



## MSDS: EPHEDRINE SULFATE INJECTION, USP, 50 mg/mL

### Material Safety Data Sheet

Manufacturer:

Akorn Incorporated  
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### Section 1 - IDENTIFICATION

**TRADE NAME:** Ephedrine Sulfate Injection, USP, 50mg/mL

**Description:** Ephedrine Sulfate Injection, USP is indicated in the treatment of allergic disorders, such as bronchial asthma. The drug has long been used as a pressor agent, particularly during spinal anesthesia when hypotension frequently occurs. It is indicated as a central nervous system stimulant in narcolepsy and depressive states. Also used in myasthenia gravis.

<u>Composition</u>	<u>CAS#</u>	<u>TLV (mg/m<sup>3</sup>)</u>	<u>PEL (mg/m<sup>3</sup>)</u>	<u>%Content</u>
Ephedrine Sulfate	134-72-5	Unknown	Unknown	5.0

Ephedrine Sulfate Injection, USP is a sterile solution of 50mg ephedrine sulfate in water for injection for intramuscular, intravenous, or subcutaneous use.

**Common name of active ingredients:** Ephedrine Sulfate, USP

**Chemical Formula (s):**  $(C_{10}H_{15}NO)_2 \cdot H_2SO_4$

**Molecular Weight:** 428.54g/mole

**Legal Category:** Prescription Only

### Section 2 - HAZARDOUS INGREDIENTS

**Principal Hazardous Ingredients:** ephedrine sulfate

**Carcinogenicity:** NE

**Mutagenicity:** NE

**Teratogenicity:** NE

**Developmental Toxicity:** NE



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### Section 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS

<b>Appearance/Physical State:</b>	Clear, colorless solution
<b>Boiling Point:</b>	Water (Approximate)
<b>Melting/Freezing Point:</b>	Water (Approximate)
<b>Vapor Pressure (mm Hg):</b>	NE
<b>Vapor Density:</b>	NE
<b>Evaporation Rate:</b>	NE
<b>Solubility:</b>	Aqueous solution
<b>Specific Gravity:</b>	Approximately 1.01
<b>Viscosity:</b>	Water (Approximate)
<b>Reactivity in Water:</b>	None
<b>pH:</b>	4.5 to 7.0

### Section 4 - FIRE AND EXPLOSION HAZARD DATA

<b>Flash Point:</b>	Non-flammable
<b>Flash Point Method:</b>	NA
<b>Lower Explosive Limit (%):</b>	ND
<b>Upper Explosive Limit (%):</b>	ND
<b>Autoignition Temperature:</b>	ND
<b>Extinguisher Media:</b>	Water spray, carbon dioxide, dry chemical, or foam as appropriate for surrounding fire and materials
<b>Auto Ignition Temperature:</b>	NE
<b>Special Firefighting Procedures:</b>	<b>Method:</b> NE Wear protective clothing and self-contained breathing apparatus.
<b>Specific Hazards:</b>	NE

#### CONDITIONS TO AVOID

<b>Incompatibility:</b>	Concentrated acids or bases
<b>Hazardous Decomposition Products:</b>	When heated to decomposition it emits very toxic fumes such as NO <sub>x</sub> , SO <sub>x</sub> and H <sub>2</sub> SO <sub>4</sub> .
<b>Hazardous Polymerization:</b>	ND

### Section 5 - REACTIVITY DATA

<b>Chemical Stability:</b>	Stable
<b>Conditions to Avoid:</b>	NA



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### Section 6 - HEALTH HAZARDS

**Emergency Overview:** In clinical use, the material is used as a bronchodilator and to treat shock. The active material stimulates the sympathetic nervous system. It is toxic by ingestion, and can exert changes on the heart, lungs, cardiovascular system and central nervous system.

**Target Organs:** Sympathetic nervous system, respiratory system, central nervous system, heart, cardiovascular system.

**Medical conditions Aggravated by Exposure:** Data suggests pre-existing cardiovascular, kidney, nervous system or ocular ailments.

**Overdosage:**

**Manifestations:** The principal manifestation of ephedrine sulfate poisoning is convulsions. In acute poisoning the following signs and symptoms may occur: nausea, vomiting, chills, cyanosis, irritability, nervousness, fever, suicidal behavior, tachycardia, dilated pupils, blurred vision, opisthotonos, spasms, convulsions, pulmonary edema, gasping respirations, coma and respiratory failure. Initially the patient may have hypertension, followed later by hypotension accompanied by anuria.

**Treatment:** If respirations are shallow or cyanosis is present, artificial respiration should be administered. Vasopressors are contraindicated. In cardiovascular collapse blood pressure should be maintained.

**Chemical Listed as Carcinogen or Potential Carcinogen:**

<b>National Toxicology Program:</b>	Yes _____	No <input checked="" type="checkbox"/>
<b>I.A.R.C. Monographs:</b>	Yes _____	No <input checked="" type="checkbox"/>
<b>OSHA:</b>	Yes _____	No <input checked="" type="checkbox"/>
<b>AGGIH Threshold Limit Value:</b>	NA	
<b>Other Exposure Limit Used:</b>	NA	

**Emergency and First Aid Procedures:**

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care, monitoring cardiovascular and respiratory function, as necessary.

**Eyes:** Remove from source of exposure. Flush with copious amount of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care, monitoring cardiovascular and respiratory function, as necessary.

**Skin:** 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, monitoring cardiovascular and respiratory function, as necessary.

**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care, monitoring cardiovascular and respiratory function, as necessary.



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**Note to physicians:** Treat symptomatically and supportively.

### Section 7 - PROTECTION INFORMATION

<b>Engineering Controls:</b>	No special provisions are required under normal use conditions.
<b>Respiratory Protection:</b>	Respiratory protection is not needed during normal product use.
<b>Skin Protection:</b>	If skin contact is likely, impervious gloves are recommended.
<b>Eye Protection:</b>	Eye protection is not required during typical product use conditions. Eye protection is recommended if contact is likely.

### Section 8 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

<b>Handling:</b>	No special handling required.
<b>Storage:</b>	Store at controlled room temperature of 15°-25°C. Protect from light.
<b>Steps to be taken in case material is released or spilled:</b>	Absorb with suitable material, and containerize prior to disposal in accordance with local, state, and federal regulations. Use personal protective equipment recommended in section 7.
<b>Waste Disposal Methods:</b>	Dispose of in accordance with county, regional, federal, state, and local regulations.

### Section 9 - DISPOSAL CONSIDERATIONS

<b>Waste Disposal Methods:</b>	Observe all federal, state, and local environmental regulations for disposal guidelines.
<b>Appropriate Method of Disposal of Product, Preparation, Packaging:</b>	Disposal must be made according to official regulations. Consult state, local and national governmental requirements.

### Section 10 - TOXICOLOGY INFORMATION

<b>Oral Toxicity:</b>	LD 50 equal to or greater than 75 to 1072 mg/kg in mice, rats, and rabbits. Estimated oral MLD of 2000 mg in adults for ephedrine sulfate (toxic).
<b>Dermal Toxicity:</b>	ND
<b>Inhalation Toxicity:</b>	ND
<b>Corrosiveness:</b>	ND
<b>Dermal Irritation:</b>	ND
<b>Ocular Irritation:</b>	Ephedrine sulfate produces dilated pupils (mydriasis) upon local application to the eyes.



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**Dermal Sensitization:** Sensitization responses reported from application of a formulation containing 1% ephedrine in olive oil.

**Special Target Organ Effects:** In clinical use, ephedrine stimulates the sympathetic nervous system. It relaxes smooth muscle in the bronchi of the lungs, affects the heart, increases blood pressure and constricts some blood vessels while dilating others. Chronic nasal use can lead to chronic nasal congestion and personality changes in emotionally unstable people.

**Carcinogenicity Information:** Ephedrine sulfate was negative in NTP studies in rats and mice at diet concentrations up to 250 ppm.

### Section 11 - REGULATORY and ECOLOGICAL INFORMATION

**Ecotoxicity:** ND

**BOD<sub>5</sub> and COD:** NA

**Other Information:**

Legend: NA = Not Applicable  
ND = Not Determined  
NE = Not Established

**The information given herein is in good faith and to the best of our knowledge but no warranty, expressed or implied, is made.**