



MATERIAL SAFETY DATA SHEET

Chemical Name: Phenylephrine Hydrochloride Injection

1. Identification:

Product identifier: Phenylephrine Hydrochloride Injection USP

Generic Developed by: Aragen Life Sciences Limited

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2. Hazard(s) identification

Signal Word: Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements : P 101 If medical advice is needed, have product container or label at hand.
P 102 Keep out of reach of children.
P 103 Read label before use.
P 261 Avoid breathing dust/fume/gas/mist/vapors/spray.
P 280 Wear protective gloves.
P 272 Contaminated work clothing should not be allowed out of the workplace.
P 333+P 313 If skin irritation or rash occurs: Get medical advice/attention.
P 302+P 352 if on skin: Wash with plenty of water.
P 501 Dispose of contents/container in accordance with local/regional/national /international regulations

3. Composition/information on ingredients:

Chemical name	CAS number	Composition %
Phenylephrine hydrochloride	61-76-7	1.0%
Sodium Chloride	7647-14-5	0.35%
Sodium Metabisulphite	7681-57-4	0.2%
Citric Acid Monohydrate	5949-29-1	0.1%
Sodium Citrate Dihydrate	6132-04-3	0.4%
Water for Injection	7732-18-5	q.s.*

*Used for volume make-up.

4. First aid measures:

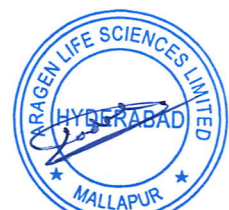
Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

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Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

5. Fire-fighting measures

Suitable extinguishing media: Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material.

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Fire hazard: None known.

Protection during firefighting: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Hazardous Combustion Byproducts: Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

6. Accidental release measures

Personal Precautions: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area.

Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

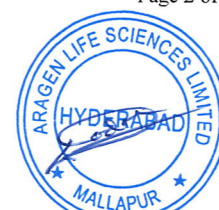
Methods for containment: Contain spills with an inert absorbent material such as soil, sand or oil dry.

Methods for cleanup: Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

7. Handling and storage

Precautions for safe handling: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

(See Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process





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emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage conditions: Store at 20°C to 25°C (68° to 77°F), Protect from light.

8. Exposure controls/personal protection

Engineering Controls: Local exhaust and general ventilation must be adequate to meet exposure standards.

Eye/Face Protection: Wear safety glasses or goggles if eye contact is possible.

Skin and body protection: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Hand protection: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations Nitrile, rubber or natural rubber gloves are recommended.

Respiratory Protection: Wear NIOSH approved respirator if workplace exposure standards are exceeded.

9. Physical and chemical properties

Physical State:	Liquid solution.
Color:	Colorless
Boiling Point:	100°C.
Melting Point:	Not established.
Solubility:	Soluble in cold and hot water
Vapor Density:	Not established.
Vapor Pressure:	23hPa
Percent Volatile:	Not established.
pH:	3.0 to 6.5
Molecular Formula:	Mixture
Molecular Weight:	Not established.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

10. Stability and Reactivity

Chemical Stability: Stable under normal temperatures and pressures.

Conditions to Avoid: No conditions contributing to instability are known to exist for normal handling of this product.

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Hazardous Decomposition Products: Not Determined.

11. Toxicological information

Reproductive Toxicity: Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Phenylephrine hydrochloride:

Ingestion: Oral - Rat LD50 - Lethal dose, 50 percent kill: 350 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Sodium Chloride:

Eye: Administration into the eye - Rabbit Standard Draize test: 100 mg/24H [Moderate] Administration into the eye - Rabbit Standard Draize test: 10 mg [Moderate] (RTECS)

Ingestion: Oral - Rat LD50 - Lethal dose, 50 percent kill: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Citric Acid Monohydrate:

Eye: Administration into the eye - Rabbit Rinsed with water: 5 mg/30S [Mild] (RTECS)

12. Ecological information

Ecotoxicity : No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

13. Disposal consideration

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

14. Transport information

US DOT : Not Regulated.

EUADR : Not Regulated.

IATA : Not Regulated.

IMDG : Not Regulated.

15. Regulatory information

Phenylephrine hydrochloride:

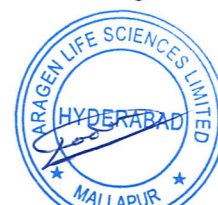
TSCA Inventory Status: Listed

Canada DSL: Listed

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EC Number: 200-517-3

Sodium Chloride :

TSCA Inventory Status: Listed

Canada DSL: Listed

EC Number: 231-598-3

Citric Acid Monohydrate :

Canada DSL: Listed

Sodium Citrate Dihydrate :



EC Number: 200-675-3

Water for Injection :

EC Number: 231-791-2

16. Other Information:

Aragen Life Sciences provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product individual receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. Aragen Life Sciences will not be responsible for damages resulting from use or reliance upon information.

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