

SAFETY DATA SHEET
Phenylephrine Hydrochloride Injection, USP



Caplin Steriles Limited

**SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/
UNDERTAKING**

Product Identifier : Phenylephrine Hydrochloride Injection, USP (Caplin Steriles Ltd.)
Chemical Family : Phenylethanolamine
Synonyms : 3-hydroxy-a-[(methylamino)methyl]-benzenemethanol, monohydrochloride;
L-Phenylephrine

Relevant identified uses of the substance or mixture and uses advised against

Identified Uses : Pharmaceutical product used as Cardiovascular drug
Details of the Supplier of the Safety Data Sheet : Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai,
Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin
Code: 601 201, Tamil Nadu (State), INDIA.
Emergency Telephone Number : +91-4467901901/02/03

SECTION 2: HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

GHS Label elements, including precautionary statements

Emergency Overview

Signal word	None	
The product contains no substances which at their given concentration are considered to hazardous to health		
Appearance: Clear, Colorless	Physical state: Liquid	Odor No information available

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SECTION 7: HANDLING AND STORAGE

Precautions for safe handling

Handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Remove and wash contaminated clothing before re-use.

Conditions for safe storage, including any incompatibilities

Storage

Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products

Acids. Bases. Oxidizing agents.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Control parameters

Exposure Guidelines

This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Measures

Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as protective equipment

Eye/Face Protection

No special protective equipment required

Skin and Body Protection

No special protective equipment required

Respiratory Protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State

Liquid

Appearance

Clear Colorless

Odor

No information

Odor Threshold

No information

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available

available

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	3.5 - 5.5	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None Known
Flammability (solid, gas)	No data available	None Known
Flammability Limits in Air		
upper flammability limit	No data available	None Known
lower flammability limit	No data available	None Known
Vapor Pressure	No data available	None Known
Vapor Density	No data available	None Known
Specific Gravity	No data available	None Known
Water Solubility	No data available	None Known
Solubility in other Solvents	No data available	None Known
Partition coefficient: n-octanol/ water	No data available	None Known
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Autoignition Temperature	No data available	None Known
Decomposition Temperature	No data available	None Known
Viscosity	No data available	None Known
Flammable properties	Not flammable	None Known
Explosive Properties	No data available	None Known
Oxidizing Properties	No data available	None Known
Other information		
VOC Content (%)	No data available	None Known

SECTION 10: STABILITY AND REACTIVITY

- Reactivity** : No data available.
- Chemical Stability** : Stable under recommended storage condition.
- Possibility of Hazardous Reactions**
- Oxidizing Properties** : None under normal processing.
- Conditions to Avoid** : None known based on information supplied..

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Incompatible Materials : Acids. Bases. Oxidizing agents.
Hazardous Decomposition Products : None known based on information supplied.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation Inhalation of mist may cause irritation to the respiratory system.
Eye Contact May cause irritation and pupillary dilation.
Skin Contact May cause irritation.
Ingestion May be harmful if swallowed. Ingestion may cause nausea and vomiting.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Phenylephrine hydrochloride	= 350 mg/kg (Rat)	-	-

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms May cause hypertensive crisis, bradycardia, mydriasis, pulmonary edema, diaphoresis, pallor.

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization No information available.
Mutagenic Effects Negative for mutagenicity (Ames) and clastogenic effects (sister chromatic exchange, chromosomal aberrations, DNA damage, micronuclei).
Carcinogenicity Not carcinogenic in mice or rats when administered in the diet for 2 years.
Reproductive Toxicity No information available.
STOT - single exposure No information available.
STOT - repeated exposure No information available
Aspiration Hazard No information available.

Numerical measures of toxicity - Product

The following values are calculated based on chapter 3.1 of the GHS document:

LD50 Oral 35000 mg/kg; Acute toxicity estimate

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SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Persistence and Degradability No information available.

Bioaccumulation No information available.

Other Adverse Effects No information available

SECTION 13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods Dispose of in accordance with federal, state, and local regulations

Contaminated Packaging Do not re-use empty containers.

SECTION 14: TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

IATA Not regulated.

IMDG/IMO Not regulated.

SECTION 15: REGULATORY INFORMATION

International Inventories

TSCA Exempt

DSL Exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product Does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

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Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

"X" designates that the ingredients are listed on the state right to know list.

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Sodium metabisulfite	X	X	X		X

U.S. EPA Label Information

EPA Pesticide Registration Number: Not applicable

SECTION 16: OTHER INFORMATION

<u>NFPA</u>	Health Hazard 1	Flammability 0	Instability 0	Physical and Chemical Hazards-
<u>HMIS</u>	Health Hazard 1	Flammability 0	Physical Hazard 0	Personal protection x

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Prepared By

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General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of Its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet