

## Section I: IDENTIFICATION OF SUBSTANCE AND SOCIETY

### 1.1. Identification of the substance

**Product form:** Sterile solution for intravenous injection.

**Product name:** Phenylephrine hydrochloride injection, USP, 10 mg/ml.

**Chemical name:** Phenylephrine hydrochloride/ 3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol hydrochloride (1:1).

**Synonym:** None.

**National Drug Code (NDC):** 1 ml: 81284-211-00; 5 ml: 81284-212-00; 10 ml: 81284-213-00

**Trade name:** Not available.

**Molecular formula:** C<sub>9</sub>H<sub>13</sub>NO<sub>2</sub>.HCl

**CAS No.:** 61-76-7.

**EC No.:** 200-517-3.

**REACH No.:** 01-2120047675-50.

### 1.2. Uses

Pharmaceutical. Treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

### 1.3. Information about the security data sheet provider

| Company                                                                                                                                                                                                                                         | Supplier                                                                                  | Distributor                                                                                                          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| <b>Provepharm SAS</b><br>22 Rue Marc Donadille<br>13013 Marseille, France<br>Phones: 04 91 08 69 30<br>Website: <a href="http://www.provepharm.com">www.provepharm.com</a><br>Email: <a href="mailto:hse@provepharm.com">hse@provepharm.com</a> | <b>Indoco Remedies Limited</b><br>L-32-33-34, Verna Industrial Area,<br>Verna, GOA-403722 | <b>Provepharm Inc.</b><br>100 Springhouse drive, Suite 105,<br>Collegeville, PA 19426, USA<br>Phone: +1 610 601 8600 |

### 1.4. Emergency telephone number:

**CHEMTREC:** 1-800-424-9300 (within USA and Canada), +1 703-527-3887 (outside USA and Canada).

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or the mixture

**Potential Acute Health Effects:** Hazardous in case of skin contact (irritant), of inhalation. May cause an allergic skin reaction.

**Potential Chronic Health Effects:** Not available.

**Carcinogenic Effects:** Not available.

**Mutagenic Effects:** Not available.

**Teratogenic Effects:** Not available.

**Developmental Toxicity:** Not available.

**Adverse effects:** Not available.

### 2.2. Label elements

**Warning mention:** Danger

**Hazard statements:**

H317 - May cause an allergic skin reaction.

**Precautionary statements:**

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 - IF ON SKIN: Wash with plenty of water.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.





## Phenylephrine hydrochloride injection, USP

### Safety Data Sheet

Creation date: 2021/05/03

Revision date: 2023/03/28

Version: 3.0

Page 2 on 6

### 2.3. Other hazards

Not available.

### 2.4. Unknown acute toxicity

Not applicable.

## Section 3: COMPOSITION/INFORMATIONS ON THE SUBSTANCE

### 3.1. Substances

| Name                                                                                                 | Product identifier                                                                                                                                                               | %   | Classification                                                           |
|------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|--------------------------------------------------------------------------|
| Phenylephrine hydrochloride/<br>3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol<br>hydrochloride (1:1) | CAS-No.: 61-76-7<br>EC-No.: 200-517-3<br>REACH No.: 01-2120047675-50<br>Molecular formula: C <sub>9</sub> H <sub>13</sub> NO <sub>2</sub> .HCl<br>Molecular weight: 167.21 g/mol | < 1 | Acute Tox. 4<br>Skin Sens. 1B<br>Aquatic Acute 2<br>H302<br>H317<br>H401 |

Full text of hazard classes and H-statements: see section 16.

### 3.2. Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

**General:** Remove contaminated soaked clothing immediately and dispose of safely. Take away from danger area and lay down affected person. If you feel unwell, seek medical advice.

**After inhalation:** In case of inhalation of mist seek medical advice. Information on label instructions. Remove the casualty into fresh air and keep him immobile. Medical treatment.

**After skin contact:** Wash off immediately with soap and plenty of water. Consult a doctor if skin irritation persists.

