

## Safety Data Sheet

# Ketoconazole

Version : V2.0.0.1

Report No. : BWJ5782-2016-MSDS-US

Creation Date : 2025/09/23

Revision Date : -



\*Prepared according to American OSHA HCS-2024 (29 CFR 1910.1200)

## 1 Identification

### Product identifier

Product Name	Ketoconazole
Cat No.	BWJ5782-2016
CAS No.	65277-42-1
EC No.	265-667-4
Molecular Formula	C <sub>26</sub> H <sub>28</sub> Cl <sub>2</sub> N <sub>4</sub> O <sub>4</sub>

### Recommended use of the product and restrictions on use

Relevant identified uses	Please consult manufacturer.
Uses advised against	Please consult manufacturer.

### Details of the supplier of the Safety Data Sheet

Name of the company	Weiyel Inc
Address of the company	Hedian Light Industrial Park, Chengguan Town, Shangcheng County, Xinyang City, Henan Province, China
Post code	465350
Telephone number	010-58103678
Fax number	010-84840368
E-mail address	info@weiyel.com

### Emergency phone number



Emergency phone number	010-58103678
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## 2 Hazard(s) identification

### Hazard classification according to 29 CFR 1910.1200

Acute Toxicity - Oral	Category 3
Reproductive Toxicity	Category 1B
Specific target organ toxicity - repeated exposure	Category 2

### Label elements

Hazard pictograms	 
Signal word	<b>Danger</b>

**Hazard statements**

H301	Toxic if swallowed
H360	May damage fertility
H373	May cause damage to organs through prolonged or repeated exposure

**Precautionary statements**

## ◆ Prevention

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/fume.
P264	Wash hands and other parts of the body (if related) thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

## ◆ Response

P321	Specific treatment (see related instructions on the label).
P330	Rinse mouth.

## ◆ Storage

P405	Store locked up.
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## ◆ Disposal

P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
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**Other hazards**

	Not applicable.
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**Hazard description**

## ◆ Physical and chemical hazards

	No information available
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## ◆ Health hazards

Inhaled	Cough.
Ingestion	Nausea. Headache. Dizziness. Vomiting. Diarrhoea.
Skin Contact	Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.
Eye	Redness.

## ◆ Environmental hazards

	Please refer to 12th chapter of SDS.
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**3 Composition/information on ingredients****Substance/mixture**

	Substance
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Component	CAS No.	EC No.	Concentration (wt, %)
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<b>Ketoconazole</b>	65277-42-1	265-667-4	99.8
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## 4 First-aid measures

### Description of first aid measures

<b>General advice</b>	Immediate medical attention is required. Show this safety data sheet (SDS) to the doctor in attendance.
<b>Eye contact</b>	Rinse with plenty of water (remove contact lenses if easily possible).
<b>Skin contact</b>	Rinse and then wash skin with water and soap.
<b>Ingestion</b>	Rinse mouth. Give a slurry of activated charcoal in water to drink. Refer immediately for medical attention.
<b>Inhalation</b>	Fresh air, rest.
<b>Protecting of first-aiders</b>	Ensure that medical personnel are aware of the substance involved. Take precautions to protect themselves and prevent spread of contamination.

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

1	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.
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### Indication of any immediate medical attention and special treatment needed

1	Treat symptomatically.
2	Symptoms may be delayed.

## 5 Fire-fighting measures

### Extinguishing media

<b>Suitable extinguishing media</b>	Small fire: dry chemical, CO <sub>2</sub> or water spray; Large fire: dry chemical, CO <sub>2</sub> , alcohol-resistant foam or water spray; Fire involving tanks, rail tank cars or highway tanks: Fight fire from maximum distance or use unmanned master stream devices or monitor nozzles. Cool containers with flooding quantities of water until well after fire is out. Do not get water inside containers.
<b>Unsuitable extinguishing media</b>	No information available.

### Specific hazards arising from the substance or mixture

1	May emit poisonous fumes on fire.
2	Development of hazardous combustion gases or vapor possible in the event of fire.
3	May expansion or decompose explosively when heated or involved in fire.

