



# SAFETY DATA SHEET

Revision date: 22-Mar-2018

Version: 3.1

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Voriconazole for IV infusion

**Trade Name:** Vfend; SPIONIC; VIMERO; Voriconazole pfizer

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as antifungal agent

### Details of the Supplier of the Safety Data Sheet

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## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Skin Sensitization: Category 1

Reproductive Toxicity: Category 1B

Carcinogenicity: Category 2

Specific target organ systemic toxicity (repeated exposure): Category 2

#### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

### Label Elements

**Signal Word:** Danger

**Hazard Statements:**  
H317 - May cause an allergic skin reaction  
H351 - Suspected of causing cancer  
H360D - May damage the unborn child  
H373 - May cause damage to organs through prolonged or repeated exposure  
May form combustible dust concentrations in air

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### Precautionary Statements:

P202 - Do not handle until all safety precautions have been read and understood  
P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
P272 - Contaminated work clothing must not be allowed out of the workplace  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
P363 - Wash contaminated clothing before reuse  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations



### Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

### 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	GHS Classification	%
Voriconazole	137234-62-9	Not Listed	Acute Tox.3 (H301) Carc. 2 (H351) Repr. 1B (H360D) STOT RE 2 (H373) Aquatic Acute 3 (H402)	5-7
Sulfobutylether b-cyclodextrin sodium (SBECD)	7585-39-9	231-493-2	Skin Sens. 1 (H317)	*

### Additional Information:

\* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

## 4. FIRST AID MEASURES

### Description of First Aid Measures

#### Eye Contact:

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

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

### Most Important Symptoms and Effects, Both Acute and Delayed

- 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.
- Medical Conditions Aggravated by Exposure:** None known

### Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

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

### Special Hazards Arising from the Substance or Mixture

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

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

### Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

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

### Environmental Precautions

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

### Methods and Material for Containment and Cleaning Up

- 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.

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

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Avoid generating airborne dust. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

### Conditions for Safe Storage, Including any Incompatibilities

- Storage Conditions:** Store as directed by product packaging.

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Specific end use(s): Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

##### Voriconazole

Pfizer OEL TWA-8 Hr: 100µg/m<sup>3</sup>

##### Sulfobutylether b-cyclodextrin sodium (SBECD)

Pfizer OEL TWA-8 Hr: 3000µg/m<sup>3</sup>

#### Exposure Controls

##### 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.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

##### Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

##### Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

##### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

##### Respiratory protection:

Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Lyophilized powder

Odor: No data available.

Molecular Formula: Mixture

Color: White

Odor Threshold: No data available.

Molecular Weight: Mixture

Solvent Solubility: No data available

Water Solubility: No data available

pH: 5.7-7.3 (reconstituted)

Melting/Freezing Point (°C): No data available

Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Sulfobutylether b-cyclodextrin sodium (SBECD)

No data available

Voriconazole

Measured 7 Log P 1.75

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

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Vapor Density (g/ml): No data available  
Relative Density: No data available  
Viscosity: No data available

### Flammability:

Autoignition Temperature (Solid) (°C): No data available  
Flammability (Solids): No data available  
Flash Point (Liquid) (°C): No data available  
Upper Explosive Limits (Liquid) (% by Vol.): No data available  
Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

## 10. STABILITY AND REACTIVITY

Reactivity: No data available  
Chemical Stability: Stable under normal conditions of use.

### Possibility of Hazardous Reactions

Oxidizing Properties: No data available  
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: No data available

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

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

**Short Term:** May produce slight eye irritation., May be harmful if swallowed. (based on components) .  
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.

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

#### Sulfobutylether b-cyclodextrin sodium (SBECD)

Rat Oral LD50 > 2000 mg/kg  
Rat/Mouse IV LD50 > 2000mg/kg

#### Voriconazole

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

#### Sulfobutylether b-cyclodextrin sodium (SBECD)

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### 11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Non-irritating  
Skin Irritation Rabbit Non-irritating  
Skin Sensitization - GPMT Guinea Pig Positive

#### 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)

##### Sulfobutylether b-cyclodextrin sodium (SBECD)

6 Month(s) Rat Intravenous 600 mg/kg/day NOAEL Kidney, Liver  
1 Month(s) Rat Intravenous 160 mg/kg/day NOAEL Kidney  
6 Month(s) Dog Intravenous 600 mg/kg/day NOAEL Kidney  
1 Month(s) Dog Intravenous 120 mg/kg/day NOAEL Kidney

#### 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))

##### Sulfobutylether b-cyclodextrin sodium (SBECD)

Fertility and Embryonic Development Rat Intravenous 1500 mg/kg/day NOAEL No effects at maximum dose  
Embryo / Fetal Development Rabbit Intravenous 1500 mg/kg/day NOAEL Not Teratogenic  
Prenatal & Postnatal Development Rat Intravenous 600 mg/kg/day NOAEL Maternal Toxicity

#### Voriconazole

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

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

##### Sulfobutylether b-cyclodextrin sodium (SBECD)

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vitro* Chromosome Aberration Human Lymphocytes Negative  
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells HGPRT Negative  
*In Vivo* Micronucleus Mouse Bone Marrow Negative

#### 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

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### 11. TOXICOLOGICAL INFORMATION

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### 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.

#### Toxicity:

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

##### **Sulfobutylether b-cyclodextrin sodium (SBECD)**

*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours > 220 mg/L

*Daphnia magna* (Water Flea) OECD EC-50 48 Hours > 96 mg/L

Green algae OECD IC50 72 Hours > 100 mg/L

##### **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 > 810 mg/L

Polytox MIC > 100 mg/L

#### **Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)**

##### **Voriconazole**

*Daphnia magna* (Water Flea) OECD 21 Day(s) NOEC > 1 mg/L

*Pimephales promelas* (Fathead Minnow) OECD 32 Day(s) NOEC 1.2 mg/L

*Chironomus riparius* (Sediment-Dwelling Midges) OECD 28 Day(s) NOEC 100 mg/L

#### **Persistence and Degradability:**

##### **Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)**

##### **Voriconazole**

OECD Activated sludge Ultimate (CO2 Evolution) -0.24% After 28 Day(s) Not Ready

#### **Bio-accumulative Potential:**

##### **Partition Coefficient: (Method, pH, Endpoint, Value)**

##### **Voriconazole**

Measured 7 Log P 1.75

**Mobility in Soil:** No data available

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### 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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Voriconazole

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

#### Sulfobutylether b-cyclodextrin sodium (SBECD)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-493-2

### 16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3



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Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed  
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer  
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child  
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure  
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction  
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

**Data Sources:** Pfizer proprietary drug development information.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

**Revision date:** 22-Mar-2018  
Product Stewardship Hazard Communication

**Prepared by:** 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**