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

Product Identifier

Material Name: Linezolid Tablets
Trade Name: ZYVOX, ZYVOXID; ZYVOXAM; GABRIOX; LINEZOLIDA
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

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

Label Elements

Signal Word: Warning
Hazard Statements: H373 - May cause damage to organs through prolonged or repeated exposure
Precautionary Statements: P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical attention/advice if you feel unwell
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
No data available
SAFETY DATA SHEET

Material Name: Linezolid Tablets
Revision date: 07-Oct-2015

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Linezolid</td>
<td>165800-03-3</td>
<td>Not Listed</td>
<td>STOT RE 2 (H373)</td>
<td>70</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<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>Carnauba wax</td>
<td>8015-86-9</td>
<td>232-399-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>9004-64-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
<td>Not Listed</td>
<td>Not Listed</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

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:
Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:**
Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters
During all fire fighting 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. Clean up 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 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.

**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.

**Corn Starch**

<table>
<thead>
<tr>
<th>ACGIH Threshold Limit Value (TWA)</th>
<th>10 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

LINEZOLID TABLETS
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>OEL</th>
<th>MAK</th>
<th>MAKs</th>
<th>MAKs - Notice of Intended Changes</th>
<th>MAKs - Notice of Intended Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linezolid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pfizer OEL TWA-8 Hr:</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>3 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>10 mg/m³</td>
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<td></td>
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<tr>
<td>Polyethylene glycol</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>1000 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>1000 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>1000 mg/m³ average molecular weight 200-600</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>1000 ppm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACGIH OELs - Notice of Intended Changes</td>
<td>Listed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>6 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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).

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.

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: Tablet
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: No data available.
Melting/Freezing Point (^C): No data available
Boiling Point (^C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)
Linezolid
Measured 6-8 Log D 0.55

Microcrystalline cellulose
No data available
Magnesium stearate
No data available
Corn Starch
No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

Carnauba wax
No data available

Polyethylene glycol
No data available

Sodium starch glycolate
No data available

Hydroxypropyl cellulose
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

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 following information is available for the individual ingredients.
Short Term: May cause minimal eye irritation (based on animal data). May cause negligible skin irritation (based on animal data). Not acutely toxic (based on animal data). May cause stomach irritation, diarrhea, nausea, or vomiting.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.

Known Clinical Effects: The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Effects on blood and blood-forming organs have also occurred.

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

Linezolid
Rat (F) Oral Minimum Lethal Dose 5000 mg/kg
### 11. TOXICOLOGICAL INFORMATION

#### 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)

**Linezolid**
- Eye Irritation: Rabbit, Minimal
- Skin Irritation: Rabbit, Minimal
- Antigenicity- Passive cutaneous anaphylaxis: Mouse, Negative
- Antigenicity- Active anaphylaxis: Guinea Pig, Negative

**Microcrystalline cellulose**
- Skin Irritation: Rabbit, Non-irritating
- Eye Irritation: Rabbit, Non-irritating

**Polyethylene glycol**
- Eye Irritation: Rabbit, Mild
- Skin Irritation: Rabbit, Mild

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

**Linezolid**
- 1 Month(s) Rat Oral 20 mg/kg/day NOAEL Blood forming organs, Blood
- 3 Month(s) Rat Oral 10 mg/kg/day NOAEL Blood forming organs, Blood
- 1 Month(s) Dog Oral 20 mg/kg/day NOAEL Blood forming organs, Blood, Gastrointestinal system
- 3 Month(s) Dog Oral 20 mg/kg/day NOAEL Blood forming organs, Blood, Gastrointestinal system

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

**Linezolid**
- Reproductive & Fertility: Rat Oral 50 mg/kg/day NOAEL Fertility
- Embryo / Fetal Development Rat Oral 2.5 mg/kg/day NOAEL Fetotoxicity, Not Teratogenic
- Embryo / Fetal Development Rat Oral 15 mg/kg/day NOAEL Maternal Toxicity
- Embryo / Fetal Development Mouse Oral 150 mg/kg/day NOAEL Fetotoxicity, Maternal Toxicity, Not Teratogenic

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

**Microcrystalline cellulose**
- Rat Oral Minimum Lethal Dose 5000 mg/kg
- Dog Oral Minimum Lethal Dose 2000 mg/kg

**Magnesium stearate**
- Rat Oral LD50 > 5000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

**Titanium dioxide**
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD50 50 mg/kg

**Eye Irritation**
- Rabbit Minimal

**Skin Irritation**
- Rabbit Non-irritating

**Antigenicity- Passive cutaneous anaphylaxis**
- Mouse Negative

**Antigenicity- Active anaphylaxis**
- Guinea Pig Negative

**Microcrystalline cellulose**
- Skin Irritation: Rabbit, Non-irritating
- Eye Irritation: Rabbit, Non-irritating

**Polyethylene glycol**
- Eye Irritation: Rabbit, Mild
- Skin Irritation: Rabbit, Mild

**Titanium dioxide**
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³
11. TOXICOLOGICAL INFORMATION

Linezolid
In Vitro Unscheduled DNA Synthesis  Negative
Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vitro Chromosome Aberration  Human Lymphocytes  Negative
In Vivo Micronucleus  Mouse  Negative

Carcinogen Status:  See below

Titanium dioxide
IARC:  Group 2B (Possibly Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties have not been investigated. Releases to the environment should be avoided.

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

Linezolid
Daphnia magna (Water Flea)  OECD  EC50  48 Hours  > 100 mg/L
Oncorhynchus mykiss (Rainbow Trout)  OECD  LC50  96 Hours  > 1.4 mg/L
Anabaena flos-aquae (Cyanobacteria) Algae  OECD  ErC50  72 Hours  1.5 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Linezolid
Activated sludge  OECD  EC50  > 1000 mg/L

Persistence and Degradability:  No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Linezolid
Measured  6-8  Log D  0.55

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

Carnauba wax
- **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**: 232-399-4

Corn Starch
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **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

Hydroxypropyl cellulose
- **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**: Not Listed

Linezolid
- **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

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
15. REGULATORY INFORMATION

**Microcrystalline cellulose**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex XVII - Restrictions on Certain Dangerous Substances: Use restricted. See item 9[f]. powder
- EU EINECS/ELINCS List: 209-150-3

**Polyethylene glycol**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 3
- EU EINECS/ELINCS List: Not Listed

**Sodium starch glycolate**
- 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: Not Listed

**Titanium dioxide**
- CERCLA/SARA 313 Emission reporting: Not Listed
carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 236-675-5

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

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

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 12 - Ecological Information.

Revision date: 07-Oct-2015

Prepared by: Product Stewardship Hazard Communication

Pfizer Global Environment, Health, and Safety Operations
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End of Safety Data Sheet