



## Safety Data Sheet

### Section 1: Identification

#### Product identifier

- Product Name** • Tobramycin Ophthalmic Solution
- Product Code** • AB24207; Core No. 242; NDC 24208-0290-05

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

- Recommended use** • Finished Pharmaceutical Product; Tobramycin Ophthalmic Solution is a topical antibiotic indicated in the treatment of external infections of the eye and its adnexa caused by susceptible bacteria.
- 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** • Classification criteria not met

#### Label elements

**UN GHS**

#### Precautionary statements

- Storage/Disposal** • Keep tightly closed and store in upright position.  
Store product at 2-25°C (36-77°F).  
Avoid excessive heat.  
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                |
| Benzalkonium Chloride 50% Solution | CAS:139-07-1<br>EINECS:205-351-5   | 0.01%    | UN GHS: NDA                                                      |
| Boric acid                         | CAS:10043-35-3<br>EINECS:233-139-2 | 1% TO 5% | UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5; Repr. 1 |
| Sodium chloride                    | CAS:7647-14-5<br>EINECS:231-598-3  | < 1%     | UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5          |
| Sodium Sulfate Decahydrate         | CAS:7727-73-3                      | < 1%     | UN GHS: Skin Irrit. 2; Eye Irrit. 2A                             |
| Tobramycin                         | CAS:32986-56-4<br>EINECS:251-322-5 | 0.3%     | UN GHS: NDA                                                      |
| Tyloxapol                          | CAS:25301-02-4                     | < 1%     | UN GHS: Skin Irrit. 2; Eye Irrit. 2A                             |
| Water                              | CAS:7732-18-5<br>EINECS:231-791-2  | Balance  | UN GHS: Classification criteria not met                          |

Sulfuric Acid (CAS:7664-93-9, EINECS:231-639-5) and/or Sodium Hydroxide (CAS# 1310-73-2, EINECS: 215-185-5) may be added to adjust the pH.

*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

- Refer to Section 5 Firefighting Procedures.

## 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** • Keep tightly closed. Store between 2-25°C (36-77°F), to maintain product integrity. use before expiration date marked on carton and/or container. Avoid excessive heat.

**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 Limits/Guidelines |        |                                                                             |
|----------------------------|--------|-----------------------------------------------------------------------------|
|                            | Result | ACGIH                                                                       |
| Boric acid<br>(10043-35-3) | STELs  | 6 mg/m3 STEL (inhalable fraction, listed under Borate compounds, inorganic) |
|                            | TWAs   | 2 mg/m3 TWA (inhalable fraction, listed under Borate compounds, inorganic)  |

### Exposure Control Notations

#### ACGIH

- Boric acid (10043-35-3): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (listed under Borate compounds, inorganic))

### 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            | Clear, colorless to pale yellow. |
| Odor                              | No odor.          | Odor Threshold   | Not relevant                     |
| General Properties                |                   |                  |                                  |
| Boiling Point                     | No data available | Melting Point    | Not relevant                     |
| Decomposition Temperature         | No data available | pH               | 7 to 8                           |
| Specific Gravity/Relative Density | = 1.009           | Water Solubility | Water soluble                    |
| Viscosity                         | No data available |                  |                                  |
| Volatility                        |                   |                  |                                  |

|                                     |                   |               |              |
|-------------------------------------|-------------------|---------------|--------------|
| Vapor Pressure                      | Not relevant      | Vapor Density | Not relevant |
| Evaporation Rate                    | No data available |               |              |
| <b>Flammability</b>                 |                   |               |              |
| Flash Point                         | Not relevant      | UEL           | Not relevant |
| LEL                                 | Not relevant      | Autoignition  | Not relevant |
| <b>Environmental</b>                |                   |               |              |
| 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

- Avoid exposure to extreme heat or cold.

### Incompatible materials

- None known.

### Hazardous decomposition products

- None known.

## Section 11 - Toxicological Information

### Information on toxicological effects

| Components                                 |            |                                                                                                                                              |
|--------------------------------------------|------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Tobramycin (0.3%)                          | 32986-56-4 | <b>Acute Toxicity:</b> Ingestion/Oral-Mouse LD50 • >11500 mg/kg                                                                              |
| Boric acid (1% TO 5%)                      | 10043-35-3 | <b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 2500 mg/kg; <i>Behavioral:Convulsions or effect on seizure threshold; Behavioral:Ataxia</i> |
| Sodium chloride (< 1%)                     | 7647-14-5  | <b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 3000 mg/kg                                                                                  |
| Tyloxapol (< 1%)                           | 25301-02-4 | <b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • >5 g/kg                                                                                     |
| Benzalkonium Chloride 50% Solution (0.01%) | 139-07-1   | <b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 400 mg/kg                                                                                   |

| GHS Properties                | Classification                           |
|-------------------------------|------------------------------------------|
| <b>Acute toxicity</b>         | UN GHS • Classification criteria not met |
| <b>Aspiration Hazard</b>      | UN GHS • Classification criteria not met |
| <b>Carcinogenicity</b>        | UN GHS • Classification criteria not met |
| <b>Germ Cell Mutagenicity</b> | UN GHS • Classification criteria not met |

