


SAFETY DATA SHEET

Ephedrine Sulfate Injection, USP 50 mg/mL

1. IDENTIFICATION

Product Identifier:	Ephedrine Sulfate Injection, USP 50 mg/mL
Synonyms:	I-Ephedrine sulfate
National Drug Code (NDC):	17478-517-01 17478-415-10
Recommended Use:	Pharmaceutical. Ephedrine Sulfate Injection is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)

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
Symbol(s):		
Signal Word:	Warning.	
Hazard Statement(s):	H316 Causes mild skin irritation. H320 Causes eye irritation. H335 May cause respiratory irritation.	
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.	

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- 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 feel unwell.
+
P312
- P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
+
P351
+
P338
- P337 If eye irritation persists: Get medical advice/attention.
+
P313
- P332 If skin irritation occurs: Get medical advice/attention.
+
P313
- P308 IF exposed or concerned: Get medical advice/attention.
+
P313
- 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: None.
Supplementary Information: None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Ephedrine Sulfate	l-Ephedrine sulfate	134-72-5	C ₁₀ H ₁₅ NO ₂ •H ₂ SO ₄	428.5	5%

The pH is adjusted with Sodium Hydroxide and/or Glacial Acetic Acid, if necessary.

4. FIRST AID MEASURES

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

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Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 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.

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. Use soap. 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 water, carbon dioxide, dry chemical or alcohol-resistant foam as necessary.

Unsuitable Extinguishing Media: Not determined.

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Specific Hazards Arising from the Chemical

Hazardous Combustion Products: Toxic gases and vapors may be released if involved in a fire. 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 and Precautions for Firefighters: Wear self-contained breathing apparatus and full and 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, Including Any Incompatibilities: Store at 20° to 25°C (68° to 77°F), with excursions permitted from 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Protect from light. Store in carton until time of use.

Specific End Use: Pharmaceutical drug product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Ephedrine Sulfate	TWA	0.1 mg/m ³

TWA: Time Weighted Average

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Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
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 Protection:	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 Protection:	Chemically compatible gloves are recommended. 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 Protection:	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
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 to remove contaminants.

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):	Freely soluble in water and ethanol, very slightly soluble in chloroform, and practically insoluble in ether.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.

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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 irritation to the nose and/or respiratory tract.

Ingestion: May be harmful if swallowed.

Skin Contact: May causes 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 chemical, 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

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Ephedrine Sulfate	Rat	Oral	LD ₅₀	404 mg/kg
Ephedrine Sulfate	Mouse	Oral	LD ₅₀	812 mg/kg

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Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Doses Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Effect(s)
Ephedrine Sulfate	Reproductive and Development	Rat	No route specified	<50 mg/kg	Increase in cardiovascular abnormalities
Ephedrine Sulfate	Reproductive and Development	Human	No route specified	No dosage specified	No increase in birth defects

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
Ephedrine Sulfate	<i>In vitro</i> (Ames)	Salmonella	Negative

Aspiration Hazard:

No data available.

Toxicokinetics/Metabolism:

Prolong/enhance neural transmission; block channel gating; modulated G-protein coupled signal transduction.

Target Organ Effects:

Ephedrine Sulfate may cause damage to organs (cardiovascular system, nervous system).

Systemic Effects:

No data available.

Reproductive Effects:

Animal reproduction studies have not been conducted with Ephedrine Sulfate.

Carcinogenicity:

Two-year feeding studies in rats and mice demonstrated no evidence of carcinogenic potential with Ephedrine Sulfate at dose up to 10 mg/kg/day and 27 mg/kg/day (approximately 2 times and 3 times the maximum human recommended dose on a mg/m² basis, respectively).

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.

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12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

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

13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Ephedrine Sulfate	Yes

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

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EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Ephedrine Sulfate	Listed	Listed	Not Listed

California Proposition 65:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

The vial stopper is not made with natural rubber latex.

See footer of this document for Revision Date and Revision Number.

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