MATERIAL SAFETY DATA SHEET

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 scours tablets

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	%
Starch	9005-25-8	232-679-6	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Oxytetracycline hydrochloride	2058-46-0	218-161-2	8
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Sorbitol	6706-59-8	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: Yellow tablets
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 liver, male reproductive system, 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

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. If irritation occurs or persists, get 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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

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

Fire / Explosion Hazards: Not applicable

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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Starch

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA = 5 mg/m^3 TWA	total
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	

Microcrystalline cellulose

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA = 5 mg/m^3 TWA	total
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	

Oxytetracycline hydrochloride

Pfizer OEL TWA-8 Hr:	0.5 mg/m^3

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m^3 TWA	

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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

Engineering Controls: Good general ventilation should be sufficient to control airborne levels.

Personal Protective Equipment:

Hands:	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection:	None required under normal conditions of use. 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:

Physical State:	Tablet	**Color:**	Yellow
Odor:	Odorless	**Molecular Formula:**	Mixture
Molecular Weight:	Mixture		

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: Strong oxidizing agents, strong bases

Hazardous Decomposition Products: See Section 5 - under Hazardous combustion products.
Polymerization: Will not occur

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)

Starch
Mouse IP LD50 6600 mg/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

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

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)

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

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:

S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
May damage the unborn child.

Canada - WHMIS: Classifications

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

Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9

Oxytetracycline hydrochloride

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

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

16. OTHER INFORMATION

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