



# 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 Film Coated Tablets

**Trade Name:** Vfend; SPIONIC; 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

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Contact E-Mail: pfizer-MSDS@pfizer.com

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 4

Reproductive Toxicity: Category 1B

Carcinogenicity: Category 2

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

Acute aquatic toxicity: Category 3

### Label Elements

**Signal Word:** Danger

**Hazard Statements:**  
H302 - Harmful if swallowed  
H351 - Suspected of causing cancer  
H360D - May damage the unborn child  
H373 - May cause damage to organs through prolonged or repeated exposure  
H402 - Harmful to aquatic life

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**Precautionary Statements:**

- P202 - Do not handle until all safety precautions have been read and understood
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P281 - Use personal protective equipment as required
- P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
- P330 - Rinse mouth
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P314 - Get medical attention/advice if you feel unwell
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations
- P273 - Avoid release to the environment



**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)	33.3
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

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

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**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

### 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:** Not applicable

#### 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.

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**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

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.

#### Conditions for Safe Storage, Including any Incompatibilities

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

**Specific end use(s):** Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Voriconazole

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

#### Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Denmark OEL - TWA	6 mg/m <sup>3</sup>
Estonia OEL - TWA	5 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10.0 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Russia OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	6 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

#### Starch, pregelatinized

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>

**Magnesium stearate**

Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/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

<b>Physical State:</b>	Tablets	<b>Color:</b>	White
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

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

**Magnesium stearate**

No data available

**Water, purified**

No data available

**Starch, pregelatinized**

No data available

**Lactose NF, monohydrate**

No data available

**Croscarmellose sodium**

No data available

**Povidone**

No data available

**Voriconazole**

Measured 7 Log P 1.75

**Hydroxypropyl methylcellulose**

No data available

**Triacetin**

No data available

**Titanium dioxide**

No data available

**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.

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### 11. TOXICOLOGICAL 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.

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

##### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### **Povidone**

Rat Oral LD50 100 g/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

##### **Hydroxypropyl methylcellulose**

Rat Oral LD50 > 10,000 mg/kg

##### **Triacetin**

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

##### **Titanium dioxide**

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

#### 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

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### 11. TOXICOLOGICAL INFORMATION

#### 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 (Not Classifiable)

##### **Titanium dioxide**

**IARC:** Group 2B (Possibly Carcinogenic to Humans)

### 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)

##### **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



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### 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 (CO<sub>2</sub> 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

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**15. REGULATORY INFORMATION**

<p><b>California Proposition 65                      Standard for the Uniform Scheduling                      for Drugs and Poisons:                      EU EINECS/ELINCS List</b></p>	<p>Not Listed                      Schedule 4                      Not Listed</p>
<p><b>Hydroxypropyl methylcellulose</b></p>	
<p><b>CERCLA/SARA 313 Emission reporting                      California Proposition 65                      Inventory - United States TSCA - Sect. 8(b)                      Australia (AICS):                      Standard for the Uniform Scheduling                      for Drugs and Poisons:                      EU EINECS/ELINCS List</b></p>	<p>Not Listed                      Not Listed                      Present                      Present                      Schedule 4                      Not Listed</p>
<p><b>Triacetin</b></p>	
<p><b>CERCLA/SARA 313 Emission reporting                      California Proposition 65                      Inventory - United States TSCA - Sect. 8(b)                      Australia (AICS):                      EU EINECS/ELINCS List</b></p>	<p>Not Listed                      Not Listed                      Present                      Present                      203-051-9</p>
<p><b>Titanium dioxide</b></p>	
<p><b>CERCLA/SARA 313 Emission reporting                      California Proposition 65                      Inventory - United States TSCA - Sect. 8(b)                      Australia (AICS):                      EU EINECS/ELINCS List</b></p>	<p>Not Listed                      carcinogen 9/2/2011 airborne, unbound particles of respirable size                      Present                      Present                      236-675-5</p>
<p><b>Croscarmellose sodium</b></p>	
<p><b>CERCLA/SARA 313 Emission reporting                      California Proposition 65                      Australia (AICS):                      EU EINECS/ELINCS List</b></p>	<p>Not Listed                      Not Listed                      Present                      Not Listed</p>
<p><b>Povidone</b></p>	
<p><b>CERCLA/SARA 313 Emission reporting                      California Proposition 65                      Inventory - United States TSCA - Sect. 8(b)                      Australia (AICS):                      EU EINECS/ELINCS List</b></p>	<p>Not Listed                      Not Listed                      Present                      Present                      Not Listed</p>
<p><b>Water, purified</b></p>	
<p><b>CERCLA/SARA 313 Emission reporting                      California Proposition 65                      Inventory - United States TSCA - Sect. 8(b)                      Australia (AICS):                      REACH - Annex IV - Exemptions from the                      obligations of Register:                      EU EINECS/ELINCS List</b></p>	<p>Not Listed                      Not Listed                      Present                      Present                      Present                      231-791-2</p>
<p><b>Starch, pregelatinized</b></p>	
<p><b>CERCLA/SARA 313 Emission reporting</b></p>	<p>Not Listed</p>

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California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

#### Magnesium stearate

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	209-150-3

#### Lactose NF, monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

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  
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

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

**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**