

Material Safety Data Sheet

Amikacin Sulfate Injection, USP

1. PRODUCT AND COMPANY IDENTIFICATION

Common name : Amikacin Sulfate Injection, USP
Category : Antibiotic
Manufacturer : Emcure Pharmaceuticals Limited
(Sterile Products Division)
Plot No.- P-1, I.T.B.T. Park, Phase – II
M.I.D.C Hinjwadi
Pune-411057 (Maharashtra State)
INDIA
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2. HAZARDS IDENTIFICATION

Emergency Overview : This material may cause hearing loss and impaired balance. It may be absorbed in toxic amounts through damaged skin. It may cause numbness, rash, and eye irritation.

Occupational Exposure Potential : Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms : No signs or symptoms from occupational exposure are known. Clinical data suggest the following: rashes, hearing loss, changes in equilibrium, numbness, dizziness, vertigo, tinnitus and increased BUN are reported.

Medical Conditions Aggravated by Exposure : Medical conditions exacerbated due to exposure to the following organs kidney, ears/auditory system. Hypersensitivity to the material and/or similar materials.

3. COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS#	Qty per mL	EXPOSURE LIMITED IN AIR				
			ACGIH		OSHA		Other
			TLV	STEL	PEL	STEL	
Amikacin Sulfate, USP	39831-55-5	250.0 mg	NE	NE	NE	NE	NE
Sodium Citrate Dihydrate, USP	18996-35-5	25.0 mg	NE	NE	NE	NE	NE
Sodium Metabisulfite, USP	7681-57-4	6.6 mg	5 mg/m ³	NE	NE	NE	NE
Activated Charcoal USP	7440-44-0	Q.S.	NE	NE	NE	NE	NE
Sulfuric acid USP	7664-93-9	Q.S.	NE	NE	NE	NE	NE
Water	7732-18-5	Balance	NE	NE	NE	NE	NE

NE - Not Established Q.S. – Quantity Sufficient

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1 format

CHEMTREC NUMBER: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this drug.

4. FIRST AID MEASURES

- 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.
- Skin 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.
- Inhalation** : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.
- Ingestion** : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.

5. FIRE FIGHTING MEASURES

- Flammability** : Non-flammable.
- Fire & Explosion Hazard** : None
- Extinguishing Media** : Use extinguishing media appropriate for primary cause of fire.
- Special Fire Fighting Procedures** : No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

- Release to Land** : Absorb Amikacin Sulfate with sorbent materials and dispose of according to local, state, and federal guidelines.
- Release to Air** : If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation.
- Release to Water** : Refer to local water authority. Drain disposal is not recommended; however, refer to local, state, and federal disposal guidelines.

7. HANDLING AND STORAGE

- Work and Hygiene Practices** : As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:
- Withdrawal of needles from drug vials.
 - Drug transfers using syringes and needles or filter straws.
 - Expulsion of air from drug-filled syringes.
- Storage and Handling Practices** : Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Protect from

light.

Protective Practices During Maintenance of Contaminated Equipment : When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipments with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure limits		
	OSHA-PEL	ACGIH-TLV	Hospira EEL
Amikacin Sulfate	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 1 mg/m ³ STEL: Not Established

OSHA PEL : US Occupational Safety and Health Administration – Permissible Exposure Limit

ACGIH TLV : American Conference of Governmental Industrial Hygienists – Threshold Limit Value.

EEL : Employee Exposure Limit.

TWA : 8 hour Time Weighted Average.

STEL : 15-minute Short Term Exposure Limit.

Respiratory Protection : Respiratory protection is not needed during normal product use.

Skin Protection : If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.

Eye Protection : Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.

Engineering Controls : Engineering controls are not needed during normal product use conditions.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State : Liquid

Appearance and Odor : Clear, odorless, aqueous solution

Boiling Point : 100°C (approx.) with no odour

Vapor Pressure : Approximate to water
Vapor Density : Approximate to water
Specific Gravity : Unknown
Melting Point : Not Applicable
Evaporation Rate : Unknown
Solubility in Water : Solution will mix with water
pH : Between 3.5 & 5.5

10. STABILITY AND REACTIVITY

Stability : Stable
Incompatibility : Strong oxidizers and water reactive materials
(Materials to Avoid)

Hazardous Decomposition: As with any burning material carbon monoxide, carbon dioxide, or **Byproducts** nitrogen oxides and sulfur oxides may be produced.

Hazardous Polymerization: Will not occur

Conditions to Avoid : Store away from oxidizers and water reactive materials.

11. TOXICOLOGICAL INFORMATION

Ingredient(s)	Percent	Test Type	Value	Units	Species
Amikacin	100	LD50 (iv)	4000	mg/kg	Rats
Sulfate			10,679	mg/kg	Mice
			3000	mg/kg	Rabbits

LD50 (iv) is the intravenous dosage that produces 50% mortality.

Mutagenicity : Not determined.

Target Organ Effects : In clinical use target organ effects include kidney and the ears. Amikacin sulfate, an aminoglycoside antibiotic, has the potential to cause kidney injury, hearing loss and changes in vestibular function and peripheral renal injury. These effects could also occur in the developing fetus.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity : Not Available

13. DISPOSAL CONSIDERATIONS

Preparing Wastes for Disposal : This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number : None

14. TRANSPORT INFORMATION

DOT : Not Regulated

Notes : DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status : Amikacin Sulfate is not listed on the TSCA inventory

CERCLA Status : Not Regulated

SARA Status : Not Regulated

RCRA Status : Not Regulated

PROP 65 (Calif.) : Amikacin Sulfate is identified in the state of California to cause reproductive toxicity.

Notes: TSCA Toxic Substance Control Act

CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act

SARA Superfund Amendments and Reauthorization Act

RCRA US EPA, Resource Conservation and Recovery Act

Prop 65, California Proposition 65

16. OTHER INFORMATION

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