

SAFETY DATA SHEET

Date of Original Issue: 18OCT2021

Revision Number: 2

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SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1. Product identifier

Product name: Phenylephrine HCl Injection

1.2. Relevant identified uses of the substance or mixture

Product Use: Pharmaceuticals used to relieve nasal discomfort

1.3. Details of the responsible party of the safety data sheet

Manufacturer

Caplin Steriles Private Limited
Survey No. 895 & 897, Guruvarajakamdigai
Tamil Nadu 601 201
India
+91 4467901901 / 02 / 03

Distributor

Xellia Pharmaceuticals USA LLC
2150 East Lake Cook Road
Buffalo Grove, IL 60089
USA
+1 833-657-3519

Email address for the competent person responsible for the safety data sheet: sales@xellia.com

1.4. Emergency telephone number

Poison Control Center (USA): +1 877 800 5553

CHEMTREC (USA Transportation): +1 800 424 9300

CANUTREC (Canadian Transportation): +1 613 996 6666

EU: <http://apps.who.int/poisoncentres/>

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Skin Sens. 1B;

2.2. Label elements

Content:



WARNING

H317 – May cause an allergic skin reaction.

P261 – Avoid breathing
dust/fume/gas/mist/vapor/spray.

P280 – Wear protective gloves/protective
clothing/eye protection/face protection.

P302+P352 – If on skin: Wash with plenty of water.

P333+P313 – If skin irritation or rash occurs get
medical advice/attention.

P362+P364 – Take off contaminated clothing and
wash it before use.

2.3. Other hazards:

The active ingredient is not considered PBT/vPvB, or endocrine disruptive according to the criteria in the CLP regulation.

SECTION 3: Composition/Information on Ingredients

3.2. Mixtures

Active component	CAS #	EU/List #
Phenylephrine Hydrochloride	61-76-7	200-517-3

REACH #: exempted.

SECTION 4: First Aid Measures

4.1. Description of first aid measures

Eye contact: Flush eyes for 15 minutes with plenty of water. Get medical attention immediately.

Skin contact: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation or rash develops.

Ingestion: Do not induce vomiting. Call a physician or poison control center. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None

4.3. Indication of any immediate medical attention and special treatment needed

In case of discomfort or unconsciousness: Show this safety data sheet to a physician or emergency center, treat symptomatically.

SECTION 5: Firefighting Measures

5.1. Extinguishing media

Water, carbon dioxide, dry chemical, foam, or other alternatives.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Unsuitable extinguishing media: None

Specific methods: Not available

5.3. Advice 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

6.1. Personal precautions, protective equipment, and emergency response

Wear personal protective equipment to avoid exposure – see section 8.

6.2. Environmental precautions

Water spill: Do not empty into drains.

Release notes: If the spill could potentially enter any waterway, including intermittent dry creeks, contact the local authorities. In the USA, contact the USA Coast Guard National Response Center toll free +1 800 424 8802.

6.3. Methods and materials for containment and cleaning up

Absorb product with sand or similar materials.

6.4. References to other sections

See section 1 for emergency contact information, section 8 for personal protective equipment details, and section 13 for disposal information.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

For large quantities: Engineering controls are recommended to ensure adequate ventilation such that exposures do not exceed TWA for an eight-hour exposure. The need for additional personal protective equipment including respirators, eye and skin protection should be based on a job-specific risk assessment. Additional personal protective equipment may include chemical-resistant gloves and body covering, goggles, and face shield. Adequate eye protection is always required.

For small quantities: Keep the bottle tightly closed when not in use.

Work hygienic practices: Facilities storing or using this material should be equipped with an emergency eyewash and safety shower. Good personal hygiene practices should always be followed.

7.2. Conditions for safe storage, including any incompatibilities

Store securely, inaccessible for unauthorized persons. Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F). Protect from light. Store in carton until time of use.

7.3. Specific end uses

See section 1.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

OSHA'S hazardous components (29 CFR 1910.1020) EXPOSURE LIMITS AND GUIDELINES

	<u>OSHA PEL</u>		<u>ACGIH TLV</u>		<u>OTHER OEL (TWA)</u>	
	<u>ppm</u>	<u>mg/ m³</u>	<u>ppm</u>	<u>mg/ m³</u>	<u>ppm</u>	<u>mg/ m³</u>
Phenylephrine Hydrochloride (CAS# 61-76-7)	N/A	N/A	N/A	N/A	N/A	0.03

Other country exposure limits: Not listed.

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

8.2. Exposure controls

PERSONAL PROTECTIVE EQUIPMENT:

Eyes and face: Wear safety glasses with side shields or goggles as appropriate when handling this material.

Skin: Chemical resistant gloves (nitrile or latex) and body covering.

Respiratory: Use an approved respirator suitable to provide level of protection required.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

(a) **Physical state:** Liquid

(b) **Color:** Clear, colorless

(c) **Odor:** Not available

(d) **Melting point/freezing point:** Below 0°C of the product. 284-293°C Phenylephrine hydrochloride.

(e) **Boiling point or initial boiling point and boiling range:** Above 100°C

(f) **Flammability:** Not flammable.

(g) **Lower and upper explosion limit:** Not applicable

(h) **Flash point:** Not applicable

(i) **Auto-ignition temperature:** Not available

(j) **Decomposition temperature:** Not available

(k) **pH:** about 5 (1% aqueous solution of active ingredients), 3.5 – 5.5 (solutions)

(l) **Kinematic viscosity:** Not available

(m) **Solubility:** >10% in water (active ingredient).

