



Product name: Fluconazole for Oral Suspension

Issue date: 01/15/24

# SDS

## Safety Data Sheet

SDS No. : 24865710115302



Creator: Cairui Chemical Technology (Shanghai) CO.,LTD

TEL : +86 21 69110391

E-mail: service@51ghs.com

# SAFETY DATA SHEET

Version 1.0

Revision Date: 01/15/24

## 1. Product and Company Identification

Product name : Fluconazole for Oral Suspension

Product use : It is an antifungal drug used for the treatment of mucosal candidiasis and for systemic infections including systemic candidiasis, coccidioidomycosis, and cryptococcosis.

Manufacturer/Supplier : Zhejiang Poly Pharm. Co., Ltd

Address : No. 78, Xinzhou Road, Economic Development Zone, Linping District, Hangzhou, Zhejiang 311199, China (CHN)

Telephone : +86 571-89385060

E-mail : zjpolyqa@hnpoly.com

Emergency telephone : +86 571-89385060  
number of the company

## 2. Hazards Identification

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

GHS classification of the product : Reproductive toxicity category 1B  
Reproductive toxicity (additional)  
Specific target organ toxicity (single exposure) category 2

### Label elements

Pictogram :



Signal word : Danger

Hazard statement : May damage fertility or the unborn child  
May cause harm to breast-fed children  
May cause damage to organs

### 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.  
Do not breathe dust/fume/gas/mist/vapours/spray.  
Avoid contact during pregnancy and while nursing.  
Wash exposed skin thoroughly after handling.  
Do not eat, drink or smoke when using this product.

# SAFETY DATA SHEET

Version 1.0

Revision Date: 01/15/24

|                                  |   |   |
|----------------------------------|---|---|
| Response                         | : | IF exposed or concerned: Get medical advice/attention.<br>IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician. |
| Storage                          | : | Store locked up.  |
| Disposal                         | : | Dispose of contents/container in accordance with local/regional/national/international regulations.                                   |
| Hazards not otherwise classified | : | No specific dangers known, if the regulations/notes for storage and handling are considered.  |

## 3. Composition / Information on Ingredients

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

| Chemical Name             | CAS-No.     | Concentration |
|---------------------------|-------------|---------------|
| Sucrose                   | 57-50-1     | 90-95 %       |
| Fluconazole               | 86386-73-4  | 5-10 %        |
| Citric acid               | 77-92-9     | 0.5-1.0 %     |
| Sodium citrate dihydrate  | 6132-04-3   | 0.5-1.0 %     |
| Sodium benzoate           | 532-32-1    | 0.1-0.5 %     |
| Xanthan gum               | 11138-66-2  | 0.1-0.5 %     |
| Titanium dioxide          | 13463-67-7  | 0.1-0.5 %     |
| Colloidal Silicon Dioxide | 112945-52-5 | 0.1-0.5 %     |

## 4. First-Aid Measures

Description of first aid measures

|              |   |  |
|--------------|---|--|
| Inhalation   | : | Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Maintain an open airway. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Get medical attention. Place unconscious person on their side in the recovery position and ensure breathing can take place. In the event of any sensitisation symptoms developing, ensure further exposure is avoided. |
| Skin contact | : | It is important to remove the substance from the skin immediately. In the event of any sensitisation symptoms developing, ensure further exposure is avoided. Remove contamination with soap and water or recognised skin cleansing agent. Get medical attention if symptoms are severe or persist after washing.  |
| Eye contact  | : | If you use contact lenses, remove the lenses first. Wash affected eyes for at least 15 minutes under running water with eyelids held open. If symptoms occur, consult a physician, preferably an ophthalmologist.  |

# SAFETY DATA SHEET

Version 1.0

Revision Date: 01/15/24

Ingestion : Rinse mouth thoroughly with water. Stop if the affected person feels sick as vomiting may be dangerous. Never give anything by mouth to an unconscious person. Place unconscious person on their side in the recovery position and ensure breathing can take place. Keep affected person under observation. Get medical attention if symptoms are severe or persist.

Most important symptoms and effects, both acute and delayed : Further important symptoms and effects are so far not known.

Indication of any immediate medical attention and special treatment needed

Note to physician : No information available.

## 5: Fire-Fighting Measures

Suitable extinguishing media : Water fog or fine spray. Dry chemical fire extinguishers. Carbon dioxide fire extinguishers.

Unsuitable extinguishing media : Do not use water jet.

Special hazards arising from the substance or mixture

Hazardous combustion products : During a fire, smoke may contain the original material in addition to combustion products of varying composition which may be toxic and/or irritating. Combustion products may include and are not limited to: Carbon monoxide. Carbon dioxide. Nitrogen oxides. Hydrogen fluoride.

Advice for firefighters

Special protective equipment for firefighters : Wear positive-pressure self-contained breathing apparatus (SCBA) and protective fire fighting clothing (includes fire fighting helmet, coat, trousers, boots, and gloves). If protective equipment is not available or not used, fight fire from a protected location or safe distance.

## 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Avoid dust formation. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

Environmental precautions : Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.

# SAFETY DATA SHEET

Version 1.0

Revision Date: 01/15/24

Methods and materials for containment and cleaning up : Clear up spills immediately and dispose of waste safely. Collect spillage with a shovel and broom, or similar and reuse, if possible. Collect and place in suitable waste disposal containers and seal securely. Flush contaminated area with plenty of water. Wash thoroughly after dealing with a spillage. For waste disposal, see Section 13.

## 7: Handling and storage

Advice on safe handling : Minimize dust generation and accumulation. Avoid breathing dust and avoid contact to eyes, skin and clothing. When handling, use appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities : Keep in a cool, well ventilated place.

## 8: Exposure Controls/Personal Protection

### Control parameters

| Chemical name    | Occupational Exposure Limits |  | Regulation |
|------------------|------------------------------|--|------------|
| Sucrose          | 8-hour TWA                   | 15 mg/m <sup>3</sup> (total dust), 5 mg/m <sup>3</sup> (respirable fraction)   | OSHA PEL   |
| Sucrose          | 8-hour TWA                   | 10 mg/m <sup>3</sup>   | ACGIH TLV  |
| Titanium dioxide | 8-hour TWA                   | 15 mg/m <sup>3</sup> (total dust)  | OSHA PEL   |
| Titanium dioxide | 8-hour TWA                   | Nanoscale particles: 0.2 mg/m <sup>3</sup> (respirable particulate matter) [2021]<br>Finescale particles: 2.5 mg/m <sup>3</sup> (respirable particulate matter) [2021] | ACGIH TLV  |

### Personal protective equipment

Respiratory protection : For most conditions no respiratory protection should be needed; however, if discomfort is experienced, use an approved air-purifying respirator.

Hand protection : Skin protection is not normally necessary, however it is good practice to avoid direct contact with chemical to use suitable gloves when handling.

Eye protection : None required under normal conditions. If concerned wear protective goggles or glasses.

Skin and body protection : None required under normal conditions.

## 9: Physical and chemical properties

Form : powder or granules

Colour : white or off-white

Odour : odorless

# SAFETY DATA SHEET

Version 1.0

Revision Date: 01/15/24

|                                   |   |                   |
|-----------------------------------|---|-------------------|
| pH                                | : | no data available |
| Melting point                     | : | no data available |
| Boiling point                     | : | no data available |
| Flash point                       | : | no data available |
| Thermal decomposition temperature | : | no data available |
| Density                           | : | no data available |
| Water solubility                  | : | partially soluble |
| Viscosity, dynamic                | : | not applicable    |

