



SAFETY DATA SHEET

EMERPHED (ephedrine sulfate) Injection, 5mg/mL

1. Identification

Product Identifier: EMERPHED (ephedrine sulfate) Injection, 5mg/mL

Synonyms: Ephedrine sulfate injection, 0.5%; Ephedrine sulfate; Benzenemethanol α -[1 - (methylamino) ethyl] – sulfate (2:1) (salt); Bis [[R-(R*,S*)]- β -hydroxyamethylphenethyl) methylammonium] sulphate.

National Drug Code (NDC):

14789-250-07	10 mL clear glass, single-dose vial; strength 5 mg/mL
14789-250-10	10 mL vials packaged in a carton of 10
14789-251-09	5 mL clear glass, single-dose syringe: strength 5 mg/mL
14789-251-10	5 mL syringes packaged in a carton of 10
14789-252-09	10 mL clear glass, single-dose syringe: strength 5 mg/mL
14789-252-10	10 mL syringes packaged in a carton of 10

Recommended Use: Pharmaceutical

Company: Nexus Pharmaceuticals, Inc.
400 Knightsbridge Pkwy
Lincolnshire IL, 60069
USA

Contact Phone: (847) 996-3790

Website: www.nexuspharma.net

Emergency Contact: Chemtrec (24 hours): 1-800-424-9300
Email: CHEMTREC@chemtrec.com

2. Hazard(s) Identification

Physical Hazards:

Not classifiable.

Health Hazards:

Skin irritation	Category 3
Eye irritation	Category 2B
Specific target organ toxicity – single exposure (respiratory tract irritation)	Category 3
Skin irritation	Category 3

Classification of the Substance or Mixture:

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

Symbol(s):



Signal Word:

Warning

Hazard Statement(s):

H302 Harmful if swallowed
H316 Causes mild skin irritation.
H320 Causes eye irritation.
H335 May cause respiratory irritation.
H361d Suspected of damaging the unborn child.
H373 May cause damage to cardiovascular and central nervous systems through prolonged or repeated exposure.

Precautionary Statement(s):

P233 Keep container tightly closed.
P261 Avoid breathing dust/fume/gas/mist/vapor/spray.
P271 Use only in a well-ventilated area.
P264 Wash potentially exposed skin after handling.

P304 IF INHALED: Remove person to fresh air and keep
+ comfortable for breathing.
P340

P304
+ IF INHALED: Call a POISON CENTER/doctor/physician if you
P312 feel unwell.

P305
+ IF IN EYES: Rinse cautiously with water for several minutes.
P351 Remove contact lenses, if present and easy to do. Continue
rinsing.

P338
+ If eye irritation persists: Get medical advice/attention.
P337

P313
+ If skin irritation occurs: Get medical advice/attention.
P332

P313 IF exposed or concerned: Get medical advice/attention.
+
P308

P403 Store in a well-ventilated place.

P405 Store locked up.

P501 Dispose of contents/container in accordance
with local/provincial/federal regulations.

Hazards Not Otherwise Classified:

Ephedrine sulfate is a sympathetic nervous system activator. Most common adverse effects were observed in the cardiovascular system. This included: high blood pressure, palpitations, increased heart rate, heart attacks, cardiac arrhythmia. Effects observed in the central nervous system: seizure, stroke, agitation, restlessness, anxiety, insomnia. Effects observed in the gastrointestinal system: nausea, vomiting. Limited data suggests ephedrine may cause fetal heart defects when administered to pregnant women. Ephedrine has potential for addiction following prolonged exposure, patients may experience withdrawal symptoms upon abrupt cessation.

Supplementary Information:

None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Ephedrine Sulfate	134-72-5	L- Ephedrine Sulfate	$(C_{10}H_{15}NO)_2 \cdot H_2SO_4$	428.54	0.5%
Sodium Chloride	7647-14-5	Sodium Chloride	NaCl	58.44	0.g%

Inactive Ingredients: Water for Injection.

4. First Aid Measures**Ingestion:**

Do not induce vomiting without medical advice. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.

Eye Contact:	Remove from source of exposure. Check for and remove any contact lenses. Flush with copious amounts of water for at least 20 minutes. Effects of exposure may be delayed. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Dizziness; rapid or pounding heartbeat; high blood pressure; headache; sweating; dry mouth, nose, or throat; muscle cramps; nausea; vomiting; anxiety, restlessness, or nervousness; trembling; vertigo; trouble sleeping; possible allergic reaction to material if inhaled, ingested or in contact with skin; chills; fever; seizures; spasms; rapid, pounding, or irregular heartbeat; changes in blood pressure; mood or mental changes; troubled breathing; pulmonary edema; enlarged pupils; blurred vision; nausea; vomiting; respiratory distress; hallucinations; delusions; coma.

Medical Conditions

Aggravated by Exposure: Hypersensitivity to any of the components of the product; pre-existing cardiovascular, kidney, nervous system or ocular diseases; enlarged prostate, psychoneurotic disorders, hypertension, diabetes mellitus history of seizures; hyperthyroidism.

Notes to Physician: Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media: Use extinguishing media (water spray (fog), foam, dry powder, or carbon dioxide as appropriate) for type of surrounding fire.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: These products include carbon oxides, nitrogen oxides, sulfur oxides, and other hazardous products of combustion.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment

Precautions for FireFighters Wear self-contained breathing apparatus and full protective gear.

6. Accidental Release Measures

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Do not touch or walk through spilled material. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Store according to label and/or product insert information.
Including Any incompatibilities Store away from concentrated acids and bases.

Specific End Use: Pharmaceuticals

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Ephedrine Sulfate	OSHA PEL: 15 mg/m ³ Total dust, 8 Hour TWA; OSHA PEL: 5 mg/m ³ Respirable fraction, 8 Hour TWA; ACGIH TLV: 10 mg/m ³ Total; ACGIH TLV: 3 mg/m ³ Respirable fraction, 8 hour TWA; OEL*: 0.1 mg/m ³ , 8 Hour TWA; OEL*: 0.08 mg/m ³ , 12 Hour TWA

* Occupational Exposure Levels (OELs) have been established by private industry.

Engineering Controls: Not required during the normal use of this product.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are

sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin: Protective laboratory coat, apron, or disposable garment.

9. Physical and Chemical Properties

Physical State/Color: Clear, colorless liquid.

Odor: No data available.

Odor Threshold: No data available.

pH: 4.5 to 7.0.

Melting Point: No data available.

Freezing Point: No data available.

Boiling Point: No data available.

Flash Point: No data available.

Evaporation Rate: No data available.

Flammability (solid, gas): No data available.

Flammability Limit - Lower: No data available.

Flammability Limit - Upper: No data available.

Vapor Pressure: No data available.

Vapor Density: No data available.

Relative Density: No data available.

Solubility(ies): Miscible in water.

**Partition Coefficient
(n-octanol/water):** No data available.

Auto-Ignition Temperature: No data available.

Decomposition Temperature: No data available.

Viscosity: No data available.

10. Stability and Reactivity

Reactivity: The product is stable and non-reactive under normal conditions of use, storage, and transport.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static discharge, shock, or vibration): No data available.

Incompatible Materials: Concentrated acids and bases.

Hazardous Decomposition Products: No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May cause respiratory tract irritation.

Ingestion: May be harmful if swallowed.

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the, physical and toxicological properties have not been thoroughly investigated

Delayed and Immediate Effects of Exposure: The most common adverse effects seen during clinical use of Ephedrine has been shown to raise systolic and mean blood pressure when administered as a bolus dose following the development of hypotension during anesthesia.

Acute Toxicity – Oral: LD50, Rat: 404 mg/kg (Ephedrine Sulfate)

Acute Toxicity – Dermal: LD50, Rat (sc): 318 mg/kg (Ephedrine Sulfate)

Acute Toxicity – Inhalation:	No data available.
Corrosivity:	No data available.
Dermal Irritation:	No data available.
Eye Irritation:	No data available.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	Prolong/enhance neural transmission; block channel gating; modulate G-protein coupled signal transduction.
Target Organ Effects:	Possible target organs include the heart, lungs, cardiovascular system and central nervous system.
Reproductive Effects:	No data available.
Carcinogenicity:	
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
Mutagenicity:	No data available.
Aspiration Hazard:	No data available.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available. Other Adverse Effects: No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
DOT:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

International Regulations:

Ozone depleting substance:	Not applicable
Persistent Organic Pollutant:	Not applicable
The Rotterdam Convention	Not applicable

US Federal Regulations:

TSCA Inventory	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.
DEA:	List I Chemical.

State Regulations

Massachusetts:	Not listed.
New Jersey:	Ephedrine Sulfate.
Pennsylvania:	Ephedrine Sulfate. California Proposition 65: Not listed.

16. Other Information

NFPA Rating: (Ephedrine Sulfate)	HMIS Classification: (Ephedrine Sulfate)
Health: 2	Health: 2
Flammability: 0	Flammability: 0
Reactivity: 0	Physical Hazard: 0

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