SAFETY DATA SHEETS

This SDS packet was issued with item:

078806885

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078840816 078876953 078934617

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078907833

BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

Issued:	09/07/94	Prepared by:	Gary Wong
Revised:	01/28/02		Manager EHS
Revision:	01	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^3)	PEL(mg/m^3)	% 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

3. HAZARDS IDENTIFICATION

****

EMERGENCY OVERVIEW

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

****

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.

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

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Hazardous Products: Sulfur oxides (SO_x), 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, 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

10. STABILITY AND REACTIVITY

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_x).

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

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.

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

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

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

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.

NE- Not Established
< - Less Than
> - Greater Than

Safety Data Sheet

BAUSCH + LOMB
See better. Live better.

Section 1: Identification

Product identifier

Product Name • **Gentamicin Sulfate Ophthalmic Solution**

Product Code • AB07707; AB07711; Core No. 077; NDC 24208-0580-60; NDC 24208-0580-64

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Finshed Pharmaceutical Product; Gentamicin sulfate ophthalmic solution is indicated in the topical treatment of ocular bacterial infections.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Bausch & Lomb

1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com

Telephone (General) • 1-800-553-5340

Emergency telephone number

Manufacturer • 1-800-535-5053 - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Eye Mild Irritation 2B
Skin Sensitization 1B

Label elements

UN GHS

WARNING

Precautionary statements

Prevention • Wash thoroughly after handling.
Wear protective gloves .

Response
- IF ON SKIN: Wash with plenty of soap and water.
  If skin irritation or rash occurs: Get medical advice/attention.
  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  If eye irritation persists: Get medical advice/attention.

Storage/Disposal
- Keep tightly closed. Store at room temperature 2-25ºC (36-77ºF), to maintain product integrity. use before expiration date marked on carton and/or container.

Other hazards

UN GHS
- No data available.

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	**Identifiers**	**%**	**Classifications According to Regulation/Directive**
Gentamicin, sulfate	**CAS:**1405-41-0 **EINECS:**215-778-9	0.3%	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A
Sodium Phosphate, Anhydrous Monobasic	**CAS:**7558-80-7 **EINECS:**231-449-2	< 1%	**UN GHS:** NDA
Sodium Phosphate, Anhydrous Dibasic	**EINECS:**231-448-7	< 1%	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A
Sodium chloride	**CAS:**7647-14-5 **EINECS:**231-598-3	< 1%	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Benzalkonium Chloride	**CAS:**139-07-1 **EINECS:**205-351-5	0.01%	**UN GHS:** NDA
Water	**CAS:**7732-18-5 **EINECS:**231-791-2	Balance	**UN GHS:** Classification criteria not met

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation
- No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention if cough or other symptoms develop.

Skin
- IF ON SKIN (and not prescribed): Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

Eye
- For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention.

Ingestion
- If swallowed, get medical help or contact a Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Other information

- Additional details are provided on the product packaging and/or the product insert.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media
- Water spray, carbon dioxide, dry chemical powder, or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media
- No data available.

Firefighting Procedures
- As in any fire, wear self-contained breathing apparatus and full protective gear.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards
- None known.

Hazardous Combustion Products
- None known.

Advice for firefighters

- No data available

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions
- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures
- No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available on the environmental impact of this product.

Methods and material for containment and cleaning up

Containment/Clean-up Measures
- Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Prohibited Materials
- None known.

Reference to other sections

- Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage

Precautions for safe handling

Handling
- When using this product: do not touch tip of container to any surface to avoid contamination, remove contact lenses before using, and always replace the cap after use. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

Storage
- No data available

Special Packaging Materials
- Maintain product in original container only.

Incompatible Materials or Ignition Sources
- None specified.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines
- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

Engineering Measures/Controls
- No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Respiratory
- No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, a NIOSH-certified air-purifying respirator equipped with HEPA -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/Face
- No special personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands
- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves.

Skin/Body
- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Thermal hazards
- None known.

General Industrial Hygiene Considerations
- Wash thoroughly with soap and water after handling.

Environmental Exposure Controls
- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Color	Not relevant
Odor	Not relevant	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	6.5 to 7.5
Specific Gravity/Relative Density	= 1.014	Density	Not relevant
Bulk Density	Not relevant	Water Solubility	Miscible
Solvent Solubility	Not relevant	Viscosity	Not relevant
Explosive Properties	Not relevant	Oxidizing Properties:	Not relevant
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant	VOC (Wt.)	Not relevant
Flammability			

Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- Stable under normal temperatures and pressures.

Chemical stability

- Stable when stored at room temperature 15-25ºC (59-77ºF). Use before expiration date marked on carton and/or container.

Possibility of hazardous reactions

- Will not occur.

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None known.

Hazardous decomposition products

- None known.

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Gentamicin, sulfate (0.3%)	1405-41-0	**Acute Toxicity:** Ingestion/Oral-Mouse LD50 • >11269 mg/kg
Sodium Phosphate, Anhydrous Monobasic (< 1%)	7558-80-7	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 8290 mg/kg
Sodium Phosphate, Anhydrous Dibasic (< 1%)	7558-79-4	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 17000 mg/kg
Sodium chloride (< 1%)	7647-14-5	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 3000 mg/kg
Benzalkonium Chloride (0.01%)	139-07-1	**Acute Toxicity:** Ingestion/Oral-Rat LD50 • 400 mg/kg

GHS Properties	Classification
Acute toxicity	**UN GHS** • Classification criteria not met
Aspiration Hazard	**UN GHS** • Classification criteria not met
Carcinogenicity	**UN GHS** • Classification criteria not met
Germ Cell Mutagenicity	**UN GHS** • Classification criteria not met
Skin corrosion/Irritation	**UN GHS** • Classification criteria not met
Skin sensitization	**UN GHS** • Skin Sensitizer 1B
STOT-RE	**UN GHS** • Classification criteria not met
STOT-SE	**UN GHS** • Classification criteria not met
Toxicity for Reproduction	**UN GHS** • Classification criteria not met

Respiratory sensitization	**UN GHS** • Classification criteria not met
Serious eye damage/Irritation	**UN GHS** • Eye Mild Irritation 2B

Potential Health Effects

Inhalation

Acute (Immediate)
- No hazard when used as directed.

Chronic (Delayed)
- No data available.

Skin

Acute (Immediate)
- Not expected to cause skin irritation.

Chronic (Delayed)
- No data available. Repeated or prolonged contact can induce hypersensitivity (anaphylactic) in some individuals.

Eye

Acute (Immediate)
- May cause mild irritation. Ocular burning and irritation.

Chronic (Delayed)
- No data available

Ingestion

Acute (Immediate)
- May be harmful if swallowed.

Chronic (Delayed)
- No data available.

Reproductive Effects
- Pregnancy Category C. 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 approximately 500 times the maximum recommended ophthalmic human dose. There are no adequate and well-controlled studies in pregnant women. Gentamicin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available.

Bioaccumulative potential

- No data available.

Mobility in Soil

- No data available.

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste
- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste
- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications • No data available

Inventory				
Component	**CAS**	**Canada DSL**	**EU EINECS**	**TSCA**
Benzalkonium Chloride	139-07-1	Yes	Yes	Yes
Gentamicin, sulfate	1405-41-0	No	Yes	No
Sodium Phosphate, Anhydrous Monobasic	7558-80-7	Yes	Yes	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Sodium Phosphate, Anhydrous Dibasic	7558-79-4	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Gentamicin, sulfate	1405-41-0	Not Listed
• Sodium Phosphate, Anhydrous Dibasic	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Benzalkonium Chloride	139-07-1	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Sodium Phosphate, Anhydrous Monobasic	7558-80-7	Uncontrolled product according to WHMIS classification criteria

United States

Environment

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• Gentamicin, sulfate	1405-41-0	Not Listed

• Sodium Phosphate, Anhydrous Dibasic	7558-79-4	5000 lb final RQ; 2270 kg final RQ
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate, Anhydrous Monobasic	7558-80-7	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Gentamicin, sulfate	1405-41-0	Not Listed
• Sodium Phosphate, Anhydrous Dibasic	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate, Anhydrous Monobasic	7558-80-7	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Gentamicin, sulfate	1405-41-0	Not Listed
• Sodium Phosphate, Anhydrous Dibasic	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate, Anhydrous Monobasic	7558-80-7	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Gentamicin, sulfate	1405-41-0	Not Listed
• Sodium Phosphate, Anhydrous Dibasic	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate, Anhydrous Monobasic	7558-80-7	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Gentamicin, sulfate	1405-41-0	Not Listed
• Sodium Phosphate, Anhydrous Dibasic	7558-79-4	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium Chloride	139-07-1	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate, Anhydrous Monobasic	7558-80-7	Not Listed

Section 16 - Other Information

Last Revision Date
- 12/May/2015

Preparation Date
- 12/May/2015

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