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

Product Identifier

Material Name: Pantoprazole Sodium Delayed-Release Granules, for Suspension

Trade Name: PROTONIX
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product for the treatment of gastrointestinal disorders

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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Carcinogenicity: Category 1B

US OSHA Specific - Classification
Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger
Hazard Statements:
H350 - May cause cancer
May form combustible dust concentrations in air

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

Material Name: Pantoprazole Sodium Delayed-Release Granules, for Suspension
Revision date: 19-Oct-2015

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

<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>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Pantoprazole Sodium Sesquihydrate</td>
<td>164579-32-2</td>
<td>Not Listed</td>
<td>Acute Tox.4 (H302) Carc.1B (H350) Aquatic Acute 3 (H402)</td>
<td>22</td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</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>

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

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: 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. 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
SAFETY DATA SHEET

Material Name: Pantoprazole Sodium Delayed-Release Granules, for Suspension
Revision date: 19-Oct-2015

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.

Microcrystalline cellulose
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³
Vietnam OEL - TWAs 10 mg/m³

Pantoprazole Sodium Sesquihydrate
Pfizer OEL TWA-8 Hr: 300µg/m³

Sodium lauryl sulfate
Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Talc (non-asbestiform)
ACGIH Threshold Limit Value (TWA) 2 mg/m³
Australia TWA 2.5 mg/m³
Austria OEL - MAKs 2 mg/m³
Belgium OEL - TWA 2 mg/m³
Bulgaria OEL - TWA 1.0 fiber/cm³
Czech Republic OEL - TWA 2.0 mg/m³
Denmark OEL - TWA 0.3 fiber/cm³
Finland OEL - TWA 0.5 fiber/cm³
Greece OEL - TWA 10 mg/m³
Hungary OEL - TWA 2 mg/m³
Ireland OEL - TWAs 10 mg/m³
Lithuania OEL - TWA 2 mg/m³
Netherlands OEL - TWA 0.25 mg/m³
OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf

OSHA - Final PELS - Table Z-3 Mineral D: 20 mppcf

Version: 2.0
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA</th>
<th>Portugal OEL - TWA</th>
<th>Romania OEL - TWA</th>
<th>Slovakia OEL - TWA</th>
<th>Slovenia OEL - TWA</th>
<th>Spain OEL - TWA</th>
<th>Sweden OEL - TWAs</th>
<th>Switzerland OEL -TWAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poland</td>
<td>4.0 mg/m³</td>
<td>2 mg/m³</td>
<td>2 mg/m³</td>
<td>2 mg/m³</td>
<td>2 mg/m³</td>
<td>2 mg/m³</td>
<td>2 mg/m³</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Portugal</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Romania</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slovakia</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slovenia</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Titanium dioxide
ACGIH Threshold Limit Value (TWA) 10 mg/m³
ACGIH OELs - Notice of Intended Changes Listed

Exposure Controls
Engineering Controls: 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. Engineering controls should be used as the primary means to control exposures.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical State</strong></td>
<td>Granules</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>Molecular Formula</strong></td>
<td>Mixture</td>
</tr>
<tr>
<td><strong>Solvent Solubility</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Water Solubility</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Melting/Freezing Point (°C)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Boiling Point (°C)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Partition Coefficient: (Method, pH, Endpoint, Value)</strong></td>
<td>Predicted 7.4 Log P 2.05</td>
</tr>
<tr>
<td><strong>Decomposition Temperature (°C)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Evaporation Rate (Gram/s)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Vapor Pressure (kPa)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Vapor Density (g/ml)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Relative Density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flammability</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Autoignition Temperature (Solid) (°C)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flammability (Solids)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash Point (Liquid) (°C)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Upper Explosive Limits (Liquid) (% by Vol.)</strong></td>
<td>No data available</td>
</tr>
</tbody>
</table>

**Material Name:** Pantoprazole Sodium Delayed-Release Granules, for Suspension

**Revision date:** 19-Oct-2015

**Molecular Formula:** Mixture

**Molecular Weight:** Mixture

**Color:** Pale yellow to dark brown

**Odor Threshold:** 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 information included in this section describes the potential hazards of various forms of the active ingredients. The remaining information describes the potential hazards of the individual ingredients.

Short Term:
May be harmful if swallowed. (based on animal data) Accidental ingestion may cause effects similar to those seen in clinical use.

Known Clinical Effects:
Adverse effects most commonly reported in clinical use include headache, diarrhea, nausea, and flatulence. May cause mild skin rash.

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

Pantoprazole Sodium

Rat Oral LD 50 747 mg/kg
Mouse Oral LD 50 > 1000 mg/kg
Rat Intravenous LD 50 256 mg/kg

Titanium dioxide

Rat Oral LD 50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Sodium lauryl sulfate

Rat Oral LD 50 1288 mg/kg

Pantoprazole Sodium Sesquihydrate

Rat Oral LD 50 ~ 900 mg/kg
Mouse Oral LD 50 > 700 mg/kg
Rat Intravenous LD 50 240 mg/kg
Mouse Intravenous LD 50 ~ 370 mg/kg

Polysorbate 80

Rat Oral LD 50 25 g/kg

Povidone

Rat Oral LD 50 100 g/kg

Talc (non-asbestiform)
11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 > 1600 mg/kg

Hydroxypropyl methylcellulose
Rat Oral LD50 > 10,000 mg/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 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)

