MATERIAL SAFETY DATA SHEET

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

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Material Name: Oxytetracycline intramuscular solution

Trade Name: Not determined
Synonyms: TERRAMYCIN® intramuscular solution
Chemical Family: Tetracycline derivative
Intended Use: Antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Lidocaine USP	137-58-6	205-302-8	*
Monoethanolamine 99% - NF	141-43-5	205-483-3	*
Monothioglycerol	96-27-5	202-495-0	*
Citric acid	77-92-9	201-069-1	*
Magnesium chloride hexahydrate	7791-18-6	Not listed	*
Sodium formaldehyde sulfoxylate - NF	149-44-0	205-739-4	*
Oxytetracycline	79-57-2	201-212-8	*

Ingredient	CAS Number	EU EINECS List	%
Propylene glycol	57-55-6	200-338-0	*

Additional Information: * Proprietary

3. HAZARDS IDENTIFICATION

Appearance: Liquid in glass ampules or vials
Signal Word: CAUTION

Statement of Hazard: May cause eye, skin and respiratory tract irritation Accidental ingestion of large amounts of this material may be harmful; see known clinical effects, below May cause allergic skin reaction.

Eye Contact: None known; however, direct contact with any foreign material may cause eye irritation. Signs and symptoms might include redness, swelling, blurred vision or pain.
Skin Contact: May cause skin irritation. May cause allergic reactions in susceptible individuals.
Inhalation: May cause nose, throat and lung irritation. May cause allergic reaction.
Ingestion: None known

Known Clinical Effects: 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. May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal 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.

EU Indication of danger: Not classified

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. If not breathing, give artificial respiration. Get 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, sulfur oxides and other sulfur-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 the spill or leak. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. 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: Review Sections 3, 8 and 12 before proceeding with clean up. Contain the source of the spill or leak if it is safe to do so. Dike, pump, or use non-combustible material to absorb spill; then place in a suitable, labeled recovery container. Transfer all waste to a labeled container and move it to a secure holding area. Close container and move it to a secure holding area. Clean spill area thoroughly with detergent and water. Collect wash water with a non-combustible absorbant material and transfer to labeled container for treatment and disposal.

7. HANDLING AND STORAGE

General Handling: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Use only in a well-ventilated area. Avoid contact with eyes. Avoid contact with skin and clothing. Avoid breathing vapor or mist.

Storage Conditions: Store out of direct sunlight in a well ventilated area at room temperature.

Storage Temperature <30°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Monoethanolamine 99% - NF

OSHA - Final PELS - TWAs	3 ppm 6 mg/m³
ACGIH Threshold Limit Value (TWA)	3 ppm TWA
ACGIH Threshold Limit Value (STEL)	6 ppm STEL

Oxytetracycline

Pfizer OEL TWA-8 Hr: 0.5 mg/m³

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

Analytical Method: Oxytetracycline: CAM-KAS-99-003; STP O 12.93 (contact Pfizer for additional details).

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

Personal Protective Equipment:

Hands:	None required under normal and foreseeable conditions of use.
Eyes:	Not required under normal conditions of use.
Skin:	None required under normal and foreseeable conditions of use.
Respiratory protection:	None required under normal conditions of use. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Liquid	**Color:**	Colorless
Odor:	Odorless	**Molecular Formula:**	Mixture
Molecular Weight:	Mixture		

pH: 7

10. STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: Strong oxidizers

Hazardous Decomposition Products: No data available See Section 5 - under Hazardous combustion products.
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

Carcinogenicity: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
NTP: Not classified
IARC: Not classified
OSHA: No

Lidocaine USP
Rat Oral LD50 317 mg/kg

Magnesium chloride hexahydrate
Rat Oral LD 50 8100 mg/kg
Mouse Oral LD 50 7600mg/kg

Citric acid
Rat Oral LD50 3000 mg/kg

Monoethanolamine 99% - NF
Rat Oral LD 50 1720 mg/kg
Mouse Oral LD 50 700mg/kg

Propylene glycol
Mouse Oral LD50 22 g/kg
Rat Oral LD50 20 g/kg
Rabbit Dermal LD50 20.8 g/kg

Oxytetracycline
Mouse Oral LD50 > 5200 mg/kg
Rat Oral LD50 4800mg/kg
Mouse Subcutaneous LD50 > 3500mg/kg

Ingestion Acute Toxicity The acute oral LD50 for the active ingredient is listed in the table, above. While this formulation has not been tested as a whole, it would not be expected to be toxic orally based on the amount of active ingredient it contains.

