

SAFETY DATA SHEETS

According to the UN GHS revision 9

Version: 1.0
Creation Date: July 15, 2019
Revision Date: July 15, 2019

SECTION 1: Identification

1.1 GHS Product identifier

Product name Ketoconazole

1.2 Other means of identification

Product number -
Other names fungoral; Onofin K; nizoral

1.3 Recommended use of the chemical and restrictions on use

Identified uses Industrial and scientific research use.
Uses advised against no data available

1.4 Supplier's details

Company Shanghai Yien Chemical Technology Co., Ltd
Address Building 6, 28 Yingong Road, Fengxian District, Shanghai
Chemical Industry Zone, Shanghai, 201400, China
Telephone +86-400-133-2688

1.5 Emergency phone number

Emergency phone number +86-400-133-2688
Service hours Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

SECTION 2: Hazard identification

2.1 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

2.2 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.

2.3 Other hazards which do not result in classification

no data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
Ketoconazole	Ketoconazole	65277-42-1	265-667-4	100%

SECTION 4: First-aid measures

4.1 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.

4.2 Most important symptoms/effects, acute and delayed

no data available

4.3 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: Fire-fighting measures

5.1 Suitable extinguishing media

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

5.2 Specific hazards arising from the chemical

Not combustible.

5.3 Special protective actions for fire-fighters

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

SECTION 6: Accidental release measures

6.1 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.

6.2 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.

6.3 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

7.1 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.

7.2 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

8.1 Control parameters

Occupational Exposure limit values

no data available

Biological limit values

no data available

8.2 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.

8.3 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	6.41X10-14 mm Hg at 25 deg C (est)
Density and/or relative density	1.38g/cm3
Relative vapour density	no data available
Particle characteristics	no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

no data available

10.2 Chemical stability

no data available

10.3 Possibility of hazardous reactions

Not combustible.

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

Incompatible materials: Strong oxidizing agents.

10.6 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

12.1 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

12.2 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 biotransformed, 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 theazole pharmaceuticals except for fluconazole. The seasonal difference was smoothed out after treatment in the STPs.

12.3 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).

12.4 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 9.7×10^3 L/kg and 8.5×10^3 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).

12.5 Other adverse effects

no data available

SECTION 13: Disposal considerations

13.1 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

14.1 UN Number

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

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

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

14.2 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.)

14.3 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.)

14.4 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.)

14.5 Environmental hazards

ADR/RID: Yes

IMDG: Yes

IATA: Yes

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to IMO instruments

no data available

SECTION 15: Regulatory information

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

Chemical name	Common names and synonyms	CAS number	EC number
Ketoconazole	Ketoconazole	65277-42-1	265-667-4
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.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Not Listed.
Vietnam National Chemical Inventory			Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Not Listed.
Korea Existing Chemicals List (KECL)			Listed.

SECTION 16: Other information

Information on revision

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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
- 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-4-4'-2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-ylmethoxyphenylpiperazine and 1-4-4'-(2SR,4RS)-2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan-4-ylmethoxyphenylpiperazin-1-ylethanone.

Any questions regarding this SDS, Please send your inquiry to sds@xixisys.com

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 damage resulting from handling or from contact with the above product.