



MATERIAL SAFETY DATA SHEET

Revision date: 23-Jan-2007

Version: 1.2

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
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CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Vfend (Voriconazole) Powder For Oral Suspension

Trade Name: Vfend®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antifungal agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Voriconazole	137234-62-9	Not listed	6.67
Titanium dioxide	13463-67-7	236-675-5	*
Sucrose	57-50-1	200-334-9	*
Citric acid, anhydrous	77-92-9	201-069-1	*
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	*

Ingredient	CAS Number	EU EINECS List	%
Natural orange flavor	NOT ASSIGNED	Not listed	*
Xanthan gum	11138-66-2	234-394-2	*
Sodium citrate, dihydrate	6132-04-3	Not listed	*
Sodium benzoate	532-32-1	208-534-8	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White to off-white powder
Signal Word: DANGER

Statement of Hazard: Harmful if swallowed.
May damage the unborn child.
Suspected of causing cancer.
May cause damage to liver through prolonged or repeated exposure.

Additional Hazard Information:
Short Term: May produce slight eye irritation, Active ingredient is not a skin irritant, Active ingredient is not a skin sensitizer (based on animal data). Accidental ingestion may cause effects similar to those seen in clinical use.

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Long Term: Adverse reproductive effects seen in repeat-dose animal studies are consistent with the pharmacologic action of this drug and are expected to be relevant to humans. Animal studies indicate that this material may cause adverse effects on the liver, the developing fetus.

Known Clinical Effects: The most common adverse effects reported with clinical use of voriconazole include visual disturbances, elevations of liver function tests and skin rash. Voriconazole has been associated with photosensitivity skin reactions especially during long term therapy.

EU Indication of danger: Toxic to Reproduction: Category 2
Carcinogenic: Category 3

EU Hazard Symbols:



EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect.
R61 - May cause harm to the unborn child.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Avoid generating airborne dust. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Voriconazole

Pfizer OEL TWA-8 Hr: 0.1 mg/m³

Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA

Australia TWA = 10 mg/m³ TWA

Sucrose

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total

= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA

Australia TWA = 10 mg/m³ TWA

Silicon dioxide, colloidal NF

OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO₂) mg/m³ TWA

= 20 mppcf TWA

Australia TWA = 2 mg/m³ TWA

Analytical Method: Analytical method available for Voriconazole. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk.

Personal Protective Equipment:

Hands: Rubber gloves

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Powder	Color:	White to off-white
Molecular Formula:	Mixture	Molecular Weight:	Mixture
pH:	3.5-4.5 (reconstituted)		

10. STABILITY AND REACTIVITY

Stability: Stable at ambient temperatures
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: Thermal decomposition products include oxides of nitrogen, carbon monoxide, carbon dioxide and halogen containing gases.

Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Voriconazole

Rat/Mouse Oral LD50 < 300 mg/kg
Rat/Mouse Oral LDmin. > 100 mg/kg
Rat IV LD50 > 100 mg/kg
Rat Dermal LD50 > 2000 mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Xanthan gum

Rat Oral LD50 > 5000 mg/kg

Sodium benzoate

Rat Oral LD50 4,070 mg/kg
Mouse Oral LD50 1600 mg/kg

Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

Sucrose

Rat Oral LD50 29.7 g/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Voriconazole

Skin Irritation Rabbit Non-irritating

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Skin Sensitization - GPMT Guinea Pig Negative
Eye Irritation Rabbit Minimal

Citric acid, anhydrous

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Voriconazole

1 Month(s) Rat Oral 30 mg/kg/day NOEL Liver
6 Month(s) Rat Oral 3 mg/kg/day NOEL Liver, Kidney
12 Month(s) Dog Oral 8 mg/kg/day NOEL Liver
6 Month(s) Rat Intravenous 10 mg/kg/day NOEL Liver
6 Month(s) Dog Oral 6 mg/kg/day NOEL Liver

Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOEL Liver, Kidney, Blood, Ureter, Bladder

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Voriconazole

Reproductive & Fertility Rat Oral 3 mg/kg/day NOEL Fetotoxicity
Embryo / Fetal Development Rat Oral 10 mg/kg/day LOEL Teratogenic

Sodium benzoate

Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Voriconazole

Bacterial Mutagenicity (Ames) Bacteria Negative
In Vitro Human Lymphocytes Equivocal
In Vivo Micronucleus Mouse Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Voriconazole

2 Year(s) Rat Oral 18 mg/kg/day NOEL Benign tumors, Liver
2 Year(s) Mouse Oral 30 mg/kg/day NOEL Malignant tumors, Liver

Carcinogen Status: See below

Silicon dioxide, colloidal NF

IARC: Group 3

Titanium dioxide

IARC: Group 2B
OSHA: Present

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12. ECOLOGICAL INFORMATION

Environmental Overview: In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater and degrade slowly. Harmful effects to aquatic organisms could occur.

Mobility, Persistence and Degradability: The active ingredient in this formulation is water soluble and is expected to remain primarily in water and degrade slowly.

Bioaccumulation and Toxicity: Moderate acute toxicity to aquatic organisms could occur. The active ingredient in this formulation has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. No toxicity to wastewater treatment microorganisms is expected. See the aquatic toxicity data for the active ingredient in the table, below.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Voriconazole

Mysid Shrimp	NPDES	LC50	48 Hours	62 mg/L
Red Algae		IC50		73 mg/L
Skeletonema Algae	NPDES	IC-50	48 Hours	74.7 mg/L
Green Algae	OECD	EbC50/72hr (OECD)	EC50 72 Hours	> 97 mg/L
Rainbow Trout	OECD	LC50	96 Hours	110 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

Voriconazole

Activated sludge	OECD	EC50	3 Hours	> 810 mg/L
Polytox	MIC		24 Hours	> 100 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to Reproduction: Category 2
Carcinogenic: Category 3

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect.
R61 - May cause harm to the unborn child.

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EU Safety Phrases:

S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:

DANGER

Harmful if swallowed.

May damage the unborn child.

Suspected of causing cancer.

May cause damage to liver through prolonged or repeated exposure.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Voriconazole

Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 236-675-5

Sucrose

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 200-334-9

Citric acid, anhydrous

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 201-069-1

Silicon dioxide, colloidal NF

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-545-4

Xanthan gum

Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS List 234-394-2

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Sodium citrate, dihydrate

Australia (AICS): Present

Sodium benzoate

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS List 208-534-8

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet