



MATERIAL SAFETY DATA SHEET

Product Name: Amikacin Sulfate Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

**Manufacturer Name
And Address** Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA

**Emergency Telephone
Hospira, Inc.** CHEMTREC: 800 424-9300
224 212-2055

Product Name Amikacin Sulfate Injection, USP

Synonyms None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Amikacin Sulfate
Chemical Formula $C_{22}H_{47}N_5O_{21}S_2$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Amikacin Sulfate	5-25	39831-55-5	N/A
Water	75-95	7732-18-5	ZC0110000

3. HAZARD INFORMATION

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, dizziness, 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.

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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

Spill Cleanup and Disposal	Absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.
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7. HANDLING AND STORAGE

Handling	No special handling required.
Storage	No special storage required for hazard control. For product protection store unopened vials at controlled room temperature of 15-30 °C (59-86 °F).
Special Precautions	Protect from freezing and extreme heat.

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

Notes: 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.

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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/CHEMICAL PROPERTIES

Appearance/Physical State	Clear, colorless, to slight yellow solution
Odor	None
Boiling Point	Not Determined
Freezing Point	Not Determined
Vapor Pressure	Not Determined
Vapor Density (Air=1)	Not Determined
Evaporation Rate	Not Determined
Bulk Density	1.154 g/mL at 25 °C for the 250 mg/mL solutions
Specific Gravity	Not Determined
Solubility	Water soluble
pH	3.5 - 5.5

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under standard use and storage conditions.
Incompatibilities	None
Hazardous Decomposition Products	Oxides of sulfur and nitrogen
Hazardous Polymerization	Not Determined

11. TOXICOLOGICAL INFORMATION:

Toxicity

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

LD50 (iv) is the intravenous dosage that produces 50% mortality.
Product contains between 5-25% Amikacin Sulfate.

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.
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12. ECOLOGICAL INFORMATION:

Aquatic Toxicity Not Available

13. DISPOSAL CONSIDERATIONS:

Waste Disposal Disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal Dispose of container and unused contents in accordance with federal, state, and local regulations.

14. TRANSPORTATION 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:

MSDS Coordinator Global Occupational Toxicology
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