SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Ephedrine Sulfate Injection USP, 50 mg/mL

Other means of identification

Synonyms Not available.

Recommended use of the chemical and restrictions on use

Recommended Use Not available.

Uses Advised Against Not available.

Details of the supplier of the safety data sheet

Caplin Steriles Ltd.
Survey No 895 & 897
Guruvarajakandigai
Sirupuzhalpettai (post)
Gummidipoondi Taluk,
Thiruvallur District – 601 201.
India.

2. HAZARDS IDENTIFICATION

Classification

Health Hazards

Not classified.

Physical Hazards

Not classified.

OSHA Regulatory Status

This product is not considered hazardous according to the OSHA Hazard Communication Standard (29 CFR 1910.1200, Revision 3).

Label elements

Emergency Overview

Danger

Appearance Clear. **Physical State** Liquid. **Odor** Not available.

Precautionary Statements - Prevention

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves/clothing/eye protection/face protection.

Precautionary Statements - Response

If exposed or concerned: Get medical attention.

Precautionary Statements - Storage
Store in a well-ventilated place. Keep container tightly closed.

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal facility.

Hazards not otherwise classified (HNOC)
None.

Other information
Not available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is not considered hazardous by the 2012 OSHA Hazard Communication Standard/Globally Harmonized System of Classification and Labelling of Chemicals (GHS); (29 CFR 1910.1200; Revision 3).
Other hazardous ingredients include Glacial Acetic acid and/or sodium hydroxide are added to adjust the pH, and non-hazardous ingredient includes water.

Synonyms Not available.

Chemical Name	CAS No.	Weight-%
Ephedrine Sulfate USP	134-72-5	5

4. FIRST AID MEASURES

First aid measures

General Advice Take a copy of the Safety Data Sheet when going for medical treatment.

Eye Contact In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Inhalation In case of inhalation, remove to fresh air. If not breathing, provide artificial respiration. Do not use mouth-to-mouth method; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device if breathing is difficult. Seek emergency medical attention immediately.

Ingestion In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Self-Protection of the First Aider Do not use mouth-to-mouth methods if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or another proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

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

Indication of any immediate medical attention and special treatment needed

Note to Physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

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

Unsuitable Extinguishing Media None known.

Specific hazards arising from the chemical
Not available.

Hazardous Combustion Products Not available.

Explosion data
Sensitivity to Mechanical Impact Not applicable.
Sensitivity to Static Discharge Not available.

Protective equipment and precautions for firefighters
Wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Use personal protective equipment as required.

Environmental Precautions

Environmental precautions Not available.

Methods and material for containment and cleaning up

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

Methods for Cleaning Up Package all material in appropriate container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling Handle in accordance with good industrial hygiene and safety practices.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store at 20-25°C (68° to 77° F); with excursion permitted from 15°C to 30 °C (59° to 86° F). Store in carton until time of use.

Incompatible Materials Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, may contain hazardous materials with Occupational Exposure Limits (OELs) established by the region-specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Glacial acetic acid 64-19-7	STEL: 15 ppm |par TWA: 10ppm	TWA: 10 ppm |par TWA: 25 mg/m^3 |par (vacated) TWA: 10 ppm |par (vacated) TWA: 25 mg/m^3	IDLH: 50 ppm |par TWA: 10 ppm |par TWA: 25 mg/m^3 |par STEL:15 ppm|par STEL: 37 mg/m$^{3.}$
Sodium hydroxide 1310-73-2	Ceiling: 2 mg/m^3	TWA: 2 mg/m^3 |par (vacated)Ceiling: 2 mg/m3	IDLH: 10 mg/m3 |par Ceiling: 2mg/m^3

Appropriate engineering controls

Engineering Controls None under normal use conditions. The health hazard risks of handling this material are dependent on factors such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/Face Protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin and Body Protection None required for consumer use. Wear impervious protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact.

Respiratory Protection None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

General Hygiene Considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid.		
Appearance	Clear.	**Odor**	Not available.
Color	Colorless.	**Odor Threshold**	Not available.

Property	Values	Remarks • Method
pH	4.5-7.0	
Melting point/freezing point	Not available.	
Boiling point/boiling range	Not available.	
Flash point	Not available.	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	Not available.	
Lower flammability limit:	Not available.	
Vapor pressure	Not available.	
Vapor density	Not available.	
Specific Gravity	Not available.	
Water solubility	Soluble in water.	
Solubility in other solvents	Not available.	
Partition coefficient	Not available.	
Autoignition temperature	Not available.	
Decomposition temperature	Not available.	
Kinematic viscosity	Not available.	
Dynamic viscosity	Not available.	
Explosive Properties	Not available.	
Oxidizing Properties	Not available.	

