

SAFETY DATA SHEET



1. Identification

Product identifier	Oxytetracycline Long Acting Injectable Solution 200 mg/mL
Other means of identification	
Synonyms	Liquamycin LA-200® * Liquamycin® LA-200® * TMLA * LA-200 * Liquamycin * Primamycin * Terramycin * Primamycin LA Injectable Solution * TM LA
Recommended use	Veterinary product used as antibiotic agent
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A
	Reproductive toxicity (the unborn child)	Category 1A
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3
	Hazardous to the aquatic environment, long-term hazard	Category 3
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Causes skin irritation. Causes serious eye irritation. May damage the unborn child. Harmful to aquatic life with long lasting effects.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.

Response	If exposed or concerned: Get medical advice/attention. If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash before reuse.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	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. Exposure to sunlight following contact may result in skin reactions in rare instances. 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.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
2-Pyrrolidone		616-45-5	30-50
Oxytetracycline Dihydrate		6153-64-6	20
Magnesium oxide		1309-48-4	<5
HYDROCHLORIC ACID		7647-01-0	**
Monoethanolamine 99% - NF		141-43-5	**

Composition comments ** to adjust pH
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
Skin contact	Wash off immediately with soap and plenty of water. Remove contaminated clothing. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.
Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Ventilate closed spaces before entering them. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Avoid release to the environment.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

Environmental precautions

7. Handling and storage

Precautions for safe handling Wear personal protective equipment. Provide adequate ventilation. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities Store in a well-ventilated place. @ 15-30°C (59-86°F). Keep away from heat, sparks and open flame. Do not store in direct sunlight. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis

Components	Type	Value
Oxytetracycline Dihydrate (CAS 6153-64-6)	TWA	0.5 mg/m3

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
HYDROCHLORIC ACID (CAS 7647-01-0)	Ceiling	7 mg/m3	
Magnesium oxide (CAS 1309-48-4)	PEL	5 ppm 15 mg/m3	Total particulate.
Monoethanolamine 99% - NF (CAS 141-43-5)	PEL	6 mg/m3 3 ppm	

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Magnesium oxide (CAS 1309-48-4)	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
HYDROCHLORIC ACID (CAS 7647-01-0)	Ceiling	2 ppm	
Magnesium oxide (CAS 1309-48-4)	TWA	10 mg/m3	Inhalable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Monoethanolamine 99% - NF (CAS 141-43-5)	STEL	6 ppm	
	TWA	3 ppm	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
HYDROCHLORIC ACID (CAS 7647-01-0)	Ceiling	7 mg/m ³
Monoethanolamine 99% - NF (CAS 141-43-5)	STEL	5 ppm 15 mg/m ³
	TWA	6 ppm 8 mg/m ³
		3 ppm

Biological limit values	No biological exposure limits noted for the ingredient(s).
Control banding approach	Not available.
Appropriate engineering controls	Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.
Individual protection measures, such as personal protective equipment	
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Wear protective gloves.
Other	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. 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.
Thermal hazards	Not applicable.
General hygiene considerations	Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	Sterile solution
Physical state	Liquid.
Form	Liquid.
Color	Yellow. - Amber.
Odor	Not available.
Odor threshold	Not available.
pH	8.6 - 8.8
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.

Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.
Specific gravity	1.11 - 1.17

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks. Sunlight.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Causes skin irritation.
Eye contact	Causes serious eye irritation.
Ingestion	Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea. 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.
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Information on toxicological effects

Acute toxicity	Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.
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Components	Species	Test Results
2-Pyrrolidone (CAS 616-45-5)		
Acute		
Oral		
LD50	Rat	6500 mg/kg
HYDROCHLORIC ACID (CAS 7647-01-0)		
Acute		
Oral		
LD50	Rat	238 - 277 mg/kg

Components	Species	Test Results
Monoethanolamine 99% - NF (CAS 141-43-5)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	1025 mg/kg
Oral		
LD50	Mouse	700 mg/kg
	Rat	1720 mg/kg
<u>Chronic</u>		
Oral		
LOEL	Rat	115 g/kg, 90 days Liver Kidney Ureter Bladder 105 mg/kg, 30 weeks Liver
Oxytetracycline Dihydrate (CAS 6153-64-6)		
<u>Acute</u>		
Oral		
LD50	Mouse	7200 mg/kg
<u>Chronic</u>		
Oral		
NOAEL	Dog	250 mg/kg/day, 24 months (No target organs identified - data for oxytetracycline HCL) 125 mg/kg/day, 12 months (Male reproductive system - data for oxytetracycline HCL)
NOEL	Mouse	1372 mg/kg/day, 103 weeks (Not carcinogenic - data for oxytetracycline HCL)
	Rat	150 mg/kg/day, 24 months (Not carcinogenic - data for oxytetracycline HCL)
<u>Subchronic</u>		
Oral		
NOAEL	Mouse	3821 mg/kg/day, 13 weeks (No target organs identified - data for oxytetracycline HCL)
	Rat	3352 mg/kg/day, 13 weeks (Liver - data for oxytetracycline HCL)
Skin corrosion/irritation	Causes skin irritation.	
Serious eye damage/eye irritation	Causes serious eye irritation.	
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Oxytetracycline Dihydrate	Bacterial Mutagenicity (Ames), (data for oxytetracycline HCL) Result: Negative Species: Salmonella	
	In Vitro Chromosome Aberration, (data for oxytetracycline HCL) Result: Negative Species: Chinese Hamster Ovary (CHO) cells	

