

# MATERIAL SAFETY DATA SHEET



Revision date: 04-Sep-2013

Version: 2.0

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## 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

**Zoetis Belgium S.A.**  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

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

**Emergency telephone number:**  
**International CHEMTREC (24 hours): +1-703-527-3887**

## 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

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### 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.  
Hazardous Substance. Non-Dangerous Goods.

### Australian Hazard Classification (NOHSC):

#### 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Light mineral oil (liquid paraffin)	8042-47-5	232-455-8	Not Listed	Not Listed	*
Oxytetracycline hydrochloride	2058-46-0	218-161-2	Repr. Cat.1;R61	Repr. 1A (H360D)	0.5
Polymyxin B sulfate	1405-20-5	215-774-7	Xn;R22 Xn;R42/43	Acute Tox 4 (H302) Resp Sens 1 (H334) Skin Sens 1 (H317)	10,000 units/g
White petrolatum	8009-03-8	232-373-2	Carc.Cat.2; R45	Carc. 1B (H350)	*

### 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.

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**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 Products:** 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.

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### 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

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

#### Light mineral oil (liquid paraffin)

**ACGIH Threshold Limit Value (TWA)** 5 mg/m<sup>3</sup>

#### Oxytetracycline hydrochloride

**Zoetis OEL TWA 8-hr** 500µg/m<sup>3</sup>

#### White petrolatum

**ACGIH Threshold Limit Value (TWA)** 5 mg/m<sup>3</sup> (oil mist, mineral)

**ACGIH Threshold Limit Value (STEL)** 10 mg/m<sup>3</sup> (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 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

#### Polymyxin B sulfate

**Zoetis OEB** OEB 2 (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

#### 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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Ointment	<b>Color:</b>	Light yellow
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	No data available		
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>		No data available	
<b>Flammability (Solids):</b>		No data available	
<b>Flash Point (Liquid) (°C):</b>		No data available	
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Polymerization:</b>		Will not occur	

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	None
<b>Conditions to Avoid:</b>	Contact with moist air causes darkening of this material. Direct sunlight, excessive heat, sparks or open flame
<b>Incompatible Materials:</b>	Bases, strong oxidizers
<b>Hazardous Decomposition Products:</b>	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

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### 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

#### Acute Toxicity Comments:

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

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Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative  
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative  
Micronucleus Mouse Negative  
Mammalian Cell Mutagenicity Mouse Lymphoma Positive with activation

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Oxytetracycline hydrochloride**

24 Month(s) Rat Oral, in feed 150 mg/kg/day NOEL Not carcinogenic  
103 Week(s) Mouse Oral, in feed 1372 mg/kg/day NOEL Not carcinogenic

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### 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)

##### **Light mineral oil (liquid paraffin)**

*Lepomis macrochirus* (Bluegill Sunfish) OECD LC50 96 Hours > 10000 mg/L

##### **Oxytetracycline hydrochloride**

*Oncorhynchus mykiss* (Rainbow Trout) ASTM EPA LC50 96 Hours > 116 mg/L  
*Daphnia magna* (Water Flea) ASTM EPA EC50 48 Hours > 102 mg/L  
*Lepomis macrochirus* (Bluegill Sunfish) ASTM EPA LC50 96 Hours > 94.9 mg/L  
*Selenastrum capricornutum* (Green Alga) ISO EC50 72 Hours 4.18 mg/L

#### **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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### 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
California Proposition 65	developmental toxicity initial date 10/1/91 internal use
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



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### 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 - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 28.
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**