Safety Data Sheet
European Format

Protonix Solid Products

Preparation Date 01-Nov-2006 **Revision Date** 31-Mar-2008 **Revision Number** 3

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

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Pharmaceutical tablet, Powder or Granules **Physical State** Solid **Odor** Not available

Potential Physical Hazards

Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes May cause mechanical eye irritation.
Skin Not available
Inhalation Not available
Ingestion 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.

May cause harm to the unborn child.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s) Gastrointestinal system.

—	Not listed by OSHA, NTP or IARC.
Potential Environmental Effects	See Section 12.

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	**Exposure Guideline**
Pantoprazole Sodium Sesquihydrate	300 mcg/m^3

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 Considerations 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**	Not available
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 available
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 798 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.
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Multiple Dose Toxicity

Pantoprazole Sodium Sesquihydrate

No Toxicologic Effect Dose/Species/Study Length:	See Carcinogenicity

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

Target Organ(s) of Toxicity	No data available

12. ECOLOGICAL INFORMATION

Chemical Fate Information

Pantoprazole Sodium Sesquihydrate

Mobility	Not available
Biodegradability	Not available
Stability in Water	Not available
Bioaccumulation	Not available

Ecotoxicity

Pantoprazole Sodium Sesquihydrate

Microorganisms	EC50 ≥ 1000 g/l mg/l
Algae	EC50/72h/algae = 48 mg/l, NOEC < 0.018 mg/l
Daphnia	EC50/48h/daphnia > 95 mg/l, NOEC = 23 mg/l
Fish	LC50/96h/fathead minnow > 95 mg/l, NOEC = 95 mg/l

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

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End of MSDS