9689.

C13299
C13300

MATERIAL SAFETY DATA SHEET

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

Product Identifier

Material Name: Oxytetracycline Long Acting Injectable Solution 200 mg/mL

Trade Name: Terramycin; Liquamycin; LA-200
Synonyms: TM LA; LA-200
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

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

Zoetis Belgium S.A.
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

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

2. HAZARDS IDENTIFICATION

Appearance: Clear, yellow to amber sterile solution

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
P281 - Use personal protective equipment as required
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

Short Term: Exposure to sunlight following contact may result in skin reactions in rare instances.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

Known Clinical Effects: Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, 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. 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 require the inclusion of all known hazards of the product or its ingredients 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Magnesium oxide	1309-48-4	215-171-9	Not Listed	Not Listed	*
Monoethanolamine 99% - NF	141-43-5	205-483-3	Xn; R20/21/22 C; R34	Acute Tox. 4 (H302) Skin Corr. 1B (H314) Acute Tox. 4 (H332)	**
Sodium formaldehyde sulfoxylate dihydrate	6035-47-8	Not Listed	Not Listed	Not Listed	< 1
Oxytetracycline hydrochloride	2058-46-0	218-161-2	Repr. Cat.1;R61	Repr. 1A (H360D)	20
Oxytetracycline Dihydrate	6153-64-6	Not Listed	Repr. Cat.1;R61	Not Listed	20
HYDROCHLORIC ACID	7647-01-0	231-595-7	T; R23 C; R35	Skin Corr.1B (H314) STOT SE 3 (H335)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
2-Pyrrolidone	616-45-5	210-483-1	Not Listed	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	Not Listed	*

Additional Information: * Proprietary
** to adjust pH
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: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek 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.

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: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

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

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 hands and any exposed skin after removal of PPE. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Magnesium oxide

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Austria OEL - MAKs	5 mg/m^3 10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
Czech Republic OEL - TWA	5 mg/m^3
Denmark OEL - TWA	6 mg/m^3
France OEL - TWA	10 mg/m^3
Germany (DFG) - MAK	1.5 mg/m^3 4 mg/m^3
Greece OEL - TWA	10 mg/m^3 5 mg/m^3
Hungary OEL - TWA	6 mg/m^3
Ireland OEL - TWAs	4 mg/m^3 5 mg/m^3 10 mg/m^3
Lithuania OEL - TWA	4 mg/m^3
Vietnam O EL - TWAs	5 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Poland OEL - TWA	5 mg/m^3 10 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Romania OEL - TWA	5 mg/m^3
Slovakia OEL - TWA	1.5 mg/m^3 4 mg/m^3
Spain OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Monoethanolamine 99% - NF

ACGIH Threshold Limit Value (TWA)	3 ppm
ACGIH Threshold Limit Value (STEL)	6 ppm
Australia STEL	6 ppm 15 mg/m^3
Australia TWA	3 ppm 7.5 mg/m^3
Austria OEL - MAKs	1 ppm 2.5 mg/m^3
Belgium OEL - TWA	1 ppm 2.5 mg/m^3
Bulgaria OEL - TWA	2.5 mg/m^3 1 ppm
Cyprus OEL - TWA	1 ppm 2.5 mg/m^3
Czech Republic OEL - TWA	5 mg/m^3
Denmark OEL - TWA	1 ppm 2.5 mg/m^3
Estonia OEL - TWA	1 ppm 2.5 mg/m^3
Finland OEL - TWA	1 ppm 2.5 mg/m^3
France OEL - TWA	1 ppm 2.5 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 5.1 mg/m^3
Germany (DFG) - MAK	2 ppm 5.1 mg/m^3
Greece OEL - TWA	1 ppm 2.5 mg/m^3
Hungary OEL - TWA	2.5 mg/m^3
Ireland OEL - TWAs	1 ppm 2.5 mg/m^3
Italy OEL - TWA	1 ppm 2.5 mg/m^3
Latvia OEL - TWA	0.2 ppm 0.5 mg/m^3
Lithuania OEL - TWA	3 ppm 8 mg/m^3
Luxembourg OEL - TWA	1 ppm 2.5 mg/m^3
Malta OEL - TWA	1 ppm 2.5 mg/m^3
Netherlands OEL - TWA	2.5 mg/m^3
Vietnam O EL - TWAs	8 mg/m^3
OSHA - Final PELS - TWAs:	3 ppm 6 mg/m^3
Poland OEL - TWA	2.5 mg/m^3
Portugal OEL - TWA	3 ppm
Romania OEL - TWA	1 ppm 2.5 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Slovakia OEL - TWA	1 ppm 2.5 mg/m^3
Slovenia OEL - TWA	1 ppm 2.5 mg/m^3
Spain OEL - TWA	1 ppm 2.5 mg/m^3
Sweden OEL - TWAs	3 ppm 8 mg/m^3
Switzerland OEL -TWAs	2 ppm 5 mg/m^3

