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

### Product Identifier
- **Material Name:** Pantoprazole Sodium Delayed-Release Granules
- **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

- **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

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture
- **GHS - Classification**
  - Carcinogenicity: Category 1B

- **US OSHA Specific - Classification**
  - **Physical Hazard:** Combustible Dust

- **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
  - 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
Revision date: 10-Nov-2014
Version: 1.0

Other Hazards
Australian Hazard Classification (NOHSC):

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>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>Pantoprazole Sodium Sesquihydrate</td>
<td>164579-32-2</td>
<td>Not Listed</td>
<td>Xn;R22</td>
<td>Acute Tox.4 (H302) Carc.1B (H350) Aquatic Acute 3 (H402)</td>
<td>22</td>
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<tr>
<td>Sodium lauryl sulfate</td>
<td>151-21-3</td>
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<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
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<tr>
<td>Titanium dioxide</td>
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<td>236-675-5</td>
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<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>
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<tr>
<td>Crospovidone</td>
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<td>Ferric oxide yellow</td>
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<td>Hydroxypropyl methylcellulose</td>
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<td>Methacrylic acid copolymer</td>
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<tr>
<td>Polysorbate 80</td>
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<tr>
<td>Povidone</td>
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<td>Triethyl Citrate</td>
<td>77-93-0</td>
<td>201-070-7</td>
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<td>*</td>
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</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 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
7. HANDLING AND STORAGE

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

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 - TWA 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 6.0 mg/m³
Denmark OEL - TWA 3.0 mg/m³
Finland OEL - TWA 0.5 fiber/cm³
Greece OEL - TWA 10 mg/m³
Hungary OEL - TWA 2 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).

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

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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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>Physical State:</th>
<th>Tablet</th>
<th>Color:</th>
<th>Yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
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<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

**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

- **Titanium dioxide**
  - No data available

- **Sodium lauryl sulfate**
  - No data available

- **Pantoprazole Sodium Sesquihydrate**
  - No data available

- **Crospovidone**
  - No data available

- **Ferric oxide yellow**
  - No data available

- **Methacrylic acid copolymer**
  - No data available

- **Polysorbate 80**
  - No data available

- **Povidone**
  - No data available

- **Triethyl Citrate**
  - No data available

- **Talc (non-asbestiform)**
  - No data available

- **Hydroxypropyl methylcellulose**
  - No data available

- **Microcrystalline cellulose**
  - 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
SAFETY DATA SHEET

Material Name: Pantoprazole Sodium Delayed-Release Granules
Revision date: 10-Nov-2014

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 > 1000mg/kg
  Rat Intravenous LD 50 256mg/kg

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

Sodium lauryl sulfate
  Rat Oral LD50 1288 mg/kg

Pantoprazole Sodium Sesquihydrate
  Rat Oral LD50 ~ 900 mg/kg
  Mouse Oral LD50 > 700mg/kg
  Rat Intravenous LD50 240mg/kg
  Mouse Intravenous LD50 ~ 370mg/kg
11. TOXICOLOGICAL INFORMATION

Polysorbate 80
Rat  Oral  LD50  25 g/kg

Povidone
Rat  Oral  LD50  100 g/kg

Talc (non-asbestiform)
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

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

PZ02469
11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>In Vivo Chromosome Aberration</th>
<th>Rat Bone Marrow</th>
<th>Negative</th>
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</thead>
<tbody>
<tr>
<td>Titanium dioxide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IARC:</td>
<td></td>
<td>Group 2B (Possibly Carcinogenic to Humans)</td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Salmonella</td>
<td>Negative</td>
</tr>
</tbody>
</table>

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)

**Crospovidone**
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)**

**Pantoprazole**
- *Pseudokirchneriella subcapitata* (Green Alga)  OECD  EC50  72 Hours  48 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

**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

Crosopovidone
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Not Listed
- 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
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>EU EINECS/ELINCS List</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS:</th>
<th>REACH - Annex XVII - Restrictions on Certain Dangerous Substances:</th>
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</thead>
<tbody>
<tr>
<td>Hydroxypropyl methylcellulose</td>
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<tr>
<td>Methacrylic acid copolymer</td>
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<td>Microcrystalline cellulose</td>
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<tr>
<td>Pantoprazole Sodium Sesquihydrate</td>
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</tr>
<tr>
<td>Polysorbate 80</td>
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<tr>
<td>Povidone</td>
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<td></td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td></td>
<td></td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

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

Talc (non-asbestiform)
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 238-877-9

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

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

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.

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

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