(n) **Partition coefficient n-octanol/water (log value):** Not available

(o) **Vapor pressure:** Not available

(p) **Density and/or relative density:** Not available

(q) **Relative vapor density:** Not available

(r) **Particle characteristics:** Solution

9.2. Other information:

Not available.

SECTION 10: Stability and Reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization has not been reported.

10.4. Conditions to avoid

Incompatible materials, excess heat, alkaline materials, strong oxidants.

10.5. Incompatible materials

Strong oxidants.

10.6. Hazardous decomposition products

Nitrogen oxides, carbon monoxide, oxides of sulfur, irritating and toxic fumes and gases, carbon dioxide.

SECTION 11: Toxicological Information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute dermal LD50:	Not determined. Based on available studies the classification criteria are not met.
Acute oral LD50:	350 mg/kg (rat), 120 mg/kg (mouse)
Acute inhalation LC50:	Not determined. Based on available studies the classification criteria are not met.
Eye effects:	May cause irritation and pupillary dilation. Based on available studies the classification criteria are not met.
Skin effects:	Irritant. Based on available studies the classification criteria are not met.
Sensitization:	Possible allergic skin rash.
Target organ:	Respiratory System. Based on available studies the classification criteria are not met.
Carcinogenicity:	Based on available studies the classification criteria are not met.
Listed by IARC: No Listed by NTP: No Listed by OSHA: No	
Mutagenicity:	Negative for mutagenicity (Ames) and clastogenic effects (sister chromatic exchange, chromosomal aberrations, DNA damage, micronuclei). Based on available studies the classification criteria are not met.
Reproductive effects:	Not determined.
Teratogenic effects:	Not determined.

11.2. Information on other hazard

Not available

SECTION 12: Ecological Information

12.1. Toxicity

No applicable information found. Releases to the environment should be avoided.

12.2. Persistence and degradability

No applicable information found.

12.3. Bio-accumulative potential

No applicable information found.

12.4. Mobility in soil

No applicable information found.

12.5. Results of PBT and vPvB assessment

The substance is not considered PBT/vPvB according to criteria in Annex XIII.

12.6. Endocrine disrupting properties

No such properties are known to the substance.

12.7. Other adverse effects

The substance is possibly harmful for the aquatic environment, due to its antibiotic properties.

SECTION 13: Disposal Considerations

13.1. Waste treatment methods: Do not empty into drain. Dispose of any cleanup materials and waste residue according to applicable laws and regulations.

SECTION 14: Transport Information

14.1. UN Number or ID number

Not Regulated.

14.2. UN proper shipping name

Not Regulated.

14.3. Transport hazard class(es)

Not Regulated.

14.4. Packing group

Not Regulated.

14.5. Environmental hazards

Not Regulated.

14.6. Special precautions for user

Not Regulated.

14.7. Maritime transport in bulk according to IMO instruments

Not relevant.

USA DOT (DEPARTMENT OF TRANSPORTATION)

Proper Shipping Name: Not regulated

CANADA TRANSPORT OF DANGEROUS GOODS

Proper Shipping Name: Not regulated.

AIR (ICAO/IATA)

Proper Shipping Name: Not regulated.

VESSEL (IMO/IMDG)

Proper Shipping Name: Not regulated.

EUROPEAN TRANSPORTATION:

ADR/RID HAZARD CLASSIFICATION: Not Regulated.

U.S. CUSTOMS HARMONIZATION NUMBER: Not Available.

SECTION 15: Regulatory Information

15.1. Safety, health, and environmental regulation/legislation specific for the substance or mixture

EUROPEAN UNION

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work:

Must not be used by persons under 18 years of age.

Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding:

The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions.

Implementation of directive 2001/82/EC of the European Parliament and of the council of 6 November 2001 in the Community code relating to veterinary medical products:

Denmark: The Danish Medicines Agency (Lægemiddelstyrelsen) must be notified that this substance is produced, imported, exported, stored, sold, delivered, packed, possessed or in other ways handled in Denmark (Bekendtgørelse nr. 1226 af 7 December 2005 om omgang med visse stoffer og produkter hvis indhold kan anvendes som lægemidler til dyr.).

For other countries: Please contact national authorities regarding notification of the substance.

UNITED STATES FEDERAL REGULATIONS

Superfund Amendments and Reauthorization Act (SARA) Title III 311/312 hazard categories:

Fire: No **Pressure generating:** No **Reactivity:** No **Acute:** No **Chronic:** No

313 Reportable Ingredients: Not Listed

Title III notes:

Comprehensive Response, Compensation, and Liability Act (CERCLA)

CERCLA RQ: Not listed

Toxic Substances Control Act (TSCA)

TSCA Regulatory: Exempt

National Response Center: US Coast Guard National Center Response Telephone
+1 800 424 8802.

UNITED STATES STATE REGULATIONS

California Proposition 65: This product does not contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

CANADA

Workplace Hazardous Material Information System (WHMIS) hazard symbol and classification

WHMIS Controlled: Not regulated.

Canadian Environmental Protection Act: Not listed

15.2. Chemical safety assessment

No CSR is compiled because the substance is exempted.

SECTION 16: Other Information

Reason for issue: Update to include 2020/878 EU Commission regulation as well changing the type of SDS to mixture SDS and classifications accordingly.

Contact Information: See Section 1.

Revision summary: Second issue.



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