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

Product Identifier

<table>
<thead>
<tr>
<th>Material Name:</th>
<th>Pantoprazole Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name:</td>
<td>PROTONIX; NOXANTOR</td>
</tr>
<tr>
<td>Synonyms:</td>
<td>Pantoprazole Delayed-Release Tablets</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-800-879-3477</td>
<td>United Kingdom</td>
</tr>
<tr>
<td></td>
<td>+00 44 (0)1304 616161</td>
</tr>
</tbody>
</table>

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

<table>
<thead>
<tr>
<th>GHS - Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogenicity: Category 1B</td>
</tr>
</tbody>
</table>

EU Classification:

| EU Indication of danger: Carcinogenic: Category 2 |
| EU Risk Phrases: R45 - May cause cancer. |

Label Elements

| Signal Word: Danger |
| Hazard Statements: H350 - May cause cancer |

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 |
Other Hazards
Australian Hazard Classification (NOHSC):
No data available

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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium stearate</td>
<td>1592-23-0</td>
<td>216-472-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Pantoprazole Sodium Sesquihydrate</td>
<td>164579-32-2</td>
<td>Not Listed</td>
<td>Xn;R22</td>
<td>Acute Tox.4 (H302)</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Carc. Cat.2 ;R45</td>
<td>Carc.1B (H350)</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium carbonate</td>
<td>498-19-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>Not Listed</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>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>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crospovidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Ferric oxide yellow</td>
<td>51274-00-1</td>
<td>257-098-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Methacrylic acid copolymer</td>
<td>25086-15-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Triethyl Citrate</td>
<td>77-93-0</td>
<td>201-070-7</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 R phrases and 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: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion: 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 forContainment 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
7. HANDLING AND STORAGE

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.

Calcium stearate

- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Lithuania OEL - TWA: 5 mg/m³
- Sweden OEL - TWAs: 5 mg/m³

Pantoprazole Sodium Sesquihydrate

- Pfizer OEL TWA-8 Hr: 300µg/m³

Propylene glycol

- Australia TWA: 150 ppm, 474 mg/m³, 10 mg/m³
- Ireland OEL - TWAs: 150 ppm, 470 mg/m³, 10 mg/m³
- Latvia OEL - TWA: 7 mg/m³
- Lithuania OEL - TWA: 7 mg/m³

Sodium lauryl sulfate

- Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Titanium dioxide

- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- ACGIH OELs - Notice of Intended Changes: Listed
- 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: 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
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Physical State: Tablet
Odor: No data available.
Molecular Formula: Mixture
Color: Yellow
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)

Pantoprazole
- Predicted 7.4  Log P 2.05

Pantoprazole Sodium
- No data available
Calcium stearate
- No data available
Ferric oxide yellow
- No data available
Hydroxypropyl methylcellulose
- No data available
Polysorbate 80
- No data available
Propylene glycol
- No data available
Titanium dioxide

PZ00404
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Data Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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: No data available
- 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.
11. TOXICOLOGICAL INFORMATION

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

**Pantoprazole Sodium**
- Rat Oral LD50 747 mg/kg
- Mouse Oral LD50 > 1000 mg/kg
- Rat Intravenous LD50 256 mg/kg

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

**Polysorbate 80**
- Rat Oral LD50 25 g/kg

**Propylene glycol**
- Rat Oral LD50 22,000 mg/kg
- Mouse Oral LD50 24,900 mg/kg
- Rabbit Dermal LD50 20,800 mg/kg

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

**Povidone**
- Rat Oral LD50 100 g/kg

**Sodium lauryl sulfate**
- Rat Oral LD50 1288 mg/kg

**Mannitol**
- Rat Oral LD50 13500 mg/kg
- Mouse Oral LD50 22 g/kg

**Pantoprazole Sodium Sesquihydrate**
- Rat Oral LD50 ~ 900 mg/kg
- Mouse Oral LD50 > 700 mg/kg
- Rat Intravenous LD50 240 mg/kg
- Mouse Intravenous LD50 ~ 370 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)

**Propylene glycol**
- Skin Irritation Rabbit Mild
- Eye Irritation Rabbit Mild

**Sodium lauryl sulfate**
- Eye Irritation Rabbit Moderate
- Skin Irritation Rabbit Mild Moderate
- Skin Sensitization - GPMT Guinea Pig Negative
11. TOXICOLOGICAL INFORMATION

Skin Sensitization - LLNA  Mouse  Negative

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))

Pantoprazole
24 Month(s)  Rat  Oral  0.5 mg/kg/day  LOEL  Tumors, Gastrointestinal system, Liver
24 Month(s)  Rat  Oral  5 mg/kg/day  LOEL  Tumors, Gastrointestinal system
24 Month(s)  Mouse  Oral  150 mg/kg/day  LOEL  Tumors, Liver
24 Month(s)  Rat  Oral  200 mg/kg/day  LOEL  Tumors, Thyroid

Carcinogen Status:
See below

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

Povidone
IARC:  Group 3 (Not Classifiable)

Crospovidone
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:

PZ00404
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Pantoprazole

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours >95 mg/L
Daphnia magna (Water Flea) OECD EC50 48 Hours >95 mg/L
Pimephales promelas (Fathead Minnow) OECD LC50 96 Hours >95 mg/L
Activated sludge OECD EC50 3 Hours > 1000 mg/L

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)

Pantoprazole

Predicted 7.4 Log P 2.05

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

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A
### 15. REGULATORY INFORMATION

**Calcium 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**: 216-472-8

**Crospovidone**
- **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

**Ferric oxide yellow**
- **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**: 257-098-5

**Hydroxypropyl methylcellulose**
- **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 4
- **EU EINECS/ELINCS List**: Not Listed

**Mannitol**
- **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**: 200-711-8

**Methacrylic acid copolymer**
- **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

**Pantoprazole Sodium Sesquihydrate**
15. REGULATORY INFORMATION

Sodium carbonate

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Polysorbate 80

- 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

Povidone

- 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

Propylene glycol

- 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: 200-338-0

Sodium carbonate

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Sodium lauryl sulfate

- 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 6
- EU EINECS/ELINCS List: 205-788-1

Titanium dioxide

- CERCLA/SARA 313 Emission reporting: Not Listed
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

Triethyl Citrate

- 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: 201-070-7
15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of R phrases and 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

Carcinogenic: Category 2
Xn - Harmful

R22 - Harmful if swallowed.
R45 - May cause cancer.

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

Reasons for Revision:
Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 3 - Composition / Information on Ingredients. Updated Section 9 - Physical and Chemical Properties. Updated Section 16 - Other Information.

Revision date: 10-Nov-2014
Prepared by: Product Stewardship Hazard Communication
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