|                                      |                                                 |
|--------------------------------------|-------------------------------------------------|
| <b>Skin corrosion/Irritation</b>     | <b>UN GHS • Classification criteria not met</b> |
| <b>Skin sensitization</b>            | <b>UN GHS • Classification criteria not met</b> |
| <b>STOT-RE</b>                       | <b>UN GHS • Classification criteria not met</b> |
| <b>STOT-SE</b>                       | <b>UN GHS • Classification criteria not met</b> |
| <b>Toxicity for Reproduction</b>     | <b>UN GHS • Classification criteria not met</b> |
| <b>Respiratory sensitization</b>     | <b>UN GHS • Classification criteria not met</b> |
| <b>Serious eye damage/Irritation</b> | <b>UN GHS • Classification criteria not met</b> |

## 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.

### Eye

- Acute (Immediate)**
  - May cause mild irritation. Clinically apparent signs and symptoms of an overdose of tobramycin ophthalmic solution (punctate keratitis, erythema, increased lacrimation, edema and lid itching).
- Chronic (Delayed)**
  - No data available

### Ingestion

- Acute (Immediate)**
  - May be harmful if swallowed.
- Chronic (Delayed)**
  - No data available.

| Carcinogenic Effects |            |                             |
|----------------------|------------|-----------------------------|
|                      | CAS        | NTP                         |
| Boric acid           | 10043-35-3 | Evidence of Carcinogenicity |

## 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 50% Solution | 139-07-1   | Yes        | Yes       | Yes  |
| Boric acid                         | 10043-35-3 | Yes        | Yes       | Yes  |
| Tyloxapol                          | 25301-02-4 | Yes        | No        | No   |
| Sodium chloride                    | 7647-14-5  | Yes        | Yes       | Yes  |
| Sodium Sulfate Decahydrate         | 7727-73-3  | No         | No        | No   |
| Tobramycin                         | 32986-56-4 | Yes        | Yes       | No   |
| Water                              | 7732-18-5  | Yes        | Yes       | Yes  |

## Canada

### Labor

#### Canada - WHMIS - Classifications of Substances

|                                      |            |                                                                 |
|--------------------------------------|------------|-----------------------------------------------------------------|
| • Sodium chloride                    | 7647-14-5  | Uncontrolled product according to WHMIS classification criteria |
| • Boric acid                         | 10043-35-3 | D2A                                                             |
| • Benzalkonium Chloride 50% Solution | 139-07-1   | Not Listed                                                      |
| • Sodium Sulfate Decahydrate         | 7727-73-3  | Not Listed                                                      |
| • Tyloxapol                          | 25301-02-4 | Not Listed                                                      |
| • Tobramycin                         | 32986-56-4 | Not Listed                                                      |
| • Water                              | 7732-18-5  | Uncontrolled product according to WHMIS classification criteria |

**Canada - WHMIS - Ingredient Disclosure List**

|                                      |            |            |
|--------------------------------------|------------|------------|
| • Sodium chloride                    | 7647-14-5  | Not Listed |
| • Boric acid                         | 10043-35-3 | 1 %        |
| • Benzalkonium Chloride 50% Solution | 139-07-1   | Not Listed |
| • Sodium Sulfate Decahydrate         | 7727-73-3  | Not Listed |
| • Tyloxapol                          | 25301-02-4 | Not Listed |
| • Tobramycin                         | 32986-56-4 | Not Listed |
| • Water                              | 7732-18-5  | Not Listed |

**Environment****Canada - CEPA - Priority Substances List**

|                                      |            |            |
|--------------------------------------|------------|------------|
| • Sodium chloride                    | 7647-14-5  | Not Listed |
| • Boric acid                         | 10043-35-3 | Not Listed |
| • Benzalkonium Chloride 50% Solution | 139-07-1   | Not Listed |
| • Sodium Sulfate Decahydrate         | 7727-73-3  | Not Listed |
| • Tyloxapol                          | 25301-02-4 | Not Listed |
| • Tobramycin                         | 32986-56-4 | Not Listed |
| • Water                              | 7732-18-5  | Not Listed |

**Europe****Other****EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification**

|                                      |            |                    |
|--------------------------------------|------------|--------------------|
| • Sodium chloride                    | 7647-14-5  | Not Listed         |
| • Boric acid                         | 10043-35-3 | Repr.Cat.2; R60-61 |
| • Benzalkonium Chloride 50% Solution | 139-07-1   | Not Listed         |
| • Sodium Sulfate Decahydrate         | 7727-73-3  | Not Listed         |
| • Tyloxapol                          | 25301-02-4 | Not Listed         |
| • Tobramycin                         | 32986-56-4 | Not Listed         |
| • Water                              | 7732-18-5  | Not Listed         |

