


**SECTION 1: PRODUCT IDENTIFICATION**

|                            |  |
|----------------------------|--|
| <b>PRODUCT NAME</b>        | <b>PHENYLEPHRINE HYDROCHLORIDE, USP</b>  |
| <b>PRODUCT CODE</b>        | <b>0247</b>  |
| <b>SUPPLIER</b>            | <b>MEDISCA Inc.</b><br>Tel.: 1.800.932.1039   Fax.: 1.855.850.5855<br>626 Tom Miller Road, Plattsburgh, NY, 12901<br><b>MEDISCA Pharmaceutique Inc.</b><br>Tel.: 1.800.665.6334   Fax.: 514.338.1693<br>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8<br><b>MEDISCA Australia PTY LTD</b><br>Tel.: 1.300.786.392   Fax.: 61.2.9700.9047<br>Unit 7, Heritage Business Park<br>5-9 Ricketty Street, Mascot, NSW 2020 |
| <b>EMERGENCY PHONE</b>     | CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300<br>NSW Poisons Information Centre: 131 126<br>National Chemical Emergency Centre 44(0)1235239670   |
| <b>RECOMMENDED USES</b>    | Pharmaceutical Manufacturing   |
| <b>RESTRICTIONS ON USE</b> | Not applicable   |

**SECTION 2: HAZARDS IDENTIFICATION**

|  |  |
|--|--|
| <b>GHS CLASSIFICATION</b>  | Acute Toxicity - Oral (Category 4)<br>Specific Target Organ Toxicity - Single Exposure (Category 2) - Cardiovascular system  |
| <b>PICTOGRAM</b>   |   |
| <b>SIGNAL WORD</b>   | Warning  |
| <b>HAZARD STATEMENT(S)</b>   | Harmful if swallowed.<br>Harmful if absorbed through skin.<br>May cause damage to organs (cardiovascular system).<br>May cause an allergic reaction.   |
| <b>ADVERSE PHYSIOCHEMICAL,<br/>HUMAN HEALTH AND<br/>ENVIRONMENTAL EFFECTS<br/>PRECAUTIONARY STATEMENT(S)</b> | <b>Prevention</b><br>Not Applicable.<br><br>Wash hands thoroughly after handling.<br>Do not eat, drink or smoke when using this product.<br>Do not breathe dust/fume/gas/mist/ vapors/spray.<br>Obtain, read and follow all special instructions before use.<br>Do not handle until all safety precautions have been read and understood.<br>Wear protective gloves, protective clothing, eye protection, face protection. |

|                     |                      |   |                            |   |
|---------------------|----------------------|---|----------------------------|---|
| HMIS CLASSIFICATION | <b>Response</b>      | IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth.<br>IF EXPOSED: Get emergency medical help immediately. Call a poison center or doctor. |                            |   |
|                     | <b>Storage</b>       | Store locked up.  |                            |   |
|                     | <b>Disposal</b>      | Dispose of contents and/or container in accordance with local regulations.  |                            |   |
|                     | <b>Health Hazard</b> | 2   | <b>Flammability</b>        | 0 |
|                     | <b>Reactivity</b>    | 0   | <b>Personal Protection</b> | F |

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

|                             |   |
|-----------------------------|---|
| <b>CHEMICAL NAME</b>        | Benzenemethanol, 3-hydroxy-alpha-[(methylamino)methyl]-, hydrochloride (R)- |
| <b>BOTANICAL NAME</b>       | Not applicable  |
| <b>SYNONYM</b>              | m-Synephrine hydrochloride  |
| <b>CHEMICAL FORMULA</b>     | C <sub>9</sub> H <sub>13</sub> NO <sub>2</sub> · HCl                        |
| <b>CHEMICAL FAMILY</b>      | Phenethylamine derivative; Adrenergic.                                      |
| <b>CAS NUMBER</b>           | 61-76-7   |
| <b>ALTERNATE CAS NUMBER</b> | Not applicable  |
| <b>MOLECULAR WEIGHT</b>     | 203.6676  |

| CHEMICAL NAME     | CAS NUMBER | EC NUMBER | % BY WEIGHT |
|-------------------|------------|-----------|-------------|
| PHENYLEPHRINE HCl | 61-76-7    | 200-517-3 | 100         |

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

**NOTES** Phenylephrine hydrochloride is a sympathomimetic with mainly direct effects on adrenergic receptors. It is a alpha adrenergic receptor agonist that has mainly alpha-adrenergic activity.