### Special protective equipment and precautions for fire-fighters

1	As in any fire, wear self-contained breathing apparatus (MSHA/NIOSH approved or equivalent) and full protective gear.
2	Fight fire from a safe distance, with adequate cover.
3	Prevent fire extinguishing water from contaminating surface water or the ground water system.

## 6 Accidental release measures

### Personal precautions, protective equipment and emergency procedures

1	Fully encapsulating, vapor protective clothing should be worn for spills and leaks with no fire.
2	Do not touch or walk through spilled material.
3	Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

4	Ensure adequate ventilation. Remove all sources of ignition. Take precautionary measures against static discharges.
5	Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
6	Use personal protective equipment, do not breathe dust/fume.

### Environmental precautions

1	Prevent further leakage or spillage if safe to do so.
2	Discharge into the environment must be avoided.

### Methods and materials for containment and cleaning up

1	Isolation of contaminated areas and restrictions on access.
2	It is recommended that emergency personnel wear dust masks and wear anti-virus suits.
3	Do not touch broken containers and spills before putting on appropriate protective clothing.
4	Cover the spill with a plastic sheet to reduce scattering.
5	Cut off the source of the leak as much as possible.
6	Keep leaks in a ventilated place.
7	It is recommended that emergency personnel wear dust masks.
8	Collect the spill with a clean shovel and place it in a clean, dry, loosely closed container and move the container away from the leak.
9	Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

## 7 Handling and storage

### Precautions for safe handling

1	Handling is performed in a well ventilated place.
2	Wear suitable protective equipment.
3	Avoid contact with skin and eyes.
4	Keep away from heat/sparks/open flames/ hot surfaces.

### Conditions for safe storage, including any incompatibilities

1	Keep containers tightly closed.
2	Keep containers in a dry, cool and well-ventilated place.
3	Keep away from heat/sparks/open flames/hot surfaces.

## 8 Exposure controls/personal protection

### Control parameters

#### ◆ Occupational exposure limit values

<b>Occupational Exposure limit values</b>	No relevant regulations
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### Engineering controls

1	Ensure adequate ventilation, especially in confined areas.
2	Ensure that eyewash stations and safety showers are close to the workstation location.
3	Use explosion-proof electrical/ventilating/lighting/equipment.
4	Set up emergency exit and necessary risk-elimination area.

## Personal protection equipment

General requirement	
Eye protection	Must wear appropriate safety goggles.
Hand protection	Must wear appropriate chemical protective gloves.
Respiratory protection	Must wear appropriate personal respiratory protective equipment.
Skin and body protection	Must wear appropriate chemical protective clothing and chemical resistant shoes.

## 9 Physical and chemical properties and safety characteristics

### Physical and chemical properties

Appearance (physical state, color, etc.)	Off-white, solid
Odor	No information available
Odor threshold	No information available
pH	No information available
Melting point/freezing point(°C)	148~152
Initial boiling point and boiling range(°C)	No information available
Flash point(Closed cup, °C)	Not applicable
Evaporation rate	Not applicable
Flammability	No information available
Upper/lower explosive limits[%(v/v)]	Upper limit : No information available ; Lower limit : No information available
Vapor pressure	Difficult volatile liquid
Vapor density(Air = 1)	Not applicable
Relative density(Water=1)	No information available
Solubility	Insoluble in water
n-octanol/water partition coefficient	4.35
Auto-ignition temperature(°C)	No information available
Decomposition temperature(°C)	No information available
Kinematic viscosity	Not applicable

## 10 Stability and reactivity

### Stability and reactivity

Reactivity	Contact with incompatible substances can cause decomposition or other chemical reactions.
Chemical stability	Stable under proper operation and storage conditions.
Possibility of hazardous reactions	No information available.
Conditions to avoid	Incompatible materials, heat, flame and spark.
Incompatible materials	No information available.
Hazardous decomposition	Under normal conditions of storage and use, hazardous decomposition products

products	should not be produced.
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## 11 Toxicological information

