

Revision date: 02-Jun-2015

Version: 5.2

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

**Product Identifier** 

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

Trade Name: Synonyms: Chemical Family: Terramycin; Liquamycin; LA-200, Primamycin TM LA; TMLA; LA-200, Primamycin LA Injectable Solution Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use: Veterinary product used as antibiotic agent Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.Zoe100 Campus Drive, P.O. Box 651MerFlorham Park, New Jersey 07932 (USA)1930Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896BelgProduct Support/Technical Services Phone: 1-800-366-5288

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300 Contact E-Mail: VMIPSrecords@zoetis.com Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem 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

Т

EU Symbol: EU Risk Phrases:

RISK Phrases:

R60 - May impair fertility. R61 - May cause harm to the unborn child.

## Label Elements

Signal Word: Hazard Statements: Danger H360 - May damage fertility or the unborn child

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Precautionary Statements:	<ul> <li>P201 - Obtain special instructions before use</li> <li>P202 - Do not handle until all safety precautions have been read and understood</li> <li>P280 - Wear protective gloves/protective clothing/eye protection/face protection</li> <li>P308 + P313 - IF exposed or concerned: Get medical attention/advice</li> <li>P405 - Store locked up</li> <li>P501 - Dispose of contents/container in accordance with all local and national regulations</li> </ul>
Other Hazards	
Short Term: Long Term:	Exposure to sunlight following contact may result in skin reactions in rare instances. 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**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Oxytetracycline Dihydrate	6153-64-6	Not Listed	Repr. Cat.1;R61	Repr. 1A (H360)	20
Magnesium oxide	1309-48-4	215-171-9	Not Listed	Not Listed	<5
HYDROCHLORIC ACID	7647-01-0	231-595-7	T; R23 C; R35	Skin Corr.1B (H314) STOT SE 3 (H335)	**
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)	**

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Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
2-Pyrrolidone	616-45-5	210-483-1	Not Listed	Not Listed	*

## **Additional Information:**

# \*\* to adjust pH

\* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

### 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 no 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 Effe Symptoms and Effects of Exposure: Medical Conditions Aggravated by Exposure:	cts, Both Acute and Delayed For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information. None known				
Indication of the Immediate Medical Notes to Physician:	Attention and Special Treatment Needed None				
	5. FIRE-FIGHTING MEASURES				
Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.				
Special Hazards Arising from the Su Hazardous Combustion Products:	Ibstance or Mixture 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**

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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 /<br/>Collecting:Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill<br/>area thoroughly.

Additional Consideration for<br/>Large Spills:Non-essential personnel should be evacuated from affected area. Report emergency<br/>situations immediately. Clean up operations should only be undertaken by trained personnel.

# 7. HANDLING AND STORAGE

### **Precautions for Safe Handling**

When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid accidental injection. Wash thoroughly after handling. Keep away from heat, sparks, and flame. Releases to the environment should be avoided.

#### Conditions for Safe Storage, Including any Incompatibilities Storage Conditions: Store in a cool place out

Store in a cool place out of sun and away from heat, sparks, and flame. Protect from light and freezing. Store as directed by product packaging. At or below 25°C (77°F) Veterinary antibiotic agent

# Storage Temperature: Specific end use(s):

# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

500 µg/m<sup>3</sup>

## **Control Parameters**

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

Oxytetracycline Dihydrate	
Zoetis OEL TWA 8-h	r

### Magnesium oxide

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m³
	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	5 mg/m³
Denmark OEL - TWA	6 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany (DFG) - MAK	1.5 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m³
Hungary OEL - TWA	6 mg/m <sup>3</sup>
Ireland OEL - TWAs	4 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	4 mg/m <sup>3</sup>
Vietnam OEL - TWAs	5 mg/m³
OSHA - Final PELS - TWAs:	15 mg/m³
Poland OEL - TWA	5 mg/m³
	10 mg/m³
Portugal OEL - TWA	10 mg/m <sup>3</sup>

