



MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.1

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

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CHEMTREC (24 hours): 1-800-424-9300

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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Pantoprazole Tablets

Trade Name: SOMAC
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of gastrointestinal disorders

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Titanium dioxide	13463-67-7	236-675-5	*
Propylene glycol	57-55-6	200-338-0	*
Sodium lauryl sulfate	151-21-3	205-788-1	*
Calcium stearate	1592-23-0	216-472-8	*
Sodium carbonate	497-19-8	207-838-8	*
Pantoprazole Sodium Sesquihydrate	164579-32-2	Not listed	20 or 40 mg***

Ingredient	CAS Number	EU EINECS List	%
Mannitol	69-65-8	200-711-8	*
Polysorbate 80	9005-65-6	Not listed	*
Hypromellose	9004-65-3	Not listed	*
Triethyl Citrate	77-93-0	201-070-7	*
Crospovidone	9003-39-8	Not listed	*
Povidone	9003-39-8	Not listed	*
Ferric oxide yellow	51274-00-1	257-098-5	*

Additional Information:

* Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Tablet
Signal Word: WARNING

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

Additional Hazard Information:

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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.

EU Indication of danger: Harmful
Carcinogenic: Category 2

EU Hazard Symbols:



EU Risk Phrases:

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

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.

4. FIRST AID MEASURES

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, oxides of nitrogen, and fluorine-containing compounds

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

Fire / Explosion Hazards: Not determined

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.

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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.

7. HANDLING AND STORAGE

General Handling:

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions:

Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Propylene glycol

Australia TWA = 10 mg/m³ TWA
= 150 ppm TWA
= 474 mg/m³ TWA

Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr: 0.3 mg/m³
Pfizer STEL 0.75 mg/m³

Calcium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Engineering Controls:

Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands:

Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes:

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin:

Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection:

Not required for the normal use of this product. 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:

Tablet

Color:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

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10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Not determined
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

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.

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

Mannitol

Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Povidone

Rat Oral LD50 100 g/kg

Polysorbate 80

Rat Oral LD50 25 g/kg

Hypromellose

Rat Oral LD50 > 10,000 mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Propylene glycol

Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

Sodium lauryl sulfate

Rat Oral LD50 1288 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)

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Sodium lauryl sulfate

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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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
<i>In Vivo</i> DNA Binding Assay	Rat	Equivocal
<i>In Vivo</i> 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: See below

Povidone

IARC: Group 3

Crospovidone

IARC: Group 3

Titanium dioxide

IARC: Group 2B

OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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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



Mannitol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-711-8

Polysorbate 80

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

Propylene glycol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-338-0

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Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Triethyl Citrate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-070-7

Sodium lauryl sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-788-1

Calcium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	216-472-8

Crospovidone

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Povidone

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Sodium carbonate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	207-838-8

Ferric oxide yellow

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	257-098-5

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet