# SAFETY DATA SHEET



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

**Product Identifier**

**Material Name: Oxytetracycline Hydrochloride Soluble Powder**

**Trade Name:** Oxytet® Soluble
**Synonyms:** Terramycin
**Chemical Family:** Tetracycline antibiotic

**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 and Drug 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:** Yellow powder

**Classification of the Substance or Mixture**

**GHS - Classification**

Reproductive Toxicity: Category 1A

**US OSHA Specific - Classification**

**Physical Hazard:** Combustible Dust

**EU Classification:**

EU Indication of danger: Toxic

EU Symbol: T
EU Risk Phrases:
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

**Label Elements**

**Signal Word:** Danger
**Hazard Statements:** H360 - May damage fertility or the unborn child
May form combustible dust concentrations in air

**Precautionary Statements:**

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
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.

**Australian Hazard Classification (NOHSC):** Hazardous Substance. Non-Dangerous Goods.

**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 | % |
|---|---|---|---|---|---|
| Sucrose | 57-50-1 | 200-334-9 | Not Listed | Not Listed | 50-70 |
| Oxytetracycline hydrochloride | 2058-46-0 | 218-161-2 | Repr. Cat.1;R61 | Repr. 1A (H360D) | 30-50 |

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**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. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. Get 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:** Breathing dust may worsen asthma symptoms.

**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:** May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions. Dust can form an explosive mixture in air.

**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. Avoid dust formation.

**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:** Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. 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:** Avoid generating airborne dust. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. 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**

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Minimize dust generation and accumulation. Use with adequate ventilation. Wash thoroughly after handling. When handling, use appropriate personal protective equipment (see Section 8). 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 at room temperature in properly labeled containers. Keep away from heat, sparks, flame, and other sources of ignition. Keep away from direct sunlight.

**Storage Temperature:** 20-25°C

**Specific end use(s):** Veterinary antibiotic agent

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

**Refer to available public information for specific member state Occupational Exposure Limits.**

**Sucrose**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 10 $mg/m^3$ |
| **Australia TWA** | 10 $mg/m^3$ |
| **Belgium OEL - TWA** | 10 $mg/m^3$ |
| **Bulgaria OEL - TWA** | 10.0 $mg/m^3$ |
| **Estonia OEL - TWA** | 10 $mg/m^3$ |
| **France OEL - TWA** | 10 $mg/m^3$ |
| **Ireland OEL - TWAs** | 10 $mg/m^3$ |
| **Latvia OEL - TWA** | 5 $mg/m^3$ |
| **Lithuania OEL - TWA** | 10 $mg/m^3$ |
| **OSHA - Final PELS - TWAs:** | 15 $mg/m^3$ |
| **Portugal OEL - TWA** | 10 $mg/m^3$ |
| **Slovakia OEL - TWA** | 6 $mg/m^3$ |
| **Spain OEL - TWA** | 10 $mg/m^3$ |

**Oxytetracycline hydrochloride**

| | |
|---|---|
| **Zoetis OEL TWA 8-hr** | 500 $\mu g/m^3$ |

**Exposure Controls**

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

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

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|---|
| **Hands:** | Wear impervious gloves if skin contact is possible. |
| **Eyes:** | Wear safety glasses or goggles if eye contact is possible. |
| **Skin:** | Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. |
| **Respiratory protection:** | If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---|---|---|---|
| **Physical State:** | Powder | **Color:** | Yellow |
| **Odor:** | No data available. | **Odor Threshold:** | No data available. |
| **Molecular Formula:** | Mixture | **Molecular Weight:** | 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: (Method, pH, Endpoint, Value)**
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 |

**Flammablity:**

| | |
|---|---|
| **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 |

## 10. STABILITY AND REACTIVITY

| | |
|---|---|
| **Reactivity:** | No data available |
| **Chemical Stability:** | Stable |
| **Possibility of Hazardous Reactions** | |
| **Oxidizing Properties:** | No data available |
| **Conditions to Avoid:** | Keep away from heat, spark, flames and all other sources of ignition. Avoid dispersion as a dust cloud. Dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions. |
| **Incompatible Materials:** | As a precautionary measure, keep away from strong oxidizers |
| **Hazardous Decomposition Products:** | Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors. |

## 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**
**General Information:** Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. Routes of exposure: eye contact , skin contact , inhalation

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

**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

**Sucrose**
Rat Oral LD50 29.7 g/kg

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

**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) Rat Oral 108 g/kg LOEL Brain

**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,

**Reproductive & Developmental Toxicity Comments:** may have the potential to produce effects on the developing fetus.

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

**Oxytetracycline hydrochloride**
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

**Sucrose**
Bacterial Mutagenicity (Ames) *Salmonella* Negative

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

## 11. TOXICOLOGICAL INFORMATION

**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 of the formulation have not been 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)**

**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 aquatic toxicity was not observed at the maximum dose tested.

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

## 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Should not be released into the environment. 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
This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

**Sucrose**

| | |
|---|---|
| **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 IV - Exemptions from the obligations of Register:** | Present |
| **EU EINECS/ELINCS List** | 200-334-9 |

**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 |

## 16. OTHER INFORMATION

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

Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

Toxic to reproduction: Category 1

R61 - May cause harm to the unborn child.

**Data Sources:** The data contained in this SDS 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 11 - Toxicology Information.

**Prepared by:** Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this 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**