


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	PHENYLEPHRINE HYDROCHLORIDE, USP
PRODUCT CODE	0247
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126
USES	Mydriatic; Decongestant.

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 4) Specific Target Organ Toxicity - Single Exposure (Category 2) - Cardiovascular system																		
PICTOGRAM																			
SIGNAL WORD	Warning																		
HAZARD STATEMENT(S)	Harmful if swallowed. Harmful if absorbed through skin. May cause damage to organs (cardiovascular system). May cause an allergic reaction.																		
AUSTRALIA-ONLY HAZARDS	Not Applicable.																		
PRECAUTIONARY STATEMENT(S)	<table><tr><td>Prevention</td><td colspan="3">Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Do not breathe dust/fume/gas/mist/ vapors/spray. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye protection, face protection.</td></tr><tr><td>Response</td><td colspan="3">IF SWALLOWED: Immediately call a poison center or medical professional. Rinse mouth. IF EXPOSED OR CONCERNED: Get medical advice/attention.</td></tr><tr><td>Storage</td><td colspan="3">Store locked up.</td></tr><tr><td>Disposal</td><td colspan="3">Dispose of contents and/or container in accordance with local regulations.</td></tr></table>			Prevention	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Do not breathe dust/fume/gas/mist/ vapors/spray. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye protection, face protection.			Response	IF SWALLOWED: Immediately call a poison center or medical professional. Rinse mouth. IF EXPOSED OR CONCERNED: Get medical advice/attention.			Storage	Store locked up.			Disposal	Dispose of contents and/or container in accordance with local regulations.		
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Health Hazard	2																		
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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Benzenemethanol, 3-hydroxy-alpha-[(methylamino)methyl]-, hydrochloride (R)-						
BOTANICAL NAME	Not applicable						
SYNONYM	m-Synephrine hydrochloride						
CHEMICAL FORMULA	C ₉ H ₁₃ NO ₂ · HCl						
CAS NUMBER	61-76-7						
ALTERNATE CAS NUMBER	Not applicable						
MOLECULAR WEIGHT	203.6676						
COMPOSITION	<table><tr><th>CHEMICAL NAME</th><th>CAS NUMBER</th><th>% BY WEIGHT</th></tr><tr><td>PHENYLEPHRINE HCl</td><td>61-76-7</td><td>100</td></tr></table>	CHEMICAL NAME	CAS NUMBER	% BY WEIGHT	PHENYLEPHRINE HCl	61-76-7	100
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PHENYLEPHRINE HCl	61-76-7	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	Chemical family: Phenethylamine derivative; Adrenergic. 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.
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SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
SYMPTOMS AND EFFECTS	Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable
FLAMMABLE PROPERTIES	May be combustible at high temperature
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , 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.
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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.

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.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

Preserve in tight, light-resistant containers. Store at 25°C, excursions permitted between 15° and 30°C.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: PHENYLEPHRINE HYDROCHLORIDE **CAS #:** 61-76-7

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

N/L = Not Listed

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³.

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.

SPECIFIC ENGINEERING CONTROLS

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

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					
ODOR THRESHOLD	Not available	pH	Neutral	MELTING POINT	(140 - 145)°C, (284 - 293)°F
BOILING POINT	Not available	FREEZING POINT	(140 - 145)°C, (284 - 293)°F	FLASH POINT	Not available
SPECIFIC GRAVITY	Not available	EVAPORATION RATE	< 1	EXPLOSIVE LIMIT	Not available
UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	VAPOR PRESSURE	2.22E-05 mmHg (25°C)
VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	Not available	log P (OCTANOL-WATER)	-0.31
AUTO-IGNITION TEMPERATURE	480 °C, 896 °F	DECOMPOSITION TEMPERATURE	Not available	VISCOSITY	Not available

SECTION 10: STABILITY AND REACTIVITY

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

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 350 Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LD50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Irritancy test: Rabbit: Skin: Non-irritant. Based on available data, the classification criteria are not met.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY OR SKIN SENSITIZATION	Respiratory sensitization: Due to lack of data the classification is not possible. Skin sensitization: Due to lack of data the classification is not possible. Cross-sensitivity to phenylephrine has been reported in a patient hypersensitive to pseudoephedrine. May cause an allergic reaction.

GERM CELL MUTAGENICITY

Mutagenicity:
 Chromosomal aberration assay in Chinese hamster ovary cells: Negative.
 Mouse lymphoma test (without activation): Positive.
 S. typhimurium assay (with and without activation): Negative.
 Sister chromatid exchange assay in Chinese hamster ovary cells: Positive.
 Due to lack of data the classification is not possible.

CARCINOGENICITY

OSHA	PHENYLEPHRINE HYDROCHLORIDE is not listed.
NTP	PHENYLEPHRINE HYDROCHLORIDE is not listed.
IARC	PHENYLEPHRINE HYDROCHLORIDE is not evaluated.
California Proposition 65	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	Not available

REPRODUCTIVE TOXICITY

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.
 Due to lack of data the classification is not possible.

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

Not expected to present a significant hazard under anticipated conditions of normal use.

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.

Delayed and immediate effects of exposure:
 Change in heart rhythm. Change in blood pressure.

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

TOXICITY

EC50: 48 Hr: Daphnia magna: (mg/L): Not available
 LC50: 96 Hr: Fish: (mg/L): Not available
 IC50: 72 Hr: Algae: (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-m³/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

WASTE DISPOSAL

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

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA

UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

AUSTRALIA

UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

HAZCHEM

Not applicable

ENVIRONMENTAL HAZARDS

Not available

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355 Appendix A	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 Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
PHENYLEPHRINE HYDROCHLORIDE 61-76-7	Not Listed	Listed as Schedule 2*	Not Listed

NOTES

*PHENYLEPHRINE is listed.

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** – Mine Safety and Health Administration; **ACGIH** – American Conference of Governmental Industrial Hygienists; **IDHL** – Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** – Recommended Exposure Limit

LAST REVISION

03/2016

SUPERSEDES

06/2013

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.