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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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
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

<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>
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<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
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<td>Croscarmellose sodium</td>
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<tr>
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<tr>
<td>Magnesium stearate</td>
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<tr>
<td>Hydroxypropyl methylcellulose</td>
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</tr>
<tr>
<td>Triacetin</td>
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<td>203-051-9</td>
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<tr>
<td>Povidone</td>
<td>9003-39-8</td>
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<tr>
<td>Water, purified</td>
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<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
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</tbody>
</table>
SAFETY DATA SHEET

Material Name: Voriconazole Film Coated Tablets
Revision date: 22-Mar-2018

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.
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/m³

Titanium dioxide
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Austria OEL - MAKs 5 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Denmark OEL - TWA 6 mg/m³
Estonia OEL - TWA 5 mg/m³
France OEL - TWA 10 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Poland OEL - TWA 10.0 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Sweden OEL - TWAs 5 mg/m³
Switzerland OEL - TWAs 3 mg/m³
Vietnam OEL - TWAs 6 mg/m³
5 mg/m³

Starch, pregelatinized
ACGIH Threshold Limit Value (TWA) 10 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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.)

**Solvent Solubility:** No data available
**Water Solubility:** No data available
**pH:** No data available.
**Melting/Freezing Point (°C):** No data available
**Boiling Point (°C):** No data available.

---

9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Tablets
**Color:** White
**Odor:** No data available.
**Odor Threshold:** No data available.
**Molecular Formula:** Mixture
**Molecular Weight:** Mixture

**Solvent Solubility:** No data available
**Water Solubility:** No data available
**Melting/Freezing Point (°C):** No data available
**Boiling Point (°C):** No data available.
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
Crocarmellose 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.
# 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)

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Povidone</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>100 g/kg</td>
</tr>
<tr>
<td>Voriconazole</td>
<td>Rat/Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>&lt; 300 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 100mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Intravenous</td>
<td>LD50</td>
<td>&gt; 100mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Dermal</td>
<td>LD50</td>
<td>&gt; 2000mg/kg</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 10,000 mg/kg</td>
</tr>
<tr>
<td>Triacetin</td>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>3000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>1100mg/kg</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 7500 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>LD50</td>
<td>50 mg/kg</td>
</tr>
</tbody>
</table>

### 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)

<table>
<thead>
<tr>
<th>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>Voriconazole</td>
<td>1 Month(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>30 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td>6 Month(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>3 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver, Kidney</td>
</tr>
<tr>
<td></td>
<td>12 Month(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>8 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td>6 Month(s)</td>
<td>Rat</td>
<td>Intravenous</td>
<td>10 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td>6 Month(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>6 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
</tbody>
</table>
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
Mysis crisis (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

### 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
# 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>California Proposition 65</th>
<th>California Proposition 65 Description</th>
<th>Standard for the Uniform Scheduling</th>
<th>Standard for the Uniform Scheduling Description</th>
<th>Australia (AICS)</th>
<th>Australia (AICS) Description</th>
<th>EU EINECS/ELINCS List</th>
<th>EU EINECS/ELINCS List Description</th>
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<tbody>
<tr>
<td>Titanium dioxide</td>
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<td>Schedule 4</td>
<td></td>
<td></td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>CERCLA/SARA 313 Emission reporting</td>
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<td></td>
<td>Present</td>
<td>Present</td>
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<tr>
<td>Triacetin</td>
<td>CERCLA/SARA 313 Emission reporting</td>
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<tr>
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<td>Present</td>
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<tr>
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<td>Present</td>
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<tr>
<td>Water, purified</td>
<td>CERCLA/SARA 313 Emission reporting</td>
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<td></td>
<td></td>
<td>Present</td>
<td>Present</td>
<td>231-791-2</td>
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<tr>
<td>Starch, pregelatinized</td>
<td>CERCLA/SARA 313 Emission reporting</td>
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<td></td>
<td></td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Voriconazole Film Coated Tablets
Revision date: 22-Mar-2018

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th></th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td></td>
<td>232-679-6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose NF, monohydrate</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td></td>
<td>209-150-3</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
Prepared by: Product Stewardship Hazard Communication

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End of Safety Data Sheet