SAFETY DATA SHEET

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

Product Identifier

Material Name: Pantoprazole Sodium for Injection
Trade Name: PROTONIX
Chemical Family: Not determined

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
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Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification
Acute Oral Toxicity: Category 4
Carcinogenicity: Category 1B
Acute aquatic toxicity: Category 3

US OSHA Specific - Classification
Physical Hazard: Combustible Dust

EU Classification:
EU Indication of danger: Harmful
Carcinogenic: Category 2

EU Risk Phrases:
R22 - Harmful if swallowed.
R45 - May cause cancer.

Label Elements
Signal Word: Danger
Hazard Statements:
H302 - Harmful if swallowed
H350 - May cause cancer
H402 - Harmful to aquatic life
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
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P405 - Store locked up
P273 - Avoid release to the environment
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards


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>Pantoprazole Sodium</td>
<td>138786-67-1</td>
<td>Not Listed</td>
<td>Xn;R22</td>
<td>Acute Tox.4 (H302)</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Carb. Cat. 2;R45</td>
<td>Carb.1B (H350)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(H402)</td>
<td></td>
</tr>
</tbody>
</table>

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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.
SAFETY DATA SHEET

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.

Products:

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 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

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

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: | Freeze-dried powder |
| Odor: | No data available |
| Molecular Formula: | C16H14F2N3NaO4S |
| Solvent Solubility: | No data available |
| Water solubility: | 303 g/L |
| Water Solubility: | No data available |
| pH: | No data available |
| Melting/Freezing Point (°C): | 149-150 |
| Boiling Point (°C): | No data available |
| Partition Coefficient: (Method, pH, Endpoint, Value) Pantoprazole Sodium | No data available |
| Pantoprazole | Predicted 7.4 Log P 2.05 |
| 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 information included in this section describes the potential hazards of various forms of the active ingredients.
Short Term: 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. Additionally weight changes, fatigue, malaise, insomnia, sleepiness (somnolence), weakness, and electrolyte imbalance may occur.

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pantoprazole Sodium</td>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>747</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>&gt;1000</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Intravenous</td>
<td>LD 50</td>
<td>256</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.

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose (mg/kg/day)</th>
<th>NOEL</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pantoprazole</td>
<td>24 Month(s)</td>
<td>Rat/Male</td>
<td>Oral</td>
<td>500</td>
<td>NOEL</td>
<td>No effects at maximum dose</td>
</tr>
<tr>
<td></td>
<td>24 Month(s)</td>
<td>Rat/Female</td>
<td>Oral</td>
<td>450</td>
<td>NOEL</td>
<td>No effects at maximum dose</td>
</tr>
<tr>
<td></td>
<td>Fertility and Embryonic Development</td>
<td>Rat</td>
<td>Oral</td>
<td>450</td>
<td>NOEL</td>
<td>Not Teratogenic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rabbit</td>
<td>Oral</td>
<td>40</td>
<td>NOEL</td>
<td>Not Teratogenic</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Study Type</th>
<th>Cell/Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pantoprazole</td>
<td>Chromosome Aberration</td>
<td>Human Lymphocytes</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Micronucleus</td>
<td>Mouse</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>Mammalian Cell Mutagenicity</td>
<td>Chinese Hamster Ovary (CHO) cells</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td>In Vivo DNA Binding Assay</td>
<td>Rat</td>
<td>Equivocal</td>
</tr>
<tr>
<td></td>
<td>In Vivo Chromosome Aberration</td>
<td>Rat Bone Marrow</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

<table>
<thead>
<tr>
<th>Substance</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose (mg/kg/day)</th>
<th>NOEL</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pantoprazole</td>
<td>24 Month(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>0.5</td>
<td>LOEL</td>
<td>Tumors, Gastrointestinal system, Liver</td>
</tr>
<tr>
<td></td>
<td>24 Month(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>5</td>
<td>LOEL</td>
<td>Tumors, Gastrointestinal system</td>
</tr>
<tr>
<td></td>
<td>24 Month(s)</td>
<td>Mouse</td>
<td>Oral</td>
<td>150</td>
<td>LOEL</td>
<td>Tumors, Liver</td>
</tr>
<tr>
<td></td>
<td>24 Month(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>200</td>
<td>LOEL</td>
<td>Tumors, Thyroid</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

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

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

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

PZ01408
15. REGULATORY INFORMATION

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A
(Bad file name or number)

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

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

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 11 - Toxicology Information. Updated Section 7 - Handling and Storage. Updated Section 3 - Composition / Information on Ingredients.

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