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8. EXPOSURE CON	TROLS / PERSONAL PROTECTION
Romania OEL - TWA	5 mg/m <sup>3</sup>
Slovakia OEL - TWA	1.5 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
HYDROCHLORIC ACID	
ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
Austria OEL - MAKs	7.5 mg/m <sup>3</sup>
AUSUIA DEL - MARS	5 ppm 8 mg/m³
Belgium OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Bulgaria OEL - TWA	5 ppm
5	8.0 mg/m <sup>3</sup>
Cyprus OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Czech Republic OEL - TWA	8 mg/m <sup>3</sup>
Estonia OEL - TWA	5 ppm
500000 TH/A	8 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m <sup>3</sup>
Germany (DFG) - MAK	2 ppm
Germany (Di G) - MAR	3.0 mg/m <sup>3</sup>
Greece OEL - TWA	5 ppm
	7 mg/m <sup>3</sup>
Hungary OEL - TWA	8 mg/m <sup>3</sup>
Ireland OEL - TWAs	5 ppm
	8 mg/m <sup>3</sup>
Italy OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Japan - OELs - Ceilings	5 ppm 7.5 mg/m <sup>3</sup>
Latvia OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Luxembourg OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Malta OEL - TWA	5 ppm
Notherlando OEL TWA	8 mg/m <sup>3</sup>
Netherlands OEL - TWA Vietnam OEL - TWAs	8 mg/m³ 5 mg/m³
Poland OEL - TWAS	5 mg/m <sup>3</sup>
Portugal OEL - TWA	5 ng/m² 5 ppm
	8 mg/m <sup>3</sup>
Romania OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Slovakia OEL - TWA	5 ppm
	8.0 mg/m <sup>3</sup>

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	ROLS / PERSONAL PROTECTION
Slovenia OEL - TWA	5 ppm
	8 mg/m <sup>3</sup>
Spain OEL - TWA	5 ppm
Switzerland OEL -TWAs	7.6 mg/m <sup>3</sup>
Switzerland OEL - I WAS	2 ppm 3.0 mg/m <sup>3</sup>
Monoethanolamine 99% - NF	
ACGIH Threshold Limit Value (TWA)	3 ppm
ACGIH Threshold Limit Value (STEL)	6 ppm
Australia STEL	6 ppm 15 mg/m³
Australia TWA	3 ppm
	7.5 mg/m <sup>3</sup>
Austria OEL - MAKs	1 ppm
	2.5 mg/m <sup>3</sup>
Belgium OEL - TWA	1 ppm
Bulgaria OEL - TWA	2.5 mg/m <sup>3</sup> 2.5 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1 ppm
Cyprus OEL - TWA	1 ppm
	2.5 mg/m <sup>3</sup>
Czech Republic OEL - TWA	2.5 mg/m <sup>3</sup>
Denmark OEL - TWA	1 ppm
	2.5 mg/m <sup>3</sup>
Estonia OEL - TWA	1 ppm 2.5 mg/m³
Finland OEL - TWA	1 ppm
	2.5 mg/m <sup>3</sup>
France OEL - TWA	1 ppm
	2.5 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	2 ppm 5.1 mg/m <sup>3</sup>
Germany (DFG) - MAK	2 ppm
	5.1 mg/m <sup>3</sup>
Greece OEL - TWA	1 ppm
	2.5 mg/m <sup>3</sup>
Hungary OEL - TWA	2.5 mg/m <sup>3</sup>
Ireland OEL - TWAs	1 ppm 2.5 mg/m³
Italy OEL - TWA	1 ppm
	2.5 mg/m <sup>3</sup>
Latvia OEL - TWA	0.2 ppm
	0.5 mg/m <sup>3</sup>
Lithuania OEL - TWA	3 ppm 8 mg/m <sup>3</sup>
Luxembourg OEL - TWA	8 mg/m² 1 ppm
LUNGHINDUIN OLL - IWA	2.5 mg/m <sup>3</sup>
Malta OEL - TWA	1 ppm
	2.5 mg/m <sup>3</sup>
Netherlands OEL - TWA	2.5 mg/m <sup>3</sup>
Vietnam OEL - TWAs	8 mg/m <sup>3</sup>