### SECTION 4: FIRST-AID MEASURES

|  |   |
|--|---|
| <b>IN CASE OF EYE CONTACT</b>                  | Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid. |
| <b>IN CASE OF SKIN CONTACT</b>                 | Wash with soap & water for 15 minutes. If irritation persists seek medical aid.   |
| <b>IF SWALLOWED</b>                            | Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.                                   |
| <b>IF INHALED</b>                              | Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician  |
| <b>MEDICAL ATTENTION AND SPECIAL TREATMENT</b> | Get emergency medical help.   |
| <b>SYMPTOMS CAUSED BY EXPOSURE</b>             | Not expected to present a significant hazard under anticipated conditions of normal use.                                      |

### SECTION 5: FIREFIGHTING MEASURES

|   |                |
|---|----------------|
| <b>SPECIFIC HAZARDS ARISING FROM THE CHEMICAL</b> | Not applicable |
|---|----------------|

**FLAMMABLE PROPERTIES**

May be combustible at high temperature

**HAZARDOUS COMBUSTION PRODUCTS**

Under fire conditions, hazardous fumes will be present.

**SUITABLE & UNSUITABLE EXTINGUISHING MEDIA**

**Small fire:** dry chemical, CO<sub>2</sub> or water spray. **Large fire:** dry chemical, CO<sub>2</sub>, alcohol resistant foam or water spray. Do not get water inside containers.

**PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS**

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**
**PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

**METHODS & MATERIAL FOR CONTAINMENT**

On land, sweep or shovel into suitable containers. Minimize generation of dust.

**CLEANUP PROCEDURE**

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**REFERENCE TO OTHER SECTIONS**

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

**SECTION 7: HANDLING AND STORAGE**
**PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**CONDITIONS FOR SAFE STORAGE**

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Store at 25°C. Short term excursions, temperature excursions as experienced during shipping and warehousing, are permitted between 15° and 30°C.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**

Chemical Name: PHENYLEPHRINE HCl CAS #: 61-76-7

|      | Country | Limit value-8 hours |                   | Limit value-Short Term |                   | IDLH | REL | Advisory | Notes |
|------|---------|---------------------|-------------------|------------------------|-------------------|------|-----|----------|-------|
|      |         | ppm                 | mg/m <sup>3</sup> | ppm                    | mg/m <sup>3</sup> |      |     |          |       |
| OSHA | USA     | N/L                 | N/L               | N/L                    | N/L               | N/L  | N/L | N/A      | N/A   |

|               |             |     |     |     |     |     |     |     |     |
|---------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|
| <b>ACGIH</b>  | USA         | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| <b>NIOSH</b>  | USA         | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| <b>WEEL</b>   | USA         | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| <b>HSIS</b>   | Australia   | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| <b>HSE</b>    | UK          | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| <b>GESTIS</b> | Add Country | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

#### EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>.

#### PERSONAL PROTECTIVE EQUIPMENT

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

#### SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

#### BIOLOGICAL MONITORING

Not available

#### CONTROL BANDING

Not available

#### NOTES

USP: ELV: Industrial: TWA: 5 micrograms/m<sup>3</sup>

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### PHYSICAL STATE

Solid

#### DESCRIPTION

White or practically white, odorless crystals.

#### SOLUBILITY

Freely soluble in water and in alcohol.

#### ODOR

Odorless

#### FLAMMABILITY

May be combustible at high temperature

#### AUTO-IGNITION TEMPERATURE

480 °C, 896 °F

#### BOILING POINT

Not available

#### DECOMPOSITION TEMPERATURE

Not available

#### EVAPORATION RATE

< 1

#### EXPLOSIVE LIMIT

Not available

#### FLASH POINT

Not available

#### log P (OCTANOL-WATER)

-0.31

#### LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

#### MELTING/FREEZING POINT

(140 - 145)°C,  
(284 - 293)°F

#### PARTICLE CHARACTERISTICS

Not available

#### OXIDIZING PROPERTY

Not available

#### pH

Neutral

|   |               |                         |                           |  |               |
|---|---------------|-------------------------|---------------------------|--|---------------|
| <b>RELATIVE DENSITY<br/>(WATER = 1)</b> | Not available | <b>SPECIFIC GRAVITY</b> | Not available             | <b>UPPER FLAMMABLE/<br/>EXPLOSIVE LIMIT(S)</b> | Not available |
| <b>VAPOR DENSITY<br/>(AIR = 1)</b>      | Not available | <b>VAPOR PRESSURE</b>   | < 0.000001<br>kPa (25 °C) | <b>VISCOSITY</b>                               | Not available |

The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

|  |   |
|--|---|
| <b>REACTIVITY</b>                            | Not established   |
| <b>CHEMICAL STABILITY</b>                    | Stable under recommended storage conditions   |
| <b>INCOMPATIBLE MATERIALS</b>                | Strong oxidants, acids, acid chlorides, acid anhydrides, hydrogen chloride gas, and nitrogen oxides.                              |
| <b>HAZARDOUS DECOMPOSITION<br/>PRODUCTS</b>  | Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrochloric acid and other irritating and toxic gases may occur |
| <b>HAZARDOUS POLYMERIZATION</b>              | Will not occur  |
| <b>POSSIBILITY OF HAZARDOUS<br/>REACTION</b> | Not established   |
| <b>CONDITIONS TO AVOID</b>                   | Moisture, sunlight and extreme temperatures. Light sensitive.   |

## SECTION 11: TOXICOLOGICAL INFORMATION

|  |  |
|--|--|
| <b>ACUTE TOXICITY</b>                        | Oral: Rat: LD50: (mg/kg): 350<br>Dermal: Rabbit: LD50: (mg/kg): Not available<br>Inhalation: Rat: LC50: (mg/L/4hr): Not available  |
| <b>SKIN CORROSION/IRRITATION</b>             | Based on available data, the classification criteria are not met.<br>Irritancy test: Rabbit: Skin: Non-irritant.   |
| <b>SERIOUS EYE DAMAGE/EYE<br/>IRRITATION</b> | Due to lack of data the classification is not possible.  |
| <b>RESPIRATORY SENSITIZATION</b>             | Due to lack of data the classification is not possible.<br>Cross-sensitivity to phenylephrine has been reported in a patient hypersensitive to pseudoephedrine.  |
| <b>SKIN SENSITIZATION</b>                    | May cause an allergic skin reaction.   |
| <b>GERM CELL MUTAGENICITY</b>                | Due to lack of data the classification is not possible.<br>Mutagenicity:<br>Chromosomal aberration assay in Chinese hamster ovary cells: Negative.<br>Mouse lymphoma test (without activation): Positive.<br>S. typhimurium assay (with and without activation): Negative.<br>Sister chromatid exchange assay in Chinese hamster ovary cells: Positive.    |
| <b>CARCINOGENICITY</b>                       | <b>OSHA</b> PHENYLEPHRINE HYDROCHLORIDE is not listed.<br><b>NTP</b> PHENYLEPHRINE HYDROCHLORIDE is not listed.<br><b>IARC</b> PHENYLEPHRINE HYDROCHLORIDE is not evaluated.<br><b>California Proposition</b> This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm. |

**ADDITIONAL CARCINOGENICITY  
INFORMATION**

Due to lack of data the classification is not possible.

**REPRODUCTIVE TOXICITY**

Due to lack of data the classification is not possible.  
This material may cause vasoconstriction of uterine blood vessels and the reduction of uterine blood flow, resulting in fetal hypoxia. Some case-controlled studies in humans suggest a small increase in unusual birth defects.

**SPECIFIC TARGET ORGAN  
TOXICITY - SINGLE EXPOSURE**

May cause damage to organs (cardiovascular system).

**SPECIFIC TARGET ORGAN  
TOXICITY - REPEATED  
EXPOSURE**

Due to lack of data the classification is not possible.

**ASPIRATION HAZARDS**

Based on available data, the classification criteria are not met.

**SIGNS AND SYMPTOMS OF  
EXPOSURE**
**ROUTES OF EXPOSURE:**

Oral, Dermal, Inhalation, Eye contact

**EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:**

Not available

**DELAYED HEALTH EFFECT FROM EXPOSURE:**

Change in heart rhythm. Change in blood pressure

**Symptoms related to the physical, chemical, and toxicological characteristics:**

Headache. Nausea. Anxiety. Seizures. Hallucinations. Sweating. Palpitations. Eye pain. Skin rash. Itching. Stomach pain. Frequent, painful, or difficult urination. Fever. Fainting. Bleeding or bruising. Tremor. Chest pain. Difficulty breathing. Restlessness. Numbness, pain, tingling, or weakness in hands or feet. Vomiting.

