Annora

SAFETY DATA SHEET

Section 1: Identification	
Material	Promethazine Hydrochloride Suppositories USP 12.5 mg and 25 mg
Recommended use	Pharmaceutical Use
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	According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.
Hazard Statements	This product presents minimal hazards in the workplace due to form of product. Handling of the unwrapped suppository may result in skin irritation or allergic reactions in persons susceptible to Promethazine Hydrochloride, other phenothiazines, or any of the other ingredients in this product. May be harmful if accidentally ingested. Therapeutic use of Promethazine Hydrochloride can cause adverse symptoms on the respiratory, cardiovascular, and central nervous systems. There is some evidence that the active ingredient may cause harm to the fetus.
Reactivity Hazards	This product is not reactive
Flammability Hazards	This product is combustible and may ignite if involved in a fire. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, nitrogen and silicon oxides).
Environmental Hazards	Large quantities released to the aquatic and terrestrial environment may have an adverse effect.
Emergency Considerations	Emergency responders should wear appropriate protection for situation to which they respond.

Section 3: Composition/Information on Ingredients	
Active Ingredient	Promethazine hydrochloride
CAS	58-33-3
Section 4: First-Aid Measures	
Protection of First Aid Responders	First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.
Eye Contact	If this product enters the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.
Skin Contact	Basic hygiene should prevent any problems. If the product contaminates the skin, and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.
Inhalation	If mists or sprays from this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air. In case of unconsciousness place patient stably in side position for transportation.
Section 5: Fire-Fighting Measures	
Suitable extinguishing agents	In the event of a fire, use suppression methods for surrounding materials, including water spray (for cooling), dry extinguishing media, carbon dioxide, foam.
Special hazards arising from the substance or mixture	This product may be combustible and ignite if involved in a fire and the water evaporates. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon, nitrogen and silicon oxides).

Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	In the event of a spill, clear the area and protect people. Spills will be slippery. Small Spills: For incidental spills (e.g., 1 package), wear double latex or nitrile disposable gloves and eye protection. Large Spills: For large spills (e.g., carton of packages), protective apparel should be used with a respirator when there is any danger of airborne mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus
Environmental Precautions	Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.
Methods for Containment and Clean Up	Small Spills: If product has been released from foil packaging, absorb up spilled material with damp sponge, polypads or other suitable material. If intact packages have been spilled, pick-up, and dispose of properly. Large Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Absorb any spilled product carefully, onto polypads or other non-reactive absorption material. All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures.

Section 7: Handling and Storage	
Precautions for Safe Handling	All employees who handle this material should be thoroughly trained to handle it safely. Open containers slowly on a stable surface in areas that have been designated for use of this product. As with all chemicals, avoid getting this product ON YOU or IN YOU. Ensure this product is used with adequate ventilation (refer to Section 8, Exposure Controls-Personal Protection). Remove contaminated clothing and launder. Keep container tightly closed when not in use. Keep away from heat, sparks, and other sources of ignition. Use non-sparking tools. Empty containers may contain residual material; therefore, empty containers should be handled with care. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration.
Protective Practices During Maintenance of Contaminated Equipment	When cleaning nondisposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad.
Conditions for safe storage, including any incompatibilities	Store refrigerated between 2º to 8ºC (36º to 46ºF).
8. Exposure controls / personal protection	
Ventilation and Engineering Controls	Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.
Personal Protective Equipment	Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.
Respiratory Protection	A respirator is not required for routine conditions of use with adequate engineering controls. A full-face Air-Purifying Respirator with high-efficiency particulate filter or a Supplied-Air Respirator must be worn during operations where engineering controls are not sufficient, large spill cleanup, or when processing generates airborne aerosols. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

Hand Protection	During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.
Eye protection	During operations in which mists or sprays may be generated, splash goggles or safety glasses should be considered.
Body Protection	Use appropriate protective clothing for the task (e.g., lab coat, etc.)
Section 9: Physical and Chemical Properties	
Physical State	Suppository
Description	Promethazine Hydrochloride Rectal Suppositories USP are available in boxes of 12 as follows: 12.5 mg, white to off-white colored bullet shaped suppository wrapped in an Alu/PE shell. NDC 31722-040-31 25 mg, white to off-white colored bullet shaped suppository wrapped in an Alu/PE shell. NDC 31722-041-31 Store refrigerated between 2º to 8ºC (36º to 46ºF). Dispense in well-closed container.
Section 10: Stability and Reactivity	
Chemical Stability	This product is stable. May discolor upon exposure to air and light.
Decomposition Products	Combustion: If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon, nitrogen and silicon oxides). Hydrolysis: None known.

