

Safety Data Sheet**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** • Finished 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 2-25°C (36-77°F), 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 15-25°C (59-77°F). 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

Disclaimer/Statement of Liability

- 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.
