

SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS),
Third Revised Edition UNITED NATIONS
New York and Geneva, 2019

Ephedrine Sulphate Injection USP (50 mg/ml)

1. IDENTIFICATION

GHS Product identifier: Ephedrine sulphate

Product code: #

Chemical Description: 1-Phenyl-2-methylamine-propanol-1-sulfate; (-)-erythro-1-Hydroxy-2-(methylamino) -1-phenylpropane sulfate

Other means of identification: -

Recommended use of the injection: Ephedrine Sulfate Injection, USP is indicated in the treatment of allergic disorders, such as bronchial asthma. It is a vasopressor agent, particularly during anesthesia, when hypotension frequently occurs.

Restrictions on use: The product should be used only for the above-mentioned use and may not be used for any other purpose than stated above.

Manufactured by:

Maiva Pharma Pvt Ltd.,
No 32, Sipcot Industrial Complex
Phase 1, Hosur, Krishnagiri
Tamil nadu 635126

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2. HAZARDS IDENTIFICATION

Classification

Globally Harmonized System, UN (GHS)

Not classified as hazardous. No Labelling required.

Classification	
Signal Word	None
Hazard Statements:	Not classified in accordance with international standards for workplace safety
Precautionary Statements:	<p>P264: Wash hands thoroughly after handling.</p> <p>P272: Contaminated work clothing should not be allowed out of the Workplace.</p> <p>P273: Avoid release to the environment.</p> <p>P280: Wear protective gloves/protective clothing/eye protection/face Protection.</p> <p>P284: Wear respiratory protection.</p> <p>P305 + P351 + P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing</p> <p>P332+P313 If skin irritation occurs: Get medical advice/attention.</p> <p>P337+P313: If eye irritation persists: Get medical advice/attention.</p> <p>P362: Take off contaminated clothing.</p> <p>P405: Store locked up.</p>
Other hazards	None

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Ephedrine Sulphate

Hazardous ingredients	CAS	Content
Ephedrine sulphate	134-72-5	50 mg/ml (5%)
Glacial acetic acid	64-19-7	q.s.
Other ingredients		
Sodium hydroxide	1310-73-2	q.s.
Water for injection	7732-18-5	q.s.

4. FIRST-AID MEASURES

Inhalation

Move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

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

Ingestion

If this product is swallowed, call physician or Poison Control Centre. Rinse mouth with water. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Use water spray, dry chemical or carbon dioxide.

Fire/explosion hazard

None anticipated for this aqueous product.

Specific hazards arising from the chemical

Not known.

Personal protection

Self-contained breathing apparatus. Fire-fighters must wear self-contained breathing apparatus for firefighting if necessary

Special exposure hazards

Do not release chemically contaminated water into drains, soil, or surface water. Absorb liquid with suitable material. Clean affected area with soap and water. Dispose contaminated water and soil according to local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Wear respiratory protection. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental precautions

Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer.

7. HANDLING AND STORAGE

Handling

Occupational hygiene

Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed).

Conditions for safe storage

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the insert.

Storage facilities

Store away from light, in a cool, dry area with adequate ventilation. Keep tightly closed.

Segregation

Store locked up.

Storage conditions

Store as directed by instructions on product packaging.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

CAS No	Name	TWA
134-72-5	Ephedrine Sulphate	200 µg/m ³ (8 hr)
64-19-7	Glacial Acetic Acid	10 ppm (25 mg/m ³)

Occupational exposure controls

Appropriate engineering controls

Maintain air concentrations below occupational exposure standards. Prevent spillage.

General Personal Protection

Goggles, gloves, protective clothing.

Respiratory protection

Where the neat active ingredient is weighed and diluted, wear a NIOSH-approved half face respirator equipped with an organic vapor/acid gas cartridge (specific for organic vapors, HCl, acid gas and SO₂) with a dust/mist filter. (NTP, 1992).

Hand protection

Protective gloves.

Eye protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear liquid

Form: Solution Injection

Colour: Colourless

Odour: Odourless

pH: 4 – 7.0

Melting point: Not applicable

Boiling point: Not applicable

Flash point: Not applicable

Vapour pressure: Not applicable

Auto-ignition temperature: Not applicable

Decomposition temperature: Not applicable

Density: 1 gm/cm³

Solubility in water: Soluble

Solubility in solvents: Not tested

n-Octanol/Water Partition Coefficient: Not applicable

Viscosity: Not tested

10. STABILITY AND REACTIVITY

Chemical stability

Stable under recommended storage conditions

Conditions to avoid

None in particular

Materials to avoid

As a precautionary measure keep away from strong oxidising agents.

Hazardous decomposition products

No data available.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Ephedrine active ingredient has been tested for acute toxicity.

LC₅₀: 404 and 812 mg/kg (rat and mouse respectively) Route: oral

Based on toxicity data of ephedrine and its excipients, mixture is not classifiable.

Primary Irritation:

Skin/eye irritation - No data available

Respiratory or Skin sensitization

Ephedrine Sulphate is not classifiable for respiratory or skin sensitization

CMR consideration:

Germ cell mutagenicity:

Not mutagenic. Mixture not classifiable.

Carcinogenicity

No carcinogenicity was observed a two year study in rats and mice administered up to 10 and 27 mg/kg/day of ephedrine sulphate, respectively. Not classifiable as human carcinogen.

Reproductive toxicity: Data not available

Specific target organ toxicity single exposure: Mixture is not classifiable for STOT-SE

Specific target organ toxicity repeated exposure:

Due to lack of data the GHS classification is not possible.

Aspiration hazard:

GHS Classification is not possible.

12. ECOLOGICAL INFORMATION

Ecotoxicity- Unknown

A BCF of 1.4 suggests ephedrine's potential for bioaccumulation is low.
Mixture is not classifiable owing to lack of studies.

Persistence and degradability

Ephedrine is readily biodegradable. Mobility in soil is high.

Behaviour in treatment plants

Data not available. GHS Classification is not possible.

Additional information

Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal

All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or onsite wastewater treatment facility.

Contaminated packaging

Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2019 as amended
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2009

16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes

Prepared on 20/06/2022