

SAFETY DATA SHEET

Section 1: Identification	
Material	Pantoprazole Sodium Delayed-Release Granules, for Suspension
Recommended use	Pharmaceutical product for the treatment of gastrointestinal disorders
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Classification of the Substance or Mixture GHS – Classification Carcinogenicity	Category 1B
US OSHA Specific - Classification Physical Hazard	Combustible Dust
Hazard Statements	May cause cancer May form combustible dust concentrations in air
Precautionary Statements	Obtain special instructions before use Do not handle until all safety precautions have been read and understood Use personal protective equipment as required IF exposed or concerned: Get medical attention/advice Store locked up Dispose of contents/container in accordance with all local and national regulations
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Pantoprazole Sodium Sesquihydrate	164579-32-2
Microcrystalline cellulose	9004-34-6
Sodium lauryl sulfate	151-21-3
Talc (non-asbestiform)	14807-96-6
Titanium dioxide	13463-67-7
Crospovidone	9003-39-8

Ferric oxide yellow	51274-00-1
Methacrylic acid copolymer	25086-15-1
Polysorbate 80	9005-65-6
Triethyl Citrate	77-93-0
Povidone	9003-39-8
Hydroxypropyl methylcellulose	9004-65-3

Section 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
Medical Conditions Aggravated by Exposure	None known
Indication of the Immediate Medical Attention and Special Treatment Needed Notes to Physician	None

Section 5: Fire-Fighting Measures

Extinguishing Media	Extinguish fires with CO2, extinguishing powder, foam, or water
Special Hazards Arising from the Substance or Mixture Hazardous Combustion Products Fire / Explosion Hazards	Formation of toxic gases is possible during heating or fire Fine particles (such as dust and mists) may fuel fires/explosions
Advice for Fire-Fighters	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up 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

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

Precautions for Safe 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 thoroughly after handling. 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.

Conditions for Safe Storage, Including any Incompatibilities Storage Conditions Specific end use(s):

Store as directed by product packaging

Pharmaceutical drug product

Section 8: Exposure Controls/Personal Protection

Engineering Controls

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

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 Form	Granules
Colour	Pale yellow to dark brown
Description	Pantoprazole Sodium for Delayed-Release Oral Suspension, is supplied as pale yellow to brown coloured granules containing 40 mg pantoprazole in a unit-dose packet and are available as follows: Unit-dose carton of 30 NDC 31722-032-32
Section 10: Stability and Reactivity	
Reactivity	No data available
Chemical Stability	Stable under normal conditions of use
Possibility of Hazardous Reactions	No data available Fine particles (such as dust and mists) may fuel fires/explosions As a precautionary measure, keep away from strong oxidizers No data available
Oxidizing Properties	
Conditions to Avoid	
Incompatible Materials	
Hazardous Decomposition Products	
Section 11: Toxicological Information	
Information on Toxicological Effects	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.
General Information	
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
Acute Toxicity: (Species, Route, End Point, Dose)	
Pantoprazole Sodium	
Rat Oral LD 50 747 mg/kg	
Mouse Oral LD 50 > 1000mg/kg	
Rat Intravenous LD 50 256mg/kg	

Pantoprazole Sodium Sesquihydrate

Rat	Oral	LD50	~ 900 mg/kg
Mouse	Oral	LD50	> 700mg/kg
Rat	Intravenous	LD50	240mg/kg
Mouse	Intravenous	LD50	~ 370mg/kg

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**Pantoprazole Sodium Sesquihydrate**

1 Year(s)	Rat	Oral	300 mg/kg/day	LOEL	Thyroid
1 Year(s)	Dog	Oral	60 mg/kg/day	LOEL	Thyroid

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

Section 12: Ecological Information**Environmental Overview**

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

Toxicity:**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

Sodium lauryl sulfate

IARC: Group 3 (Not Classifiable)

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 3.6 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Pantoprazole

Predicted 7.4 Log P 2.05

Mobility in Soil: No data available

Section 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.

Section 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

Section 15: Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Pantoprazole Sodium Sesquihydrate

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

EU EINECS/ELINCS List Not Listed

Section 16: Other Information

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Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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