Material Safety Data Sheet

Manufacturer: Akorn
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Section 1 - IDENTIFICATION

TRADE NAME: Cromolyn Sodium Ophthalmic Solution, 4%
NDC # 17478-291-11
Description: Clear, light yellowish solution

Composition

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS#</th>
<th>TLV (mg/m³)</th>
<th>PEL (mg/m³)</th>
<th>%Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cromolyn Sodium</td>
<td>15826-37-6</td>
<td>NE</td>
<td>NE</td>
<td>4.0</td>
</tr>
<tr>
<td>Edetate Sodium</td>
<td>6381-92-6</td>
<td>NE</td>
<td>NE</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Benzalkonium Chloride 50% Sol.</td>
<td>8001-54-5</td>
<td>NE</td>
<td>NE</td>
<td>0.02</td>
</tr>
<tr>
<td>Purified Water, USP</td>
<td>7732-18-5</td>
<td>NE</td>
<td>NE</td>
<td>qs</td>
</tr>
</tbody>
</table>

Common name of active ingredients: Cromolyn Sodium
Chemical Formula: C_{23}H_{14}O_{11.2}Na

Section 2 – HAZARDOUS INGREDIENTS

Principal Hazardous Ingredients: Cromolyn Sodium
% Threshold Limit Value: NE
Carcinogenicity: NE
NTP- No
IARC- No
OSHA- No
NE= Not established
< = Greater Than
> = Less Than

Section 3 – PHYSICAL AND CHEMICAL CHARACTERISTICS

Physical State: Liquid
Appearance: Clear, light yellowish solution
Odor: Odorless
Boiling Point: NE
Vapor Density (air = 1): NE
Vapor Pressure (mm Hg): NE
Viscosity: NE
MSDS: Cromolyn Sodium Ophthalmic Solution, 4%

Solubility in Water: Freely Soluble
Specific Gravity: NE
Volatile: NE
Evaporation Rate: NE
Reactivity in Water: NE
pH: Between 4.0-7.0
Melting Point: NE
Latex Free: Yes
NE=Not established

Section 4 – FIRE AND EXPLOSION HAZARD DATA

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
Hazardous Products: Emits toxic fumes
Flammable Limits: Lower Flammable Limit: NE; Upper Flammable Limit: NE
Fire Fighting Instructions: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 5 – REACTIVITY DATA

Stability: Stable
Incompatibility: Oxidizing agents, strong acid and alkaline solutions, alkali metals and silver preparations.
Hazardous Decomposition Products: When heated to decomposition, material emits toxic fumes. Emits toxic fumes under fire conditions
Hazardous Polymerization: No
Conditions to Avoid: Extreme Heat or cold.

Section 6 – HEALTH HAZARDS

Adverse Effects: May cause wheezing, coughing, difficulty breathing, nausea, skin rash, throat irritation or dryness, headache, irritability, muscle pain, and trouble in sleeping. Allergic reaction is possible if inhaled, ingested, or in contact with skin.

Chemical Listed as Carcinogen or Potential Carcinogen: Cromolyn Sodium
National Toxicology Program: No
I.A.R.C Monographs: No
MSDS: Cromolyn Sodium Ophthalmic Solution, 4%

OSHA: No
OSHA Permissible Exposure Limit: NE
ACGIH Threshold Limit Value: NE
NE= Not established

1. **Inhalation:** May cause irritation and slight systemic absorption. Avoid inhalation. Remove to fresh air.

2. **Eyes:** May cause irritation, burning or stinging on installation. Can cause hypersensitivity to some individuals. Flush with copious quantities of water for 15 minutes.

3. **Skin:** May cause irritation. Flush with copious quantities of water.

4. **Ingestion:** May cause irritation and bitter aftertaste. Flush out mouth with water. This material is poorly absorbed from the gastrointestinal tract.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material and impaired liver or kidney function.

**Section 7 – SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES**

**Storage:** Store product upright in original containers with cap tightly closed at a controlled room temperature 20°-25° C (68°-77° F). Protect from light. **KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN**

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

**Neutralizing Chemical Agent:** Not relevant

**Waste Disposal Methods:** Dispose of waste in accordance with all applicable Federal, State and local laws.

**Section 8 – PROTECTION INFORMATION**

**Engineering Controls:**

**Airborne Exposure Limits:** NE

**Ventilation:** Recommended. Provide adequate ventilation

**Skin Protection:** Protect exposed skin and wear rubber gloves.

**Eye Protection:** Safety glasses

**Respiratory Protection:** When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.
Section 9 – TOXICOLOGY INFORMATION

**LD 50 (Acute oral toxicity of):** Cromolyn Sodium
LD 50 rat, oral >11 grams/kg
LD50 Mouse, oral >11 grams/kg
LD 50: Subcutaneous-mouse = 4400mg/kg
LD 50 intravenous-mouse = 3300mg/kg

Section 10 – ECOLOGICAL INFORMATION

**Ecotoxicity:** Not established
**BOD₅ and COD:** Not available
**Environmental fate information:** None
**Other Precautions:** None

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