



MATERIAL SAFETY DATA SHEET

Revision date: 11-Jan-2011

Version: 2.0

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

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Material Name: Voriconazole Film Coated Tablets

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

2. HAZARDS IDENTIFICATION

Appearance: White tablets
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. Accidental ingestion may cause effects similar to those seen in clinical use.

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: Harmful
Toxic to Reproduction: Category 2
Carcinogenic: Category 3

EU Hazard Symbols:



EU Risk Phrases:

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2. HAZARDS IDENTIFICATION

R22 - Harmful if swallowed.
R40 - Limited evidence of a carcinogenic effect.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R61 - May cause harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Voriconazole	137234-62-9	Not Listed	Carc. Cat.3;R40 R52/53 Repr. Cat.2;R61 Xn;R22 Xn;R48/22	33.3
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Triacetin	102-76-1	203-051-9	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*

Additional Information:

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

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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: Not applicable

6. ACCIDENTAL RELEASE MEASURES

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

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: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Voriconazole

Pfizer OEL TWA-8 Hr: 100µg/m³

Titanium dioxide

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

Australia TWA 10 mg/m³

Austria OEL - MAKs Listed

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELS - TWAs:	15 mg/m ³ total
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Starch, pregelatinized

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELS - TWAs:	15 mg/m ³ total 5 mg/m ³
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablets	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

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)

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Povidone

Rat Oral LD50 100 g/kg

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

Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/kg

Triacetin

Rat Oral LD 50 3000 mg/kg
Mouse Oral LD 50 1100 mg/kg

Titanium dioxide

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

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11. TOXICOLOGICAL INFORMATION

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

Voriconazole

Skin Irritation Rabbit Non-irritating
Skin Sensitization - GPMT Guinea Pig Negative
Eye Irritation Rabbit Minimal

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

Voriconazole

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

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

Voriconazole

Reproductive & Fertility Rat Oral 3 mg/kg/day NOAEL Fetotoxicity
Embryo / Fetal Development Rat Oral 10 mg/kg/day LOAEL Teratogenic
Liver Reproductive system

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 NOAEL Malignant tumors, Liver

Carcinogen Status: See below

Povidone

IARC: Group 3

Titanium dioxide

IARC: Group 3 (Not Classifiable)

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.

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12. ECOLOGICAL INFORMATION

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

Voriconazole

Mysidopsis bahia (Mysid Shrimp) NPDES LC50 48 Hours 62 mg/L

Red Algae IC50 73 mg/L

Skeletonema costatum (Marine Diatom) NPDES IC-50 48 Hours 74.7 mg/L

Green Algae OECD EbC50/72hr (OECD) EC50 72 Hours > 97 mg/L

Oncorhynchus mykiss (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: (Inoculum, Method, End Point, Result)

Voriconazole

Activated sludge OECD EC50 3 Hours > 810 mg/L

Polytox MIC 24 Hours > 100 mg/L

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

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

EU Risk Phrases:

R22 - Harmful if swallowed.
R40 - Limited evidence of a carcinogenic effect.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R61 - May cause harm to the unborn child.

EU Safety Phrases:

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15. REGULATORY INFORMATION

S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.
S57 - Use appropriate containment to avoid environmental contamination.

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

Hydroxypropyl methylcellulose

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
Standard for the Uniform Scheduling
for Drugs and Poisons: Schedule 4

Titanium dioxide

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

Triacetin

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 203-051-9

Water, purified

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
REACH - Annex IV - Exemptions from the
obligations of Register: Present
EU EINECS/ELINCS List 231-791-2

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15. REGULATORY INFORMATION

Lactose NF, monohydrate	
Australia (AICS):	Listed
Croscarmellose sodium	
Australia (AICS):	Listed
Magnesium stearate	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3
Povidone	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Starch, pregelatinized	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R40 - Limited evidence of a carcinogenic effect

R61 - May cause harm to the unborn child.

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 4 - First Aid 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: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet