

## SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS),  
Tenth Revised Edition UNITED NATIONS  
New York and Geneva, 2023

### Proparacaine Hydrochloride Ophthalmic Solution USP 0.5%

#### 1. IDENTIFICATION

**GHS Product identifier:** Proparacaine Hydrochloride Ophthalmic Solution USP 0.5%

**Product code: #**

**Chemical Description:** 2-(diethylamino) ethyl 3-amino-4-propoxybenzoate;hydrochloride

**Other means of identification:**

**Recommended use of the chemical:** Topical anesthetic used to numb the eye during procedures like tonometry, gonioscopy, and removal of corneal foreign bodies, as well as for short corneal and conjunctival procedures.

**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.: L74899DL1991PLC044843

**Emergency phone number: +91 1704227600**

#### 2. HAZARDS IDENTIFICATION

**Classification**

Globally Harmonized System, UN (GHS)

| Classification     | Category | Exposure Route |
|--------------------|----------|----------------|
| Skin sensitization | 1A       | Dermal         |

**Labeling**

Globally Harmonized System, UN (GHS)



|                                  |  |
|----------------------------------|--|
| <b>Classification</b>            |  |
| <b>Signal Word</b>               | <b>Warning</b>   |
| <b>Hazard Statements:</b>        | H317: May cause allergic skin reaction   |
| <b>Precautionary Statements:</b> | P273: Avoid release to the environment.<br>P264: Wash hands and face thoroughly after handling.<br>P280: Wear protective gloves, face protection.<br>P305+P351+P338+P310: If in eyes: Rinse cautiously with water for several minutes.<br>P391: Collect spillage |

**Other hazards which do not result in classification: none**

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

| Hazardous ingredients      | CAS       | Content (mg/ml)  | Content (%)      |
|----------------------------|-----------|------------------|------------------|
| Proparacaine Hydrochloride | 5875-06-9 | 5                | 0.5              |
| Glycerin                   | 56-81-5   | 24.5             | 2.45             |
| Chlorobutanol Hemihydrate  | 6001-64-5 | 2.1              | 0.21             |
| Benzalkonium chloride      | 8001-54-5 | 0.100            | 0.01             |
| Hydrochloric acid          | 7647-01-0 | q.s to adjust pH | q.s to adjust pH |
| Sodium Hydroxide           | 1310-73-2 | q.s to adjust pH | q.s to adjust pH |
| Water for Injection        | 7732-18-5 | q.s to 1 ml      | q.s to 1 ml      |

### 4. FIRST-AID MEASURES

#### Inhalation

No specific treatment is necessary since this mixture is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

#### Skin contact

Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention.

#### Eye contact

If large amounts enter into the eye, rinse immediately with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do – continue rinsing. Seek medical attention.

#### Ingestion

Rinse mouth and then drink plenty of water.

If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

#### Advice for the doctor

Additional details are available on the product package insert or the Physicians Desk Reference

### 5. FIRE-FIGHTING MEASURES

#### Fire extinguishing agents

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

#### Fire/explosion hazard

Substance slightly flammable to flammable in presence of heat.

#### Specific hazards arising from the mixture

No data available.

#### Personal protection

Self-contained breathing apparatus.

#### Special exposure hazards

None known.

### 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

Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

### Fire precautions

Avoid ignition sources.

Keep away from heat/sparks/open flames/hot surfaces.

### Storage facilities

Keep tightly closed and store in upright position. Store product refrigerated at 28°C (3646°F).

Protect from light.

## 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

### Exposure limit values

#### Components with occupational exposure limits

| CAS No    | Name              | ACGIH           | NIOSH   | OSHA  |
|-----------|-------------------|-----------------|---|---|
| 7647-01-0 | Hydrochloric acid | 2 ppm Ceiling   | 5 ppm Ceiling;<br>7 mg/m <sup>3</sup> Ceiling | 5 ppm Ceiling; 7 mg/m <sup>3</sup> Ceiling  |
| 56-81-5   | Glycerin          | Not established | Not established                               | 15 mg/m <sup>3</sup> TWA (mist, total particulate)<br>5 mg/m <sup>3</sup> TWA (mist, respirable fraction) |

### Occupational exposure controls

#### Appropriate engineering controls

Good general ventilation should be used. Ventilation rates should be matched to conditions.

If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

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:** Colourless  
**Odour:** Odourless  
**Boiling point:** ~ 100 deg C  
**Flash point:** Not applicable  
**pH:** 3.5 - 6.0  
**Vapor Density:** Not applicable  
**Solubility:** Soluble in water  
**Specific Gravity/relative density:** = 1.0063  
**Viscosity:** Not relevant  
**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:** None.

### Hazardous decomposition products

None

## 11. TOXICOLOGICAL INFORMATION

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

### Acute toxicity -

Proparacaine HCL LD<sub>50</sub>=64 mg/kg (subcutaneous in mice)  
=3371 ug/kg (IV mice)

UN GHS • Classification criteria not met

**Primary Irritation (Skin/eyes)** – Substance may cause skin irritation.

Mixture not classified since quantity is < 1 %. UN GHS • Classification criteria not met

**Respiratory or Skin sensitization** - Substance may cause skin sensitization – category 1A

**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

GHS Classification for mixture is not possible due to lack of data.

### Persistence and degradability:

Data not available

### Bio accumulative potential;

Not tested

### Mobility in soil - Not tested

Classification is not possible.

### Additional information

Do not discharge product uncontrolled into the environment.

## 13. DISPOSAL CONSIDERATIONS

### Product disposal

Observe specific local/national regulation.

### 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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