



300 Northfield Road
 Bedford, OH 44146
 Telephone: (440) 232-3320
 -or- (800) 562-4797

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Amikacin Sulfate Injection, USP 500mg/2ml
 Amikacin Sulfate Injection, USP 1 gram/4ml

Chemical Names: Amikacin

Synonyms: Amikin®, Amicacin, Antibiotic BB-K 8, BB-K 8

Manufacturer's Name: BEN VENUE LABORATORIES, INC.

Address: 300 NORTHFIELD ROAD
 BEDFORD, OH 44146

Emergency Telephone Number: Chemtrec: 1(800)424-9300

Telephone Number for Info.: (440)232-3320 or (800)562-4797

Medical Emergency: Professional Services 1(800)521-5169

Date Prepared: June 29, 1995

Date Revised: August 20, 2001

Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Amikacin Sulfate	25%	39831-55-5	NONE	NONE	0.3 mg/m ³ (Bristol-Myers
Sodium Metabisulfite	0.66%	25555-6	5mg/m ³	NONE	Squibb recommended
Sodium Citrate					concentration)
Dihydrate	2.5%	68-04-2	NONE	NONE	NONE
Sulfuric Acid for pH,					
neutralization	9.5425%	7664-93-9	1mg/m ³	1mg/m ³	NONE
Water for Injection	62.2975%	7732-18-5	NONE	NONE	NONE

Amikacin is a sterile injectable liquid drug provided in a vials.

Section III - HEALTH HAZARD DATA

Routes of Entry: Under normal use, Amikacin Sulfate presents little hazard. Amikacin Sulfate is not readily absorbed through intact skin. Amikacin Sulfate is poorly absorbed into the intestinal tract.

Health Hazard (Acute & Chronic): Amikacin is used for the short-term treatment of serious infections due to susceptible strains of gram-negative bacteria. Acute effects of ingestion include nausea, vomiting, and diarrhea. Acute effects of dermal and inhalation may include hearing loss, kidney toxicity, neuromuscular blockade. Allergic reactions in persons sensitive to aminoglycosides and Sodium Metabisulfite. Allergic reaction symptoms include redness, itching, and rash.

Carcinogenicity: NTP? NO **IARC Monographs?** None

OSHA Regulated? NO

Signs & Symptoms of Exposure: Excessive exposures may produce hearing loss, kidney/urination difficulties and irritation of the skin, eyes, and respiratory tract.

Medical Conditions Generally Aggravated by Exposure: May aggravate impaired hearing, certain kidney disorders, neuromuscular disorders, and allergies to aminoglycosides.

BVL Hazard Category: 2

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes.

Skin Exposure: Wash skin with cool soapy water for 15 minutes.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately.

If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

Inhalation: If difficulty breathing, administer oxygen. Seek attention of a physician immediately.

If necessary, provide artificial respiration.

If over-dosage/over-exposure occurs, peritoneal dialysis or hemodialysis will aid in the removal of Amikacin from the blood.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not applicable

Flammable Limits: LEL: Not Applicable UEL: Not Applicable

Extinguishing Media: Use water or a type ABC multi-purpose extinguisher

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous based and is not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards: NONE

Section VI - ACCIDENTAL RELEASE INFORMATION

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.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above. Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

Waste Disposal Method: Incineration in approved incinerator is recommended. Refer to local, state, and federal rules.

Precautions to be taken in handling and storing: Store at controlled room temperature 15°-30°C (59°-86°F).

Other Precautions: None

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators not required. If aerosols are generated, use a disposable dust/mist respirator (N95). Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Ventilation: Handle product in a well ventilated area.

Protective Gloves: Latex or nitrile

Eye Protection: Safety glasses

Other Protective Clothing or Equipment: Lab Coat

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking while handling product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Liquid

Appearance and Odor: Clear, odorless, aqueous solution

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

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: 4.5

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

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

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

Hazardous Polymerization: Will not occur

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

Section XI - TOXICOLOGICAL INFORMATION

For Amikacin Sulfate (active ingredient)

LD₅₀ rat oral 4,000 mg/kg

LD₅₀ mouse, intraperitoneal = 750 mg/kg

LD₅₀ mouse, oral = >6 gm/kg

LD₅₀ mouse, subcutaneous = 6200 mg/kg

LD₅₀ mouse, intravenous = 280 mg/kg

LD₅₀ mouse, intramuscular = 6200 mg/kg

Additional toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Amikacin. Handle in a manner that prevents spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of by incineration at an approved/permitted incinerator.
Review local, state, and federal regulations for your regulatory area.

Section XIV - TRANSPORTATION INFORMATION

Amikacin Sulfate Injection, USP is not a DOT Hazardous Material.
Amikacin Sulfate is not a Marine Pollutant

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO
CERCLA listed?: NO
RCRA listed?: NO
Amikacin is listed on the California Proposition 65 List as Code D

Section XVI - OTHER DATA

1. Aminoglycosides are not recommended for use during pregnancy since one of these in this class has been shown to cause deafness in children whose mothers used the drug during pregnancy.
See the package insert provided with the product.
2. Store Amikacin Sulfate Injection at temperatures less than 40°C.
3. Use of this product should be through or under the direction of a physician.
This MSDS does not address the therapeutic use of this material.
4. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.

The information provided is believed to be complete and accurate. It is the user's responsibility to use the information according to their application. Bedford Laboratories and Ben Venue Labs, Inc. assumes no additional liability or responsibility resulting from the use of or reliance on this information.