Other information

Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY

Reactivity
Stable at normal conditions.

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
Not available.

Hazardous Polymerization Not available.

Conditions to Avoid
Strong oxidizing agents.

Incompatible Materials
Not available.

Hazardous Decomposition Products
Not available.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute Toxicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Ephedrine Sulfate USP (134-72-5)	= 404 mg/kg (Rat)			
Glacial Acetic acid (64-19-7)	= 3310 mg/kg (Rat)	= 1060 mg/kg (Rabbit)	= 11.4 mg/L (Rat) 4h	
Sodium hydroxide (1310-73-2)	500 mg/kg (Rabbit)	1350 mg/kg (Rabbit)		

Information on toxicological effects

Symptoms Excessive IV administration of Ephedrine sulfate USP produces tachycardia, exaggerated rise in blood pressure, and adverse CNS effects. The principal manifestation of Ephedrine sulfate USP overdosage is development of seizures. Acute overdosage of ephedrine may also result in nausea, vomiting, chills, irritability, and blurred vision.

Delayed and immediate effects as well as chronic effects from short- and long-term exposure

Skin Corrosion/Irritation Irritating to skin Local application of Ephedrine sulfate USP may cause contact dermatitis (Ephedrine sulfate USP, Glacial Acetic acid).

Serious Eye Damage/Eye Irritation 4-10% acetic acid solution in the human eye causes immediate pain and conjunctival hyperemia, sometimes with injury of the corneal epithelium (Glacial Acetic acid).

Sensitization No data available.

Germ Cell Mutagenicity Not available.

Reproductive Toxicity Not available.

STOT - Single Exposure Not classified.

STOT - Repeated Exposure Not classified.

Subchronic Toxicity Not applicable.

Other adverse effects Not available.

Aspiration Hazard Not available.

Numerical measures of toxicity - Product Information

Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Glacial acetic acid		79:96 h Pimephales promelas mg/L LC50 static 75:96 h Leomis macrochirusmg/L LC50 static		65:48 h Daphnia magna mg/L EC50 Static 47:24 h Daphnia magna mg/L EC50
Sodium hydroxide	45.4 mg/L: 96 h LC50 Static(Oncorhynchus mykiss)			

Bioaccumulation
An estimated BCF of 1.4 suggests the potential for bioconcentration in aquatic organisms is low (Ephedrine sulfate USP). An estimated BCF of 3 suggests the potential for bioconcentration in aquatic organisms is low (Glacial Acetic acid).

Mobility
Ephedrine sulfate USP is expected to have high mobility in soil upon an estimated Koc of 72. The Koc value of 1, suggests that Glacial Acetic acid is expected to have very high mobility in soil.

Other adverse effects
Not available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of Wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated Packaging Disposal should be in accordance with applicable regional, national and local laws and regulations. Do not reuse container.

US EPA Waste Number Not applicable.

California Hazardous Waste Codes Not available.

14. TRANSPORT INFORMATION

DOT Not regulated.
TDG Not regulated.

MEX Not regulated.
ICAO (air) Not regulated.

IATA Not regulated.

IMDG Not regulated.

RID Not regulated.

ADR Not regulated.
ADN Not regulated.

15. REGULATORY INFORMATION

US Federal Regulations

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

CWA (Clean Water Act)
This product contains the following substance which is regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Glacial acetic acid 64-19-7	5000 lb			X
Sodium hydroxide 1310-73-2	1000 lb			X

CERCLA
This material, as supplied, contains the following substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Glacial acetic acid 64-19-7	5000 lb		RQ 5000 lb final RQRQ 2270 kg final RQ
Sodium hydroxide 1310-73-2	1000 lb		RQ 1000 lb final RQRQ 454 kg final RQ

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product contains the following substances regulated by state right-to-know regulations.

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Glacial acetic acid 64-19-7	X	X	X
Sodium hydroxide 1310-73-2	X	X	X

U.S. EPA Label Information
EPA Pesticide Registration Number Not applicable.

16. OTHER INFORMATION

Revision Date Not applicable.
Revision Note New SDS.

Disclaimer
Caplin Steriles Ltd. considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the product and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals.
Caplin Steriles Ltd. shall not be held liable for any loss, injury or damage from contact with the product.

End of Safety Data Sheet