



**Tobramycin and Dexamethasone Ophthalmic Suspension USP,  
0.3%/0.1% (Sterile)**

**MATERIAL SAFETY DATA SHEET**

Effective Date: 12/16/08 Supersedes: None

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**Section 1: IDENTIFICATION**

**PRODUCT:**

**Product Name:** Tobramycin and Dexamethasone Ophthalmic Suspension USP, 0.3%/0.1% (Sterile)  
**Product Description:** Multiple dose antibiotic and steroid combination  
**Product Code(s):**  
**NDC No(s):** NDC 24208-295-25 (2.5mL)  
NDC 24208-295-05 (5 mL)  
NDC 24208-295-10 (10 mL)  
**Intended Use:** For topical ophthalmic use

**COMPANY IDENTIFICATION:**

Bausch & Lomb, Incorporated  
1400 N. Goodman Street  
Rochester, New York 14609

**For Information:** 1-800-553-5340

**EMERGENCY TELEPHONE NUMBER:**

**24-Hour Emergency:** 1-800-535-5053

**Section 2: HAZARD(S) IDENTIFICATION**

**EMERGENCY OVERVIEW**

**Caution!! Pharmacologically Active Material.** Tobramycin and Dexamethasone Ophthalmic Suspension USP, 0.3%/0.1% (Sterile) is a multiple dose antibiotic and steroid combination for topical ophthalmic use. **Do Not Use if there exists hypersensitivity to any ingredient in this product. WARNING: Keep out of reach of children.**

**PRECAUTIONS:**

**Caution!! Pharmacologically Active Material.** Tobramycin and dexamethasone ophthalmic suspension is indicated for steroid responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. **FOR TOPICAL OPHTHALMIC USE ONLY. NOT FOR INJECTION INTO THE EYE.** Sensitivity to topically applied aminoglycosides may occur in some patients. If a sensitivity reaction does occur, discontinue use. If you are sensitive to any of its components, do not use. Use only in accordance with label instructions and supplied product literature.

**KEEP OUT OF REACH OF CHILDREN.**

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<b>Section 2: HAZARDS IDENTIFICATION (cont.)</b>
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**POTENTIAL HEALTH EFFECTS**

**EYE:**

The most frequent adverse reactions to topical ocular tobramycin are hypersensitivity and localized ocular toxicity, including lid itching and swelling, and conjunctival erythema. Refer to product literature for additional information.

**SKIN:**

Not expected to be irritating to skin or mucous membranes when used as directed.

**INGESTION:**

Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.

**INHALATION:**

Not expected to be a significant exposure route. Vapor or mist may be irritating to mucous membranes and upper respiratory tract.

**CHRONIC HEALTH EFFECTS**

Refer to the product literature for all product warnings.

**CARCINOGENICITY / MUTAGENICITY:**

No studies have been conducted to evaluate the carcinogenic or mutagenic potential of Tobramycin and Dexamethasone Ophthalmic Suspension USP, 0.3%/0.1% (Sterile)

**NTP:** NA

**IARC:** NA

**OSHA:** NA

**IMPAIRMENT OF FERTILITY:**

No impairment of fertility was noted in studies of subcutaneous tobramycin in rats at doses of 50 and 100 mg/kg/day.

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**Section 3: COMPOSITION / INFORMATION ON INGREDIENTS**

**Reportable Hazardous Substances:**

<b>CAS #</b>	<b>Chemical Identity</b>	<b>% W/W</b>
32986-56-4	Tobramycin, USP	0.3
50-02-2	Dexamethasone, USP	0.1
8001-54-5	Benzalkonium Chloride Solution, NF 50%	0.01
25301-02-4	Tyloxapol, USP	Trade Secret
6381-92-6	Edetate Disodium Dihydrate, USP	Trade Secret
7647-14-5	Sodium Chloride	Trade Secret
9004-62-0	Hydroxyethyl Cellulose, NF	Trade Secret
7757-82-6	Sodium Sulfate (Anhydrous), USP	Trade Secret
7732-18-5	Purified Water, USP	Balance

pH balanced with Sodium Hydroxide and/or Sulfuric Acid.

**Section 4: FIRST AID MEASURES**

**INHALATION:**

Normal use of this product does not pose an inhalation hazard. However, should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.

**SKIN CONTACT:**

Should irritation develop, discontinue use. Wash affected skin thoroughly with soap and water. Get medical attention if irritation or other symptoms develop or persist.

