1. **Identification**

Product Identifier: Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment, USP

Synonyms: Neomycin B Sulfates, Polymyxin B Sulfates

National Drug Code (NDC): 17478-719-35

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. **Hazard(s) Identification**

Physical Hazards: Not classifiable.

Health Hazards: Not classifiable.

Symbol(s): None.

Signal Word: None.

Hazard Statement(s): None.

Precautionary Statement(s): None.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. **Composition/Information on Ingredients**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Number</th>
<th>Synonyms</th>
<th>Chemical Formula</th>
<th>Molecular Weight</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>Neomycin Sulfate</td>
<td>C_{23}H_{46}N_{6}O_{13}*3H_{2}SO_{4}</td>
<td>908.89</td>
<td>0.35%</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>1405-20-5</td>
<td>Polymyxin B Sulfate</td>
<td>C_{43}H_{82}N_{16}O_{12}*xH_{2}O_{x}S</td>
<td>1701.97</td>
<td>equal to 10,000 Polymyxin B units</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>1405-89-6</td>
<td>Bacitracins, zinc complex</td>
<td>C_{66}H_{101}N_{17}O_{19}SZn</td>
<td>1486</td>
<td>400 units of Bacitracin</td>
</tr>
<tr>
<td>Hydrocortisone</td>
<td>50-23-7</td>
<td>Cortisol</td>
<td>C_{21}H_{39}O_{5}</td>
<td>362.47</td>
<td>10 1%</td>
</tr>
</tbody>
</table>

* The formula also contains White Petrolatum q.s.
4. **First Aid Measures**

**Ingestion:**
If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

**Eye Contact:**
Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Skin Contact:**
Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Inhalation:**
Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Protection of First-Aiders:**
Use personal protective equipment (see section 8).

**Signs and Symptoms:**
Not determined. See package insert for more information.

**Medical Conditions Aggravated by Exposure:**
Anaphylactic cross-reactions may occur for corticosteroids and antibiotics including kanamycin, paromomycin, streptomycin and possibly gentamicin. This medication is contraindicated for patients with herpes simplex, vaccinia and varicella infections. As with other anti-microbial preparations, prolonged use may result in overgrowth of nonsusceptible organisms including fungi. Preexisting conjunctival or systemic fungal infections may be aggravated. Appropriate measures should be taken if this occurs. Ophthalmic ointments may retard corneal healing.

**Notes to Physician:**
Treat supportively and symptomatically.
5. **Firefighting Measures**

**Suitable Extinguishing Media:** Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials. Use water spray to keep fire-exposed containers cool.

**Unsuitable Extinguishing Media:** Not determined.

**Specific Hazards Arising from the Chemical:**

- **Hazardous Combustion Products:** Emits SO\(_x\), NO\(_x\), and toxic fumes.
- **Other Specific Hazards:** Not determined.
- **Special Protective Equipment/Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

6. **Accidental Release Measures**

**Personal Precautions:** Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** 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.

**Environmental Precautions:** No data available.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

7. **Handling and Storage**

**Precautions for Safe 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. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store product upright in original containers with the cap tightly closed at a controlled room temperature 15°C – 30°C (59°F – 86°F). KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

**Specific End Use:** Pharmaceuticals.
8. **Exposure Controls/Personal Protection**

**Occupational Exposure Guidelines:**

<table>
<thead>
<tr>
<th>Common or Chemical Name</th>
<th>Employee Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin Sulfate</td>
<td>100 mg/m³ TWA</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>Not established.</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>Not established.</td>
</tr>
<tr>
<td>Hydrocortisone</td>
<td>0.02 mg/m³ TWA</td>
</tr>
</tbody>
</table>

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Respiratory Protection:** Warning: Do not use air purifying respirators in oxygen depleted environments. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Eyes Protection:** Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Hand Protection:** Not required for the normal use of this product. Wear chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Skin Protection:** Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. **Physical and Chemical Properties**

**Physical State/Color:** Smooth, unctuous cloudy white ointment.

**Odor:** No data available.

**Odor Threshold:** No data available.

**pH:** No data available.

**Melting Point:** No data available.

**Freezing Point:** No data available.

**Boiling Point:** No data available.

**Flash Point:** No data available.

**Evaporation Rate:** No data available.

**Flammability (solid, gas):** No data available.

**Flammability Limit - Lower:** No data available.
10. **Stability and Reactivity**

- **Reactivity:** No data available.
- **Chemical Stability:** Stable under recommended storage conditions.
- **Possibility of Hazardous Reactions:** No data available.
- **Conditions to Avoid (e.g., static discharge, shock, or vibration):** Extreme heat or cold.
- **Incompatible Materials:** This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.
- **Hazardous Decomposition Products:** No data available.

11. **Toxicological Information**

**Information on the Likely Routes of Exposure:**

- **Inhalation:** No data available.
- **Ingestion:** No data available.
- **Skin Contact:** No data available.
- **Eye Contact:** No data available.

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:**

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of Exposure:** No data available.

**Acute Toxicity:**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Route</th>
<th>Type</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacitracin Zinc</td>
<td>Guinea Pig</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>2,000 mg/kg</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>2,750 mg/kg</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>Mouse</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>790 mg/kg</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>LD₅₀</td>
<td>20.5 mg/kg</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>Mouse</td>
<td>Intravenous</td>
<td>LD₅₀</td>
<td>5.4 mg/kg</td>
</tr>
<tr>
<td>Hydrocortisone</td>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>LD₅₀</td>
<td>150 mg/kg</td>
</tr>
<tr>
<td>Hydrocortisone</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>LD₅₀</td>
<td>449 mg/kg</td>
</tr>
</tbody>
</table>
Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.
Corrosivity: No data available.
Dermal Irritation: No data available.
Eye Irritation: No data available.
Sensitization: No data available.
Toxicokinetics/Metabolism: No data available.
Target Organ Effects: No data available.
Reproductive Effects: No data available.
Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.
Mutagenicity: No data available.
Aspiration Hazard: Based on available data, the classification criteria are not met.

12. Ecological Information

Ecotoxicity
Aquatic: No data available.
Terrestrial: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

13. Disposal Considerations
Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information
UN Number: Not applicable.
UN Proper Shipping Name: Not applicable.
Transport Hazard Class(es): Not applicable.
Packing Group: Not applicable.
Department of Transportation: Not regulated as a hazardous material.
International Air Transport Association (IATA): Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.
15. **Regulatory Information**

**US Federal Regulations:**

Toxic Substance Control Act (TSCA): Not listed.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

**State Regulations**

California Proposition 65: Not listed.

16. **Other Information**

Not made with natural rubber latex.

**Revision Date:** 05/06/2015

**Revision Number:** 1

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