### Acute toxicity

Component	LD <sub>50</sub> (oral)	LD <sub>50</sub> (dermal)	LC <sub>50</sub> (inhalation,4h)
Ketoconazole	166mg/kg(Rat)	No information available	No information available

### Carcinogenicity

Component	List of carcinogens by the IARC Monographs	Report on Carcinogens by NTP	OSHA Carcinogen List
Ketoconazole	Not Listed	Not Listed	Not Listed

### Others

Ketoconazole(Component)	
Skin corrosion/irritation	Based on available data, the classification criteria are not met
Serious eye damage/irritation	Based on available data, the classification criteria are not met
Skin sensitization	Based on available data, the classification criteria are not met
Respiratory sensitization	Based on available data, the classification criteria are not met
Reproductive toxicity	May damage fertility(Category 1B)
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure(Category 2)
Aspiration hazard	Based on available data, the classification criteria are not met
Germ cell mutagenicity	Based on available data, the classification criteria are not met

## 12 Ecological information

### Acute aquatic toxicity

Acute aquatic toxicity	No information available
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### Chronic aquatic toxicity

Chronic aquatic toxicity	No information available
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### Persistence and degradability

Persistence and degradability	No information available
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### Bioaccumulative potential

Bioaccumulative potential	No information available
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### Mobility in soil

Mobility in soil	No information available
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## 13 Disposal considerations

### Disposal considerations

Waste chemicals	Before disposal should refer to the relevant national and local laws and regulation. Recommend the use of incineration disposal.
Contaminated packaging	Containers may still present chemical hazard when empty. Keep away from hot

	and ignition source of fire. Return to supplier for recycling if possible.
<b>Disposal recommendations</b>	Refer to section waste chemicals and contaminated packaging.

## 14 Transport information

### | Label and Mark

<b>Transporting Label</b>	
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### | IMDG-CODE

<b>UN number</b>	2811
<b>UN proper shipping name</b>	TOXIC SOLID, ORGANIC, N.O.S.
<b>Transport hazard class</b>	6.1
<b>Transport subsidiary hazard class</b>	None
<b>Packing group</b>	III
<b>Marine pollutant ( Yes or no )</b>	No

### | IATA-DGR

<b>UN number</b>	2811
<b>UN proper shipping name</b>	TOXIC SOLID, ORGANIC, N.O.S.
<b>Transport hazard class</b>	6.1
<b>Transport subsidiary hazard class</b>	None
<b>Packing group</b>	III

### | UN-ADR

<b>UN number</b>	2811
<b>UN proper shipping name</b>	TOXIC SOLID, ORGANIC, N.O.S.
<b>Transport hazard class</b>	6.1
<b>Transport subsidiary hazard class</b>	None
<b>Packing group</b>	III

### | Transport in bulk according to IMO instruments

- ◆ Transport in bulk according to Annex II of MARPOL and the IBC code

	Not Available
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- ◆ Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

	Not Available
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- ◆ Transport in bulk in accordance with the IGC Code

	Not Available
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### | Others

<b>Precautions for transport</b>	Transit should be anti-exposure, rain, high temperature. Strictly prohibited shipping or transportation with acids, alkalis, oxidants, food and food additives etc. Transport vehicles should be equipped with the appropriate variety and
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quantity of fire equipment and emergency equipment leakage during transport. Before transport, should be preceded by checking whether container integrity, sealing. The transport unit must be placarded and marked in accordance with relevant transporting requirements.

## 15 Regulatory information

### International chemical inventory

Component	A	B	C	D	E	F	G	H	I	J	K	L	M
<b>Ketoconazole</b>	√	√	×	√	√	×	√	×	×	×	√	√	√

