

## SAFETY DATA SHEET

According to JIS Z 7253:2019  
Revision date 09-Feb-2023  
Revision Number 1.03

## Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name	Ketoconazole
Product Code	116-00551

**Manufacturer** FUJIFILM Wako Pure Chemical Corporation  
1-2 Doshomachi 3-Chome  
Chuo-ku, Osaka 540-8605, Japan  
Phone: +81-6-6203-3741  
Fax: +81-6-6203-5964

**Supplier** FUJIFILM Wako Pure Chemical Corporation  
1-2 Doshomachi 3-Chome, Chuo-ku, Osaka 540-8605, Japan  
Phone: +81-6-6203-3741  
Fax: +81-6-6203-2029

**Emergency telephone number** +81-6-6203-3741 / +81-3-3270-8571

**Recommended uses and restrictions on use** For research use only

## Section 2: HAZARDS IDENTIFICATION

## GHS classification

Classification of the substance or mixture

Acute toxicity - Oral

Reproductive Toxicity

Specific target organ toxicity (repeated exposure)

Acute aquatic toxicity

Chronic aquatic toxicity

Category 3

Category 1B

Category 2

Category 1

Category 1

## Pictograms



## Signal word

Danger

## Hazard statements

H301 - Toxic if swallowed

H360 - May damage fertility or the unborn child

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-(Prevention)

- Obtain special instructions before use
- Do not handle until all safety precautions have been read and understood
- Use personal protective equipment as required
- Wash face, hands and any exposed skin thoroughly after handling
- Do not eat, drink or smoke when using this product
- Do not breathe dust/fume/gas/mist/vapors/spray
- Avoid release to the environment

**Precautionary statements-(Response)**

- IF exposed or concerned: Get medical advice/attention
- IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
- Rinse mouth
- Collect spillage

**Precautionary statements-(Storage)**

- Store locked up

**Precautionary statements-(Disposal)**

- Dispose of contents/container to an approved waste disposal plant

**Others**

**Other hazards** Not available

### Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

**Single Substance or Mixture** Substance

**Formula** C<sub>26</sub>H<sub>28</sub>Cl<sub>2</sub>N<sub>4</sub>O<sub>4</sub>

Chemical Name	Weight-%	Molecular weight	ENCS	ISHL No.	CAS RN
Ketoconazole	98.0	531.43	N/A	8-(2)-1304	65277-42-1

**Note on ISHL No.:** \* in the table means announced chemical substances.

**Impurities and/or Additives:** Not applicable

### Section 4: FIRST AID MEASURES

**Inhalation**

Remove to fresh air. If symptoms persist, call a physician.

**Skin contact**

Wash off immediately with soap and plenty of water. If symptoms persist, call a physician.

**Eye contact**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediate medical attention is required.

**Ingestion**

Rinse mouth. Never give anything by mouth to an unconscious person. Call a physician or poison control center immediately. Do not induce vomiting without medical advice.

**Protection of first-aiders**

Use personal protective equipment as required.

### Section 5: FIRE FIGHTING MEASURES

**Suitable extinguishing media**

Water spray (fog), Carbon dioxide (CO<sub>2</sub>), Foam, Extinguishing powder, Sand

**Unsuitable extinguishing media**

No information available

**Specific hazards arising from the chemical product**

Thermal decomposition can lead to release of irritating and toxic gases and vapors.

**Special extinguishing method**

No information available

**Special protective actions for fire-fighters**

Use personal protective equipment as required. Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

### Section 6: ACCIDENTAL RELEASE MEASURES

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

For indoor, provide adequate ventilation process until the end of working. Deny unnecessary entry other than the people involved by, for example, using a rope. While working, wear appropriate protective equipments to avoid adhering it on skin, or inhaling the gas. Work from windward, and retract the people downwind.

**Environmental precautions**

To be careful not discharged to the environment without being properly handled waste water contaminated.

**Methods and materials for contaminant and methods and materials for cleaning up**

Sweep up and gather scattered particles, and collect it in an empty airtight container.

**Recovery, neutralization**

No information available

**Secondary disaster prevention measures**

Clean contaminated objects and areas thoroughly observing environmental regulations.

## Section 7: HANDLING AND STORAGE

**Handling****Technical measures**

Avoid contact with strong oxidizing agents. Use with local exhaust ventilation.

**Precautions**

Do not rough handling containers, such as upsetting, falling, giving a shock, and dragging Prevent leakage, overflow, and scattering. Not to generate steam and dust in vain. Seal the container after use. After handling, wash hands and face, and then gargle In places other than those specified, should not be smoking or eating and drinking Should not be brought contaminated protective equipment and gloves to rest stops Deny unnecessary entry of non-emergency personnel to the handling area

**Safety handling precautions**

Use personal protective equipment as required. Avoid contact with skin, eyes or clothing.

**Storage****Safe storage conditions****Storage conditions**

Keep container protect from light, store in well-ventilated place at room temperature (preferably cool). Keep container tightly closed.

**Safe packaging material**

Glass

**Incompatible substances**

Strong oxidizing agents

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

**Engineering controls**

In case of indoor workplace, seal the source or use a local exhaust system. Provide the safety shower facility, and hand- and eye-wash facility. And display their position clearly.

