

## **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 Ophthalmic Solution USP, 10%**

#### **1. IDENTIFICATION**

**GHS Product identifier:** Phenylephrine Hydrochloride Ophthalmic Solution USP, 10%

**Product code:** #

**Chemical Description:** (R)-3- hydroxya[(methylamino) methyl]benzenemethanol hydrochloride

**Other means of identification:**

**Recommended use of the chemical:** Ophthalmic phenylephrine in strengths of 2.5% and 10% is used to dilate (enlarge) the pupil. It is used before eye examinations, before and after eye surgery, and to treat certain eye conditions.

**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
<b>Skin irritation</b>	2	-
<b>Eye irritation</b>	2	-
<b>Skin sensitization</b>	1	-
<b>Acute aquatic toxicity</b>	3	-

**Labeling**

**Globally Harmonized System, UN (GHS)**



<b>Classification</b>	
<b>Signal Word</b>	<b>Warning</b>
<b>Hazard Statements:</b>	H315+H320 Causes skin and eye irritation H317 May cause an allergic skin reaction H402 Harmful to aquatic life

<b>Precautionary Statements:</b>	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	10%
Disodium Hydrogen Phosphate Heptahydrate	7782-85-6	0.28%
Sodium Dihydrogen Phosphate Monohydrate	10049-21-5	0.64%
Benzalkonium chloride	8001-54-5	0.01%
Sodium hydroxide	1310-73-2	q.s. to pH
Phosphoric acid	7664-38-2	q.s. to pH

### 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°C – 25°C (68°F - 77°F) [See USP controlled room temperature]. Keep container tightly closed.  
Protect from light and excessive heat.

### **8. EXPOSURE CONTROLS AND PERSONAL PROTECTION**

#### **Exposure limit values**

#### **Components with occupational exposure limits**

Phenylephrine HCl - Pfizer OEL TWA-8 Hr: 0.04 mg/m<sup>3</sup>

#### **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 to yellow coloured solution

**Odour:** Not tested

**pH:** 4.0 - 7.5

**Specific gravity:** Not tested

**n-Octanol/Water Partition Coefficient:** not tested

### **10. STABILITY AND REACTIVITY**

#### **Conditions to avoid**

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

**Incompatible Materials:** Keep away from 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 product.

#### **Acute toxicity - UN GHS** • Classification criteria not met

Phenylophrine HCl LD<sub>50</sub>=350 mg/kg (oral in rat). ATE of the Mixture is 5000. It may be classified as category 5.

#### **Primary Irritation (Skin/eyes) – Skin and eye irritation category of substance – 2.**

UN GHS Classification of mixture - 2

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

**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

EC<sub>50</sub> - Daphnia magna (Water flea) – 4.59 mg/l - 48 h

**GHS Classification for mixture is acute 3.**

### 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 K<sub>ow</sub> (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

-

23-08-2022