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

Product Identifier
Material Name: Oxytetracycline Hydrochloride/Polymyxin B Sulfate Ophthalmic Ointment
Trade Name: TERRAMYCIN
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Veterinary product used as antibiotic agent
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet
Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

2. HAZARDS IDENTIFICATION

Appearance: Light yellow ointment
Classification of the Substance or Mixture
GHS - Classification
Reproductive Toxicity: Category 1A

EU Classification:
EU Indication of danger: Toxic to reproduction: Category 1
EU Symbol: T
EU Risk Phrases:
R61 - May cause harm to the unborn child.

Label Elements
Signal Word: Danger
Hazard Statements: H360D - May damage the unborn child

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on male reproductive system, liver, the developing fetus.

Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Symptoms of chronic exposure to tetracyclines include redness and swelling of the skin, rash, chills, tooth discoloration, yellowing of the skin and eyes, nausea, vomiting, diarrhea, stomach pain, and chest pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Wheezing, asthma, low or high blood pressure, dizziness, lung congestion, blood changes (leukocytosis, atypical lymphocytes, toxic granulation of granulocytes and thrombocytopenia purpura), convulsion or shock may also occur. Clinical use of this drug has caused liver effects, kidney dysfunction.


Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Light mineral oil (liquid paraffin)</td>
<td>8042-47-5</td>
<td>232-455-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Oxytetracycline hydrochloride</td>
<td>2058-46-0</td>
<td>218-161-2</td>
<td>Repr. Cat.1;R61</td>
<td>Repr. 1A (H360D)</td>
<td>0.5</td>
</tr>
<tr>
<td>Polymyxin B sulfate</td>
<td>1405-20-5</td>
<td>215-774-7</td>
<td>Xn;R22 Xn;R42/43</td>
<td>Acute Tox 4 (H302) Resp Sens 1 (H334) Skin Sens 1 (H317)</td>
<td>10,000 units/g</td>
</tr>
<tr>
<td>White petrolatum</td>
<td>8009-03-8</td>
<td>232-373-2</td>
<td>Carc.Cat.2; R45</td>
<td>Carc. 1B (H350)</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 and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. If irritation occurs or persists, get medical attention. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

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.

Most Important Symptoms and Effects, Both Acute and Delayed
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.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE-FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, hydrogen chloride and other chlorine- and sulfur-containing compounds.

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

Advice for Fire-Fighters
Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.
Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Incompatible Materials:** Bases, strong oxidizers

**Specific end use(s):** No data available

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

**Light mineral oil (liquid paraffin)**
- ACGIH Threshold Limit Value (TWA): 5 mg/m³

**Oxytetracycline hydrochloride**
- Zoetis OEL TWA 8-hr: 500µg/m³

**White petrolatum**
- ACGIH Threshold Limit Value (TWA): 5 mg/m³ (oil mist, mineral)
- ACGIH Threshold Limit Value (STEL): 10 mg/m³ (oil mist, mineral)

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

**Light mineral oil (liquid paraffin)**
- Zoetis OEB: OEB 2 (control exposure to the range of 100µg/m³ to < 1000µg/m³)

**Polymyxin B sulfate**
- Zoetis OEB: OEB 2 (control exposure to the range of 100µg/m³ to < 1000µg/m³)

**Analytical Method:** Analytical method available for Oxytetracycline Hydrochloride. Contact Pfizer Inc for further information.

**Exposure Controls**

**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 air contamination levels below the exposure limits or within the OEB range listed above in this section.

**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:** Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Ointment
Odor: No data available.
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available.
Boiling Point (°C): No data available.
Partition Coefficient: No data available
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  Upper Explosive Limits (Liquid) (% by Vol.): No data available
  Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable
Possibility of Hazardous Reactions
  Oxidizing Properties: None
  Conditions to Avoid: Contact with moist air causes darkening of this material. Direct sunlight, excessive heat, sparks or open flame
  Incompatible Materials: Bases, strong oxidizers
  Hazardous Decomposition Products: See Section 5 - under Hazardous combustion products.

11. TOXICOLOGICAL INFORMATION

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

Acute Toxicity: (Species, Route, End Point, Dose)
Light mineral oil (liquid paraffin)
  Rat Oral LD50 > 5000 mg/kg
11. TOXICOLOGICAL INFORMATION

**Oxytetracycline hydrochloride**
Mouse Oral LD50 6696 mg/kg
Mouse SC LD50 > 600mg/kg
Rat SC LD50 800mg/kg
Mouse IV LD50 100mg/kg
Rat IV LD50 302mg/kg

**Polymyxin B sulfate**
Mouse Oral LD50 790 mg/kg
Rat SC LD50 50mg/kg
Rat IV LD50 3.98mg/kg

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

**Light mineral oil (liquid paraffin)**
Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Non-irritating
Skin Sensitization - GPMT Guinea Pig Negative

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

**Light mineral oil (liquid paraffin)**
90 Day(s) Rat Oral 1800 mg/kg/day NOAEL Liver

**Oxytetracycline hydrochloride**
13 Week(s) Mouse Oral 3821 mg/kg/day NOAEL None identified
13 Week(s) Rat Oral 3352 mg/kg/day NOAEL Liver
12 Month(s) Dog Oral 125 mg/kg/day NOAEL Male reproductive system
24 Month(s) Dog Oral 250 mg/kg/day NOAEL None identified
14 Day(s) Oral 108 g/kg LOEL Brain

**Polymyxin B sulfate**
9 Day(s) Mouse Subcutaneous 284 mg/kg LOAEL Skin

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

**Oxytetracycline hydrochloride**
2 Generation Reproductive Toxicity Rat Oral 18 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Oral 1500 mg/kg/day NOAEL Maternal Toxicity
Embryo / Fetal Development Mouse Oral 2100 mg/kg/day NOAEL Embryotoxicity

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

**Light mineral oil (liquid paraffin)**
*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Negative
*In Vitro* Mammalian Cell Mutagenicity Mouse Lymphoma Negative

**Oxytetracycline hydrochloride**
## 11. TOXICOLOGICAL INFORMATION

**Carcinogenicity:**

Duration, Species, Route, Dose, End Point, Effect(s)

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

**Aquatic Toxicity:**

Species, Method, End Point, Duration, Result

- **Aquatic Toxicity Comments:**
  - A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

**Persistence and Degradability:**

- No data available

**Bio-accumulative Potential:**

- No data available

**Mobility in Soil:**

- No data available

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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:**

Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

**Toxicity:**

**Aquatic Toxicity:**

Species, Method, End Point, Duration, Result

- **Aquatic Toxicity Comments:**
  - A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

**Persistence and Degradability:**

- No data available

**Bio-accumulative Potential:**

- No data available

**Mobility in Soil:**

- No data available
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

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A
(Bad file name or number)

Light mineral oil (liquid paraffin)
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 232-455-8

Oxytetracycline hydrochloride
CERCLA/SARA 313 Emission reporting Not Listed
developmental toxicity initial date 10/1/91 internal use
California Proposition 65
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 218-161-2

Polymyxin B sulfate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
EU EINECS/ELINCS List 215-774-7
15. REGULATORY INFORMATION

White petrolatum

CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present

REACH - Carcinogens Category 2: Present
EU EINECS/ELINCS List: 232-373-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child
Carcinogenicity-Cat.1B; H350 - May cause cancer

Carcinogenic: Category 2
Toxic to reproduction: Category 1
Xn - Harmful

R22 - Harmful if swallowed.
R45 - May cause cancer.
R61 - May cause harm to the unborn child.
R42/43 - May cause sensitization by inhalation and skin contact.

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis 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