**After eye contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical treatment by eye specialist.

**After ingestion:** If swallowed, seek medical advice immediately and show this container or label. Rinse out mouth and give plenty of water to drink. Do not induce vomiting. Never give anything by mouth to an unconscious person.

**Notes to physician:** See product package insert for complete information. Treat symptoms.

### 4.2. Most important symptoms and effects, both acute and delayed

Not available.

### 4.3. Indication of any immediate medical attention and special treatment needed

Not available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1. Extinguishing media

**Suitable extinguishing media:** Fire-extinguishing activities according to surrounding. Alcohol-resistant foam, dry chemical, carbon dioxide (CO<sub>2</sub>), water-spray.

**Unsuitable extinguishing media:** Do not use full water jet.

### 5.2. Special hazards arising from the substance or mixture

**Fire or explosion hazard:** None.

**Combustion Products:** Decomposition products may include carbon oxides (CO, CO<sub>2</sub>), nitrogen oxides (NO, NO<sub>2</sub>), halogenated compounds.



## Phenylephrine hydrochloride injection, USP

### Safety Data Sheet

Creation date: 2021/05/03

Revision date: 2023/03/28

Version: 3.0

Page 3 on 6

### 5.3. Advice for firefighters

**Protective equipment & precautions for firefighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Wear appropriate protecting clothing and equipment as described in section 8. Ventilate the area. Eliminate all ignition sources.

### 6.2. Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### 6.3. Methods and material for containment and cleaning up

**Spill:** Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth.

For proper waste disposal, see section 13 of the SDS.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

Avoid formation of aerosols. Allow for sucking off. Handle and open container with care. Use personal protective clothing. No specific precautions required for protection against fire and explosion. Take the usual precautions when handling with chemicals. At work do not eat, drink and smoke.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage:** Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F). Keep only in original container. Keep container tightly closed in a dry, cool and well-ventilated place. Do not store together with oxidizing agents. Do not store with acids or alkalies. Keep away from food, drink and animal feeding stuffs.

**Incompatibilities:** Protect against direct sun radiation. Keep away from heat.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

**Exposure limit:** Not available.

### 8.2. Exposure controls

**Appropriate engineering controls:** Ensure adequate ventilation, especially in confined areas. Avoid formation of Aerosols. Provide emergency shower. Provide eye bath.

**Hand protection:** Use chemical-resistant gloves (EN 374, latex gloves.).

**Eye protection:** Use tightly fitting goggles (EN 166).

**Skin and body protection:** Wear suitable working clothes.

**Respiratory protection:** No special protection is necessary when the product is handled inside a safety cabinet or an isolator. Not required, except in case of aerosol formation. Short term: filter apparatus, filter P3.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

|                 |           |
|-----------------|-----------|
| Physical state: | Liquid    |
| Appearance:     | Clear     |
| Color:          | Colorless |



## Phenylephrine hydrochloride injection, USP

### Safety Data Sheet

Creation date: 2021/05/03

Revision date: 2023/03/28

Version: 3.0

Page 4 on 6

|                                                         |                   |
|---------------------------------------------------------|-------------------|
| <b>Odor:</b>                                            | Mild              |
| <b>Odor threshold:</b>                                  | No data available |
| <b>pH:</b>                                              | No data available |
| <b>Melting point:</b>                                   | No data available |
| <b>Freezing point:</b>                                  | No data available |
| <b>Boiling point:</b>                                   | No data available |
| <b>Flash point:</b>                                     | No data available |
| <b>Relative evaporation rate (butyl acetate=1):</b>     | No data available |
| <b>Flammability (solid, gas):</b>                       | No data available |
| <b>Vapor pressure:</b>                                  | No data available |
| <b>Relative vapor density at 20 °C:</b>                 | No data available |
| <b>Relative density:</b>                                | No data available |
| <b>Solubility:</b>                                      | Soluble at 20°C   |
| <b>Partition coefficient n-octanol/water (Log Pow):</b> | No data available |
| <b>Auto-ignition temperature:</b>                       | No data available |
| <b>Decomposition temperature:</b>                       | No data available |
| <b>Viscosity, kinematic:</b>                            | No data available |
| <b>Viscosity, dynamic:</b>                              | No data available |
| <b>Explosion limits:</b>                                | No data available |
| <b>Explosive properties:</b>                            | No data available |
| <b>Oxidizing properties:</b>                            | No data available |

