



Product name: Voriconazole for Oral Suspension
Issue date: 05/15/24

SDS

Safety Data Sheet

SDS No. : 24865710515301



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1. Product and Company Identification

Product name : Voriconazole for Oral Suspension

Product use : Voriconazole (Vfend, Pfizer) is a triazole antifungal medication used to treat serious fungal infections. It is used to treat invasive fungal infections that are generally seen in patients who are immunocompromised. These include invasive candidiasis, invasive aspergillosis, and emerging fungal infections.

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 : Acute toxicity – oral category 4
Carcinogenicity category 2
Reproductive toxicity category 2
specific target organ toxicity (repeated exposure) category 2

Label elements

Pictogram : 

Signal word : Warning

Hazard statement : Harmful if swallowed
Suspected of causing cancer
Suspected of damaging fertility or the unborn child
May cause damage to organs through prolonged or repeated exposure

Precautionary statements

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Prevention	:	Wash exposed skin thoroughly after handling. Do not eat, drink or smoke when using this product. 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.
Response	:	IF SWALLOWED: Call a POISON CENTER/doctor/if you feel unwell. Rinse mouth. IF exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.
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 %
Voriconazole	137234-62-9	5-10 %
Anhydrous citric acid	77-92-9	0.5-1.0 %
Orange flavor	/	0.5-1.0 %
Sodium citrate dihydrate	6132-04-3	0.1-0.5 %
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	7631-86-9	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.
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- 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.
- 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 and fluorine-containing compounds.

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.

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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.
- 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 ³ (total dust), 5 mg/m ³ (respirable fraction)	OSHA PEL
Sucrose	8-hour TWA	10 mg/m ³	ACGIH TLV
Titanium dioxide	8-hour TWA	15 mg/m ³ (total dust)	OSHA PEL
Titanium dioxide	8-hour TWA	Nanoscale particles: 0.2 mg/m ³ (respirable particulate matter) [2021] Finescale particles: 2.5 mg/m ³ (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.

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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

pH : 3.5~4.5

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.

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Hazardous decomposition products : No hazardous decomposition products if stored and handled as prescribed/indicated.

11: Toxicological information

Information on likely routes of exposure

Inhalation, Eye contact, Skin contact, Ingestion.

Acute toxicity

Acute Toxicity Endpoints:

Acute oral toxicity

Information for the Product:

As product: Single dose oral LD50 has not been determined.

Based on information for component(s): LD50, > 300 mg/kg Estimated.

Information for components:

Voriconazole

LD50, rat, < 300 mg/kg, estimated

Titanium dioxide

LD50, rat, > 2 000 mg/kg bw

Colloidal Silicon Dioxide

LD50, rat, > 5 000 mg/kg bw

Acute dermal toxicity

Information for the Product:

Shall not be classified as acutely toxic (dermal).

As product: The dermal LD50 has not been determined.

Based on information for component(s): LD50, > 2 000 mg/kg Estimated.

Information for components:

Anhydrous citric acid

Tussigenic potential, guinea pig, 3 min, ca. 75 mg/L air

Sodium citrate dihydrate

LD50, rat, >2000mg/kg, OECD Guideline 402

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Titanium dioxide

LC50, rat, 4h, >5.09 mg/L

Colloidal Silicon Dioxide

LC50, rat, 4 h, >5.01 mg/L

Acute inhalation toxicity

Information for the Product:

Shall not be classified as acutely toxic (inhalation).

As product: The LC50 has not been determined.

Information for components:

Anhydrous citric acid

LD50, rat, > 2 000 mg/kg bw,

Colloidal Silicon Dioxide

LD50, rabbit , 24h, 2 g/kg/bw

Skin corrosion/irritation

Information for the Product:

Shall not be classified as corrosive/irritant to skin.

