SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Sixth Revised Edition UNITED NATIONS New York and Geneva, 2015

Phenylephrine Hydrochloride Injection USP 10mg/1mL
Phenylephrine Hydrochloride Injection USP 50mg/5mL
Phenylephrine Hydrochloride Injection USP 100mg/10mL

1. IDENTIFICATION

GHS Product identifier: Phenylephrine Hydrochloride Injection USP
Product code: #
Chemical Description: Benzenemethanol, 3-hydroxy-α-[(methylamino) methyl]-, hydrochloride (*R*)-; (−)-*m*-Hydroxy-α-[(methylamino)methyl] benzyl alcohol hydrochloride

Other means of identification:
Recommended use of the chemical: Indicated in adults and children for the treatment of hypotensive states e.g. circulatory failure, during spinal anaesthesia or drug induced hypotension.
Restrictions on use: The product should be used only for the above mentioned uses and may not be used for any other purpose than stated above.
Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Manufactured by:
Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843
Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification
Globally Harmonized System, UN (GHS)

Classification	Category	Exposure Route
Skin irritation	3	-
Skin sensitization	1B	-

Labeling
Globally Harmonized System, UN (GHS)

Classification	
Signal Word	**Warning**
Hazard Statements:	H316 Causes mild skin irritation H317 May cause allergic skin reaction
Precautionary Statements:	P261 Avoid breathing dust/fume/gas/mist/vapors/spray P301+P312 If swallowed: Call a poison center/doctor if you feel unwell P264 Wash thoroughly after handling P272 Contaminated work clothing must not be allowed out of the workplace. P273: Avoid release to the environment P391:Collect spillage

Other hazards which do not result in classification: none

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous ingredients	CAS	Content
Phenylephrine Hydrochloride	61-76-7	1%
Sodium chloride	7647-14-5	0.1 – 1%
Sodium Citrate Dihydrate	6132-04-3	0.1 – 1%
Citric Acid Monohydrate	5949-29-1	0.1 – 1%
Sodium Metabisulfite	7681-57-4	0.1 – 1%
Sodium hydroxide	1310-73-2	q.s.
Hydrochloric acid	7647-01-0	q.s.
Water for injection	7732-18-5	q.s.

4. FIRST-AID MEASURES

Inhalation

Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

Skin contact

Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

Eye contact

Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

Ingestion

Wash out mouth and drink plenty of water and bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not give anything to an unconscious person. Contact physician.

Most important symptoms and effects

Headache; irregular heart rate; dizziness; increase in blood pressure; perspiration; tremor; vomiting; pallor. May cause hypersensitivity.

Advice for the doctor

Phenylephrine is a sympathomimetic drug related to epinephrine and ephedrine; although it is rare, it may produce such reactions as tremor, pallor, perspiration, abnormal palpitation, or collapse. Additional details are available on the package insert.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Dry Chemical Foam, Carbon dioxide, Water spray or alcohol-resistant foam.

Fire/explosion hazard

None known. Expected to be non-combustible.

Specific hazards arising from the mixture

No data available.

Personal protection

Self-contained breathing apparatus.

Special exposure hazards

No information is available about the potential of this product to produce adverse environmental effects.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Goggles, gloves, protective clothing, respiratory protection.
Remove ignition sources and provide sufficient ventilation.

Environmental precautions

Be careful not to let it flow into rivers, etc., since adverse effects on the environment are concerned.

Spillage procedure

Clean up any spills as soon as possible.

7. HANDLING AND STORAGE

Handling

Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

Fire precautions

Avoid ignition sources.
Keep away from heat/sparks/open flames/hot surfaces.

Storage facilities

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from light. Store in carton until time of use.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

Phenylephrine HCl - Pfizer OEL TWA-8 Hr: 0.04 mg/m³

Occupational exposure controls

Appropriate engineering controls

In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process, which will maintain the dust and vapour levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Respiratory protection

No respiratory protection required during normal handling.

Hand protection

Gloves are not required under normal handling conditions.

Eye protection

Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear
Form: Aqueous solution
Colour: Colorless
Odour: Odourless
pH: 3.0 - 6.5
Specific gravity: 1
n-Octanol/Water Partition Coefficient: not tested
Solubility: Soluble in water

10. STABILITY AND REACTIVITY

Conditions to avoid

Stable under recommended storage conditions. Avoid extreme heat or cold. Do not freeze.

Incompatible Materials: This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

Hazardous decomposition products

Toxic fumes.

11. TOXICOLOGICAL INFORMATION

Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the formulated product.

Acute toxicity - UN GHS • Classification criteria not met
Phenyephrine HCl LD_{50}=350 mg/kg (oral in rat). ATE of the Mixture is 5000. It may be classified as category 5.

Sodium metabisulfite **-** LD_{50} = 1310 mg/kg (Rat)

Primary Irritation (Skin/eyes) – Skin and eye irritation category of substance – 2.
UN GHS Classification of mixture for skin – category 3

Respiratory or Skin sensitization – Substance is categorized as 1B. (Low to moderate frequency of occurrence in animals). Mixture is classified as Category 1. (≥1.0%)

Carcinogenicity - UN GHS • Classification criteria not met

Reproductive toxicity - UN GHS • Classification criteria not met

Specific target organ toxicity single exposure - UN GHS • Classification criteria not met

Specific target repeated exposure - UN GHS • Classification criteria not met.

12. ECOLOGICAL INFORMATION

Ecotoxicity

EC50 - Daphnia magna (Water flea) – 4.59 mg/l - 48 h
GHS Classification for active ingredient is acute 2. The mixture is not classifiable for aquatic toxicity.

Persistence and degradability:
Substance - aerobic - Exposure time 28 d Result: > 90 - < 100 % - Readily biodegradable.
Not classified for chronic toxicity.

Bio accumulative potential:
Based on low Log Kow (0.07), bioaccumulation potential for phenylephrine is low.

Mobility in soil - Not tested
Classification is not possible.

Additional information
Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal
The method typically used is incineration.

Contaminated packaging
Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

Not considered dangerous for transport

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING
Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2003 as amended
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2009

16. OTHER INFORMATION

Recommended restrictions on use
This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes
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