#### 9.2. Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

#### 10.1. Reactivity

No decomposition if stored and applied as directed.

#### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

#### 10.3. Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

#### 10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

#### 10.5. Incompatible materials

None.

#### 10.6. Hazardous decomposition products

No decomposition if stored and applied as directed.

## SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1. Information on toxicological effects

##### Acute toxicity:

LD50 oral rat: 350 mg/kg

**Routes of exposure:** Dermal contact, eye contact, ingestion.

**Carcinogenic/mutagenic/toxic effects for reproduction:** May damage fertility or the unborn child.



## Phenylephrine hydrochloride injection, USP

### Safety Data Sheet

Creation date: 2021/05/03

Revision date: 2023/03/28

Version: 3.0

Page 5 on 6

**Specific target organ toxicity – single exposure:** Not available.

**Specific target organ toxicity – repeated exposure:** Not available.

**Aspiration hazard:** Not available.

**Symptoms short term:** Not available.

**Symptoms long term:** Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

Not available.

### 12.2. Persistence and degradability

Not available.

### 12.3. Bioaccumulative potential

Not available.

### 12.4. Mobility in soil

Not available.

### 12.5. Other adverse effects

Do not discharge into the drains/surface waters/ground water.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

**Waste classification:** Not available.

**Advice on disposal:** Dispose of waste in accordance with all applicable federal, state and local laws.

**Waste disposal number of waste from residues/unused products:** 180108 - WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care); wastes from natal care, diagnosis, treatment or prevention of disease in humans; cytotoxic and cytostatic medicines. Classified as hazardous waste.

**Contaminated packaging:** Empty containers should be taken for local recycling, recovery or waste disposal. Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of like the product.

## SECTION 14: TRANSPORT INFORMATION

The listed CAS ingredient(s) in this final formula for finished goods are not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### Department of Transportation (DOT) Classification:

**UN Number:** Not regulated.

**UN Shipping name:** Not available.

**Transport hazard class:** Not available.

**Packing Group:** Not available.

**Environmental hazard:** None.

**Transport in bulk:** Not available.

**Special precautions needed with transport:** Always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**SECTION 15: REGULATORY INFORMATION****15.1. EU regulatory information**

According to EC-rules and correspondent national legislation, this product, being a ready medicine, is not subject to mandatory identification.

**15.2. National regulatory information**

Employment restrictions: Observe employment restrictions for young people. Observe employment restrictions for childbearing mothers and nursing.

**15.3. Chemical safety assessment**

Chemical safety assessments for substances in this mixture were not carried out.

**SECTION 16: OTHER INFORMATION****Abbreviations and acronyms**

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

AON = Accord Européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

IMDG = International Maritime Code for Dangerous Goods

IATNCAO = International Air Transport Association/ International Civil Aviation Organization

MARPOL = International Convention for the Prevention of Pollution from Ships

IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

REACH= Registration, Evaluation, Authorization and Restriction of Chemicals CAS = Chemical Abstract Service

EN = European norm

ISO = International Organization for Standardization DIN= Deutsche Industrie Norm

PST= Persistent Bioaccumulative and Toxic

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

**Relevant R-phrases (Number and full text)**

22 - Harmful if swallowed.

43 - May cause sensitisation by skin contact.

**Relevant H- and EUH-phrases (Number and full text)**

H302 - Harmful if swallowed.

H317 - May cause an allergic skin reaction.

H401 - Toxic to aquatic life.