Mutagenicity

Oxytetracycline Dihydrate

Mammalian Cell Mutagenicity, (data for oxytetracycline HCL)
Result: Positive with activation
Species: Mouse Lymphoma

Micronucleus, (data for oxytetracycline HCL)
Result: Negative
Species: Mouse

Sister Chromatid Exchange, (data for oxytetracycline HCL)
Result: Negative
Species: Chinese Hamster Ovary (CHO) cells

Carcinogenicity

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

HYDROCHLORIC ACID (CAS 7647-01-0)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

May damage the unborn child.

Developmental effects

Oxytetracycline Dihydrate

1500 mg/kg/day Embryo / Fetal Development, (Maternal Toxicity - data for oxytetracycline HCL)

Result: NOAEL

Species: Rat

Organ: Oral

2100 mg/kg/day Embryo / Fetal Development, (Embryotoxicity - data for oxytetracycline HCL)

Result: NOAEL

Species: Mouse

Organ: Oral

Reproductivity

Oxytetracycline Dihydrate

18 mg/kg/day 2 Generation Reproductive Toxicity, (No effects at maximum dose - data for oxytetracycline HCL)

Result: NOAEL

Species: Rat

Organ: Oral

Monoethanolamine 99% - NF

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

Result: LOAEL

Species: Rat

Organ: Oral

Specific target organ toxicity - single exposure

Not classified.

Specific target organ toxicity - repeated exposure

Due to partial or complete lack of data the classification is not possible. This product may affect Liver. Kidneys. through prolonged or repeated exposure.

Aspiration hazard

Not an aspiration hazard.

Chronic effects

Prolonged inhalation may be harmful.

Further information

Photosensitivity has been reported in some individuals taking tetracyclines. High doses of tetracyclines can cause a liver condition known as fatty liver. Individuals who suffer from high cholesterol, high triglycerides, or have alcoholic liver disease may be more susceptible. May produce kidney toxicity if kidney damage already exists (based on animal data).

12. Ecological information

Ecotoxicity

Harmful to aquatic life with long lasting effects. Avoid release to the environment.

Components	Species	Test Results
2-Pyrrolidone (CAS 616-45-5)		
Aquatic		
Crustacea	EC50	Water flea (<i>Daphnia pulex</i>) 13.21 mg/l, 48 hours
HYDROCHLORIC ACID (CAS 7647-01-0)		
Aquatic		
Fish	LC50	Western mosquitofish (<i>Gambusia affinis</i>) 282 mg/l, 96 hours
Monoethanolamine 99% - NF (CAS 141-43-5)		
Aquatic		
Fish	LC50	Rainbow trout, donaldson trout (Oncorhynchus mykiss) 114 - 196 mg/l, 96 hours
Oxytetracycline Dihydrate (CAS 6153-64-6)		
Aquatic		
Crustacea	EC50	Whiteleg shrimp (<i>Penaeus vannamei</i>) > 0.16 mg/l, 48 hours
Fish	LC50	Striped bass (<i>Morone saxatilis</i>) 75 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulative potential	No data available.	
Mobility in soil	No data available.	
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.	

13. Disposal considerations

Disposal instructions	Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not discharge into drains, water courses or onto the ground. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	None known.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.	
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.	
CERCLA Hazardous Substance List (40 CFR 302.4)	HYDROCHLORIC ACID (CAS 7647-01-0)	Listed.

SARA 304 Emergency release notification

HYDROCHLORIC ACID (CAS 7647-01-0) 5000 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
 Immediate Hazard - Yes
 Delayed Hazard - Yes
 Fire Hazard - No
 Pressure Hazard - No
 Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
HYDROCHLORIC ACID	7647-01-0	5000	500		

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
 Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

HYDROCHLORIC ACID (CAS 7647-01-0)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

HYDROCHLORIC ACID (CAS 7647-01-0)

Safe Drinking Water Act (SDWA) Not regulated.

Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2) and Chemical Code Number

HYDROCHLORIC ACID (CAS 7647-01-0) 6545

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

HYDROCHLORIC ACID (CAS 7647-01-0) 20 %WV

DEA Exempt Chemical Mixtures Code Number

HYDROCHLORIC ACID (CAS 7647-01-0) 6545

US state regulations WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Developmental toxin

Oxytetracycline Dihydrate (CAS 6153-64-6) Listed: January 1, 1991

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

HYDROCHLORIC ACID (CAS 7647-01-0)

Magnesium oxide (CAS 1309-48-4)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	06-24-2013
Revision date	04-14-2017
Version #	05
Disclaimer	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. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	This document has undergone significant changes and should be reviewed in its entirety.