**Medical conditions aggravated by exposure:**

Heart problems. High blood pressure. Asthma. Diabetes. Thyroid problems. Pheochromocytoma. Recent or concurrent use of monoamine oxidase (MAO) inhibitors.

**POTENTIAL HEALTH EFFECTS**
**Inhalation**

May be harmful if inhaled. May cause respiratory tract irritation. Possible allergic reaction.

**Ingestion**

Harmful if swallowed. Possible allergic reaction.

**Skin**

Harmful if absorbed through skin. May cause skin irritation. Possible allergic reaction.

**Eyes**

May cause eye irritation.

**SECTION 12: ECOLOGICAL INFORMATION**
**ECOTOXICITY**

EC50: 48 Hr: Crustacea: (mg/L): Not available

LC50: 96 Hr: Fish: (mg/L): Not available

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND  
DEGRADABILITY**

Log Pow: -0.31

**BIOACCUMULATIVE POTENTIAL**

Not available

**MOBILITY IN SOIL**

Henry's Law Constant: 6.78E-15 atm-m<sup>3</sup>/mole (25°C).

Water Solubility: 1.00E+06 mg/L (25°C).

**OTHER ADVERSE EFFECTS**

Not available

This product is not intended to be released into the environment

**SECTION 13: DISPOSAL CONSIDERATIONS**

**DISPOSAL METHODS**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

**SECTION 14: TRANSPORT INFORMATION**
**UN PROPER SHIPPING NAME** Not dangerous good

**UN NUMBER** Not applicable

**CLASS** Not applicable

**PACKING GROUP** Not applicable

**AUSTRALIA**
**HAZCHEM** Not applicable

**EU**
**TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE** Not Listed

**ENVIRONMENTAL HAZARDS** Not available

**SPECIAL SHIPPING INFORMATION** Not applicable

**SECTION 15: REGULATORY INFORMATION**
**UNITED STATES REGULATIONS**

| Chemical Name & CAS                 | CERCLA 40 CFR Part 302.4 | SARA (Title III) 40 CFR | EPA 40 CFR Part 355 Appendix A | EPA 40 CFR Part 355 Appendix B | Pennsylvania | Right-to-know New Jersey | Massachusetts | California Prop 65 |
|-------------------------------------|--------------------------|-------------------------|--------------------------------|--------------------------------|--------------|--------------------------|---------------|--------------------|
| PHENYLEPHRINE HYDROCHLORIDE 61-76-7 | N/L                      | N/L                     | N/L                            | N/L                            | N/L          | N/L                      | N/L           | N/L                |

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

| Chemical Name & CAS                 | Poisons and Therapeutic Goods | Therapeutic Goods Act | Code of Practices - Illicit Drug | Poisons Standard | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|-------------------------------------|-------------------------------|-----------------------|----------------------------------|------------------|------------------------------------|-----------------------------------|
| PHENYLEPHRINE HYDROCHLORIDE 61-76-7 | N/L                           | Listed as Schedule 2* | N/L                              | Listed*          | N/L                                | N/L                               |

N/L = Not Listed

**EU REGULATIONS**

| Chemical Name & CAS                 | REACH ANNEX XVII | REACH ANNEX XIV | EC 1005/2009 | EC 850/2004 | EC 1107/2009 | PIC - Prior Informed Consent Regulation | EC 2012/18 |
|-------------------------------------|------------------|-----------------|--------------|-------------|--------------|---|------------|
| PHENYLEPHRINE HYDROCHLORIDE 61-76-7 | N/L              | N/L             | N/L          | N/L         | N/L          | N/L                                     | N/L        |

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

NOTES \*Listed as the base

## SECTION 16: OTHER INFORMATION

### REFERENCES

Available upon request

### ABBREVIATIONS AND ACRONYMS

**ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

### LAST REVISION

07/2023

### SUPERSEDES

05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at [www.medisca.com](http://www.medisca.com)

### DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

### SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.