## 10: Stability and Reactivity

|                                    |   |  |
|------------------------------------|---|--|
| Reactivity                         | : | No hazardous reactions if stored and handled as prescribed/indicated.              |
| Chemical stability                 | : | Stable under recommended storage conditions.                                       |
| Possibility of hazardous reactions | : | This material is considered stable.  |
| Conditions to avoid                | : | Avoid exposure to extreme heat, light and moisture.                                |
| Incompatible materials             | : | Avoid contact with: Strong acids. Strong bases. Strong oxidizers.                  |
| Hazardous decomposition products   | : | No hazardous decomposition products if stored and handled as prescribed/indicated. |

## 11: Toxicological information

Information on toxicological effects

Acute toxicity

Acute oral toxicity

Fluconazole

LD50/rat: 1271 mg/kg

**Skin corrosion/irritation**

Shall not be classified as corrosive/irritant to skin.

**Serious eye damage/irritation**

# SAFETY DATA SHEET

Version 1.0

Revision Date: 01/15/24

Shall not be classified as irritant to eye.

## **Respiratory or skin sensitisation**

Shall not be classified as a respiratory or skin sensitiser.

## **Germ cell mutagenicity**

Shall not be classified as germ cell mutagenic.

## **Carcinogenicity**

Shall not be classified as carcinogenic.

## **Reproductive toxicity**

May damage fertility or the unborn child.

May cause harm to breast-fed children.

## **STOT-single exposure**

May cause damage to organs.

## **STOT-repeated exposure**

Shall not be classified as a specific target organ toxicant (repeated exposure).

## **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

## **12: Ecological information**

### **Ecotoxicity**

No information available

### **Persistence and degradability**

No information available

### **Bioaccumulative potential**

No information available

### **Mobility in soil**

No information available

### **Other adverse effects**

No information available

## **13: Disposal considerations**

Product : Observe national and local legal requirements.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.

# SAFETY DATA SHEET

Version 1.0

Revision Date: 01/15/24

## 14: Transport Information

Land transport

DOT

UN number : not dangerous goods  
UN proper shipping : not applicable  
name  
Transport hazard : not applicable  
class(es)  
Packing group : not applicable

Sea transport

IMDG

UN number : not dangerous goods  
UN proper shipping : not applicable  
name  
Transport hazard : not applicable  
class(es)  
Packing group : not applicable

Air transport

IATA/ICAO

UN number : not dangerous goods  
UN proper shipping : not applicable  
name  
Transport hazard : not applicable  
class(es)  
Packing group : not applicable

## 15: Regulatory information

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-to-Know Act of 1986) Sections 311 and 312

reproductive toxicity  
specific target organ toxicity (single or repeated exposure)

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right-to-Know Act of 1986) Section 313

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.



# SAFETY DATA SHEET

Version 1.0

Revision Date: 01/15/24

## Pennsylvania Right To Know Components

No components are subject to the Pennsylvania Right to Know Act.

## California Proposition 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

## United States TSCA Inventory (TSCA)

All components of this product are in compliance with the inventory listing requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

## 16: Other information

### Hazard Rating System

#### NFPA Hazard codes:

Health : 3      Fire: 0      Reactivity: 0      Special:

#### HMIS III rating

Health: 3      Flammability: 0      Physical hazard: 0

#### SDS Prepared by:

Cairui Chemical Technology (Shanghai) CO.,LTD

SDS Prepared on: 01/15/24

The information herein is provided in good faith and believed to be accurate as of the effective date shown above. However, no warranty, express or implied, is given. Regulatory requirements are subject to change and may differ between various locations. It is the buyer's/user's responsibility to ensure that his activities comply with all federal, state, provincial or local laws. The information presented here pertains only to the product as shipped. Since conditions for use of the product are not under the control of the manufacturer, it is the buyer's/user's duty to determine the conditions necessary for the safe use of this product. Due to the proliferation of sources for information such as manufacturerspecific SDSs, we are not and cannot be responsible for SDSs obtained from any source other than ourselves. If you have obtained an SDS from another source or if you are not sure that the SDS you have is current, please contact us for the most current version.