



SAFETY DATA SHEET

Section 1: Identification	
Material	Phenylephrine Hydrochloride Injection USP 10 MG/ML (1 mL) Packed in vials
Recommended use	Cardiovascular drug. Specified quality tests and assay use only
Manufacturer	Aspiro Pharma Limited, Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Telangana (S), Siddipet (Dist.)-502281, India.
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Principal Hazards of the product	Not a hazardous substance or mixture. It is in vial as a liquid form.
Harmful Effect of the drug on Health	May Be Harmful if Ingested or Inhaled in large quantity.
Effects on the Environment	Product is Biodegradable
Physical & Chemical Hazards	Thermal Decomposition can generate NO _x , CO _x , etc.
Hazard Statement	May cause an allergic skin reaction
Potential Acute Health Effects	Hazardous in case of ingestion. Hazardous in case of skin contact (irritant, permeator), of eye contact (irritant). Slightly hazardous in case of inhalation.
Potential Chronic Health Effects CARCINOGENIC EFFECTS MUTAGENIC EFFECTS TERATOGENIC EFFECTS	Very hazardous in case of ingestion. Hazardous in case of skin contact (irritant, permeator), of eye contact (irritant). Slightly hazardous in case of inhalation Not available. Not available Not available.
DEVELOPMENTAL TOXICITY	Not available. The substance is toxic to lungs, mucous membranes. Repeated or prolonged exposure to the substance can produce target organs damage



Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace

Section 3: Composition/Information on Ingredients

Ingredients	CAS
Phenylephrine Hydrochloride	61-76-7
Citric acid monohydrate	5949-29-1
Hydrochloric acid NF	7647-01-0
Nitrogen NF	7727-37-9
Sodium Chloride USP	7647-14-5
Sodium Hydroxide NF	1310-73-2
Sodium metabisulfite NF	7681-57-4
Tri sodium citrate Dihydrate	6132-04-3

Section 4: First-Aid Measures

Contact With Skin	May cause an allergic skin reaction. Wash the effected part of the skin with plenty of water. Remove contaminated clothing and wash before use. Obtain medical attention, if skin reaction occurs.
Contact With Eyes	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Check for and remove any contact lenses. If pain persists or recurs get 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	As coated tablets, use proper PPE while handling it. Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Instruction for the physician	In case of inhalation of decomposition products in a fire, symptoms may be delayed. Treat according to symptoms. Keep the victim under medical surveillance.
Protection for first aiders	Use mask. Safety glasses and gloves. Wash the hand with plenty of water.

Section 5: Fire-Fighting Measures

Specific hazards	No specific fire or explosion hazard
Fire extinguishing media	Water, Dry chemical, Carbon Dioxide. For lager fire use water spray or standard foam. Use water delivered as a fine spray to control fire & cool adjacent area. Do not use water jet



Protection equipment	Fire Fighting with the use of self-content breathing apparatus, appropriate fire suit, boots, helmet and rubber hand gloves
Other advice	Cool the containers in the vicinity with sprayed water or move the containers form fire area, if possible.
Section 6: Accidental Release Measures	
Personal precautions	Avoid direct contact. Wear the Personal protective equipment.
Precautions for environmental Protection	Keep out of drains; prevent entry into the natural environment
Cleaning methods	Use appropriate tools to put the spilled liquid in a convenient waste disposal container. Dispose the product as Hazardous waste and Incinerate in an approved facility. Waste must be disposed of in accordance with state and local environmental control regulations.
Section 7: Handling and Storage	
Handling Appropriate technical measures	Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood
Storage Recommended storage conditions	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP controlled room temperature] in closed container. Protect from light. Keep container dry. Keep in a cool place. Keep container tightly closed. Keep in a cool, well-ventilated place. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.
Recommended packaging materials	Glass vials
Precautions	Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes.
Section 8: Exposure Controls/Personal Protection	
Technical measures	Handle only with an appropriate nose mask and in a well-ventilated area.
Respiratory protection	Respiratory protection like mask is required
Hand protection	Gloves
Eye protection	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 66(EU). Safety glasses
Body and skin protection	Standard working suit



Specific safety protection	Do not drink or eat during handling.
Exposure limits	Not available
Section 9: Physical and Chemical Properties	
Physical Form	Colorless clear liquid in glass vials
Description	<p>Phenylephrine hydrochloride injection, USP 10 mg/mL, is a sterile, clear, colorless solution supplied as follows:</p> <p>10 mg/mL - 1 mL single dose vial (supplied in packages of 10) 31722-343-32</p> <p>10 mg/mL - 1 mL single dose vial (supplied in packages of 25) 31722-343-33</p> <p>50 mg/5mL - 5 mL vial; Pharmacy Bulk Package (supplied in packages of 10) 31722-344-31</p> <p>100 mg// 10mL - 10 mL vial; Pharmacy Bulk Package (supplied in packages of 1) 31722-345-10</p> <p>100 mg// 10mL - 10 mL vial; Pharmacy Bulk Package (supplied in packages of 10) 31722-345-31</p> <p>Vial stoppers are not manufactured with natural rubber latex. Store phenylephrine hydrochloride injection USP, 10 mg/mL at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from light. Store in carton until time of use. The 1 mL vials are for single use only; the 5 and 10 mL vials are pharmacy bulk packages.</p>
Section 10: Stability and Reactivity	
Stability	Material is stable under normal conditions
Conditions to avoid	Heat and flame.



Materials to avoid	As a precautionary measure, keep away from strong oxidizers
Hazardous decomposition Products	No data available
Incompability	As a precautionary measure, keep away from acids
Hazardous Polymerization	Will not occur
Section 11: Toxicological Information	
Routes of Entry	Dermal contact. Eye contact. Ingestion
Toxicity to Animals	Acute oral toxicity (LD50): 350 mg/kg [Rat].
Chronic Effects on Humans	The substance is toxic to lungs, mucous membranes
Other Toxic Effects on Humans	Very hazardous in case of ingestion. Hazardous in case of skin contact (irritant, permeator). Slightly hazardous in case of inhalation.
Special Remarks on Toxicity to Animals	Not available
Special Remarks on Chronic Effects on Humans	No known significant effects or critical hazards
Special Remarks on other Toxic Effects on Humans	No known significant effects or critical hazards
Section 12: Ecological Information	
Persistence / degradation of the drug	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided
Bioaccumulation	No data available
Aquatic Toxicity	No data available
Section 13: Disposal Considerations	
Product disposal	Disposed of in accordance with state and local environmental control regulations.
Disposal of contaminated Packaging & Personal protective equipment	As Above



Section 14: Transport Information

Land	RTMD	Class	Not dangerous goods
Rail	RID/ADR	Class	Not dangerous goods
Sea	IMCO/IMDG	Class	Not dangerous goods
Air	OACI/IATA	Class	Not dangerous goods
River	DON/AONR	Class	Not dangerous goods
UN proper shipping name DOT / IATA	Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.		

Section 15: Regulatory Information

Eec regulations	US federal regulations CERCLA/SARA Hazardous Substances - Not listed
Federal and State Regulations	TSCA 8(b) inventory: No products were found.
National Fire Protection Association (U.S.A.):	Health: 2; Flammability: 1 Reactivity: 0
Protective Equipment:	Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Splash goggles.

Section 16: Other Information

Issue Date : 11-02-2025

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.

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