**EYE CONTACT:**

Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Get medical attention.

**INGESTION:**

If swallowed, DO NOT induce vomiting. Seek medical attention immediately.

**Section 5: FIRE FIGHTING MEASURES**

**EXTINGUISHING MEDIA:**

Carbon dioxide, dry chemical powder, appropriate foam or water fog.

**HAZARDOUS COMBUSTION PRODUCTS:**

During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.

**SPECIAL FIRE FIGHTING INSTRUCTIONS:**

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**Section 5: FIRE FIGHTING MEASURES (cont.)**

As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

**Section 6: ACCIDENTAL RELEASE MEASURES**

**PERSONAL PRECAUTIONS:**

Wear suitable protective eyewear, clothing, respiratory protection, rubber boots and rubber gloves. Shut off all sources of ignition. Evacuate immediate area. Ensure adequate ventilation. Refer to Sections 7 and 8.

**ENVIRONMENTAL PRECAUTIONS:**

Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

**METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:**

**Large Spill** ( $\geq$  4 liters):

Isolate hazard area. Prevent from entering drains and sewers. Cover with vermiculite or other suitable inert material, pick up and place in closed containers. Transport outdoors and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete.

**Small Spill** (< 4 liters):

Isolate hazard area. Prevent from entering drains and sewers. Cover with vermiculite or other suitable inert material, pick up and place in closed containers. Transport outdoors and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete.

Refer to Section 13 for appropriate disposal procedures.

**Section 7: HANDLING AND STORAGE**

**HANDLING:**

Use only in accordance with label instructions and supplied product literature.

Bulk Operations

Avoid contact with eyes. Avoid prolonged or repeated exposure to skin or mucous membranes, and breathing mists/vapors. Use in a well ventilated area, away from all ignition sources. Wash thoroughly with soap and water after handling.

**STORAGE:**

Store upright at 20° - 25°C (68° - 77°F) [See USP Controlled Room Temperature]. Shake well before using.

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**Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

**CONTROL PARAMETERS:**

CAS #	COMPONENT NAME	OCCUPATIONAL EXPOSURE LIMITS / GUIDELINES										UNITS	
		OSHA PEL TWA /STEL	ACGIH TLV TWA /STEL	NIOSH REL TWA /STEL	IRELAND TWA /STEL	HSE TWA /STEL							
32986-56-4	Tobramycin, USP	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
50-02-2	Dexamethasone, USP	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
8001-54-5	Benzalkonium Chloride Solution, NF 50%	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
25301-02-4	Tyloxapol, USP	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
6381-92-6	Edetate Disodium Dihydrate, USP	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7647-14-5	Sodium Chloride	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
9004-62-0	Hydroxyethyl Cellulose, NF	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7757-82-6	Sodium Sulfate (Anhydrous), USP	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7732-18-5	Purified Water, USP	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA

N/E: Not Established

TWA: 8-Hour Time-Weighted Average

N/A: Not Applicable

ACGIH: American Conference of Governmental Industrial Hygienists

NIOSH: National Institute for Occupational Safety & Health

OSHA: Occupational Safety & Health Administration

PPM: Parts Per Million

STEL: Short-Term Exposure Limit

C: Ceiling Limit

REL: Recommended Exposure Limit

NOTE: Limits/standards shown for guidance only. Follow applicable regulations.

**ENGINEERING CONTROLS:**

Use with good general ventilation. No special controls required.

**RESPIRATORY PROTECTION:**

No special controls or personal protection required under conditions of intended use.

In the event of a spill, a NIOSH-certified air-purifying respirator with organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

**EYE PROTECTION:**

No special controls or personal protection required under conditions of intended use.

In the event of a spill, appropriate eye protection should be worn.

**SKIN PROTECTION:**

No special controls or personal protection required under conditions of intended use.

In the event of a spill, use rubber gloves.

