Material Safety Data Sheet
Manufacturer: Akorn Inc. Telephone: (217) 428-1100
150 S. Wyckles Road
Decatur, IL 62522

Section 1- IDENTIFICATION

TRADE NAME: AK-PENTOLATE 1% (Cyclopentolate Hydrochloride Ophthalmic Solution USP, 1%)
Description: Anti-cholinergic: Ciliary muscle paralysis agent in a borate buffered topical ophthalmic solution.

<table>
<thead>
<tr>
<th>Composition</th>
<th>CAS#</th>
<th>TLV(mg/m³)</th>
<th>PEL(mg/m³)</th>
<th>%Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclopentolate HCl</td>
<td>512-15-2</td>
<td>NE</td>
<td>NE</td>
<td>1.0</td>
</tr>
<tr>
<td>Boric Acid</td>
<td>10043-35-3</td>
<td>10</td>
<td>15</td>
<td>≥1</td>
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</tbody>
</table>

Ingredients <1%
Potassium Chloride, Edetate Disodium, Benzalkonium Chloride

Common name of active ingredients: Cyclopentolate Hydrochloride
Chemical Formula (s): C₁₇H₂₅NO₃·HCl
Legal Category: Prescription only medication, filled inside plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.
NE: Not established

Section 2- HAZARDOUS INGREDIENTS

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EMERGENCY OVERVIEW
For eyes only. Do not engage in hazardous activity while under the influence.
May cause temporary light sensitivity. Avoid mouth and skin contact.
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Principal Hazardous Ingredients: Cyclopentolate Hydrochloride
% Threshold Limit Value: NE
Carcinogenicity:
NTP- No
IARC- No
OSHA- No
NE: Not established
Section 3- PHYSICAL AND CHEMICAL CHARACTERISTICS

- Boiling Point (C°): NE
- Vapor Pressure (mm Hg): NE
- Solubility in Water: Miscible
- Specific Gravity: 1.0
- Percent Volatile: <1
- Evaporation Rate: NE
- Reactivity in Water: None
- Appearance and Odor: Clear, colorless and odorless solution
- NE: Not established

Section 4- FIRE AND EXPLOSION HAZARD DATA

- Extinguisher Media: Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.
- Auto Ignition Temperature: NE  Method: NE
- Special Firefighting Procedures: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool.
- Hazardous Products: Toxic fumes, carbon oxides, and nitrogen oxides

- Stability: Stable ____ X ______ Unstable _______

CONDITIONS TO AVOID
- Incompatibility: This product has the same incompatibilities as water e.g. strong acids, bases, alkali metals, and alkali hydrides.
- Hazardous Decomposition Products: Emits toxic fumes.
- Hazardous Polymerization: Should not occur.
- Conditions to Avoid: Extreme heat or cold
- NE: Not established

Section 5- REACTIVITY DATA

NA

Section 6- HEALTH HAZARDS

- Threshold Limit Value: NE
- Signs and Symptoms of Exposure:
1. **Acute Overexposure**: Possible eye and/or skin irritation.
2. **Chronic Overexposure**: Possible hypersensitization.

**Medical Conditions Aggravated by Long Term Exposure**
*Hypersensitivity to Cyclopentolate or any component of the preparation.

**Chemical Listed as Carcinogen or Potential Carcinogen:**
- National Toxicology Program: Yes [ ] No [x] X
- I.A.R.C Monographs: Yes [ ] No [x] X
- OSHA: Yes [ ] No [x] X
- OSHA Permissible Exposure Limit: NE
- ACGIH Threshold Limit Value: NE
- Other Exposure Limit Used: NE

**Emergency and First Aid Procedures:**
1. **Inhalation**: Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.
2. **Eyes**: Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.
3. **Skin**: Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician in skin becomes irritated.
4. **Ingestion**: Wash out mouth and drink plenty of water and bland fluids. Contact physician.

**Note to physicians:**
* Cyclopentolate may interfere with the antiglaucoma and miotic actions of ophthalmic cholinesterase inhibitors.
* Cyclopentolate is contraindicated in case of narrow angle glaucoma or anatomical narrow angles are present.
* Cyclopentolate may interfere with the antiglaucoma action on carbachol or pilocarpine: also concurrent use of these medications may antagonize the antiglaucoma and miotic acts of ophthalmic cholinesterase inhibitors.
* It is not know whether this drug is excreted in the milk of nursing mothers, so caution should be exercised when prescribing cyclopentolate hydrochloride.
* CNS disturbances are more likely in young, premature or small infants. Children with spastic paralysis or brain damage are more susceptible to cyclopentolate.

**NE= Not established**
Section 7- PROTECTION INFORMATION


Ventilation: None required

Local Exhaust: NA

Mechanical/ Engineering Controls: In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical materials and use current Material Safety Data Sheets.

Skin Protection: Use thick rubber gloves and protective clothing if handling large quantities.

Eye Protection: (29 CFR 1910.133) Recommended goggles or chemical safety glasses.

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.

Other: None

Section 8- SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

Precautions to be taken in handling and storage: 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 upright in original containers with the cap tightly closed at a controlled room temperature 15°-30° C (59°- 86°F).

Steps to be taken in case material is released or spilled: Use personal protective equipment. 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.

Waste Disposal Methods: Disposes of material according to Federal, State and Local regulations. The method typically used is incineration.
Section 9- TOXICOLOGY INFORMATION

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

512-15-2 Cyclopentolate HCl
May cause eye, skin and respiratory tract irritation. May also cause a burning sensation in the eye. Induces paralysis of the ciliary muscle of the eye preventing the adjustment of the eye to light (cycloplegia) and dilates the pupil of the eye (mydriasis). Cyclopentolate is an anti-cholinergic agent which affects the nervous system. Hypersensitivity (anaphylactic) may be observed in some individuals. Toxicity induces clumsiness, weakness, drowsiness, confusion, hallucinations, slurred speech, rapid heartbeat, drug fever and flushed face. Oral-mouse LD₅₀ 960 mg/kg, IV-mouse LD₅₀ 84 mg/kg.

10043-35-3 Boric Acid
May cause irritation to the eyes, skin, respiratory tract and digestive system. Inhalation may cause coughing and chest discomfort. Dusts may irritate the skin. Harmful quantities may be absorbed though broken skin but is unlikely with intact skin. Ingestion may cause upset stomach and vomiting; large quantities may be fatal. Repeated or prolonged contact may cause hypersensitization (anaphylactic) in some individuals, central nervous system stimulation and erythematous flush (diffuse red skin rash). Oral-rat LD₅₀: 2660 mg/kg.

Section 10- ECOLOGICAL INFORMATION

Chemical fate information: Product administered to patients presents a negligible impact on the environment. Environmental impact of industrial release has not been established.

Other Precautions: None

The information given herein is in good faith and to the best of our knowledge but no warranty expressed or implied is made

Prepared By John Doe Date: 03-30-2005