



# MATERIAL SAFETY DATA SHEET

Revision date: 06-Dec-2006

Version: 1.3

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

Pfizer Animal Health  
Pfizer Inc  
235 East 42nd Street  
New York, NY 10017  
Poison Control Center Phone: 1-866-531-8896  
Technical Services Phone: 1-800-366-5288

Pfizer Ltd,  
Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Oxytetracycline Hydrochloride Soluble Powder**

Trade Name: TERRAMYCIN  
Chemical Family: Mixture  
Intended Use: Veterinary product used as antibiotic agent

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Sucrose	57-50-1	200-334-9	*
Oxytetracycline hydrochloride	2058-46-0	218-161-2	5-20

Ingredient	CAS Number	EU EINECS List	%
Polysorbate 80	9005-65-6	Not listed	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Yellow powder  
**Signal Word:** DANGER

**Statement of Hazard:** May damage the unborn child.

**Additional Hazard Information:**  
**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.

**EU Indication of danger:** Toxic to reproduction: Category 1

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### EU Hazard Symbols:



### EU Risk Phrases:

R61 - May cause harm to the unborn child.

### 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.

## 4. 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.

## 5. FIRE FIGHTING MEASURES

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products:** May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.
- Fire Fighting Procedures:** Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.
- 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.

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### 7. HANDLING AND STORAGE

**General Handling:** Minimize dust generation and accumulation. Use only in a well-ventilated area. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Wash thoroughly after handling.

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Sucrose

OSHA - Final PELs - TWAs:	= 15 mg/m <sup>3</sup> TWA	total
	= 5 mg/m <sup>3</sup> TWA	
ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA	
Australia TWA	= 10 mg/m <sup>3</sup> TWA	

#### Oxytetracycline hydrochloride

Pfizer OEL TWA-8 Hr:	0.5 mg/m <sup>3</sup>
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**Analytical Method:** Analytical method available for Oxytetracycline Hydrochloride. Contact Pfizer Inc for further information.

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk.

#### Personal Protective Equipment:

<b>Hands:</b>	Rubber gloves
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Wear protective clothing when working with large quantities.
<b>Respiratory protection:</b>	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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Powder	<b>Color:</b>	Yellow
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable

**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 various forms of the active ingredient.

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

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### Polysorbate 80

Rat Intravenous LD 50 1790 mg/kg  
Mouse Oral LD 50 25 g/kg

### Oxytetracycline hydrochloride

Mouse Oral LD50 6696 mg/kg  
Mouse SC LD50 600 mg/kg  
Rat SC LD50 800 mg/kg  
Mouse IV LD50 100 mg/kg  
Rat IV LD50 302 mg/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

### 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

### 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:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided. See aquatic toxicity data, below:

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## Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

### Oxytetracycline hydrochloride

Rainbow Trout LC50 > 116 mg/L

### Aquatic Toxicity Comments:

A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

## 13. DISPOSAL CONSIDERATIONS

### Disposal Procedures:

Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

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

## 15. REGULATORY INFORMATION

### EU Symbol:

T

### EU Indication of danger:

Toxic to reproduction: Category 1

### EU Risk Phrases:

R61 - May cause harm to the unborn child.

### EU Safety Phrases:

S22 - Do not breathe dust.  
S53 - Avoid exposure - obtain special instructions before use.  
S36/37 - Wear suitable protective clothing and gloves.

### OSHA Label:

DANGER

May damage the unborn child.

### Canada - WHMIS: Classifications

### WHMIS hazard class:

Class D, Division 2, Subdivision A



### Sucrose

Inventory - United States TSCA - Sect. 8(b)

Present

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Australia (AICS):	Present
EU EINECS List	200-334-9
<b>Polysorbate 80</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
<b>Oxytetracycline hydrochloride</b>	
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 List	218-161-2

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 2 - Composition / Information on Ingredients.

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

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 a warranty of any kind, expressed or implied.

**End of Safety Data Sheet**