SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Neo-Polycin™ HC Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Acetate Ophthalmic Ointment USP
Synonym: 4Y9

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451
Emergency phone number: 888-464-2986

Recommended use: Human drug – anti-infective steroid combination
Restrictions on use: Prescription use only.

Date of Preparation: July 2, 2014

2. HAZARD(S) IDENTIFICATION

Classification:

<table>
<thead>
<tr>
<th>Physical</th>
<th>Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not hazardous</td>
<td>Skin Sensitization Category 1</td>
</tr>
<tr>
<td></td>
<td>Reproductive Toxicity Category 2</td>
</tr>
<tr>
<td></td>
<td>Aspiration Toxicity Category 1</td>
</tr>
</tbody>
</table>

Label Elements: Danger!

Hazard statement(s)
May cause an allergic skin reaction.
May be fatal if swallowed and enters airways.
Suspected of damaging fertility or the unborn child.

Precautionary statement(s)
Contaminated clothing must not be allowed out of the workplace.
Wear protective clothing and gloves.
IF on skin: wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.
IF Swallowed: Immediately call a poison center or doctor. Do NOT induce vomiting.
IF exposed or concerned: Get medical attention.
Store locked up.
Dispose in accordance with local and national regulations.

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Avoid breathing mists.
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS No.</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>20-40%</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>1405-20-5</td>
<td>1-10%</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>1405-89-6</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Hydrocortisone Acetate</td>
<td>50-03-3</td>
<td>1-5%</td>
</tr>
<tr>
<td>White Petrolatum</td>
<td>8009-03-8</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Mineral Oil</td>
<td>8042-47-5</td>
<td>Proprietary</td>
</tr>
</tbody>
</table>

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin contact: This product is intended for use on the skin or eyes. For unintended contact, wash skin with soap and water. If irritation develops and persists, get medical attention. Remove contaminated clothing and wash it before reuse.

Eye contact: This product is intended for use in the eyes. For unintended contact, immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: Rinse mouth with water. Do NOT induce vomiting. Never give anything by mouth to a person who is unconscious or convulsing. Get immediate medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Ingestion may cause gastrointestinal distress. Possible aspiration hazard. May enter the lungs during swallowing or vomiting and cause severe lung damage. Contains ingredients that may cause adverse effects on reproduction and the unborn child.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is required for ingestion.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray or fog, CO2, dry chemical or foam. Do not use solid water jet as this may spread fire.

Specific hazards arising from the chemical: Product is not flammable or combustible but will burn in a fire.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.
Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

### 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid the generation of mists. Avoid unintended contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure guidelines:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Exposure Level</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin Sulfate</td>
<td>100 ug/m³ TWA</td>
<td>PERRIGO OEL</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>100 ug/m³ TWA</td>
<td>PERRIGO OEL</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>1000 ug/m³ TWA</td>
<td>PERRIGO OEL</td>
</tr>
<tr>
<td>Hydrocortisone Acetate</td>
<td>100 ug/m³ TWA</td>
<td>PERRIGO OEL</td>
</tr>
<tr>
<td>White Petrolatum</td>
<td>5 mg/m³ (inhalable)</td>
<td>TWA ACGIH TLV</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³ TWA</td>
<td>OSHA PEL</td>
</tr>
<tr>
<td>Mineral Oil</td>
<td>5 mg/m³ (inhalable)</td>
<td>TWA ACGIH TLV</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³ TWA</td>
<td>OSHA PEL</td>
</tr>
</tbody>
</table>

**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to minimize exposures levels.

**Individual protection measures:**

**Respiratory protection:** None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved organic vapor/particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

**Skin protection:** Impervious gloves recommended if contact with the drug product is possible.

**Eye protection:** None required for normal use. Chemical safety goggles recommended for manufacturing operations.

**Other:** None known.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance (physical state, color, etc.):** Pale yellow ointment

**Odor:** No odor

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor threshold</td>
<td>Not determined</td>
</tr>
<tr>
<td>pH</td>
<td>Not determined</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not determined</td>
</tr>
<tr>
<td>Flash point</td>
<td>&gt;93°C (200°F)</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not determined</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not determined</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammable limits: LEL</td>
<td>Not determined</td>
</tr>
<tr>
<td>UEL</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapor density</td>
<td>Not determined</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Insoluble in water</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.
Conditions to avoid: None known.
Incompatible materials: Avoid oxidizing agents.
Hazardous decomposition products: Thermal decomposition may yield carbon and sulfur oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract.
Ingestion: Swallowing may cause gastrointestinal distress with nausea and diarrhea. Possible aspiration hazard. May enter the lungs during swallowing or vomiting and cause severe lung damage.
Skin contact: No adverse effects are expected. Minor irritation is possible.
Eye contact: This product is intended for use in the eye. Contact may cause slight irritation.
Chronic Effects: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria.
Sensitization: May cause skin sensitization. Neomycin sulfate is a skin sensitizer.

Germ Cell Mutagenicity: Components are not classified as germ cell mutagens. Studies to determine the mutagenicity of hydrocortisone acetate were negative.
Reproductive Toxicity: Neomycin Sulfate causes adverse reproductive effects in laboratory animals. No adverse effects on male or female fertility, litter size or survival were observed in rabbits given bacitracin zinc at 100 g/ton of diet. Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.
Carcinogenicity: Long-term animal studies have not been performed to evaluate the carcinogenic potential of neomycin sulfate, polymyxin B sulfate, bacitracin zinc, or topical corticosteroids. Long-term studies in rats, rabbits and mice showed no evidence of carcinogenicity or mutagenicity attributable to oral administration of corticosteroids. None of the components are listed as carcinogens by IARC, NTP or OSHA.

Acute Toxicity Values: Neomycin Sulfate: Oral rat LD50 2750 mg/kg
Polymyxin B Sulfate: LD50 oral mouse 790 mg/kg
Bacitracin Zinc: LD50 oral mouse >3750 mg/kg
Hydrocortisone Acetate: LD50 oral rat 5000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: Hydrocortisone: EC50 daphnia magna >100 mg/L/48 hr.
Persistence and degradability: No data is available
Bioaccumulative potential: No data is available
Mobility in soil: No data is available.
Other adverse effects: Zinc is known to be toxic to aquatic organisms. Avoid release to the environment.
13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

<table>
<thead>
<tr>
<th>UN Number</th>
<th>Proper shipping name</th>
<th>Hazard Class</th>
<th>Packing Group</th>
<th>Environmental Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT</td>
<td>Not Regulated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TDG</td>
<td>Not Regulated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMDG</td>
<td>Not Regulated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IATA</td>
<td>Not Regulated</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Acute Health, Chronic Health
EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313: None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:
Canadian CEPA: This product is a drug and not subject to CEPA regulations.
Canadian WHMIS Classification: Drugs are exempt from WHMIS
This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

NFPA Rating: Health = 1  Flammability = 1  Instability = 0
HMIS Rating: Health = 1*  Flammability = 1  Physical Hazard = 0

SDS Revision History: New SDS
Date of preparation: July 2, 2014
Date of last revision: New SDS

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer’s directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user’s intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).