Manufacturer: Akorn Incorporated
150 South Wyckles Road
Decatur, IL 62522
Contact Telephone: 1-800-932-5676
Email: customer.service@akorn.com

Section 1 - IDENTIFICATION

Common / Trade Name: Atropine Sulfate Ophthalmic Solution, 1%
Category: Prescription Only. Atropine Sulfate Ophthalmic Solution is a sterile topical anticholinergic for ophthalmic use. It is a potent parasympatholytic agent for use in producing cycloplegia and mydriasis.

Section 2 – HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS #</th>
<th>TLV (mg/m³)</th>
<th>PEL (mg/m³)</th>
<th>% Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atropine Sulfate</td>
<td>5908-99-6</td>
<td>Not Established</td>
<td>Not Established</td>
<td>1.0</td>
</tr>
<tr>
<td>Hypromellose 2910</td>
<td>9004-65-3</td>
<td>Not Established</td>
<td>Not Established</td>
<td>0.5</td>
</tr>
<tr>
<td>Sodium Phosphate, dibasic</td>
<td>7782-85-6</td>
<td>Not Established</td>
<td>Not Established</td>
<td>&gt; 1.0</td>
</tr>
<tr>
<td>Sodium Phosphate, monobasic</td>
<td>10049-21-5</td>
<td>Not Established</td>
<td>Not Established</td>
<td>~ 1.0</td>
</tr>
<tr>
<td>Edetate Disodium</td>
<td>6381-92-6</td>
<td>Not Established</td>
<td>Not Established</td>
<td>&gt; 1.0</td>
</tr>
<tr>
<td>Benzalkonium Chloride</td>
<td>8001-54-5</td>
<td>Not Established</td>
<td>Not Established</td>
<td>0.01</td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>1310-73-2</td>
<td>Not Established</td>
<td>Not Established</td>
<td>&gt; 1.0</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>Not Established</td>
<td>Not Established</td>
<td>&gt; 1.0</td>
</tr>
<tr>
<td>Purified Water</td>
<td>7732-18-5</td>
<td>Not Established</td>
<td>Not Established</td>
<td>QS</td>
</tr>
</tbody>
</table>

Section 3 – HEALTH HAZARD DATA

Carcinogenicity: Not established
NTP: No
IARC: No
OSHA Regulated: No

Routes of Entry: Topical ophthalmic use only, as directed by a physician.
Not for injection.
Eye
May cause irritation and a hypersensitivity response.
May cause temporary light sensitivity.
Atropine sulfate is readily absorbed through the eyes and toxicity can occur. Overdosage (systemic toxicity) is manifested by flushing and dryness of the skin (a rash may be present in children), blurred vision, a rapid and irregular pulse, fever, abdominal distension infants, mental aberration (hallucinations), unusual drowsiness, tachycardia, hyperpyrexia, vasodilation, urinary retention, diminished gastric motility and decreased secretion in salivary and sweat glands, pharynx, bronchi, nasal passages and loss of neuromuscular coordination. Severe
reactions are manifested by low blood pressure (hypotension) with progressive respiratory depression. Coma and death have been reported in the very young. Atropine poisoning is rarely fatal. Once the drug is withdrawn, the mechanism of overdosage is self limiting.

**Skin**
May cause irritation and hypersensitivity in some individuals.
Toxic systemic effects may be induced by skin contact.

**Ingestion**
Ingestion of atropine sulfate may induce systemic toxicity effects.

**Chronic Effects**
Prolonged use may produce local irritation characterized by follicular conjunctivitis, vascular congestion, edema, exudate, and an eczematoid dermatitis.

**Target Organs**
Eyes, central nervous system, respiratory and digestive tract

**Medical Conditions Aggravated by Exposure**
- Hypersensitivity to any of the components of the product.
- Persons with a previous history of susceptibility to belladonna alkaloids may produce systemic symptoms of atropine poisoning.
- Atropine should be given to pregnant women only if clearly needed.

**Note to Physicians:**
- Atropine may interfere with the antiglaucoma and miotic actions of ophthalmic cholinesterase inhibitors.
- Atropine is contraindicated in cases of primary and narrow angle glaucoma or anatomical narrow angles.
- It is not known whether this drug is excreted in the milk of nursing mothers, so caution should be exercised when prescribing atropine sulfate.
- CNS disturbances are more likely in young, premature, or small infants.
- Additional details are available in the package insert or Physicians Desk Reference.

### Section 4 – FIRST AID MEASURES

**Eyes:** Rinse with copious amounts of water. Contact a physician.

**Skin:** Remove contaminated clothing and wash skin with copious amounts of water.
Contact a physician if skin becomes irritated.

**Inhalation:** Remove person to fresh air, and if breathing stops, use artificial respiration.
Contact a physician.

**Ingestion:** Rinse mouth thoroughly. Contact a physician or Poison Control Center.

### Section 5 – FIRE FIGHTING MEASURES

- **Flammable Properties:** Flash point: Not Established  Method: Not Established
- **Hazardous Combustion Products:** Emits toxic fumes
- **Extinguishing Media:** Dry chemical, carbon dioxide, halon, water fog and foam as appropriate for surrounding fire and materials.
- **Fire Fighting Instructions:** Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.
Section 6 – ACCIDENTAL RELEASE MEASURES

Large/Small Spills: Use personal protective equipment to prevent exposure of skin and eyes. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

Section 7 – HANDLING AND STORAGE

Handling: Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

Storage: Store product in original containers with the cap tightly closed at a controlled room temperature of 20°C to 25°C (66° to 77°F).

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTIVE

Engineering Controls: No special requirements for use in the clinical or home environment.

Eye Protection: Recommend goggles or chemical safety glasses

Skin Protection: Recommend gloves and skin covering

Respiratory Protection: No respiratory protection is required in the clinical or home environment.

Contaminated Equipment: Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

Section 9 – PHYSICAL/CHEMICAL CHARACTERISTICS

Appearance & Odor: Clear, colorless, odorless solution

Boiling Point: Not Established

Evaporation Rate: Not Established

Specific Gravity: 1.016

Vapor Pressure: Not Established

Water Solubility: Freely

Latex Free: Yes

Freezing Point: Not Established

pH: 3.5 to 6.0

Vapor Density: Not Established

Viscosity: 16 to 24 cps

Percent Volatile by Volume: < 1

Section 10 – STABILITY AND REACTIVITY

Chemical Stability: Stable

Conditions to Avoid: Extreme heat or cold

Incompatibility: This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations
Hazardous Decomposition Products: Emits toxic fumes
Hazardous Polymerization: Should not occur

Section 11 – TOXICOLOGICAL INFORMATION

Summary of Risks: Toxicological information refers to the raw materials of the product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material.

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<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral LD₅₀</td>
<td>622 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>IV LD₅₀</td>
<td>41 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral LD₅₀</td>
<td>468 mg/kg</td>
</tr>
</tbody>
</table>

Section 12 – ECOLOGICAL INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible impact on the environment.

Section 13 – DISPOSAL INFORMATION

Dispose of material according to Federal, State, and Local regulations:
The method typically used is incineration.

Section 14 – TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

Section 15 – REGULATORY INFORMATION

DOT Designation: Not classified as hazardous by DOT regulations.
EPA Designation: RCRA Hazardous Waste (40 CFR 261.33) Not Listed
FDA Designation: Prescription only medication
OSHA Designations: (29 CFR 1910.1000, Table Z) Not Listed
SARA Title III: Not listed under Section 313 of Toxic Release Reporting.
CALIFORNIA PROPOSITION 65: Not Listed

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