



MATERIAL SAFETY DATA SHEET

SECTION 1 - PRODUCT & COMPANY IDENTIFICATION

1501 East Woodfield Road **Emergency Telephone** **(800) 551-7176**
Suite 300 East
Schaumburg, IL 60173
(847) 969-2700

Product Identifier: Tobramycin Injection, USP
Chemical Name: Tobramycin Sulfate
Category: Anti-Infective

SECTION 2 - COMPOSITION

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Tobramycin Sulfate	32986-56-4	Available as 10 mg/ mL and 40 mg/mL
Phenol	108-95-2	5 mg/mL (Not present in Pharmacy Bulk Package)
Sodium Metabisulfite	7681-57-4	3.2 mg/mL
Edetate Disodium	139-33-3	0.1 mg/mL
Water for Injection	7732-18-5	QS

SECTION 3 - HAZARDS IDENTIFICATION

Route of Entry: Inhalation, eye/skin contact, or ingestion

**Chemical Listing as
Carcinogen**

NTP: No

IARC: No

OSHA: No

Note: NA

SECTION 4 - EMERGENCY & FIRST AID MEASURES

Eyes: Immediately flush eyes with water for at least 15 minutes. Seek medical attention.

Skin: Remove contaminated clothing immediately. Thoroughly wash area with soap and water. Seek medical attention.

SECTION 4 - EMERGENCY & FIRST AID MEASURES...continued

Inhalation: Remove to fresh air immediately. Observe individual(s) for signs and symptoms of respiratory distress (coughing, labored breathing, etc.) and systemic effects (see Section 11). Administer artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

Ingestion: Flush mouth out with water immediately. Provide supportive treatment. Seek medical attention.

Contact Info: For Adverse Event Information, please call (800) 551-7176 or (847) 969-2700.

SECTION 5 - FIRE FIGHTING MEASURES

Fire and Explosion Data

Closed Cup Flash Point: NA

Open Cup Flash Point: NA

Fire Point: NA

Autoignition: NA

Lower Explosion Limit: NA

Upper Explosion Limit: NA

General Hazard: When heated to decomposition, toxic fumes may be emitted.

Fire Fighting Instructions: Evacuate personnel to a safe area. Use water as appropriate to the surrounding fire.

Fire Fighting Equipment: Wear self-containing breathing apparatus and protective clothing.

Hazardous Combustion Products: Thermal decomposition or burning may produce noxious products including carbon monoxide, carbon dioxide, and nitrogen oxides.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Clean-Up: Wear recommended personal protective equipment (See Section 8 - Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.

SECTION 7 - HANDLING AND STORAGE

- General Handling:** When handling pharmaceutical products, avoid all contact with skin, eyes, nostrils, and mouth. Avoid inhalation of dust, fumes, mist, and/or vapors.
- Storage Conditions:** Store at controlled room temperature 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature].

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

- Engineering Controls:** Use local exhaust ventilation if necessary.
- Personal Protective Equipment**
- Eye Protection:** Safety glasses or goggles recommended.
- Hand Protection:** Disposable latex gloves recommended.
- Respiratory Protection:** With satisfactory ventilation, respiratory protection is usually not required.
- Skin Protection:** Disposable garments if direct skin contact is anticipated.

Exposure Limits:

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Tobramycin Sulfate	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Phenol	OSHA	PEL	19 mg/m ³ (5.0 ppm)
	ACGIH	TLV	19 mg/m ³ (5.0 ppm)
	---	STEL	NE
Sodium Metabisulfite	OSHA	PEL	5.0 ppm
	ACGIH	TLV	5.0 ppm
	---	STEL	NE
Edetate Disodium	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

- Physical Form/Appearance:** Clear and colorless solution.
- Boiling Point/Boiling Range:** Approximately 100°C

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES...continued

Melting Point/Melting Range:	Approximately 0°C
Freezing Point:	NA
Vapor Pressure :	NA
Relative Vapor Density:	NA
Percent Volatiles:	NA
pH:	3.0-6.5
Molecular Weight:	1425.45
Solvent Solubility:	Miscible in water
Note:	NA

SECTION 10 - STABILITY AND REACTIVITY

Stability:	Stable under most conditions. Thermal decomposition or burning may produce noxious products including carbon monoxide, carbon dioxide, and nitrogen oxides.
Conditions to Avoid:	None
Hazardous Polymerization:	Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Signs & Symptoms of Exposure & Overexposure:	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. The severity of the signs and symptoms following a tobramycin overdose are dependent of the dose administered, the patient's renal function, state of hydration, and age and whether or not other medications with similar toxicities are being administered concurrently. Side effects from therapeutic doses include neurotoxicity (auditory and vestibular ototoxicity), nephrotoxicity, hematologic toxicity (anemia, granulocytopenia, etc), and laboratory abnormalities. Occupational exposure has not been fully investigated.
Medical Conditions Aggravated by Accidental Exposure:	Individuals with a history of previous hypersensitivity or toxic reaction to any aminoglycoside. This product contains sodium metabisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. Concurrent and sequential use of other neurotoxic and/or nephrotoxic antibiotics particularly other aminoglycosides (amikacin, gentamicin, etc), polymyxin B, colistin, cisplatin, and vancomycin should be avoided. Other factors that may increase risk are advanced age and dehydration.

SECTION 11 - TOXICOLOGY INFORMATION...continued

Acute Toxicity:

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Tobramycin Sulfate	LD ₅₀	Oral	Mouse	>10,500 mg/kg
	LD ₅₀	SC	Rat	1,680 mg/kg
	LD ₅₀	IV	Rat	126 mg/kg
	LD ₅₀	IP	Mouse	262 mg/kg
	LD ₅₀	SC	Mouse	560 mg/kg
	LD ₅₀	IV	Mouse	77 mg/kg

Other: NA

SECTION 12 - TRANSPORTATION INFORMATION

UN/NA Number: NA

U.S. DOT Hazard Class: NA

Proper Shipping Name: NA

Shipping Label: NA

SECTION 13 - DISPOSAL INFORMATION

Disposal Procedure: Treatment, storage, transportation, and disposal must be in accordance with applicable federal, state, and local regulations.

SECTION 14 - OTHER

Key to Abbreviations: ACGIH - American Conference of Governmental Industrial Hygienists
HEPA - High Efficiency Particulate Air
IARC - International Agency for Research on Cancer
NA - Not Applicable
NE - Not Established
NG - Not Given
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OEL - Occupational Exposure Limit
OSHA - Occupational Safety and Health Administration
PEL - Permissible Exposure Limit
PPM - Parts Per Million
QS - Quantity Sufficient
RCRA - Resource Conservation and Recovery Act
STEL - Short Term Exposure Limit
TLV - Threshold Limit Value
USP - United States Pharmacopeia

SECTION 14 - OTHER...continued

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