Section 1: Identification

Product identifier

Product Name
- Flurbiprofen Sodium Ophthalmic Solution

Product Code
- AB31404; Core No. 314; NDC 24208-0314-25

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

Recommended use
- Finished Pharmaceutical Product; Flurbiprofen sodium ophthalmic solution is indicated for the inhibition of intraoperative miosis.

Restrictions on use
- Use in accordance with product literature. 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

Label elements

UN GHS

WARNING

Hazard statements
- May cause eye irritation

Precautionary statements

Prevention
- Use personal protective equipment as required.
- Wash thoroughly after handling.

Response
- 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.
Hydrochloric Acid (CAS: 7647-01-0, EINECS: 231-595-7) 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.

**Skin**
- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

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

**Ingestion**
- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.
medical attention immediately.

**Most important symptoms and effects, both acute and delayed**
- No data available

**Indication of any immediate medical attention and special treatment needed**
- With some nonsteroidal anti-inflammatory drugs, there exists the potential for increased bleeding due to interference with thrombocyte aggregation.

**Notes to Physician**
- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

**Other information**
- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

### 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

**Special hazards arising from the substance or mixture**

**Unusual Fire and Explosion Hazards**
- None known - product is not flammable or combustible.

**Hazardous Combustion Products**
- No data available

**Advice for firefighters**
- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

### 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. 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

**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.

### Section 7 - Handling and Storage

**Precautions for safe handling**

**Handling**
- No special handling is required. Refer to Section 8. 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.

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
- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment
Respiratory
- No respiratory protection required during normal handling.

Eye/Face
- Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands
- Gloves are not required under normal handling conditions.

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 data available

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>pH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Description</td>
<td>Liquid</td>
<td>Clear Colorless to slightly yellow.</td>
<td>No odor.</td>
<td>Not relevant</td>
<td>6 to 7</td>
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General Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Boiling Point</td>
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</tr>
<tr>
<td>Decomposition Temperature</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Specific Gravity/Relative Density</td>
<td>1.016</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
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</tbody>
</table>

Volutility

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Vapor Pressure</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>No data available</td>
</tr>
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</table>

Flammability

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash Point</td>
<td>Not relevant</td>
</tr>
<tr>
<td>LEL</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Burning Rate Test</td>
<td>Not relevant</td>
</tr>
</tbody>
</table>

Environmental

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Octanol/Water Partition</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Section 10: Stability and Reactivity

Reactivity

- No dangerous reactions known.

Chemical stability

Preparation Date: 13/May/2015
Revision Date: 13/May/2015
Format: GHS Language: English (US)
Stable under normal temperatures and pressures.

**Possibility of hazardous reactions**
- No data available

**Conditions to avoid**
- Extreme heat or cold. Do not freeze.

**Incompatible materials**
- None.

**Hazardous decomposition products**
- None expected.

### Section 11 - Toxicological Information

**Information on toxicological effects**

**Other Material Information**
- Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

<table>
<thead>
<tr>
<th>Components</th>
<th>Acute Toxicity: Ingestion/Ooral-Rat LD50 • 117 mg/kg; <em>Behavioral</em>: Ataxia; <em>Gastrointestinal</em>: Hypermotility, diarrhea; <em>Blood</em>: Normocytic anemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flurbiprofen (0.03%)</td>
<td>5104-49-4</td>
</tr>
<tr>
<td>Polyvinyl alcohol (1.4%)</td>
<td>9002-89-5</td>
</tr>
<tr>
<td>Thimerosal (0.005%)</td>
<td>54-64-8</td>
</tr>
<tr>
<td>Edetate Disodium Dihydrate (&lt; 1%)</td>
<td>139-33-3</td>
</tr>
<tr>
<td>Potassium chloride (&lt; 1%)</td>
<td>7447-40-7</td>
</tr>
<tr>
<td>Citric acid (&lt; 0.1%)</td>
<td>77-92-9</td>
</tr>
<tr>
<td>Sodium Citrate Dihydrate (1% TO 5%)</td>
<td>68-04-2</td>
</tr>
<tr>
<td>Sodium chloride (0.1%)</td>
<td>7647-14-5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GHS Properties</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>UN GHS - Classification criteria not met</td>
</tr>
<tr>
<td>Aspiration Hazard</td>
<td>UN GHS - Classification criteria not met</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>UN GHS - Classification criteria not met</td>
</tr>
<tr>
<td>Germ Cell Mutagenicity</td>
<td>UN GHS - Classification criteria not met</td>
</tr>
<tr>
<td>Skin corrosion/Irritation</td>
<td>UN GHS - Classification criteria not met</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>UN GHS - Classification criteria not met</td>
</tr>
<tr>
<td>STOT-RE</td>
<td>UN GHS - Classification criteria not met</td>
</tr>
<tr>
<td>STOT-SE</td>
<td>UN GHS - Classification criteria not met</td>
</tr>
</tbody>
</table>
Potential Health Effects

Inhalation
- Acute (Immediate): Under normal conditions of use, no health effects are expected.
- Chronic (Delayed): Under normal conditions of use, no health effects are expected.

Skin
- Acute (Immediate): Under normal conditions of use, no health effects are expected.
- Chronic (Delayed): Under normal conditions of use, no health effects are expected.

