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.
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

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

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.

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### 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

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### 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.

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### 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
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.

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

<table>
<thead>
<tr>
<th>Material Description</th>
<th>Physical Form</th>
<th>Color</th>
<th>Odor</th>
<th>Odor Threshold</th>
<th>Not relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Properties</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| 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 | Vapor Density | Not relevant |
| Evaporation Rate | Not relevant | VOC (Wt.) | Not relevant |
| Flammability | Not relevant | Not relevant | Not relevant |
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

<table>
<thead>
<tr>
<th>Components</th>
<th>Acute Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin, sulfate (0.3%)</td>
<td>Ingestion/Oral-Mouse LD50 • &gt;11269 mg/kg</td>
</tr>
<tr>
<td>Sodium Phosphate, Anhydrous Monobasic (&lt; 1%)</td>
<td>Ingestion/Oral-Rat LD50 • 8290 mg/kg</td>
</tr>
<tr>
<td>Sodium Phosphate, Anhydrous Dibasic (&lt; 1%)</td>
<td>Ingestion/Oral-Rat LD50 • 17000 mg/kg</td>
</tr>
<tr>
<td>Sodium chloride (&lt; 1%)</td>
<td>Ingestion/Oral-Rat LD50 • 3000 mg/kg</td>
</tr>
<tr>
<td>Benzalkonium Chloride (0.01%)</td>
<td>Ingestion/Oral-Rat LD50 • 400 mg/kg</td>
</tr>
</tbody>
</table>

GHS Properties

<table>
<thead>
<tr>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
</tr>
<tr>
<td>Aspiration Hazard</td>
</tr>
<tr>
<td>Carcinogenicity</td>
</tr>
<tr>
<td>Germ Cell Mutagenicity</td>
</tr>
<tr>
<td>Skin corrosion/Irritation</td>
</tr>
<tr>
<td>Skin sensitization</td>
</tr>
<tr>
<td>STOT-RE</td>
</tr>
<tr>
<td>STOT-SE</td>
</tr>
<tr>
<td>Toxicity for Reproduction</td>
</tr>
<tr>
<td>Potential Health Effects</td>
</tr>
<tr>
<td>---------------------------------</td>
</tr>
<tr>
<td>Inhalation</td>
</tr>
<tr>
<td>Acute (Immediate)</td>
</tr>
<tr>
<td>Chronic (Delayed)</td>
</tr>
<tr>
<td>Skin</td>
</tr>
<tr>
<td>Acute (Immediate)</td>
</tr>
<tr>
<td>Chronic (Delayed)</td>
</tr>
<tr>
<td>Eye</td>
</tr>
<tr>
<td>Acute (Immediate)</td>
</tr>
<tr>
<td>Chronic (Delayed)</td>
</tr>
<tr>
<td>Ingestion</td>
</tr>
<tr>
<td>Acute (Immediate)</td>
</tr>
<tr>
<td>Chronic (Delayed)</td>
</tr>
<tr>
<td>Reproductive Effects</td>
</tr>
</tbody>
</table>

### 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
<table>
<thead>
<tr>
<th>UN number</th>
<th>UN proper shipping name</th>
<th>Transport hazard class(es)</th>
<th>Packing group</th>
<th>Environmental hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT</td>
<td>NDA</td>
<td>Not regulated</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>TDG</td>
<td>NDA</td>
<td>Not regulated</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>IMO/IMDG</td>
<td>NDA</td>
<td>Not regulated</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>IATA/ICAO</td>
<td>NDA</td>
<td>Not regulated</td>
<td>NDA</td>
<td>NDA</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS</th>
<th>Canada DSL</th>
<th>EU EINECS</th>
<th>TSCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzalkonium Chloride</td>
<td>139-07-1</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Gentamicin, sulfate</td>
<td>1405-41-0</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sodium Phosphate, Anhydrous Monobasic</td>
<td>7558-80-7</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sodium Phosphate, Anhydrous Dibasic</td>
<td>7558-79-4</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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
<table>
<thead>
<tr>
<th>Component</th>
<th>CAS Number</th>
<th>RQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Phosphate, Anhydrous Dibasic</td>
<td>7558-79-4</td>
<td>5000 lb final RQ; 2270 kg final RQ</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Benzalkonium Chloride</td>
<td>139-07-1</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sodium Phosphate, Anhydrous Monobasic</td>
<td>7558-80-7</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

### 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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