Oxytetracycline hydrochloride

Zoetis OEL TWA 8-hr	500µg/m^3

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	8.0 mg/m^3 5 ppm
Cyprus OEL - TWA	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	8 mg/m^3
Estonia OEL - TWA	5 ppm 8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m^3
Germany (DFG) - MAK	2 ppm 3.0 mg/m^3
Greece OEL - TWA	5 ppm 7 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	5 ppm 8 mg/m^3
Italy OEL - TWA	5 ppm 8 mg/m^3
Japan - OELs - Ceilings	5 ppm 7.5 mg/m^3
Latvia OEL - TWA	5 ppm 8 mg/m^3
Lithuania OEL - TWA	5 ppm 8 mg/m^3
Luxembourg OEL - TWA	5 ppm 8 mg/m^3
Malta OEL - TWA	5 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
Vietnam O EL - TWAs	5 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Poland OEL - TWA	5 mg/m^3
Romania OEL - TWA	5 ppm 8 mg/m^3
Slovakia OEL - TWA	5 ppm 8.0 mg/m^3
Slovenia OEL - TWA	5 ppm 8 mg/m^3
Spain OEL - TWA	5 ppm 7.6 mg/m^3
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3

Analytical Method: Analytical method available for Oxytetracycline. 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 airborne contamination levels below the exposure limits 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: 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: Sterile solution
Odor: No data available.
Molecular Formula: Mixture

Color: Yellow to amber
Odor Threshold: No data available.
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: 8.6 - 8.8
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
Specific Gravity: 1.105 - 1.165
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
Polymerization:	Will not occur

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
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
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The following information describes the toxicity of a chemically-related material. The toxicities of the two materials can be expected to be similar. The remaining information describes the potential hazards of the individual ingredients.

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

2-Pyrrolidone
Rat Oral LD50 6500 mg/kg

Monoethanolamine 99% - NF
Rat Oral LD 50 1720 mg/kg
Mouse Oral LD 50 700mg/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) Oral 108 g/kg LOEL Brain

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

11. TOXICOLOGICAL INFORMATION

Reproduction & Development Toxicity: (Duration, 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

Monoethanolamine 99% - NF
Reproductive & Fertility-Females Rat Oral =500 mg/kg/day LOAEL Early embryonic development, Reproductive toxicity, Developmental toxicity

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. See below

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

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:

Toxicity: No data available

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: 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

15. REGULATORY INFORMATION

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

2-Pyrrolidone

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	210-483-1

Magnesium oxide

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	215-171-9

Monoethanolamine 99% - NF

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4 Schedule 5 Schedule 6
EU EINECS/ELINCS List	205-483-3

Sodium formaldehyde sulfoxylate dihydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Oxytetracycline hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity initial date 10/1/91
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	218-161-2

Water for injection

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

15. REGULATORY INFORMATION

EU EINECS/ELINCS List	231-791-2

Oxytetracycline Dihydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child
H335 - May cause respiratory irritation

R61 - May cause harm to the unborn child.
R23 - Toxic by inhalation.
R34 - Causes burns.
R35 - Causes severe burns.
R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 15 - Regulatory Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Prepared by: Toxicology and Hazard Communication
Zoetis Gobal 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