**Exposure limits**

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

**Personal protective equipment****Respiratory protection**

Dust mask

**Hand protection**

Protection gloves

**Eye protection**

protective eyeglasses or chemical safety goggles

**Skin and body protection**

Long-sleeved work clothes

**General hygiene considerations**

Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

**Form****Color**

White - slightly yellow

**Appearance**

crystals - powder

**Odor**

no data available

**Melting point/freezing point**

150 °C

**Boiling point, initial boiling point and boiling range**

no data available

<b>Flammability</b>	no data available
<b>Evaporation rate:</b>	no data available
<b>Flammability (solid, gas):</b>	no data available
<b>Upper/lower flammability or explosive limits</b>	
Upper:	no data available
Lower:	no data available
<b>Flash point</b>	no data available
<b>Auto-ignition temperature:</b>	no data available
<b>Decomposition temperature:</b>	no data available
<b>pH</b>	no data available
<b>Viscosity (coefficient of viscosity)</b>	no data available
<b>Dynamic viscosity</b>	no data available
<b>Solubilities</b>	methanol : soluble . Ethanol : sparingly soluble . water : practically insoluble, or insoluble .
<b>n-Octanol/water partition coefficient:(log Pow)</b>	no data available
<b>Vapour pressure</b>	no data available
<b>Specific Gravity / Relative density</b>	no data available
<b>Vapour density</b>	no data available
<b>Particle characteristics</b>	no data available

## Section 10: STABILITY AND REACTIVITY

### Stability

<b>Reactivity</b>	no data available
<b>Chemical stability</b>	May be altered by light.
<b>Hazardous reactions</b>	None under normal processing
<b>Conditions to avoid</b>	Extremes of temperature and direct sunlight
<b>Incompatible materials</b>	Strong oxidizing agents
<b>Hazardous decomposition products</b>	Carbon monoxide (CO), Carbon dioxide (CO <sub>2</sub> ), Nitrogen oxides (NO <sub>x</sub> ), Halides

## Section 11: TOXICOLOGICAL INFORMATION

### Acute toxicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Ketoconazole	166 mg/kg ( Rat )	N/A	N/A

<b>Skin irritation/corrosion</b>	no data available
<b>Serious eye damage/ irritation</b>	no data available
<b>Respiratory or skin sensitization</b>	no data available
<b>Reproductive cell mutagenicity</b>	no data available
<b>Carcinogenicity</b>	no data available
<b>Reproductive toxicity</b>	no data available
<b>STOT-single exposure</b>	no data available
<b>STOT-repeated exposure</b>	no data available
<b>Aspiration hazard</b>	no data available

## Section 12: ECOLOGICAL INFORMATION

<b>Ecotoxicity</b>	No information available
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Other data	no data available
Persistence and degradability	No information available
Bioaccumulative potential	No information available
Mobility in soil	No information available
Hazard to the ozone layer	No information available

### Section 13: DISPOSAL CONSIDERATIONS

#### Waste from residues

Disposal should be in accordance with applicable regional, national and local laws and regulations.

#### Contaminated container and contaminated packaging

Disposal should be in accordance with applicable regional, national and local laws and regulations.

### Section 14: TRANSPORT INFORMATION

#### ADR/RID

UN number	UN2811
Proper shipping name:	Toxic solid, organic, n.o.s. (Ketoconazole)
UN classification	6.1
Subsidiary hazard class	
Packing group	III
Marine pollutant	Yes

#### IMDG

UN number	UN2811
Proper shipping name:	Toxic solid, organic, n.o.s. (Ketoconazole)
UN classification	6.1
Subsidiary hazard class	
Packing group	III
Marine pollutant (Sea)	Yes
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available

#### IATA

UN number	UN2811
Proper shipping name:	Toxic solid, organic, n.o.s. (Ketoconazole)
UN classification	6.1
Subsidiary hazard class	
Packing group	III
Environmentally Hazardous Substance	Yes

### Section 15: REGULATORY INFORMATION

#### International Inventories

EINECS/ELINCS	Listed
TSCA	-

#### Japanese regulations

Fire Service Act	Not applicable
Poisonous and Deleterious Substances Control Law	Not applicable
Industrial Safety and Health Act	Not applicable
Regulations for the carriage and storage of dangerous goods in ship	Toxic Substances - Poison (Ordinance Art.3, Ministry of Transportation Ordinance Regarding Transport by Ship and Storage, Attached Table 1)

<b>Civil Aeronautics Law</b>	Toxic and Infectious Substances (Ordinance Art.194, MITL Nortification for Air Transportation of Explosives etc., Attached Table 1)
<b>Pollutant Release and Transfer Register Law (~2023.3.31)</b>	Not applicable
<b><u>Pollutant Release and Transfer Register Law (2023/4/1~)</u></b>	<u>Not applicable</u>
<b>Export Trade Control Order</b>	Not applicable

## Section 16: OTHER INFORMATION

### Key literature references and sources for data etc.

NITE: National Institute of Technology and Evaluation (JAPAN)  
<http://www.safe.nite.go.jp/japan/db.html>  
 IATA dangerous Goods Regulations  
 RTECS:Registry of Toxic Effects of Chemical Substances  
 Japan Industrial Safety and Health Association GHS Model SDS  
 Dictionary of Synthetic Oraganic Chemistry , SSOCJ, Koudansha Scientific Co.Ltd.  
 Chemical Dictionary, Kyouritsu Publishing Co., Ltd.  
 etc

### Disclaimer

This SDS is according to JIS Z 7253: 2019. The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

GHS Classification is according to JIS Z7252(2019). \*JIS: Japanese Industrial Standards

**End of Safety Data Sheet**