BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

Issued:	09/07/94	Prepared by:	Gary Wong
Revised:	01/29/02		Manager EHS
Revision:	01	Core No. 242	

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Tobramycin Ophthalmic Solution USP, 0.3%
Generic Name: Same
NDC No. 24208-290-05 (5 ml)

Legal Category: Prescription only medicine, filled inside plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.

Drug Composition: Aminoglycoside antibiotic/antibacterial

BAUSCH & LOMB PHARMACEUTICALS, INC.
8500 Hidden River Parkway
Tampa, FL 33637
Information: (800) 323-0000 (M-F) 8am-5pm EST
Emergency: (800) 227-1427 24 hrs

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description	CAS #	TLV (mg/m^3)	PEL(mg/m^3)	% Content
Tobramycin	32986-56-4	NE	NE	0.3
Boric Acid	10043-35-3	NE	NE	$\geq$1
Purified Water	7732-18-5	NE	NE	$\geq$1

Ingredients <1% - Sodium Chloride, Sodium Sulfate Decahydrate, Tyloxapol, Benzalkonium Chloride

3. HAZARDS IDENTIFICATION

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EMERGENCY OVERVIEW

Plastic bottle packed in a cardboard carton. Clear, colorless to pale yellow, solution.

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POTENTIAL HEALTH HAZARDS

Carcinogenicity: **(NTP)** No **(IARC)** No **(OSHA)** No

Eye: This is an ophthalmic preparation. May cause irritation and hypersensitivity in some individuals. Adverse reactions include localized ocular toxicity, lid itch and swelling and redness of the mucous membrane of the eye (conjunctival erythema). These reactions occur in less than 3% of patients. Signs of overdose of Tobramycin Ophthalmic Solution include inflammation of the cornea (punctate keratitis), erythema, increased tearing (lacrimation), swelling (edema) and lid itching.

Skin: May cause irritation. Repeated or prolonged contact can induce hypersensitivity (anaphylactic) in some individuals.

Ingestion: May cause irritation and hypersensitivity in some individuals. Ingestion of large quantities can cause nausea and vomiting.

Inhalation: May cause irritation to the respiratory tract and hypersensitivity in some individuals.

Chronic Effects: May cause irritation and hypersensitivity (anaphylactic) in some individuals. Prolonged use of topical antibiotics can give rise to overgrowth of nonsusceptible organisms, including fungi. Bacterial resistance to tobramicin may also develop.

Target Organs: Eyes, skin and digestive tract.

Medical Conditions Aggravated by Long Term Exposure: Allergies to aminoglycoside antibiotics or any component of the product. As with other antibiotic preparations, prolonged use may result in overgrowth of other nonsusceptible organisms, including fungi. ppropriate measures should be taken if this occurs. Reproduction studies, in three different types of animals, at doses up to thirty-three times the normal human systemic dose have revealed no evidence of impaired fertility or harm to the fetus due to tobramycin. There are no adequate and well controlled studies in pregnant women. Tobramycin should be used in pregnancy

only if the potential benefits justify the risk to the fetus. Because of the potential for adverse reactions in nursing infants from Tobramycin Ophthalmic Solution, a decision should be made whether to discontinue nursing the infant or discontinue taking the drug, taking into account the importance of the drug to the mother.

4. FIRST AID MEASURES

Eyes: If not prescribed this medication, rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

Skin: Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.
Ingestion: Wash out mouth and give plenty of water and bland fluids. Seek professional assistance.

Inhalation: Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician immediately.

Note to Physicians: Erythromycin is excreted in breast milk, so caution should be exercised when administered to nursing mothers.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Toxic Fumes.

Extinguishing Media: Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.

Fire Fighting Instructions: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

6. ACCIDENTAL RELEASE MEASURES

Large/Small Spills: Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

7. HANDLING AND STORAGE

Handling: Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the

clinical or home environment.

Storage: Store product upright in original containers with the cap tightly closed at a controlled room temperature 15^0-30^0 C (59^0- 86^0 F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Engineering Controls: In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

Eye Protection: (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

Skin Protection: Thick impermeable gloves and protective clothing.

Respiratory Protection: (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials. **Warning: Do not use air purifying respirators in oxygen depleted environments**. No respiratory protection is required in the clinical or home environment.

Other: None

Ventilation: Recommended

Contaminated Equipment: Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

9. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor:	Clear, colorless, to pale yellow solution.		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Miscible	Percent Volatile by Volume:	<1

10. STABILITY AND REACTIVITY

Chemical Stability: Stable

Conditions to avoid: Extreme heat or cold.

Incompatibility: This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

Hazardous Decomposition Products: Emits toxic fumes.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

Summary of Risks: Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material.

CAS #

32986-56-4 **Tobramycin**
May cause irritation to the eyes, skin and respiratory tract. Can cause hypersensitivity (anaphylactic) in some individuals. May cause localized ocular toxicity including itching, swelling and conjunctival erythema. Intravenous-rat LD_{50} 104 mg/kg.

10043-35-3 **Boric Acid**
Inhalation may cause coughing and chest discomfort. Prolonged skin contact can cause burns and sensitization. Ingestion can cause nausea and vomiting. Swallowing large quantities may be fatal and chronic exposure can cause central nervous system stimulation and skin redness or rash. Oral-rat LD_{50} 2660 mg/kg, Inhalation-rat LC_{50} >16 mg/L.

12. ECOLOGICAL INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible impact on the environment.

13. DISPOSAL INFORMATION

Dispose of material according to Federal, State, and Local regulations.
The method typically used is incineration.

EPA Designations: RCRA Hazardous Waste: Not Listed

SARA Title III: Not Listed

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations.

EPA Designations: RCRA Hazardous Waste
(40 CFR 261.33) Not Listed

FDA Designations: Prescription only medication.
NDC No. 24208-290-05 (5 ml)

OSHA Designations: (29 CFR 1910.1000, Table Z)
Not Listed

SARA Title III: Not listed under Section 313 of Toxic Release Reporting.

CALIFORNIA PROPOSITION 65: Not Listed

16. OTHER INFORMATION

None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NA – Not Applicable
NE - Not Established
< - Less Than
> - Greater Than