)  
IMDG: I (For reference only, please check.)  
IATA: I (For reference only, please check.)

#### **Environmental hazards**

ADR/RID: Yes  
IMDG: Yes  
IATA: Yes

#### **Special precautions for user**

no data available

#### **Transport in bulk according to IMO instruments**

no data available

### **SECTION 15: Regulatory information**

**Safety, health and environmental regulations specific for the product in question**

**European Inventory of Existing Commercial Chemical Substances (EINECS)**

Listed.

**EC Inventory**

Listed.

**United States Toxic Substances Control Act (TSCA) Inventory**

Not Listed.

**China Catalog of Hazardous chemicals 2015**

Not Listed.

**New Zealand Inventory of Chemicals (NZIoC)**

Listed.

**(PICCS)**

Not Listed.

**Vietnam National Chemical Inventory**

Listed.

**IECSC)**

Not Listed.

**Korea Existing Chemicals List (KECL)**

Listed.

**SECTION 16: Other information**

**Abbreviations and acronyms**

CAS: Chemical Abstracts Service

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: Regulation concerning the International Carriage of Dangerous Goods by Rail

IMDG: International Maritime Dangerous Goods

IATA: International Air Transportation Association

TWA: Time Weighted Average

STEL: Short term exposure limit

LC50: Lethal Concentration 50%

LD50: Lethal Dose 50%

EC50: Effective Concentration 50%

### References

IPCS - The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>

HSDB - Hazardous Substances Data Bank, website: <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>

IARC - International Agency for Research on Cancer, website: <http://www.iarc.fr/>

eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: [http://www.echemportal.org/echemportal/index?pageID=0&request\\_locale=en](http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en)

CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>

ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>

ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>

Germany GESTIS-database on hazard substance, website: <http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>

ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

### Other Information

Synonyms for this substance are: (+)-cis-1-Acetyl-4-(2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-ylmethoxyphenyl)piperazine and 1-(4-(2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan-4-ylmethoxyphenyl)piperazin-1-ylethanone.

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. We as supplier shall not be held liable for any