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

Precautionary Statements:

Prevention

• None

General Advice

• None

Storage

• None

Disposal

• None

Hazard Not Otherwise Classified (HNOC)

Not applicable

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	**CAS #**	Ingredients (mg/mL)
Phenylephrine hydrochloride	61-76-7	10 mg/mL
Sodium chloride	7647-14-5	3.5 mg/mL
Citric acid monohydrate	5949-29-1	1 mg/mL
Sodium citrate dihydrate	6132-04-3	4 mg/mL
Sodium metabisulfite	7681-57-4	2 mg/mL
Sodium hydroxide	1310-73-2	Qs to pH adjust
Hydroxide acid	7647-01-0	Qs to pH adjust
Water for Injection	7732-18-5	Quantity sufficient by volume

SECTION 4: FIRST AID MEASURES

Description of necessary first-aid measures

Eye Contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Skin Contact Wash skin with soap and water.

Inhalation Move to fresh air.

Ingestion Clean mouth with water and afterwards drink plenty of water.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects: Nausea. Vomiting. Headache. Nervousness.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician Treat symptomatically.

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SECTION 5: FIRE FIGHTING MEASURES

Suitable Extinguishing Media

Use water spray, fog, carbon dioxide (CO 2), foam or dry chemical

Unsuitable Extinguishing Media: None

Specific Hazards Arising from the Chemical

No information available.

Explosion Data

Sensitivity to Mechanical impact: None

Sensitivity to static Discharge: None

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Use personal protective equipment.

Environmental Precautions

Environmental Precautions See Section 12 for additional Ecological Information

Methods and materials for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled Container

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact withskin, 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 shouldbe 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

	available	available

Property	Values	Remarks/ - Method
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
artition coefficient: n-octanol/water	No data available	None Known
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..

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

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

NFPA	**Health Hazard** 1	**Flammability** 0	**Instability** 0	**Physical and Chemical Hazrds-**
HMIS	**Health Hazard** 1	**Flammability** 0	**Physical Hazard** 0	**Personal protection x**

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