MSDS: AK-Poly-Bac Ophthalmic Ointment

Manufacturer: Akorn
72-6 Veronica Ave
Somerset, N.J. 08873

Contact Telephone: 1-800-932-5676
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Section 1 - IDENTIFICATION

TRADE NAME: AK-POLY-BAC (Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment, USP)
NDC # 17478-238-35

Description: Colorless to light yellowish translucent ointment

<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>Bacitracin Zinc, Sterile</td>
<td>1405-89-6</td>
<td>NE</td>
<td>NE</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Polymyxin B Sulfate, Sterile</td>
<td>1405-20-5</td>
<td>NE</td>
<td>NE</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>White Petrolatum</td>
<td>8009-03-8</td>
<td>NE</td>
<td>NE</td>
<td>85</td>
</tr>
<tr>
<td>Mineral Oil</td>
<td>8042-47-5</td>
<td>5(mist)</td>
<td>5</td>
<td>14</td>
</tr>
</tbody>
</table>

Common name of active ingredients: Bacitracin Zinc & Polymyxin B Sulfate
Chemical Formula: N/A

Section 2 – HAZARDOUS INGREDIENTS

Principal Hazardous Ingredients: Bacitracin Zinc & Polymyxin B Sulfate
% 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: Sami solid
Appearance: Colorless to light yellowish translucent ointment
Odor: Odorless
Boiling Point: NE
Vapor Density: NE
Viscosity: NE
Solubility in Water: Immiscible
Specific Gravity: NE
Volatile: NE
Evaporation Rate: NE
Reactivity in Water: NE
Latex Free: Yes NE=Not Established
Section 4 – FIRE AND EXPLOSION HAZARD DATA

Flammable Properties: Flash Point: NE Method: NE
Extinguisher Media: Alcohol foam, dry chemical and Carbon dioxide
Hazardous Products: Toxic fumes.
Fire Fighting Instructions: Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

Section 5 – REACTIVITY DATA

Stability: Stable
Incompatibility: The product has no incompatibilities except those of water e.g. strong acids, bases, alkali metals, alkali hydrides.
Hazardous Decomposition Products: Emits So₂, NOₓ and toxic fumes.
Hazardous Polymerization: Should not occur.
Conditions to Avoid: Extreme heat, sparks, open flame, oxidizers, strong acids and alkalies.

Section 6 – HEALTH HAZARDS

Potential Health Hazards:

1. Eyes: Use only specified ophthalmic ointment in eyes. Topical ointment could cause eye irritation. May also cause hypersensitivity in some individuals.
2. Skin: Non-toxic under standard application.
3. Ingestion: May cause irritation and hypersensitivity to some individuals. Ingestion of large quantities may induce gastric disturbances.
4. Inhalation: Not likely due to the physical state of the product.

Chronic Effects: May cause irritation and hyper-sensitivity. As with other antibiotic preparations, prolonged use may result in the overgrowth of non-susceptible organisms, including fungi. Appropriate measures should be taken if such situation occurs.

Chemical Listed as Carcinogen or Potential Carcinogen: Bacitracin Zinc & Polymyxin B Sulfate

National Toxicology Program: No
I.A.R.C Monographs: No
OSHA: No
OSHA Permissible Exposure Limit: NE
ACGIH Threshold Limit Value: NE
NE= Not established

Emergency and First Aid Procedures:

1. Eyes: Flush eyes with copious amounts of water for at least 15 minutes.
2. Skin: Wash with soap and water.
3. Ingestion: Induce vomiting. Do not give anything to an unconscious person.
Section 7 – SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

Storage: Store product upright in original containers with the cap tightly closed at a controlled room temperature 20°C – 25°C (68°F – 77°F). Avoid physical damage and heat.

Neutralizing Chemical Agent: Not relevant

Steps to be taken in case material is released or spilled: Assure slippery conditions are nullified. Add dry sand or a suitable absorbent. Scoop up and remove. Dispose in accordance with federal, state and local regulations.

Waste Disposal Methods: Assure conformity with applicable disposal regulations. Dispose of absorbed material at approved incineration or chemical landfill waste disposal site.

Section 8 – PROTECTION INFORMATION

Engineering Controls: Personal involved in handling the raw material in compounding process should use adequate personal protective equipment, e.g. NIOSH approved respirator, goggles, gloves and protective clothing. Ensure training in the handling of chemical material and use of current Material Safety Data Sheets.

Airborne Exposure Limits: NE

Ventilation: Recommended

Skin Protection: Normal hygiene

Eye Protection: Normal hygiene

Respiratory Protection: General ventilation.

Section 9 – TOXICOLOGY INFORMATION

<table>
<thead>
<tr>
<th>LD 50 (Acute oral toxicity of)</th>
<th>Bacitracin Zinc</th>
<th>Polymyxin B Sulfate</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD 50 rat, oral =</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>LD 50 rat, intravenous =</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>LD 50 rat, intramuscular =</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>LD 50 mouse, Oral =</td>
<td>NE</td>
<td>790 mg (base)/kg</td>
</tr>
<tr>
<td>LD 50 mouse, intravenous =</td>
<td>NE</td>
<td>5.4 mg/kg</td>
</tr>
</tbody>
</table>

Chronic Effects on Humans: NE

Section 10 – ECOLOGICAL INFORMATION

Ecotoxicity: Not established

BOD₅ and COD: Not available

Environmental fate information: NE

Other Precautions: None

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