**Section 1: Identification**

**Product identifier**

- **Product Name**: Antipyrine, Benzocaine Otic Solution
- **Product Code**: AB12409; Core No. 124; NDC 24208-0561-62

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

- **Recommended use**: Finished Pharmaceutical Product; Prompt relief of pain and reduction of inflammation in the congestive and serous stages. Adjuvant therapy during systemic antibiotic administration for resolution of the infection. Facilitates the removal of excessive or impacted cerumen.

- **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 - Inforac

---

*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. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

**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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Identifiers</th>
<th>%</th>
<th>Classifications According to Regulation/Directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antipyrine</td>
<td>CAS:60-80-0</td>
<td>5.4%</td>
<td>UN GHS: NDA</td>
</tr>
<tr>
<td></td>
<td>EINECS:200-486-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzocaine</td>
<td>CAS:94-09-7</td>
<td>1.4%</td>
<td>UN GHS: NDA</td>
</tr>
<tr>
<td></td>
<td>EINECS:202-303-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycerine</td>
<td>CAS:56-81-5</td>
<td>&gt; 90%</td>
<td>UN GHS: Skin Irrit. 3; Eye Irrit. 2B</td>
</tr>
<tr>
<td></td>
<td>EINECS:200-289-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxyquinoline Sulfate</td>
<td>EINECS:205-137-1</td>
<td>&lt; 1%</td>
<td>UN GHS: Acute Tox. Oral 4</td>
</tr>
<tr>
<td>Water</td>
<td>CAS:7732-18-5</td>
<td>&lt; 1%</td>
<td>UN GHS: Classification criteria not met</td>
</tr>
<tr>
<td></td>
<td>EINECS:231-791-2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
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 at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light. 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.

<table>
<thead>
<tr>
<th>Exposure Limits/Guidelines</th>
<th>Result</th>
<th>Canada Quebec</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine (56-81-5) TWAs</td>
<td>10 mg/m³ TWA EV (mist)</td>
<td>15 mg/m³ TWA (mist, total particulate); 5 mg/m³ TWA (mist, respirable fraction)</td>
<td></td>
</tr>
</tbody>
</table>

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

- 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

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

General Properties

| Boiling Point         | No data available | Melting Point | Not relevant |
| Decomposition Temperature | No data available | pH | No data available |
| Specific Gravity/Relative Density | = 1.25 | Water Solubility | Soluble |
| Viscosity             | Not relevant | | |

Vapor Pressure        | Not relevant | Vapor Density | Not relevant |
Evaporation Rate       | No data available | | |

Flammability

| Flash Point          | Not relevant | UEL | Not relevant |
| Autoignition         | Not relevant | | |

Environmental

| Octanol/Water Partition coefficient | 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

- Avoid exposure to extreme heat or cold.

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: Ingestion/Oral-Mouse LD50</th>
<th>Acute Toxicity: Ingestion/Oral-Rat LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antipyrine (5.4%) 60-80-0</td>
<td>1310 mg/kg</td>
<td>1200 mg/kg</td>
</tr>
<tr>
<td>Benzocaine (1.4%) 94-09-7</td>
<td>2500 mg/kg; Behavioral: Ataxia; Lungs, Thorax, or Respiration: Cyanosis; Lungs, Thorax, or Respiration: Respiratory depression</td>
<td></td>
</tr>
<tr>
<td>Oxyquinoline Sulfate (&lt; 1%)</td>
<td>12600 mg/kg; Behavioral: General anesthetic; Behavioral: Muscle weakness; Liver: Other changes; Irritation: Eye-Rabbit • 500 mg 24 Hour(s) • Mild irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation</td>
<td></td>
</tr>
<tr>
<td>Glycerine (&gt; 90%) 56-81-5</td>
<td></td>
<td></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>Respiratory sensitization</td>
</tr>
<tr>
<td>Serious eye damage/Irritation</td>
</tr>
</tbody>
</table>
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.

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></th>
<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>
<td>NDA</td>
</tr>
<tr>
<td>TDG</td>
<td>NDA</td>
<td>Not regulated</td>
<td>NDA</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>
<td>NDA</td>
</tr>
</tbody>
</table>
IATA/ICAO | NDA | NDA | NDA | 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

<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>Oxyquinoline Sulfate</td>
<td>134-31-6</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Antipyrine</td>
<td>60-80-0</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Benzocaine</td>
<td>94-09-7</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</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

- Benzocaine 94-09-7 Not Listed Uncontrolled product according to WHMIS classification criteria
- Glycerine 56-81-5 Not Listed
- Antipyrine 60-80-0 Not Listed
- Oxyquinoline Sulfate 134-31-6 Not Listed Uncontrolled product according to WHMIS classification criteria
- Water 7732-18-5 Not Listed

Europe

Other

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

- Benzocaine 94-09-7 Not Listed
- Glycerine 56-81-5 Not Listed
- Antipyrine 60-80-0 Not Listed
- Oxyquinoline Sulfate 134-31-6 Xn; R22
- Water 7732-18-5 Not Listed

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

- Benzocaine 94-09-7 Not Listed
- Glycerine 56-81-5 Not Listed
- Antipyrine 60-80-0 Not Listed
- Oxyquinoline Sulfate 134-31-6 Xn R:22 S:(2)-36
- Water 7732-18-5 Not Listed

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

- Benzocaine 94-09-7 Not Listed
• Glycerine 56-81-5 Not Listed
• Antipyrine 60-80-0 Not Listed
• Oxyquinoline Sulfate 134-31-6 S;(2)-36
• Water 7732-18-5 Not Listed

United States

Environment

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

• Benzocaine 94-09-7 Not Listed
• Glycerine 56-81-5 Not Listed
• Antipyrine 60-80-0 Not Listed
• Oxyquinoline Sulfate 134-31-6 Not Listed
• Water 7732-18-5 Not Listed

United States - California

Environment

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

• Benzocaine 94-09-7 Not Listed
• Glycerine 56-81-5 Not Listed
• Antipyrine 60-80-0 Not Listed
• Oxyquinoline Sulfate 134-31-6 Not Listed
• Water 7732-18-5 Not Listed

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

• Benzocaine 94-09-7 Not Listed
• Glycerine 56-81-5 Not Listed
• Antipyrine 60-80-0 Not Listed
• Oxyquinoline Sulfate 134-31-6 Not Listed
• Water 7732-18-5 Not Listed

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

• Benzocaine 94-09-7 Not Listed
• Glycerine 56-81-5 Not Listed
• Antipyrine 60-80-0 Not Listed
• Oxyquinoline Sulfate 134-31-6 Not Listed
• Water 7732-18-5 Not Listed

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

• Benzocaine 94-09-7 Not Listed
• Glycerine 56-81-5 Not Listed
• Antipyrine 60-80-0 Not Listed
• Oxyquinoline Sulfate 134-31-6 Not Listed
• Water 7732-18-5 Not Listed

Section 16 - Other Information

Last Revision Date 13/May/2015
Preparation Date 13/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.