SAFETY DATA SHEET

SECTION 1. PRODUCT IDENTIFICATION

Product Name: PANTOPRAZOLE SODIUM FOR INJECTION, 40 MG/VIAL (FOR US)

Synonyms: Pantoprazole Sodium for Injection

Supplier: Sun Pharmaceuticals Industries Ltd. Halol, Gujarat.

SECTION 2. HAZARD(S) IDENTIFICATION

% Threshold Limit Value	**:**	N/A
Appearance	**:**	White to off-white freeze-dried powder
Emergency Overview	**:**	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.
Route of Exposure	**:**	Inhalation, ingestion, eye contact, skin absorption, injection
Potential Health Effects		
Eye	**:**	Contact with eyes may cause irritation.
Skin	**:**	May cause skin irritation.
Inhalation	**:**	May cause irritation of respiratory tract.
Ingestion	**:**	May be harmful if ingested.
Target Organs	**:**	Eyes, skin, respiratory system, digestive system
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, diarrhoea, nausea, and flatulence. May cause mild skin rash. Additionally weight changes, fatigue, malaise, insomnia, sleepiness (somnolence), weakness, and electrolyte imbalance may occur.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS Number	Quantity per Vial
Pantoprazole Sodium	138786-67-1	40 mg
Edetate disodium (EDTA)	6381-92-6	1 mg
Sodium hydroxide	1310-73-2	for pH adjustment

SECTION 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 attention.

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.

SECTION 5. FIRE-FIGHTING MEASURES

Extinguishing Media: : Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Protective Equipment: : As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

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

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

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions	:	Personnel involved in clean-up should wear appropriate personal protective equipment. 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 labelled, 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.

SECTION 7. HANDLING AND STORAGE

General Handling	:	When handling pharmaceutical products, avoid all contact and inhalation of vapour, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage Conditions	:	Keep container tightly closed. Store at controlled room temperature 15 to 30°C (59 to 86°F). Protect from sunlight
Work Practices	:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices	:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapour or mist.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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.
Environmental Exposure Controls	:	Refer to specific 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	**:**	Freeze-dried powder
Colour	**:**	White to off-white
Odour	**:**	Odourless
Molecular Formula	**:**	$C_{16}H_{14}F_2N_3NaO_4S$
Molecular Weight	**:**	405.4
Water solubility	**:**	Soluble in water (303 g/L)
Melting/Freezing Point (°C)	**:**	149-150
Latex Free	**:**	Yes

SECTION 10. STABILITY AND REACTIVITY

Chemical Stability	**:**	Stable under recommended storage conditions.
Incompatibility	**:**	As a precautionary measure, keep away from strong Oxidizers.
Hazardous Decomposition Products	**:**	Decomposition products of this compound may include Potentially hazardous by products, acrid, and toxic fumes.
Conditions to avoid	**:**	Fine particles (such as dust and mists) may fuel Fires/explosions.

SECTION 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)

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))

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)

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)

24 Months, Rat, Oral, 0.5 mg/kg/day, LOEL - Tumors, Gastrointestinal system, Liver

24 Months ,Rat, Oral, 5 mg/kg/day, LOEL - Tumors, Gastrointestinal system

24 Months, Mouse, Oral, 150 mg/kg/day, LOEL - Tumors, Liver

24 Months, Rat, Oral, 200 mg/kg/day, LOEL - Tumors, Thyroid

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

SECTION 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)

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

SECTION 13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of in accordance with Local, State, Federal and Provincial regulations. 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 waste water.

SECTION 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

SECTION 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 hazard class: Class D, Division 2, and Subdivision A

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SECTION 16. OTHER INFORMATION

Disclaimer:
The information and recommendations contained herein are based upon tests believed to be reliable. However, Sun Pharmaceuticals Industries Ltd. does not guarantee their accuracy or completeness nor shall any of this information constitute a warranty, whether expressed or implied, as to the safety of the goods, the merchantability of the goods, or the fitness of the goods for a particular purpose. Adjustment to conform to actual conditions of usage may be required. Sun Pharmaceuticals Industries Ltd. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

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