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**Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION (cont.)**

**ADDITIONAL PROTECTIVE CLOTHING & EQUIPMENT:**

NA

**Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

<b>Physical State:</b>	Liquid
<b>Color:</b>	White suspension
<b>Odor:</b>	No Odor
<b>Odor Threshold:</b>	Not determined
<b>pH-Value:</b>	~ 5.8
<b>Melting Point:</b>	Not applicable
<b>Freezing Point:</b>	Not determined
<b>Initial Boiling Point:</b>	Not determined
<b>Flash Point:</b>	Not applicable
<b>Evaporation Rate:</b>	Not determined
<b>Flammability (solid,gas):</b>	Not applicable
<b>Explosion Limits:</b>	Not determined
<b>Vapor Pressure:</b>	Not determined
<b>Vapor Density:</b>	Not determined
<b>Specific Gravity (H<sub>2</sub>O=1):</b>	~ 1.00
<b>Solubility:</b>	Dexamethasone: Soluble in ethanol, acetone, chloroform
<b>Partition Coefficient:</b>	Not applicable
<b>Auto-Ignition Temperature:</b>	Not determined
<b>Decomposition Temperature:</b>	Not determined
<b>Viscosity:</b>	Not determined

**Section 10: STABILITY AND REACTIVITY**

**REACTIVITY:**

No known hazards.

**CHEMICAL STABILITY:**

Stable under normal conditions.

**POSSIBILITY OF HAZARDOUS REACTIONS:**

None are known.

**CONDITIONS TO AVOID:**

Excessive heat or cold. Refer to Section 7, Handling and Storage.

**INCOMPATIBLE MATERIALS:**

Refer to product literature.

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**Section 10: STABILITY AND REACTIVITY (cont.)**

**HAZARDOUS DECOMPOSITION:**

None known

**Section 11: TOXICOLOGICAL INFORMATION**

**RTECS No.: WK2100000**

**Tobramycin**

**Toxicity Data:** ORL-RAT LD50: 7500 MG/KG

**RTECS No.: TU3980000**

**Dexamethasone**

**Toxicity Data:** ORL-RAT LD50: >3 GM/KG

**RTECS No.: BO3150000**

**Benzalkonium Chloride**

**Toxicity Data:** ORL-RAT LD50: 240 MG/KG

**RTECS No.: SM9750000**

**Tyloxapol**

**Toxicity Data:** ORL-RAT LD50: > 5 GM/KG

**RTECS No.: AH4375000**

**Edetate Disodium Dihydrate**

**Toxicity Data:** ORL-RAT LD50: 2000 MG/KG

**RTECS No.: VZ4725000**

**Sodium Chloride**

**Toxicity Data:** ORL-RAT LD50: 3000 MG/KG

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**Section 11: TOXICOLOGICAL INFORMATION (cont.)**

**RTECS No.:** FJ5958000

**Hydroxyethyl Cellulose**

**Toxicity Data:** ORL-RAT LD50: Not Determined

**RTECS No.:** WE1650000

**Sodium Sulfate (Anhydrous)**

**Toxicity Data:** ORL-MOUSE LD50: 5989 MG/KG

**NOTE:** Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information.

**Section 12: ECOLOGICAL INFORMATION**

No specific ecological data are available for this product.

**Section 13: DISPOSAL CONSIDERATIONS**

All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the sole responsibility of the waste generator.

**Section 14: TRANSPORT INFORMATION**

	<b>US DOT</b>	<b>IATA</b>	<b>IMO</b>	<b>RID/ADR</b>	<b>Canadian DG</b>
<b>Shipping Name:</b>	Not Regulated	Not Regulated	No Information Available	No Information Available	No Information Available
<b>Hazard Class:</b>	NA	NA			
<b>UN Number:</b>	NA	NA			
<b>Package Group:</b>	NA	NA			

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.

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**Section 15: REGULATORY INFORMATION**

**OSHA HAZARD COMMUNICATION STANDARD (29 CFR 1910.1200):**

Tobramycin and Dexamethasone Ophthalmic Suspension USP, 0.3%/0.1% (Sterile) is considered hazardous under the Occupational Safety & Health Administration Hazard Communication Standard.

**TOXIC SUBSTANCE CONTROL ACT (TSCA):**

All components are listed or are exempt from listing on the TSCA Inventory.

**SARA TITLE III (Superfund Amendments and Reauthorization Act):**

SECTION 302 (Extremely Hazardous Substances):	No Components Listed
SECTION 311, 312 (Hazard Categories):	Acute, Chronic
SECTION 313 (Toxic Chemicals):	No Components Listed

**CALIFORNIA PROPOSITION 65:**

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels which would require a warning under the statute.

**Section 16: OTHER INFORMATION**

*To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb Incorporated nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Bausch & Lomb Incorporated or any of its subsidiaries be liable for any special, incidental or consequential damages.*