



## **SAFETY DATA SHEET**

<b>Section 1: Identification</b>	
<b>Material</b>	Pantoprazole Sodium for Injection
<b>Recommended use</b>	Pharmaceutical product for the treatment of gastrointestinal disorders
<b>Manufacturer</b>	Aspiro Pharma Limited, Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Telangana (S), Siddipet (Dist.)-502281, India.
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.</b> , Piscataway, NJ 08854
<b>Section 2: Hazard(s) Identification</b>	
<b>GHS - Classification</b>	Acute Oral Toxicity: Category 4 Carcinogenicity: Category 1B Acute aquatic toxicity: Category 3
<b>US OSHA Specific - Classification</b>	
Physical Hazard:	Combustible Dust
<b>Section 3: Composition/Information on Ingredients</b>	
<b>Ingredients</b>	Pantoprazole Sodium
CAS	138786-67-1
<b>Section 4: First-Aid Measures</b>	
<b>Ingestion:</b>	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.
<b>Inhalation</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately
<b>Skin Contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Eye Contact</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately
<b>Section 5: Fire-Fighting Measures</b>	



<b>Extinguishing Media</b>	Extinguish fires with CO <sub>2</sub> , extinguishing powder, foam, or water.
<b>Hazardous Combustion Products</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire / Explosion Hazards</b>	Fine particles (such as dust and mists) may fuel fires/explosions
Advice for Fire-Fighters During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus	

### Section 6: Accidental Release Measures

<b>Personal Precautions, Protective Equipment and Emergency Procedures</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure
<b>Environmental Precautions:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release
<b>Methods and Material For Containment and Cleaning Up:</b>	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
<b>Additional Consideration for Large Spills</b>	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 hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Releases to the environment should be avoided. Review and implement appropriate technical and procedural wastewater 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.

**Storage Conditions:**

Store as directed by product packaging.

**Specific end use(s):**

Pharmaceutical drug product

### Section 8: Exposure Controls/Personal Protection



<b>Engineering Controls</b>	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. Keep airborne contamination levels below the exposure limits									
<b>Personal protection equipment:</b>										
<b>Hands</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.									
<b>Eyes</b>	Wear safety glasses or goggles if eye contact is possible.									
<b>Skin</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations									
<b>Respiratory protection</b>	Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)									
<b>Section 9: Physical and Chemical Properties</b>										
<b>Physical Form</b>	Freeze-dried powder									
<b>Colour</b>	White to off-white									
<b>Description</b>	<p>Pantoprazole Sodium for Injection is supplied in a single-dose vial as a white to off-white freeze-dried powder for reconstitution containing 40 mg of pantoprazole.</p> <p>Pantoprazole sodium for injection is available as follows:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">NDC Number</th> <th style="text-align: left;">Strength</th> <th style="text-align: left;">Package Size</th> </tr> </thead> <tbody> <tr> <td>31722-204-10</td> <td>40 mg/vial</td> <td>10 vials</td> </tr> <tr> <td>31722-204-32</td> <td>40 mg/vial</td> <td>25 vials</td> </tr> </tbody> </table>	NDC Number	Strength	Package Size	31722-204-10	40 mg/vial	10 vials	31722-204-32	40 mg/vial	25 vials
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<b>Section 10: Stability and Reactivity</b>										
<b>Chemical stability</b>	Stable under normal conditions of use.									
<b>Section 11: Toxicological Information</b>										
<b>Known Clinical Effects</b>	Adverse effects most commonly reported in clinical use include headache, diarrhea, nausea, and flatulence. May cause mild skin rash. Additionally, weight changes, fatigue, malaise, insomnia, sleepiness (somnolence), weakness, and electrolyte imbalance may occur.									
<b>Short Term</b>	Accidental ingestion may cause effects similar to those seen in clinical use.									



<b>Acute Toxicity: (Species, Route, End Point, Dose)</b>	<b>Pantoprazole</b> Rat Oral LD 50 747 mg/kg Mouse Oral LD 50 > 1000mg/kg Rat Intravenous LD 50 256mg/kg
<b>Acute Toxicity Comments:</b>	A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.
<b>Carcinogen Status</b>	Not listed as a carcinogen by IARC, NTP or US OSHA

**Section 12: Ecological Information**

<b>Environmental Overview</b>	Environmental properties have not been investigated. Releases to the environment should be avoided
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**Section 13: Disposal Considerations**

<b>Waste Treatment Methods</b>	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 wastewater 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
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**Section 14: Transport Information**

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	
<b>Pantoprazole Sodium</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed



## Section 16: Other Information

**Issue Date: 30-01-2023**

**Version : 00**

**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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