**EU - CLP (1272/2008) - Annex VI - Table 3.2 - Concentration Limits**

|                                      |            |                             |
|--------------------------------------|------------|-----------------------------|
| • Sodium chloride                    | 7647-14-5  | Not Listed                  |
| • Boric acid                         | 10043-35-3 | 5.5%≤C: Repr.Cat.2; R:60-61 |
| • Benzalkonium Chloride 50% Solution | 139-07-1   | Not Listed                  |
| • Sodium Sulfate Decahydrate         | 7727-73-3  | Not Listed                  |
| • Tyloxapol                          | 25301-02-4 | Not Listed                  |
| • Tobramycin                         | 32986-56-4 | Not Listed                  |
| • Water                              | 7732-18-5  | Not Listed                  |

**EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling**

|                                      |            |                   |
|--------------------------------------|------------|-------------------|
| • Sodium chloride                    | 7647-14-5  | Not Listed        |
| • Boric acid                         | 10043-35-3 | T R:60-61 S:53-45 |
| • Benzalkonium Chloride 50% Solution | 139-07-1   | Not Listed        |
| • Sodium Sulfate Decahydrate         | 7727-73-3  | Not Listed        |
| • Tyloxapol                          | 25301-02-4 | Not Listed        |
| • Tobramycin                         | 32986-56-4 | Not Listed        |
| • Water                              | 7732-18-5  | Not Listed        |

**EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases**

|                                      |            |            |
|--------------------------------------|------------|------------|
| • Sodium chloride                    | 7647-14-5  | Not Listed |
| • Boric acid                         | 10043-35-3 | S:53-45    |
| • Benzalkonium Chloride 50% Solution | 139-07-1   | Not Listed |

|                              |            |            |
|------------------------------|------------|------------|
| • Sodium Sulfate Decahydrate | 7727-73-3  | Not Listed |
| • Tyloxapol                  | 25301-02-4 | Not Listed |
| • Tobramycin                 | 32986-56-4 | Not Listed |
| • Water                      | 7732-18-5  | Not Listed |

## United States

### Environment

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

|                                      |            |            |
|--------------------------------------|------------|------------|
| • Sodium chloride                    | 7647-14-5  | Not Listed |
| • Boric acid                         | 10043-35-3 | Not Listed |
| • Benzalkonium Chloride 50% Solution | 139-07-1   | Not Listed |
| • Sodium Sulfate Decahydrate         | 7727-73-3  | Not Listed |
| • Tyloxapol                          | 25301-02-4 | Not Listed |
| • Tobramycin                         | 32986-56-4 | Not Listed |
| • Water                              | 7732-18-5  | Not Listed |

## United States - California

### Environment

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

|                                      |            |            |
|--------------------------------------|------------|------------|
| • Sodium chloride                    | 7647-14-5  | Not Listed |
| • Boric acid                         | 10043-35-3 | Not Listed |
| • Benzalkonium Chloride 50% Solution | 139-07-1   | Not Listed |
| • Sodium Sulfate Decahydrate         | 7727-73-3  | Not Listed |
| • Tyloxapol                          | 25301-02-4 | Not Listed |
| • Tobramycin                         | 32986-56-4 | Not Listed |
| • Water                              | 7732-18-5  | Not Listed |

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

|                                      |            |            |
|--------------------------------------|------------|------------|
| • Sodium chloride                    | 7647-14-5  | Not Listed |
| • Boric acid                         | 10043-35-3 | Not Listed |
| • Benzalkonium Chloride 50% Solution | 139-07-1   | Not Listed |
| • Sodium Sulfate Decahydrate         | 7727-73-3  | Not Listed |
| • Tyloxapol                          | 25301-02-4 | Not Listed |
| • Tobramycin                         | 32986-56-4 | Not Listed |
| • Water                              | 7732-18-5  | Not Listed |

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

|                                      |            |            |
|--------------------------------------|------------|------------|
| • Sodium chloride                    | 7647-14-5  | Not Listed |
| • Boric acid                         | 10043-35-3 | Not Listed |
| • Benzalkonium Chloride 50% Solution | 139-07-1   | Not Listed |
| • Sodium Sulfate Decahydrate         | 7727-73-3  | Not Listed |
| • Tyloxapol                          | 25301-02-4 | Not Listed |
| • Tobramycin                         | 32986-56-4 | Not Listed |
| • Water                              | 7732-18-5  | Not Listed |

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

|                                      |            |            |
|--------------------------------------|------------|------------|
| • Sodium chloride                    | 7647-14-5  | Not Listed |
| • Boric acid                         | 10043-35-3 | Not Listed |
| • Benzalkonium Chloride 50% Solution | 139-07-1   | Not Listed |
| • Sodium Sulfate Decahydrate         | 7727-73-3  | Not Listed |
| • Tyloxapol                          | 25301-02-4 | Not Listed |
| • Tobramycin                         | 32986-56-4 | Not Listed |
| • Water                              | 7732-18-5  | Not Listed |

**Section 16 - Other Information**

|                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Last Revision Date</b>                | <ul style="list-style-type: none"><li>● 04/May/2015</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Preparation Date</b>                  | <ul style="list-style-type: none"><li>● 04/May/2015</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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