



MATERIAL SAFETY DATA SHEET

**Product Name: Phenylephrine Hydrochloride Injection, USP
(Neo-Synephrine® Hydrochloride)**

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

**Manufacturer Name
And Address** Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA

**Emergency Telephone
Hospira, Inc.** CHEMTREC: 800 424-9300
224 212-2055

Product Name Phenylephrine Hydrochloride Injection, USP
(Neo-Synephrine® Hydrochloride)

Synonyms Neo-Synephrine® Hydrochloride

2. COMPOSITION/INFORMATION ON INGREDIENTS

**Ingredient Name
Chemical Formula** Phenylephrine Hydrochloride
 $C_9H_{14}ClNO_2$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Phenylephrine Hydrochloride	1	61-76-7	DO7525000
Water	99	7732-18-5	ZC0110000

3. HAZARD INFORMATION

Emergency Overview In clinical use, this material constricts blood vessels and increases blood pressure. Possible target organs include the cardiovascular system and the eyes.

**Occupational Exposure
Potential** Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms No signs or symptoms from occupational exposure are known. Clinical data suggest the following: headaches, slow heart rate, psychiatric changes. Overdose may cause variable cardiovascular system effects. Direct contact with eyes may cause dilated pupils.

**Medical Conditions
Aggravated by Exposure** Hypersensitivity to the material and/or similar materials. Pre-existing ailments in the following organs: eyes, central nervous system, cardiovascular system, thyroid.

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4. FIRST AID MEASURES

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability: Non-flammable

Fire & Explosion Hazard: None

Extinguishing Media: Use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Absorb with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling Protect from light by retaining in carton until contents have been used.

Storage No special storage required for hazard control. For product protection store at controlled room temperature of 15-30°C (59-86°F).

Special Precautions Protect from freezing, light and extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure limits		
	OSHA-PEL	ACGIH-TLV	Hospira EEL
Phenylephrine Hydrochloride	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established STEL: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
 EEL: Employee Exposure Limit.
 TWA: 8 hour Time Weighted Average.
 STEL: 15-minute Short Term Exposure Limit.

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Respiratory Protection	Respiratory protection is not needed during normal product use.
Skin Protection	If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.
Eye Protection	Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.
Engineering Controls	Engineering controls are not needed during normal product use conditions.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Clear, colorless liquid
Odor	None
Boiling Point	Approximately that of water (100 °C, 212 °F).
Freezing Point	Approximately that of water (0 °C, 32 °F).
Vapor Pressure	Approximately that of water (17.5 mm Hg at 20 °C).
Vapor Density (Air=1)	Not Applicable
Evaporation Rate	Not Applicable
Bulk Density	Not Determined
Specific Gravity	1.006-1.008
Solubility	Water
pH	3.0 – 6.5

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under standard use and storage conditions.
Incompatibilities	Not Determined
Hazardous Decomposition Products	Toxic fumes of HCl.
Hazardous Polymerization	Not Determined.

11. TOXICOLOGICAL INFORMATION:

Acute Toxicity – Oral:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Phenylephrine Hydrochloride	100	LD50	350 120	mg/kg	Rats Mice

LD50 is the dosage producing 50% mortality.
Product contains 1% Phenylephrine Hydrochloride.

Acute Toxicity – Dermal:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Phenylephrine Hydrochloride	100	LD50(sc)	27	mg/kg	Rats

LD50 (sc) is the value for skin contact.

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Mutagenicity Negative in the Ames test. Induced sister chromatid exchanges in cultured cells.
Negative in the chromosomal aberration assay.

Target Organ Effects In clinical use target organ effects include cardiovascular system, eyes and respiratory system.

12. ECOLOGICAL INFORMATION:

Aquatic Toxicity Not Available

13. DISPOSAL CONSIDERATIONS:

Waste Disposal Disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal Dispose of container and unused contents in accordance with federal, state, and local regulations.

14. TRANSPORTATION INFORMATION

DOT Not Regulated

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status Phenylephrine Hydrochloride is listed on the TSCA inventory.
CERCLA Status Not Regulated
SARA Status Not Regulated
RCRA Status Not Regulated
PROP 65 (Calif.) Not Regulated

Notes: TSCA Toxic Substance Control Act
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
SARA Superfund Amendments and Reauthorization Act
RCRA US EPA, Resource Conservation and Recovery Act
Prop 65, California Proposition 65

16. OTHER INFORMATION:

MSDS Coordinator Global Occupational Toxicology
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