1. **Identification**

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

   **Synonyms:** Bacitracins, zinc complex, Neomycin B Sulfates, Polymyxin B Sulfates.

   **National Drug Code (NDC):** 17478-235-35

   **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 B Sulfate</td>
<td>( \text{C}<em>{23}\text{H}</em>{46}\text{N}<em>8\text{O}</em>{13}\cdot 3\text{H}_2\text{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>( \text{C}<em>{43}\text{H}</em>{82}\text{N}<em>{16}\text{O}</em>{12}\cdot x\text{H}_2\text{O} \cdot s )</td>
<td>1701.97</td>
<td>10,000 Units of Polymyxin B</td>
</tr>
</tbody>
</table>

* The formula also contains Bacitracin Zinc equal to 400 units of Bacitracin units, and White Petrolatum.
4. **First Aid Measures**

**Ingestion:** May cause irritation and hypersensitivity in some individuals. Ingestion of large quantities may induce gastric disturbances. If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

**Eye Contact:** When used topically, Bacitracin Zinc and Polymyxin B Sulfate are rarely irritating. May cause hypersensitivity (anaphylactic) in some individuals. The most frequent adverse reactions are localized hypersensitivity with itching, swelling, and diffused redness of the eye (conjunctival erythema). If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 15 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

**Skin Contact:** When used topically, Bacitracin Zinc and Polymyxin B Sulfate are rarely irritating, and absorption from the intact skin or mucous membrane is insignificant. May cause hypersensitivity in some individuals. If adverse skin effects occur, discontinue use. Seek medical attention.

**Inhalation:** May cause irritation and hypersensitivity in some individuals. Inhalation is not likely with an ointment preparation. If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

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

**Signs and Symptoms:** No data available. See package insert for more information.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to any of the components of the product. Ophthalmic ointments may retard corneal healing.

**Notes to Physician:** Treat supportively and symptomatically.

5. **Firefighting Measures**

**Suitable Extinguishing Media:** Use extinguishing media for type of surrounding fire.

**Unsuitable Extinguishing Media:** Not determined.
Fire Fighting Equipment: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, and sulfur oxides).

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>
</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. No respiratory protection is required in the clinical or home environment. 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:** Pale yellow 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): This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

Incompatible Materials: No data available.

Hazardous Decomposition Products: Emits SO\textsubscript{x}, NO\textsubscript{x}, and toxic fumes.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May cause irritation and hypersensitivity in some individuals. Inhalation is not likely with an ointment preparation. If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

Ingestion: May cause irritation and hypersensitivity in some individuals. Ingestion of large quantities may induce gastric disturbances. If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION.

Skin Contact: When used topically, Bacitracin Zinc and Polymyxin B Sulfate are rarely irritating, and absorption from the intact skin or mucous membrane is insignificant. May cause hypersensitivity in some individuals. If adverse skin effects occur, discontinue use. Seek medical attention.
Eye Contact: When used topically, Bacitracin Zinc and Polymyxin B Sulfate are rarely irritating. May cause hypersensitivity (anaphylactic) in some individuals. The most frequent adverse reactions are localized hypersensitivity with itching, swelling, and diffused redness of the eye (conjunctival erythema).

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>Neomycin Sulfate</td>
<td>Woman</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>12,600 mg/kg/7 days</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Mouse</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>8,000 mg/kg</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Human</td>
<td>Skin</td>
<td>TC₅₀</td>
<td>20 pph/48 hours</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Human</td>
<td>Skin</td>
<td>Standard Draize Test</td>
<td>6 mg/3 days</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>LD₅₀</td>
<td>305 mg/kg</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>LD₅₀</td>
<td>200 mg/kg</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>TD₉₀</td>
<td>280 mg/kg/7 days</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>LD₅₀</td>
<td>190 mg/kg</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>TD₉₀</td>
<td>560 mg/kg/7 days</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Mouse</td>
<td>Intravenous</td>
<td>LD₅₀</td>
<td>17,400 mg/kg</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Mouse</td>
<td>Intramuscular</td>
<td>LD₅₀</td>
<td>142 mg/kg</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Guinea Pig</td>
<td>Intramuscular</td>
<td>LD₅₀</td>
<td>&gt;250 mg/kg</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Guinea Pig</td>
<td>Intramuscular</td>
<td>TD₉₀</td>
<td>2,000 mg/kg/8 days</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Monkey</td>
<td>Intramuscular</td>
<td>TD₉₀</td>
<td>500 mg/kg/5 days</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Cat</td>
<td>Intramuscular</td>
<td>TD₉₀</td>
<td>5,050 mg/kg/14 weeks</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Mouse</td>
<td>Intracerebral</td>
<td>LD₅₀</td>
<td>32 mg/kg</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Rat</td>
<td>Intracerebral</td>
<td>TD₉₀</td>
<td>714.3 mg/kg</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>Rat</td>
<td>Intraspinal</td>
<td>TD₉₀</td>
<td>36.88 ug/kg</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>Mouse</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>&gt;3,750 mg/kg</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>Guinea Pig</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>2,000 mg/kg</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>Quail</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>&gt;316 mg/kg</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>LD₅₀</td>
<td>190 mg/kg</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>LD₅₀</td>
<td>300 mg/kg</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>LD₅₀</td>
<td>1300 mg/kg</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>Mouse</td>
<td>Intravenous</td>
<td>LD₅₀</td>
<td>360 mg/kg</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>E. Coli</td>
<td>Bacteria</td>
<td>DNA Adduct</td>
<td>50 umol/L</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>Human</td>
<td>Skin</td>
<td>TC₅₀</td>
<td>20 pph/48 hours</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>20,500 ug/kg</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>LD₅₀</td>
<td>59,500 ug/kg</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>LD₅₀</td>
<td>284 mg/kg/9 days</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>Guinea Pig</td>
<td>Subcutaneous</td>
<td>LD₅₀</td>
<td>58 mg/kg</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>Mouse</td>
<td>Intravenous</td>
<td>LD₅₀</td>
<td>5,400 ug/kg</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>Dog</td>
<td>Intravenous</td>
<td>LD₅₀</td>
<td>8 mg/kg</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>Dog</td>
<td>Intracerebral</td>
<td>LD₅₀</td>
<td>320 ug/kg</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>E. Coli</td>
<td>Bacteria</td>
<td>DNA Adduct</td>
<td>50 mg/L</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

**Disclaimer:** This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user’s responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.