



MATERIAL SAFETY DATA SHEET

Revision date: 13-Dec-2011

Version: 2.0

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

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Material Name: Pantoprazole Sodium for Injection

| | |
|------------------|--|
| Trade Name: | PROTONIX |
| Chemical Family: | Not determined |
| Intended Use: | Pharmaceutical product for the treatment of gastrointestinal disorders |

2. HAZARDS IDENTIFICATION

Appearance: White to off-white freeze-dried powder
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed.
Possible carcinogen

Additional Hazard Information:

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 (somnia), weakness, and electrolyte imbalance may occur.

EU Indication of danger: Harmful
Carcinogenic: Category 2

EU Hazard Symbols:



EU Risk Phrases:

R22 - Harmful if swallowed.
R45 - May cause cancer.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | % |
|---------------------|-------------|-----------------------|-------------------|-----|
| Pantoprazole Sodium | 138786-67-1 | Not Listed | Xn;R22 T;R45 | 100 |

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

For the full text of the R phrases 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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.

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7. HANDLING AND STORAGE

General 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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 | Color: | White to off-white |
| Molecular Formula: | C ₁₆ H ₁₄ F ₂ N ₃ NaO ₄ S | Molecular Weight: | 405.4 |

| | |
|-------------------------------------|---------|
| Water solubility: | 303 g/L |
| Melting/Freezing Point (°C): | 149-150 |

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

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

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11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of various forms of the active ingredients.

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

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))

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

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: 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.

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

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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

EU Symbol: T
EU Indication of danger: Harmful
Carcinogenic: Category 2

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

EU Safety Phrases:
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

OSHA Label:
WARNING
May be harmful if swallowed.
Possible carcinogen

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



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16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

R22 - Harmful if swallowed.

R45 - May cause cancer.

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

Reasons for Revision: Updated Section 2 - Hazard Identification.

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