Section 11: Toxicological Information

Toxicity Data: This SDS presents only toxicity data currently available for the active component. Additional animal data are available for the excipient components of this product, but are not presented in this SDS. Contact Watson Pharmaceuticals for more information.

Promethazine Hydrochloride:

LD50 (Oral-Mouse) 255 mg/kg: Behavioral: convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration: other changes
LD50 (Intraperitoneal-Rat) 170 mg/kg
LD50 (Intraperitoneal-Mouse) 160 mg/kg
LD50 (Intraperitoneal-Guinea Pig) 35 mg/kg
LD50 (Subcutaneous-Rat) 400 mg/kg
LD50 (Subcutaneous-Mouse) 240 mg/kg
LD50 (Subcutaneous-Dog) 250 mg/kg
LD50 (Intravenous-Rat) 15 mg/kg
LD50 (Intravenous-Mouse) 50 mg/kg
LD50 (Intravenous-Guinea Pig) 42,500 µg/kg
LD50 (Parenteral-Rat) 525 mg/kg

Section 12: Ecological Information

Mobility: This product has not been tested for mobility in soil; it is expected to be somewhat mobile due to its composition.

Persistence and Biodegradability: This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known.

Bio-Accumulation Potential: This product has not been tested for bio-accumulation potential.

Ecotoxicity: This product may be harmful to contaminated plant and animal life, especially in large quantities. All releases to terrestrial, atmospheric and aquatic environments should be avoided. No specific data is available for this product. There are no aquatic toxicity data currently available for the active component of this product.

Other Adverse Effects: This product does not contain any component with known ozone depletion potential.

Results of PBT and vPvB Assessment: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

Environmental Exposure Controls: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

Section 13: Disposal Considerations

Waste treatment methods

Waste disposal must be in accordance with appropriate Federal, State, and local regulations. Waste containers should be handled with uncontaminated gloves. Reusable equipment should be decontaminated using 0.05M Boric acid solution adjusted to pH 9 with 10 N sodium hydroxide followed by a detergent wash and then clean water rinse or by using a bleach solution (triple wash) and a detergent solution followed by clean water rinse.

Precautions to be Followed During Waste Handling: Wear proper protective equipment when handling waste materials.

U.S. EPA Waste Number: Wastes of the liquid should be tested to see if they meet the criteria for D001 (Characteristic/Ignitability).

European Waste Codes: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

Section 14: Transport Information

U.S. Department of Transportation Regulations: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

Transport Canada Transportation of Dangerous Goods Regulations: This product is NOT classified as Dangerous Goods, per regulations of Transport Canada.

International Air Transport Association (IATA): This product is NOT classified as Dangerous Goods, by rules of IATA.

International Maritime Organization (IMO) Designation: This product is NOT classified as Dangerous Goods by the International Maritime Organization.

United Nations Economic Commission for Europe (UNECE): This product is NOT classified by the United Nations Economic Commission for Europe to be dangerous goods. Refer to current regulations for all additional provisions other information not given here.

Transport in Bulk According to the IBC Code: See the information under the UN ADR and IMO, in this section.

Environmental Hazards: This compound is neither environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) nor a marine pollutant according to the IMDG Code and is not listed in Annex III under MARPOL 73/78

Section 15: Regulatory Information

Additional United States Regulations:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. Cercla Reportable Quantities (RQ): Not applicable.

U.S. TSCA Inventory Status: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

California Safe Drinking Water And Toxic Enforcement Act (PROPOSITION 65): No component of this product is on the California Proposition 65 lists.

Other U.S. Federal Regulations: Not applicable.

Section 16: Other Information, including date of preparation or last revision

Issue Date: 14-12-2022

Version: 00

Further information

Revision date: NA

Revision note: NA

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.

Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.