Information for components:

Anhydrous citric acid

Shall not be classified as corrosive/irritant to skin

Sodium citrate dihydrate

Shall not be classified as corrosive/irritant to skin

Titanium dioxide

Shall not be classified as corrosive/irritant to skin

Colloidal Silicon Dioxide

Shall not be classified as corrosive/irritant to skin

Serious eye damage/eye irritation

Information for the Product:

Shall not be classified as irritant to eye.

Information for components:

Anhydrous citric acid

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Causes serious eye irritation

Sodium citrate dihydrate

Shall not be classified as irritant to eye

Titanium dioxide

Shall not be classified as irritant to eye

Colloidal Silicon Dioxide

Shall not be classified as irritant to eye

Respiratory or skin sensitisation

Information for the Product:

Shall not be classified as a respiratory or skin sensitiser.

Information for components:

Anhydrous citric acid

For skin sensitization:

Shall not be classified as a skin sensitiser

For respiratory sensitization:

Shall not be classified as a respiratory sensitiser.

Sodium citrate dihydrate

For skin sensitization:

Shall not be classified as a skin sensitiser

For respiratory sensitization:

Shall not be classified as a respiratory sensitiser.

Titanium dioxide

For skin sensitization:

Shall not be classified as a skin sensitiser

For respiratory sensitization:

Shall not be classified as a respiratory sensitiser.

Colloidal Silicon Dioxide

For skin sensitization:

Shall not be classified as a skin sensitiser

For respiratory sensitization:

Shall not be classified as a respiratory sensitiser.

Germ cell mutagenicity

Information for the Product:

Shall not be classified as germ cell mutagenic.

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Information for components:

Anhydrous citric acid
Shall not be classified as germ cell mutagenic

Sodium citrate dihydrate
Shall not be classified as germ cell mutagenic

Titanium dioxide
Shall not be classified as germ cell mutagenic

Colloidal Silicon Dioxide
Shall not be classified as germ cell mutagenic

Carcinogenicity

Information for the Product:

Suspected of causing cancer.

Information for components:

Voriconazole
Suspected of causing cancer

Anhydrous citric acid
Shall not be classified as carcinogenic

Sodium citrate dihydrate
Shall not be classified as carcinogenic

Titanium dioxide
Shall not be classified as carcinogenic

Colloidal Silicon Dioxide
Shall not be classified as carcinogenic

Reproductive toxicity

Information for the Product:

Suspected of damaging fertility or the unborn child

Information for components:

Voriconazole
Suspected of damaging fertility or the unborn child

Anhydrous citric acid
Shall not be classified as a reproductive toxicant

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Sodium citrate dihydrate

Shall not be classified as a reproductive toxicant

Titanium dioxide

Shall not be classified as a reproductive toxicant

Colloidal Silicon Dioxide

Shall not be classified as a reproductive toxicant

STOT-single exposure

Information for the Product:

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

Information for components:

Anhydrous citric acid

May cause respiratory irritation

Sodium citrate dihydrate

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

Titanium dioxide

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

Colloidal Silicon Dioxide

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

STOT-repeated exposure

Information for the Product:

May cause damage to organs through prolonged or repeated exposure.

Information for components:

Voriconazole

May cause damage to organs through prolonged or repeated exposure

Anhydrous citric acid

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

Sodium citrate dihydrate

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

Titanium dioxide

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

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Colloidal Silicon Dioxide

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

Aspiration Hazard

Information for the Product:

Shall not be classified as presenting an aspiration hazard.

Information for components:

Anhydrous citric acid

Shall not be classified as presenting an aspiration hazard

Sodium citrate dihydrate

Shall not be classified as presenting an aspiration hazard

Titanium dioxide

Shall not be classified as presenting an aspiration hazard

Colloidal Silicon Dioxide

Shall not be classified as presenting an aspiration hazard

12: Ecological information

Toxicity

Anhydrous citric acid

Short-term toxicity to fish

LC50, 48h, 440 mg/L, OECD Guideline 203

Long-term toxicity to fish

Testing is not considered necessary.