Lidocaine USP
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Citric acid
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Magnesium chloride hexahydrate
13 Week(s) Mouse Oral273 g/kg LOEL Kidney, Ureter, Bladder

Monoethanolamine 99% - NF
90 Day(s) Rat Oral115 g/kg LOEL Liver, Kidney, Ureter, Bladder

30 Week(s) Rat Oral 105 mg/kg LOEL Liver

Subchronic Effects Subchronic oral toxicity studies of oxytetracycline in mice and rats at doses of 100 to 200 mg/kg showed no gross or histological effects.

Chronic Effects/Carcinogenicity No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material.

Lidocaine USP

Rat Subcutaneous 30 mg/kg NOAEL Not teratogenic

Monoethanolamine 99% - NF

Reproductive & Fertility-Females Rat Oral =500 mg/kg/day LOAEL Early embryonic development, Reproductive toxicity, Developmental toxicity

Oxytetracycline

Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Intramuscular 41.5 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rabbit Intramuscular 41.5 mg/kg/day LOEL Embryotoxicity
Embryo / Fetal Development Dog Intramuscular 20.75 mg/kg/day LOEL Embryotoxicity, Teratogenic

Reproductive Effects Effects on fertility (litter size) and embryo- or fetotoxicity were observed in rats at subcutaneous dose of oxytetracycline at 1000 mg/kg, in rabbits at intramuscular dose of 789 mg/kg, and in dogs at 643 mg/kg (no other details reported). Tetracyclines as a class are capable of crossing the placenta and causing staining of the primary teeth.

Teratogenicity No increase in congenital defects was found in mice and rats treated with oxytetracycline at oral doses of 1500 and 2100 mg/kg on days 6 - 15 of gestation, respectively. In rabbits, oxytetracycline was administered intramuscularly at 41.5 mg/kg/day from days 10 to 28 of gestation. The number and percentage of partial and total resorptions were significantly increased; no effects on fetal body weight were observed. No abnormalities were found at necropsy. Liver Reproductive system

Lidocaine USP

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Chromosome Aberration Human Lymphocytes Negative

Oxytetracycline

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

Oxytetracycline

103 Week(s) Rat Oral, in feed 2094 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.

At increase risk from exposure: Individuals who have shown hypersensitivity to this material or other materials in its chemical class and individuals with liver and/or kidney dysfunction or impairment may be more susceptible to toxicity in cases of overexposure.

Additional Information: PREGNANCY RISK FACTOR D. Results of animal studies indicate that tetracyclines as a class cross the placenta, are found in fetal tissues, and can have toxic effects on the developing fetus (retardation of skeletal development). Evidence of embryotoxicity has also been noted in animals treated early in pregnancy. Tetracyclines as a class are also known to cause tooth discoloration in young children and children exposed to the drug in utero.

12. ECOLOGICAL INFORMATION

Environmental Overview: See Aquatic toxicity data of the active ingredient, below:

Oxytetracycline
Rainbow Trout LC50/96h < 200 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. This material may also be disposed in landfills. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

Not regulated

Proper shipping name: Oxytetracycline intramuscular solution

15. REGULATORY INFORMATION

EU Labeling: None required
EU Indication of danger: Not classified

OSHA Label:
CAUTION
May cause eye, skin and respiratory tract irritation Accidental ingestion of large amounts of this material may be harmful; see known clinical effects, below May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required

Lidocaine USP
EU EINECS List 205-302-8
Inventory - United States TSCA - Sect. 8(b) Listed

Monoethanolamine 99% - NF
EU EINECS List 205-483-3
Inventory - United States TSCA - Sect. 8(b) Listed

Monothioglycerol

EU EINECS List	202-495-0
Inventory - United States TSCA - Sect. 8(b)	Listed

Propylene glycol

EU EINECS List	200-338-0
Inventory - United States TSCA - Sect. 8(b)	Listed

Citric acid

EU EINECS List	201-069-1
Inventory - United States TSCA - Sect. 8(b)	Listed

Sodium formaldehyde sulfoxylate - NF

EU EINECS List	205-739-4
Inventory - United States TSCA - Sect. 8(b)	Listed

Oxytetracycline

California Proposition 65	developmental toxicity, initial date 1/1/91 (internal use)
EU EINECS List	201-212-8
Inventory - United States TSCA - Sect. 8(b)	Listed

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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