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

Product Name
Protonix Solid Products

Common Name
Not available

Chemical Name
Not applicable

Synonyms
Not available

Product Use
Pharmaceutical product

Classification
Gastrointestinal Drug Proton Pump Inhibitor

Supplier
Wyeth
P.O. Box 8299
Philadelphia, PA 19101 USA.
Telephone: 1-610-688-4400

Emergency Telephone Number
Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

3. HAZARDS IDENTIFICATION

Potential Physical Hazards
Powders and solids are presumed to be combustible.

Potential Health Effects

   Eyes
   May cause mechanical eye irritation.
   Not available

   Skin
   Not available

   Inhalation
   The most common effects may include mild or irregular heartbeat, vasodilation, drowsiness, confusion, headache, blurred vision, abdominal pain, nausea, vomiting, diarrhea, flatulence, constipation, dyspepsia, gastrointestinal disorders, anxiety, joint pain, loss of energy, weakness, bronchitis, cough increase, flu-like syndrome, muscle rigidity or stiffness, difficulty in moving, abnormal liver function tests, migraine, neck pain, pain, pharyngitis, runny or stuffy nose, upper respiratory tract infection, urinary frequency, and urinary tract infection.

   Ingestion
   May cause harm to the unborn child.

   Please see Patient Package Insert for further information.

Therapeutic Target Organ(s)
Gastrointestinal system.
Potential Environmental Effects

4. FIRST AID MEASURES

Eye Contact
In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

Skin Contact
Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

Inhalation
Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

Ingestion
If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties
Not flammable

Extinguishing Media

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

Unsuitable Extinguishing Media
Do NOT use water jet.

Fire Fighting
Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.

Hazardous Combustion Products
Carbon oxides, nitrogen oxides.

Protective Equipment and Precautions for Firefighters
In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions
Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions
Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.

Methods for Containment
Not available

Methods for Cleaning up
Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling
For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage
No special safety precautions required. Keep container tightly closed.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name
Pantoprazole Sodium Sesquihydrate

Exposure Guideline
300 mcg/m³

Engineering Controls
Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.

Personal Protective Equipment

Eye/face Protection
Provide eye protection based on risk assessment.

Skin Protection
Wear nitrile or latex gloves. Wear protective garment.

Respiratory Protection
Base respirator selection on a risk assessment.

General Hygiene
When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.

Other
Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
Pharmaceutical tablet, Powder or Granules

Physical State
Solid

Color
Various

Odor Threshold
Not available

pH
Not applicable

Specific Gravity
Not applicable

Water Solubility
Not available

Solubility
Not applicable

Evaporation Rate
Not applicable

Partition Coefficient (n-octanol/water)
Not available

Vapor Density
Not applicable

Vapor Pressure
Not applicable

Boiling Point
Not applicable

Autoignition Temperature
Not applicable

Flash Point
Not applicable

Melting Point
Not applicable

Flammability Limits in Air
Upper Not applicable

Lower Not applicable

Explosion Limits
Upper Not applicable

Lower Not applicable

10. STABILITY AND REACTIVITY

Chemical Stability
Stable at room temperature.

Conditions to Avoid
No data available

Materials to Avoid
No materials to be especially mentioned.

Hazardous Decomposition Products
None under normal use.

Possibility of Hazardous Reactions
None under normal use.

11. TOXICOLOGICAL INFORMATION
The following effects are based on the Active Pharmaceutical Ingredient.

**Acute Toxicity**

**Pantoprazole Sodium Sesquihydrate**

**LD50 Oral**
- 709 mg/kg mice
- 796 mg/kg rats
- 887 mg/kg dogs

Signs of acute toxicity include hypoactivity, ataxia, hunched sitting, limb-splay, lateral position, segregation, absence of ear reflex, and tremor.

<table>
<thead>
<tr>
<th>Effect</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Dermal Irritation</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Primary Eye Irritation</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Sensitization</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**Multiple Dose Toxicity**

**Pantoprazole Sodium Sesquihydrate**

**No Toxicologic Effect**

<table>
<thead>
<tr>
<th>Dose/Species/Study Length:</th>
<th>See Carcinogenicity</th>
</tr>
</thead>
</table>

**Maximum Tolerated Dose (MTD), Oral**

**Pantoprazole Sodium Sesquihydrate**

**Carcinogenicity**

Pantoprazole produced benign and malignant neuroendocrine cell tumors of the gastric fundus, liver adenomas and carcinomas and an increased incidence of follicular cell adenomas and carcinomas in rats. In female mice, an increased incidence of liver adenomas and carcinomas, and gastric fundus Enterochromaffin-like cell (ECL-cell) hyperplasia were also observed.

**Genetic Toxicity**

No evidence of mutagenicity was observed in a battery of *in vitro* and *in vivo* assays.

**Reproductive Toxicity**

Studies in rats were found to have no effect on fertility and reproductive performance.

**Developmental Toxicity**

No teratogenic effects were observed in rats or rabbits. At maternally toxic doses in rats, it was embryo/fetotoxic and caused reduced pup survival. At lower doses, it delayed fetal skeletal development.

**Pantoprazole Sodium Sesquihydrate**

<table>
<thead>
<tr>
<th>Target Organ(s) of Toxicity</th>
<th>No data available</th>
</tr>
</thead>
</table>

---

**12. ECOLOGICAL INFORMATION**

**Chemical Fate Information**

**Pantoprazole Sodium Sesquihydrate**

<table>
<thead>
<tr>
<th>Mobility</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradability</td>
<td>Not available</td>
</tr>
<tr>
<td>Stability in Water</td>
<td>Not available</td>
</tr>
<tr>
<td>Bioaccumulation</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**Ecotoxicity**

**Pantoprazole Sodium Sesquihydrate**

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>EC50 ≥ 1000 g/l mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50/72h/algae</td>
<td>48 mg/l, NOEC &lt; 0.018 mg/l</td>
</tr>
<tr>
<td>EC50/48h/daphnia</td>
<td>&gt; 95 mg/l, NOEC = 23 mg/l</td>
</tr>
<tr>
<td>LC50/96h/fathead minnow</td>
<td>&gt; 95 mg/l, NOEC = 95 mg/l</td>
</tr>
</tbody>
</table>
13. DISPOSAL CONSIDERATIONS

Waste Disposal Method
Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information
This material is not classified as hazardous for transport.

15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

16. OTHER INFORMATION

Prepared By
Wyeth Department of Environment, Health & Safety

Format
This MSDS was prepared in accordance with Directive 2001/58/EC.

List of References
See Patient Package Insert for more information.

Revision Summary
Changes to Section 1

Disclaimer:
The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

End of MSDS