Sodium lauryl sulfate
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild Moderate
Skin Sensitization - GPMT Guinea Pig Negative
Skin Sensitization - LLNA Mouse Negative

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

Pantoprazole Sodium Sesquihydrate
1 Year(s) Rat Oral 300 mg/kg/day LOEL Thyroid
1 Year(s) Dog Oral 60 mg/kg/day LOEL Thyroid

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Pantoprazole
Reproductive & Fertility-Males Rat Oral 500 mg/kg/day NOEL No effects at maximum dose
Reproductive & Fertility - Females Rat Oral 450 mg/kg/day NOEL No effects at maximum dose
Fertility and Embryonic Development Rat Oral 450 mg/kg/day NOEL Not Teratogenic
Fertility and Embryonic Development Rabbit Oral 40 mg/kg/day NOEL Not Teratogenic

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

Pantoprazole
Chromosome Aberration Human Lymphocytes Positive
Micronucleus Mouse Positive
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Positive

In Vivo DNA Binding Assay Rat Equivocal
In Vivo Chromosome Aberration Rat Bone Marrow Negative

Sodium lauryl sulfate
Bacterial Mutagenicity (Ames) Salmonella Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))
### 11. TOXICOLOGICAL INFORMATION

Pantoprazole

<table>
<thead>
<tr>
<th>Material</th>
<th>Species/Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat Oral</td>
<td>24 Month(s)</td>
<td>LOEL</td>
<td>0.5 mg/kg/day</td>
<td>Tumors, Gastrointestinal system, Liver</td>
</tr>
<tr>
<td>Oral</td>
<td>24 Month(s)</td>
<td>LOEL</td>
<td>5 mg/kg/day</td>
<td>Tumors, Gastrointestinal system</td>
</tr>
<tr>
<td>Mouse</td>
<td>24 Month(s)</td>
<td>LOEL</td>
<td>150 mg/kg/day</td>
<td>Tumors, Liver</td>
</tr>
<tr>
<td>Rat Oral</td>
<td>24 Month(s)</td>
<td>LOEL</td>
<td>200 mg/kg/day</td>
<td>Tumors, Thyroid</td>
</tr>
</tbody>
</table>

Carcinogen Status: See below

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

Crosopovidone
- IARC: Group 3 (Not Classifiable)

Povidone
- IARC: Group 3 (Not Classifiable)

Talc (non-asbestiform)
- IARC: Group 3 (Not Classifiable)

### 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)

<table>
<thead>
<tr>
<th>Material</th>
<th>Species/Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pantoprazole</td>
<td>Pseudokirchneriella subcapitata (Green Alga)</td>
<td>OECD EC50</td>
<td>72 Hours</td>
<td>48 mg/L</td>
</tr>
<tr>
<td>Daphnia magna (Water Flea)</td>
<td>OECD EC50</td>
<td>48 Hours</td>
<td>&gt;95 mg/L</td>
<td></td>
</tr>
<tr>
<td>Pimephales promelas (Fathead Minnow)</td>
<td>OECD LC50</td>
<td>96 Hours</td>
<td>&gt;95 mg/L</td>
<td></td>
</tr>
<tr>
<td>Activated sludge</td>
<td>OECD EC50</td>
<td>3 Hours</td>
<td>&gt; 1000 mg/L</td>
<td></td>
</tr>
</tbody>
</table>

Sodium lauryl sulfate
- Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 3.6 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential:
- Partition Coefficient: (Method, pH, Endpoint, Value)

<table>
<thead>
<tr>
<th>Material</th>
<th>Method</th>
<th>pH</th>
<th>Endpoint</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pantoprazole</td>
<td>Predicted</td>
<td>7.4</td>
<td>Log P</td>
<td>2.05</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crospovidone</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Calcium oxide yellow</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Methacrylic acid copolymer</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

| Material Name: Pantoprazole Sodium Delayed-Release Granules, for Suspension |
| Revision date: 19-Oct-2015 | Version: 2.0 |

| Inventory - United States TSCA - Sect. 8(b) | Present |
| California (AICS): | Present |
| REACH - Annex XVII - Restrictions on Certain Dangerous Substances: | Use restricted. See item 9(f). powder |
| EU EINECS/ELINCS List | 232-674-9 |

| Pantoprazole Sodium Sesquihydrate |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |
| CERCLA/SARA 313 Emission reporting | Not Listed |

| Polysorbate 80 |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| CERCLA/SARA 313 Emission reporting | Not Listed |

| Sodium lauryl sulfate |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 6 |
| EU EINECS/ELINCS List | 205-788-1 |

| Talc (non-asbestiform) |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | 238-877-9 |

| Triethyl Citrate |
| EU EINECS/ELINCS List | 201-070-7 |

| Povidone |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

| Hydroxypropyl methylcellulose |
| California Proposition 65 | Not Listed |
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Inventory</th>
<th>United States TSCA - Sect. 8(b)</th>
<th>Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td></td>
<td>Present</td>
</tr>
<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td></td>
<td>Schedule 4</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td></td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Titanium dioxide

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | carcinogen initial date 9/2/11 airborne, unbound particles of respirable size |
| 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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Carcinogenicity-Cat.1B; H350 - May cause cancer
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 11 - Toxicology Information. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

Revision date: 19-Oct-2015
Prepared by: Product Stewardship Hazard Communication

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End of Safety Data Sheet