Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP

Safety Data Sheet
According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 11/17/2015 Date of issue: 06/05/2015 Version: 2.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier
Product Name: Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP

1.2. Intended Use of the Product
Use of the substance/mixture: Anti-infective steroid combination for topical treatment. For professional Rx use only.

1.3. Name, Address, and Telephone of the Responsible Party
Company
Putney, Inc.
One Monument Square, Suite 400
Portland, ME 04101
1-866-683-0660
www.putneyvet.com

1.4. Emergency Telephone Number
Emergency Number: 1-866-683-0660 (Monday-Friday: 8:00 AM–5:00 PM EST)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)
Skin Irrit. 2 H315
Eye Irrit. 2A H319
Resp. Sens. 1 H334
Skin Sens. 1 H317
Carc. 1B H350
STOT SE 3 H335
Asp. Tox. 1 H304
Aquatic Acute 3 H402
Aquatic Chronic 3 H412

Full text of H-phrases: see section 16

2.2. Label Elements

GHS-US Labeling
Hazard Pictograms (GHS-US): GHS07 GHS08

Signal Word (GHS-US): Danger
Hazard Statements (GHS-US): H304 - May be fatal if swallowed and enters airways.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 - May cause respiratory irritation.
H350 - May cause cancer.
H402 - Harmful to aquatic life.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary Statements (GHS-US): P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P261 - Avoid breathing vapors, mist, or spray.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P271 - Use only outdoors or in a well-ventilated area.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P273 - Avoid release to the environment.
P280 - Wear protective gloves, protective clothing, and eye protection.
P284 - In case of inadequate ventilation wear respiratory protection.
P301+P331+P310 - IF SWALLOWED: Do NOT induce vomiting. Immediately call a...
Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP
Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

2.3. Other Hazards
Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)
No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance
Not applicable

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product Identifier</th>
<th>%</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil, petroleum</td>
<td>(CAS No) Proprietary</td>
<td>Proprietary</td>
<td>Asp. Tox. 1, H304</td>
</tr>
<tr>
<td>Bacitracin zinc</td>
<td>(CAS No) 1405-89-6</td>
<td>Proprietary</td>
<td>Skin Irrit. 2, H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2A, H319</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Sens. 1A, H317</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3, H335</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 3, H402</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 3, H412</td>
</tr>
<tr>
<td>Petrolatum</td>
<td>(CAS No) Proprietary</td>
<td>Proprietary</td>
<td>Not classified</td>
</tr>
<tr>
<td>Neomycin sulfate</td>
<td>(CAS No) 1405-10-3</td>
<td>Proprietary</td>
<td>Resp. Sens. 1A, H334</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Sens. 1A, H317</td>
</tr>
<tr>
<td>Polymyxin b, sulfate (salt)</td>
<td>(CAS No) 1405-20-5</td>
<td>Proprietary</td>
<td>Acute Tox. 4 (Oral), H302</td>
</tr>
</tbody>
</table>

Full text of H-phrases: see section 16. (The chemical identity and exact percentage of composition have been withheld as a trade secret)

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures
First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.
First-aid Measures After Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.
First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water or soap and water for at least 15 minutes. Wash contaminated clothing before reuse. Obtain medical attention if irritation develops or persists.
First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
First-aid Measures After Ingestion: Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

4.2. Most important symptoms and effects, both acute and delayed
Symptoms/Injuries: May be fatal if swallowed and enters airways. Causes irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause cancer.
Symptoms/Injuries After Inhalation: May cause respiratory irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Symptoms may include: Shortness of breath. Sore throat. Cough. Burning sensation.
Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic
Ointment USP
Safety Data Sheet
According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Symptoms/Injuries After Skin Contact: Causes skin irritation. Symptoms may include: Redness, pain, swelling, itching, burning, dryness, and dermatitis. May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: Causes serious eye irritation. Symptoms may include: Redness, pain, swelling, itching, burning, tearing, and blurred vision.

Symptoms/Injuries After Ingestion: The major health threat of ingestion occurs from the danger of aspiration (breathing) of liquid drops into the lungs, particularly from vomiting. Aspiration may result in chemical pneumonia (fluid in the lungs), severe lung damage, respiratory failure and even death.

Chronic Symptoms: May cause cancer.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed
If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media
Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.
Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture
Fire Hazard: Not considered flammable but may burn at high temperatures.
Explosion Hazard: Product is not explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters
Precautionary Measures Fire: Exercise caution when fighting any chemical fire.
Firefighting Instructions: Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.
Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.
Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures
General Measures: Use only as directed. Avoid all contact with skin, eyes, or clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For Non-emergency Personnel
Protective Equipment: Use appropriate personal protection equipment (PPE).

6.1.2. For Emergency Responders
Protective Equipment: Equip cleanup crew with proper protection.
Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions
Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and Material for Containment and Cleaning Up
Methods for Cleaning Up: Absorb and/or contain spill with inert material, then place in suitable container. Clean up spills immediately and dispose of waste safely.

6.4. Reference to Other Sections
See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling
Precautions for Safe Handling: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities
Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in a dry, cool and well-ventilated place. Store locked up. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.


7.3. Specific End Use(s)
Anti-infective steroid combination for topical treatment. For professional Rx use only.
Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

<table>
<thead>
<tr>
<th>White mineral oil, petroleum (Proprietary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA ACGIH</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

8.2. Exposure Controls

Appropriate Engineering Controls

Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

Personal Protective Equipment


Materials for Protective Clothing

Chemically resistant materials and fabrics.

Hand Protection

Wear chemically resistant protective gloves.

Eye Protection

Chemical safety goggles.

Skin and Body Protection

Wear suitable protective clothing.

Respiratory Protection

In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State: Liquid
Appearance: Yellow ointment
Odor: No data available
Odor Threshold: No data available
pH: Not determined
Evaporation Rate: No data available
Melting Point: No data available
Freezing Point: No data available
Boiling Point: No data available
Flash Point: > 93 °C (> 200 °F)
Auto-ignition Temperature: No data available
Decomposition Temperature: No data available
Flammability (solid, gas): No data available
Vapor Pressure: No data available
Relative Vapor Density at 20 °C: No data available
Relative Density: No data available
Solubility: No data available
Partition Coefficient: N-Octanol/Water: No data available
Viscosity: No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.
10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).
10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, incompatible materials.
Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP

Safety Data Sheet
According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations


SECTION 11: TOXICOLOGICAL INFORMATION
11.1. Information On Toxicological Effects
Acute Toxicity: Not classified

<table>
<thead>
<tr>
<th>Substance</th>
<th>LD50/Dermal Rabbit</th>
<th>LD50/Oral Rat</th>
<th>ATE (Oral)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum (Proprietary)</td>
<td>3600 mg/kg</td>
<td>&gt; 5000 mg/kg</td>
<td>500.00 mg/kg body weight</td>
</tr>
<tr>
<td>White mineral oil, petroleum (Proprietary)</td>
<td></td>
<td>&gt; 5000 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

Skin Corrosion/Irritation: Causes skin irritation
Serious Eye Damage/Irritation: Causes serious eye irritation
Respiratory or Skin Sensitization: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction
Germ Cell Mutagenicity: Not classified
Carcinogenicity: May cause cancer
Reproductive Toxicity: Not classified
Specific Target Organ Toxicity (Single Exposure): May cause respiratory irritation.
Specific Target Organ Toxicity (Repeated Exposure): Not classified
Aspiration Hazard: May be fatal if swallowed and enters airways
Symptoms/Injuries After Inhalation: May cause respiratory irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Symptoms may include: Shortness of breath. Sore throat. Cough. Burning sensation
Symptoms/Injuries After Skin Contact: Causes skin irritation. Symptoms may include: Redness, pain, swelling, itching, burning, dryness, and dermatitis. May cause an allergic skin reaction
Symptoms/Injuries After Eye Contact: Causes serious eye irritation. Symptoms may include: Redness, pain, swelling, itching, burning, tearing, and blurred vision
Symptoms/Injuries After Ingestion: The major health threat of ingestion occurs from the danger of aspiration (breathing) of liquid drops into the lungs, particularly from vomiting. Aspiration may result in chemical pneumonia (fluid in the lungs), severe lung damage, respiratory failure and even death
Chronic Symptoms: May cause cancer

SECTION 12: ECOLOGICAL INFORMATION
12.1. Toxicity
Ecology - General: Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 Fish 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil, petroleum (Proprietary)</td>
<td>&gt; 10000 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)</td>
</tr>
</tbody>
</table>

12.2. Persistence and Degradability: No additional information available
12.3. Bioaccumulative Potential

<table>
<thead>
<tr>
<th>Substance</th>
<th>Log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil, petroleum (Proprietary)</td>
<td>&gt; 6</td>
</tr>
</tbody>
</table>

12.4. Mobility in Soil: No additional information available
12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS
13.1. Waste treatment methods
Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION
14.1. In Accordance with DOT: Not regulated for transport
14.2. In Accordance with IMDG: Not regulated for transport
14.3. In Accordance with IATA: Not regulated for transport
# Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP

## Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

---

### SECTION 15: REGULATORY INFORMATION

#### 15.1 US Federal Regulations

<table>
<thead>
<tr>
<th>Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP</th>
</tr>
</thead>
</table>
| SARA Section 311/312 Hazard Classes | Immediate (acute) health hazard  
Delay (chronic) health hazard |

- **Petrolatum (Proprietary)**  
  Listed on the United States TSCA (Toxic Substances Control Act) inventory

- **White mineral oil, petroleum (Proprietary)**  
  Listed on the United States TSCA (Toxic Substances Control Act) inventory

- **Bacitracin zinc (1405-89-6)**  
  Listed on the United States TSCA (Toxic Substances Control Act) inventory

- **Neomycin sulfate (1405-10-3)**  
  Listed on the United States TSCA (Toxic Substances Control Act) inventory

#### 15.2 US State Regulations

<table>
<thead>
<tr>
<th>Neomycin sulfate (1405-10-3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. - California - Proposition 65 - Developmental Toxicity</td>
</tr>
<tr>
<td>WARNING: This product contains chemicals known to the State of California to cause birth defects.</td>
</tr>
</tbody>
</table>

---

### SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

- **Revision Date**: 11/17/2015
- **Other Information**: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

### GHS Full Text Phrases:

<table>
<thead>
<tr>
<th>Acute Tox. 4 (Oral)</th>
<th>Hazardous to the aquatic environment - Acute Hazard Category 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 3</td>
<td>Hazardous to the aquatic environment - Chronic Hazard Category 3</td>
</tr>
<tr>
<td>Asp. Tox. 1</td>
<td>Aspiration hazard Category 1</td>
</tr>
<tr>
<td>Carc. 1B</td>
<td>Carcinogenicity Category 1B</td>
</tr>
<tr>
<td>Eye Irrit. 2A</td>
<td>Serious eye damage/eye irritation Category 2A</td>
</tr>
<tr>
<td>Resp. Sens. 1</td>
<td>Respiratory sensitisation Category 1</td>
</tr>
<tr>
<td>Resp. Sens. 1A</td>
<td>Respiratory sensitisation Category 1A</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>Skin corrosion/irritation Category 2</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>Skin sensitization Category 1</td>
</tr>
<tr>
<td>Skin Sens. 1A</td>
<td>Skin sensitization Category 1A</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity (single exposure) Category 3</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H304</td>
<td>May be fatal if swallowed and enters airways</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H334</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled</td>
</tr>
<tr>
<td>H335</td>
<td>May cause respiratory irritation</td>
</tr>
<tr>
<td>H350</td>
<td>May cause cancer</td>
</tr>
<tr>
<td>H402</td>
<td>Harmful to aquatic life</td>
</tr>
<tr>
<td>H412</td>
<td>Harmful to aquatic life with long lasting effects</td>
</tr>
</tbody>
</table>

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)