Short-term toxicity to aquatic invertebrates

EC50, Daphnia magna, 24h, 1535 mg/L

Long-term toxicity to aquatic invertebrates

Testing is not considered necessary.

Toxicity to aquatic algae and cyanobacteria

NOEC, 8d, 425 mg/L

Toxicity to microorganisms

The activated sludge respiration inhibition study does not need to be conducted as the substance is readily biodegradable.

Sodium citrate dihydrate

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Short-term toxicity to fish

LC50, *Leuciscus idus melanotus*, 48h, 590 mg/L

Long-term toxicity to fish

Testing is not considered necessary.

Short-term toxicity to aquatic invertebrates

EC50, *Daphnia magna*, 24h, 2055 mg/L

Long-term toxicity to aquatic invertebrates

Testing is not considered necessary.

Toxicity to aquatic algae and cyanobacteria

The study does not need to be conducted.

Toxicity to microorganisms

The activated sludge respiration inhibition study does not need to be conducted as the substance is readily biodegradable.

Titanium dioxide

Short-term toxicity to fish

Microsized TiO₂ is not acutely toxic up to its solubility limit

Long-term toxicity to fish

Microsized TiO₂ is not chronically toxic up to its solubility limit.

Short-term toxicity to aquatic invertebrates

EC50, > 100 mg/L

Long-term toxicity to aquatic invertebrates

NOEC, > 1 mg/L to \geq 100 mg/L

Toxicity to aquatic algae and cyanobacteria

EC10, > 2 mg/L;

EC50, > 50 mg/L

Toxicity to microorganisms

Do not inhibit microbial respiration in activated sewage sludge up to 1000 mg/L.

Colloidal Silicon Dioxide

Short-term toxicity to fish

LC50, *Pimephales promelas*, 96h, > 5 000 mg/L, OECD Guideline 203

Long-term toxicity to aquatic invertebrates

NOEC, *Daphnia magna*, 21d, 68 mg/L

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Toxicity to aquatic algae and cyanobacteria
EC50, 72h, > 173.1 mg/L, OECD Guideline 201

Toxicity to microorganisms
EC50, >1000 mg/L, OECD TG 209

Persistence and degradability

Anhydrous citric acid
readily biodegradable

Sodium citrate dihydrate
readily biodegradable

Bioaccumulative potential

Anhydrous citric acid
low potential to bioaccumulate

Sodium citrate dihydrate
BCF, 3.2 (log BCF = 0.5) estimated

Titanium dioxide
Nanosized TiO₂ does not bioaccumulate or biomagnify.

Mobility in soil

Anhydrous citric acid
log K_{ow}, <0

Sodium citrate dihydrate
log K_{ow}, <0

Titanium dioxide
Nano- and micro-sized TiO₂ has a very low mobility under almost all environmental conditions and is primarily associated with particles or colloids.

Other adverse effects

Anhydrous citric acid

This substance is not on the Montreal Protocol list of substances that deplete the ozone layer.

Sodium citrate dihydrate

This substance is not on the Montreal Protocol list of substances that deplete the ozone layer.

Titanium dioxide

This substance is not on the Montreal Protocol list of substances that deplete the ozone layer.

Colloidal Silicon Dioxide

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This substance is not on the Montreal Protocol list of substances that deplete the ozone layer.

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.

14: Transport Information

Land transport

DOT

UN number : not regulated as dangerous goods

UN proper shipping : not regulated as dangerous goods

Transport hazard : not regulated as dangerous goods

class(es)

Packing group : not regulated as dangerous goods

Sea transport

IMDG

UN number : not regulated as dangerous goods

UN proper shipping : not regulated as dangerous goods

Transport hazard : not regulated as dangerous goods

Packing group : not regulated as dangerous goods

Air transport

IATA/ICAO

UN number : not regulated as dangerous goods

UN proper shipping : not regulated as dangerous goods

Transport hazard : not regulated as dangerous goods

Packing group : not regulated as dangerous goods

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

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Carcinogenicity
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.

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: 05/15/24

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