- [A] China Inventory of Existing Chemical Substances(IECSC)  
 [B] European Inventory of Existing Commercial Chemical Substances(EC inventory)  
 [C] United States Toxic Substances Control Act Inventory(TSCA)  
 [D] Canadian Domestic Substances List(DSL)  
 [E] New Zealand Inventory of Chemicals(NZIoC)  
 [F] Philippines Inventory of Chemicals and Chemical Substances(PICCS)  
 [G] Korea Existing Chemicals Inventory(KECL)  
 [H] Australian. Inventory of Industrial Chemical (AIICS)  
 [I] Japan Inventory of Existing & New Chemical Substances(ENCS)  
 [J] Thailand Existing Chemicals Inventory(TECI)  
 [K] Mexico National Inventory of Chemical Substances (INSQ)  
 [L] Russia Inventory of Existing Substances (DRAFT)  
 [M] Inventory of Existing Chemical Substances in Taiwan, China (TCSI)

### List of Chemical Substances under International Conventions

Component	A	B	C
<b>Ketoconazole</b>	×	×	×

- [A] The Montreal Protocol on Substances that Deplete the Ozone Layer  
 [B] Stockholm Convention on Persistent Organic Pollutants (POPs)  
 [C] Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade

### US chemical inventory

Component	A	B	C	D	E	F	G	H
<b>Ketoconazole</b>	×	×	×	×	×	×	×	×

- [A] US Clean Air Act (CAA)- Section 112, Hazardous Air Pollutants  
 [B] US SARA 302- Extremely Hazardous Substance List  
 [C] US CERCLA- Hazardous Substances List  
 [D] US Massachusetts Right-to-Know Substance List  
 [E] US New Jersey Right to Know Hazardous Substance List  
 [F] US Pennsylvania Right to Know Hazardous Substance List  
 [G] US New York City Right-to-Know Hazardous Substance List  
 [H] US California Proposition 65 List

Note:

- “√” Indicates that the substance included in the regulations.  
 “×” No data or not included in the regulations.

## 16 Other information

### Information on revision

Creation Date | 2025/09/23

Revision Date	-
Reason for revision	-

## Reference

- [1] IPCS: The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>.
- [2] IARC, website: <http://www.iarc.fr/>.
- [3] OECD: The Global Portal to Information on Chemical Substances, website: <https://www.echemportal.org/echemportal/>.
- [4] CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>.
- [5] NLM: ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>.
- [6] EPA: Integrated Risk Information System, website: <http://cfpub.epa.gov/iris/>.
- [7] U.S. Department of Transportation: ERG, website: <http://www.phmsa.dot.gov/hazmat/library/erg>.
- [8] Germany GESTIS-database on hazard substance, website: <http://gestis-en.itrust.de/>.

## Abbreviations and acronyms

CAS	Chemical Abstracts Service	UN	The United Nations
PC-STEL	Short term exposure limit	OECD	Organization for Economic Co-operation and Development
PC-TWA	Time Weighted Average	IMDG-CODE	International Maritime Dangerous Goods CODE
MAC	Maximum Allowable Concentration	IARC	International Agency for Research on Cancer
DNEL	Derived No Effect Level	ICAO	International Civil Aviation Organization
PNEC	Predicted No Effect Concentration	IATA	International Air Transportation Association
NOEC	No Observed Effect Concentration	ACGIH	American Conference of Governmental Industrial Hygienists
LC <sub>50</sub>	Lethal Concentration 50%	NFPA	National Fire Protection Association
LD <sub>50</sub>	Lethal Dose 50%	NTP	National Toxicology Program
EC <sub>50</sub>	Effective Concentration 50%	PBT	Persistent, Bioaccumulative, Toxic
EC <sub>x</sub>	Effective Concentration X%	vPvB	very Persistent, very Bioaccumulative
P <sub>OW</sub>	Partition coefficient Octanol: Water	CMR	Carcinogens, mutagens or substances toxic to reproduction
BCF	Bioconcentration factor	RPE	Respiratory Protective Equipment
ED	Endocrine disruptor	HCS	Hazard Communication Standard

## Disclaimer

This Safety Data Sheet (SDS) was prepared according to OSHA HCS -2024. The data included was derived from international authoritative database and provided by the enterprise. Other information was based on the present state of our knowledge. We try to ensure the correctness of all information. However, due to the diversity of information sources and the limitations of our knowledge, this document is only for user's reference. Users should make their independent judgment of suitability of this information for their particular purposes. We do not assume responsibility for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.