1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: Neomycin Sulfate, Isoflupredone Acetate and Tetracaine Hydrochloride
Topical Powder

Trade Name: NEO-PREDEF
Chemical Family: Mixture
Intended Use: Veterinary product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Powder

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Short Term: Topical anesthetic drug: may cause localized numbness

Known Clinical Effects: The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Clinical use of this drug has caused kidney dysfunction, effects on hearing, decrease in blood pressure (hypotension), nervousness, blurred vision, anxiety, drowsiness, convolution, and respiratory arrest.

EU Indication of danger: Not classified


Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoflupredone Acetate</td>
<td>338-98-7</td>
<td>206-423-9</td>
<td>Repr.Cat.3;R63</td>
<td>0.1</td>
</tr>
<tr>
<td>Tetracaine Hydrochloride</td>
<td>136-47-0</td>
<td>205-248-5</td>
<td>Not Listed</td>
<td>0.5</td>
</tr>
</tbody>
</table>

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3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
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<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>215-773-1</td>
<td>Xn;R42/43</td>
<td>0.5</td>
</tr>
<tr>
<td>Myristyl-gamma-picolinium chloride</td>
<td>2748-88-1</td>
<td>220-387-1</td>
<td>Xn;R22</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: This material produces toxic fumes of nitrogen and sulfur oxides, carbon dioxide, and carbon monoxide during fires.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:
Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions:
Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Neomycin Sulfate
Pfizer OEL TWA-8 Hr: 100 µg/m³, Sensitizer

Isoflupredone Acetate
Pfizer Occupational Exposure Band (OEB): OEB 4 - Skin (control exposure to the range of >1µg/m³ to <10µg/m³, provide additional precautions to protect from skin contact)

Analytical Method:
Analytical method available for neomycin sulfate. Contact Pfizer Inc for further information.

Engineering Controls:
Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls:
Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:
Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:
Wear safety glasses or goggles if eye contact is possible.

Skin:
Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:
If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Powder
Molecular Formula: Mixture
Color: No data available.
Molecular Weight: Mixture
10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Tetracaine Hydrochloride
Mouse Oral LD 50 160 mg/kg
Rat Sub-tenon injection (eye) LD 50 23.5 mg/kg
Rat Subcutaneous LD 50 24 mg/kg

Neomycin Sulfate
Rat Oral LD 50 2750 mg/kg
Mouse Oral LD 50 2880 mg/kg
Mouse Intraperitoneal LD 50 116 mg/kg
Rat Subcutaneous LD 50 633 mg/kg
Mouse Subcutaneous LD 50 275 mg/kg

Myristyl-gamma-picolinium chloride
Rat Oral LD 50 250 mg/kg
Rat Para-periosteal LD50 30 mg/kg
Rat Intraperitoneal LD50 7500 ug/kg
Rat Subcutaneous LD50 200 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Neomycin Sulfate
Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Minimal

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Neomycin Sulfate
6 Week(s) Dog Oral 100 mg/kg/day NOAEL No effects at maximum dose
3 Month(s) Guinea Pig Oral 10 mg/kg/day NOAEL No effects at maximum dose
3 Month(s) Dog Subcutaneous 20 mg/kg/day LOAEL Kidney
12 Month(s) Cat Oral 12 mg/kg/day NOAEL Blood forming organs
3 Month(s) Guinea Pig Subcutaneous 10 mg/kg/day LOAEL Kidney

Myristyl-gamma-picolinium chloride
60 Day(s) Rat Oral 2400 mg/kg Death

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Neomycin Sulfate
11. TOXICOLOGICAL INFORMATION

**Genetic Toxicity:** (Study Type, Cell Type/Organism, Result)
- Neomycin Sulfate
  - Bacterial Mutagenicity (Ames)  *Salmonella*, *E. coli*  Negative
  - Mammalian Cell Mutagenicity  Chinese Hamster Ovary (CHO) cells  Negative
  - *In Vivo* Cytogenetics  Mouse  Negative
  - *In Vitro* Chromosome Aberration  Human Lymphocytes  Positive

**Carcinogenicity:** (Duration, Species, Route, Dose, End Point, Effect(s))
- Neomycin Sulfate
  - 2 Year(s)  Rat  Oral  25 mg/kg/day  NOAEL  Not carcinogenic

**Carcinogen Status:**
None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

12. ECOLOGICAL INFORMATION

**Environmental Overview:**
Releases to the environment should be avoided. Environmental properties have not been investigated.

**Aquatic Toxicity:** (Species, Method, End Point, Duration, Result)
- Neomycin Sulfate
  - *Daphnia magna* (Water Flea)  OECD  EC50  48 Hours  68 mg/L
  - *Salmo gairdneri* (Trout)  OECD  NOEC  96 Hours  >1000 mg/L

**Bacterial Inhibition:** (Inoculum, Method, End Point, Result)
- Neomycin Sulfate
  - Activated sludge  OECD  EC50  3 Hours  399 mg/L

13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:**
Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Isotropine Acetate
Australia (AICS): Listed
EU EINECS/ELINCS List 206-423-9

Tetracaine Hydrochloride
Australia (AICS): Listed
EU EINECS/ELINCS List 205-248-5

Neomycin Sulfate
California Proposition 65 development toxicity, initial date 10/1/92 (internal use)
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 215-773-1

Lactose hydrous
Australia (AICS): Listed

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.
R42/43 - May cause sensitization by inhalation and skin contact.
MATERIAL SAFETY DATA SHEET

Material Name: Neomycin Sulfate, Isoflupredone Acetate and Tetracaine Hydrochloride Topical Powder
Revision date: 21-Apr-2010

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet