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
Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voriconazole</td>
<td>137234-62-9</td>
<td>Not Listed</td>
<td>Acute Tox.3 (H301) Carc. 2 (H351) Repr. 1B (H360D) STOT RE 2 (H373) Aquatic Acute 3 (H402)</td>
<td>5-7</td>
</tr>
<tr>
<td>Sulfobutylether b-cyclodextrin sodium (SBEDC)</td>
<td>7585-39-9</td>
<td>231-493-2</td>
<td>Skin Sens. 1 (H317)</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
**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

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**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.

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**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.

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**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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

**Voriconazole**
- **Pfizer OEL TWA-8 Hr:** 100µg/m³

**Sulfobutylether b-cyclodextrin sodium (SBECD)**
- **Pfizer OEL TWA-8 Hr:** 3000µg/m³

**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 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
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).
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)
## 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)

<table>
<thead>
<tr>
<th>Substance/Compound</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Voriconazole</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>5000 mg/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>600 mg/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>120 mg/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>10 mg/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral</td>
<td>30 mg/kg/day</td>
<td></td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral</td>
<td>8 mg/kg/day</td>
<td></td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral</td>
<td>10 mg/kg/day</td>
<td></td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral</td>
<td>6 mg/kg/day</td>
<td></td>
<td>Liver</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance/Compound</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sulfobutylether b-cyclodextrin sodium (SBECD)</strong></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>1500 mg/kg/day</td>
<td>NOAEL</td>
<td>No effects at maximum dose</td>
</tr>
<tr>
<td><strong>Voriconazole</strong></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>600 mg/kg/day</td>
<td>NOAEL</td>
<td>Kidney, Liver</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>160 mg/kg/day</td>
<td>NOAEL</td>
<td>Kidney</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>600 mg/kg/day</td>
<td>NOAEL</td>
<td>Kidney</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>120 mg/kg/day</td>
<td>NOAEL</td>
<td>Kidney</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral</td>
<td>3 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver, Kidney</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral</td>
<td>8 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral</td>
<td>10 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oral</td>
<td>6 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance/Compound</th>
<th>Study Type</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sulfobutylether b-cyclodextrin sodium (SBECD)</strong></td>
<td>In Vitro</td>
<td>Human Lymphocytes</td>
<td>Negative</td>
</tr>
<tr>
<td><strong>Voriconazole</strong></td>
<td>In Vitro</td>
<td>Human Lymphocytes</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>In Vivo</td>
<td>Mouse Bone Marrow</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>In Vivo</td>
<td>Chinese Hamster Ovary (CHO) cells HGPRT</td>
<td>Negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance/Compound</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Voriconazole</strong></td>
<td>2 Year(s)</td>
<td>Oral</td>
<td>18 mg/kg/day</td>
<td>NOEL</td>
<td>Benign tumors, Liver</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 Year(s)</td>
<td>Mouse</td>
<td>30 mg/kg/day</td>
<td>NOAEL</td>
<td>Malignant tumors, Liver</td>
<td></td>
</tr>
</tbody>
</table>
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 (SBECED)

*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours > 220 mg/L
*Daphnia magna* (Water Flea) OECD EC50 48 Hours > 96 mg/L
Green algae OECD IC50 72 Hours > 100 mg/L

Voriconazole

*Myisidopsis bahia* (Mysis 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 ELC50/72hr (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 Midge) 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
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 (SBEDCD)
- 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
SAFETY DATA SHEET

Material Name: Voriconazole for IV infusion
Revision date: 22-Mar-2018

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

Prepared by: Product Stewardship Hazard Communication

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