

# BAUSCH & LOMB

Pharmaceutical Division

## MATERIAL SAFETY DATA SHEET

Issued: 09/07/94  
Revised: 01/28/02  
Revision: 01

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Core No. 077

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Gentamicin Sulfate Ophthalmic Solution USP, 0.3%  
**Generic Name:** Same  
**NDC No.** 24208-580-60 ( 5ml)  
24208-580-64 (15ml)

**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 <sup>3</sup> )	PEL(mg/m <sup>3</sup> )	% Content
Gentamicin Sulfate	1405-41-0	NE	NE	0.3
Purified Water	7732-18-5	NE	NE	≥1

Ingredients <1% - Sodium Chloride, Sodium Phosphate, Benzalkonium Chloride

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### 3. HAZARDS IDENTIFICATION

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#### EMERGENCY OVERVIEW

Plastic bottle in a cardboard box. Clear, colorless, odorless solution. For eyes only.

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#### POTENTIAL HEALTH HAZARDS

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

**Eye:** May cause irritation and hypersensitivity (anaphylactic) in some individuals. May cause burning, swelling of the inner eyelid (non-specific conjunctivitis), conjunctival epithelial defects, and increased blood flow in the inner eyelid (conjunctival hyperemia). Other rare effects include an abnormal decrease in blood clotting platelets with hemorrhages (thrombocytopenic purpura) and hallucinations.

**Skin:** May cause irritation, and repeated or prolonged contact can induce hypersensitivity (anaphylactic) in some individuals.

**Ingestion:** May cause irritation and hypersensitivity in some individuals. Ingestion of large quantities may induce gastric disturbances.

**Inhalation:** May cause irritation and induce hypersensitivity in some individuals.

**Chronic Effects:** May cause irritation and hypersensitivity (anaphylactic) in some individuals. Prolonged use of topical antibiotics may give rise to overgrowth of nonsusceptible organisms, including fungi. Bacterial resistance to gentamicin may also develop. Bacterial and fungal corneal ulcers have developed during treatment with gentamicin ophthalmic preparations.

**Target Organs:** Eyes, kidneys 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. Appropriate measures should be taken if this occurs. Gentamicin has been shown to depress body weights, kidney weights and median glomerular counts in newborn rats when administered systemically to pregnant rats in daily doses. There are no adequate and well controlled studies in pregnant women, so gentamicin should be used only if the potential benefits justify the risk to the fetus.

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#### 4. FIRST AID MEASURES

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**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:** Not for injection into the eye or introduction into the anterior chamber of the eye.

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#### 5. FIRE FIGHTING MEASURES

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**Flammable Properties:** Flash point: NE Method: NE

**Hazardous Products:** Sulfur oxides (SO<sub>x</sub>), 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.

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#### 6. ACCIDENTAL RELEASE MEASURES

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**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.

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#### 7. HANDLING AND STORAGE

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**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<sup>0</sup>-30<sup>0</sup> C (59<sup>0</sup>- 86<sup>0</sup> F). **KEEP THIS AND ALL DRUGS**

**OUT OF THE REACH OF CHILDREN.**

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**8. EXPOSURE CONTROL/PERSONAL PROTECTION**

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**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.

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**9. CHEMICAL & PHYSICAL PROPERTIES**

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Appearance & Odor: Clear, colorless, odorless 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

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**10. STABILITY AND REACTIVITY**

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**Chemical Stability:** Stable

**Conditions to avoid:** Extreme heat or cold.

**Incompatibility:** This product has no incompatibilities except those of water e.g. strong acids, bases, alkali metals, alkali hydrides.

**Hazardous Decomposition Products:** Toxic fumes, sulfur oxides (SO<sub>x</sub>).

**Hazardous Polymerization:** Should not occur.

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## 11. TOXICOLOGY INFORMATION

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

CAS#

1405-41-0                      **Gentamicin Sulfate**

May cause irritation or allergic reactions by inhalation, ingestion, skin and eye contact. Should be avoided by persons with an allergy to aminoglycoside antibiotics.

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## 12. ECOLOGICAL INFORMATION

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

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## 13. DISPOSAL INFORMATION

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**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

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## 14. TRANSPORTATION INFORMATION

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**Transportation Data:**        Not classified as hazardous by DOT regulations.

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## 15. REGULATORY INFORMATION

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**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. 24208-580-60 ( 5 ml)  
NDC No. 24208-580-64 (15 ml)

BAUSCH & LOMB Pharmaceuticals Division  
MSDS: Gentamicin Sulfate Ophthalmic Solution USP , 0.3%

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

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

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## **16. OTHER INFORMATION**

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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.

NE- Not Established

< - Less Than

> - Greater Than