Eye
- Acute (Immediate): May cause mild irritation. Transient ocular burning and stinging. With some nonsteroidal anti-inflammatory drugs, there exists the potential for increased bleeding due to interference with thrombocyte aggregation.
- Chronic (Delayed): Under normal conditions of use, no health effects are expected.

Ingestion
- Acute (Immediate): Under normal conditions of use, no health effects are expected.
- Chronic (Delayed): Under normal conditions of use, no health effects are expected.

Other
- Acute (Immediate): Under normal conditions of use, no health effects are expected.
- Chronic (Delayed): Under normal conditions of use, no health effects are expected.

Carcinogenic Effects

<table>
<thead>
<tr>
<th>CAS</th>
<th>IARC</th>
<th>NTP</th>
</tr>
</thead>
<tbody>
<tr>
<td>9002-89-5</td>
<td>Group 3-Not Classifiable</td>
<td>Evidence of Carcinogenicity</td>
</tr>
</tbody>
</table>

Reproductive Effects
- While the finished product is believed to be safe, some ingredients are suspected of causing cancer. The safety of this product in pregnant women has not been established. Flurbiprofen has been shown to be embryocidal, delay parturition, prolong gestation, reduce weight, and/or slightly retard growth of fetuses when given to rats in daily oral doses of 0.4 mg/kg (approximately 300 times the human daily topical dose) and above.

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

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>DOT</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>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>
<tr>
<td>IATA/ICAO</td>
<td>NDA</td>
<td>Not regulated</td>
<td>NDA</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>
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</thead>
<tbody>
<tr>
<td>Flurbiprofen</td>
<td>5104-49-4</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sodium Citrate Dihydrate</td>
<td>139-33-3</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Thimerosal</td>
<td>54-64-8</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Potassium chloride</td>
<td>7447-40-7</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 Citrate Dihydrate</td>
<td>68-04-2</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 - WHMIS - Classifications of Substances**

- Sodium Citrate Dihydrate
- Edetate Disodium Dihydrate

Uncontrolled product according to WHMIS classification criteria
Uncontrolled product according to WHMIS classification criteria (including 3.5%)
<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>UN No.</th>
<th>WHMIS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thimerosal</td>
<td>54-64-8</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Potassium chloride</td>
<td>7447-40-7</td>
<td></td>
<td>Uncontrolled product according to WHMIS classification criteria (including 23.8%)</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td></td>
<td>E (including 40%)</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td></td>
<td>Uncontrolled product according to WHMIS classification criteria</td>
</tr>
<tr>
<td>Flurbiprofen</td>
<td>5104-49-4</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td></td>
<td>Uncontrolled product according to WHMIS classification criteria</td>
</tr>
<tr>
<td>Polyvinyl alcohol</td>
<td>9002-89-5</td>
<td></td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**Canada - WHMIS - Ingredient Disclosure List**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>UN No.</th>
<th>WHMIS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Citrate Dihydrate</td>
<td>68-04-2</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Edetate Disodium Dihydrate</td>
<td>139-33-3</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Thimerosal</td>
<td>54-64-8</td>
<td></td>
<td>0.1 %</td>
</tr>
<tr>
<td>Potassium chloride</td>
<td>7447-40-7</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td></td>
<td>1 %</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Flurbiprofen</td>
<td>5104-49-4</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Polyvinyl alcohol</td>
<td>9002-89-5</td>
<td></td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**United States - California - Proposition 65 - Carcinogens List**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>UN No.</th>
<th>WHMIS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Citrate Dihydrate</td>
<td>68-04-2</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Edetate Disodium Dihydrate</td>
<td>139-33-3</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Thimerosal</td>
<td>54-64-8</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Potassium chloride</td>
<td>7447-40-7</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td></td>
<td>Not Listed</td>
</tr>
<tr>
<td>Flurbiprofen</td>
<td>5104-49-4</td>
<td></td>
<td>Not Listed</td>
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<tr>
<td>Water</td>
<td>7732-18-5</td>
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<td>Not Listed</td>
</tr>
<tr>
<td>Polyvinyl alcohol</td>
<td>9002-89-5</td>
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</table>

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

<table>
<thead>
<tr>
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<th>CAS Number</th>
<th>UN No.</th>
<th>WHMIS Classification</th>
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<tbody>
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</table>
### U.S. - California - Proposition 65 - Reproductive Toxicity - Female

<table>
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<th>Ingredient</th>
<th>CAS Number</th>
<th>Listed Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Citrate Dihydrate</td>
<td>68-04-2</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Edetate Disodium Dihydrate</td>
<td>139-33-3</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Thimerosal</td>
<td>54-64-8</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Potassium chloride</td>
<td>7447-40-7</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Flurbiprofen</td>
<td>5104-49-4</td>
<td>female reproductive toxicity, initial date 8/20/99</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Polyvinyl alcohol</td>
<td>9002-89-5</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>Listed Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Citrate Dihydrate</td>
<td>68-04-2</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Edetate Disodium Dihydrate</td>
<td>139-33-3</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Thimerosal</td>
<td>54-64-8</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Potassium chloride</td>
<td>7447-40-7</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Flurbiprofen</td>
<td>5104-49-4</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Polyvinyl alcohol</td>
<td>9002-89-5</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

### 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.