SAFETY DATA SHEET

1. Identification

   Product Identifier: Neomycin Sulfate Tablets, USP 500 mg
   Synonyms: Neomycin B
   National Drug Code (NDC): 50383-565-10
   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</td>
<td>C_{23}H_{46}N_{6}O_{13}\cdot2\frac{1}{2}H_{2}SO_{4}</td>
<td>614.67</td>
<td>50%</td>
</tr>
</tbody>
</table>

*The formula also contains Calcium Stearate and Povidone.*
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. Please see package insert for more information.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to the material, myasthenia gravis, parkinsonism, impaired kidney function, eighth-cranial nerve (hearing) impairment, ulcerative lesions of the bowel, intestinal obstruction, and dehydration.

**Overdose Treatment:** Since there is no specific antidote, treatment of aminoglycoside overdose or toxicity should be symptomatic and supportive. If patient has impaired kidney function, use hemodialysis or peritoneal dialysis to remove neomycin from the blood.

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

   **Suitable Extinguishing Media:** Use water, carbon dioxide, dry chemical or foam as necessary.

   **Unsuitable Extinguishing Media:** Not determined.

   **Specific Hazards Arising from the Chemical:**

   **Hazardous Combustion Products:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

   **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:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

   **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:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling. 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 in tight, light-resistant container as defined in the USP-NF and in a cold place. Store according to label and/or product insert information.

   **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>
</tbody>
</table>

**Engineering Controls:**

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

**Respiratory Protection:**

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:**

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:**

Chemically compatible gloves are recommended. 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:**

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. **Physical and Chemical Properties**

**Physical State/Color:**

White to slightly yellow powder.

**Odor:**

Odorless.

**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.

**Flammability Limit - Upper:**

No data available.

**Vapor Pressure:**

No data available.

**Vapor Density:**

No data available.

**Relative Density:**

No data available.

**Solubility(ies):**

Soluble in water.
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): Avoid exposure to moisture, light and heat.

Incompatible Materials: Acids.

Hazardous Decomposition Products: When heated to decomposition material emits very toxic fumes of SOx. Emits toxic fumes under fire conditions.

Hazardous Polymerization: Will not occur.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May cause irritation. Remove to fresh air.

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

Skin Contact: Causes mild irritation and is readily skin absorbable. Avoid contact. Flush with copious quantities of water.

Eye Contact: May cause irritation. Flush with copious quantities of water.

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>Test Type</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin Sulfate</td>
<td>Mouse</td>
<td>Oral</td>
<td>LD₅₀</td>
<td>8,000 mg/kg</td>
</tr>
</tbody>
</table>
SDS: Neomycin Sulfate Tablets, USP 500 mg

Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.
Corrosivity: No data available.

Dermal Irritation:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Study Type</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin Sulfate</td>
<td>Human</td>
<td>Skin irritation</td>
<td>Mild</td>
</tr>
</tbody>
</table>

Eye Irritation: No data available.
Sensitization: No data available.
Toxicokinetics/Metabolism: No data available.

Target Organ Effects: Kidneys and Ears.

Reproductive Effects: All aminoglycosides cross the placenta, and may cause some serious adverse effects on the fetus. Neomycin may cause kidney damage to the fetus, and therapeutic use during pregnancy is not recommended.

Pregnancy category: D

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: No data available.

Overdose Effects: Hearing loss and kidney damage may result from overdose.

Adverse Effects: Adverse effects may include a change in the amount or frequency of urination; increased thirst; gastrointestinal disturbances; muscle twitching; numbness; seizures; tingling; hearing loss; ringing, buzzing, or feeling of fullness in ears; clumsiness; dizziness; and skin rash. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Chronic Effects: Possible hypersensitization, intestinal malabsorption syndrome, and superinfection.

Cross Sensitivity: Persons hypersensitive to one aminoglycoside may be hypersensitive to this material, also.
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**

    - Massachusetts: Not listed.
    - New Jersey: Not listed.
    - Pennsylvania: Not listed.
    - California Proposition 65: Not listed.
16. **Other Information**

**Revision Date:** 05/26/2015

**Revision Number:** 0

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