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	URE CONTROLS / PERSONAL PROTECTION		
OSHA - Final PELS - TWAs:	3 ppm		
	6 mg/m <sup>3</sup>		
Poland OEL - TWA	2.5 mg/m <sup>3</sup>		
Portugal OEL - TWA	3 ppm		
Romania OEL - TWA	1 ppm 2.5 mg/m³		
Slovakia OEL - TWA	1 ppm 2.5 mg/m <sup>3</sup>		
Slovenia OEL - TWA	1 ppm 2.5 mg/m <sup>3</sup>		
Spain OEL - TWA	1 ppm 2.5 mg/m <sup>3</sup>		
Sweden OEL - TWAs	3 ppm 8 mg/m <sup>3</sup>		
Switzerland OEL -TWAs	2 ppm 5 mg/m <sup>3</sup>		
Exposure Controls			
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.		
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: Skin:	Wear safety glasses or goggles if eye contact is possible. 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: Odor: Molecular Formula:	Sterile solution No data available. Mixture	Color: Odor Threshold: Molecular Weight:	Yellow to amber No data available. Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH: Melting/Freezing Point (°C):	8.6 - 8.8 No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, E 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): Relative Density:	No data available No data available		
Specific Gravity:	1.105 - 1.165		
Viscosity:	No data available		

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Flammablity:

Autoignition Temperature (Solid) (°C): Flammability (Solids): Flash Point (Liquid) (°C): Upper Explosive Limits (Liquid) (% by Vol.): Lower Explosive Limits (Liquid) (% by Vol.): Polymerization: No data available Will not occur

# **10. STABILITY AND REACTIVITY**

No data available

Reactivity: Chemical Stability: Possibility of Hazardous Reactions Oxidizing Properties: Conditions to Avoid: Incompatible Materials: Hazardous Decomposition Products:

Stable under normal conditions of use. No data available Direct sunlight, excessive heat, sparks or open flame As a precautionary measure, keep away from strong oxidizers Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

# **11. TOXICOLOGICAL INFORMATION**

# Information on Toxicological Effects General Information:

Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. The information included in this section describes the potential hazards of various forms of the active ingredient. The toxicities of the two materials can be expected to be similar. Routes of exposure: eye contact, skin contact

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

2-Pyrrolidone

Rat Oral LD50 6500 mg/kg

## Monoethanolamine 99% - NF

Rat Oral LD 50 1720 mg/kg Mouse Oral LD 50 700mg/kg

HYDROCHLORIC ACID

Rat Oral LD 50 238-277 mg/kg

## 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

## Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Monoethanolamine 99% - NF 90 Day(s) Rat Oral115 g/kg LOEL Liver, Kidney, Ureter, Bladder Page 8 of 12

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# **11. TOXICOLOGICAL INFORMATION**

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

### Oxytetracycline hydrochloride

13 Week(s)	Mouse	Oral	3821 m	ng/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 C	Dral <sup>-</sup>	108 g/kg	LOEL	Brain	

### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

### Monoethanolamine 99% - NF

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

### 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,

**Reproductive & Development** may have the potential to produce effects on the developing fetus. **Toxicity Comments:** 

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

### Oxytetracycline hydrochloride

Bacterial Mutagenicity (Ames)SalmonellaNegativeIn Vitro Chromosome AberrationChinese Hamster Ovary (CHO) cellsNegativeSister Chromatid ExchangeChinese Hamster Ovary (CHO) cellsNegativeMicronucleusMouseNegativeMammalian Cell MutagenicityMouse LymphomaPositive 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
 See below

## HYDROCHLORIC ACID IARC:

Group 3 (Not Classifiable)

Product Level Toxicity Data
Acute Toxicity Estimate (ATE),
oral

>2000 mg/kg

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# **12. ECOLOGICAL INFORMATION**

Environmental Overview:

Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. Releases to the environment should be avoided.

Toxicity:

## 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) 4.18 mg/L ISO EC50 72 Hours

 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

5000 lb 2270 kg

The following refers to all modes of transportation unless specified below.

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

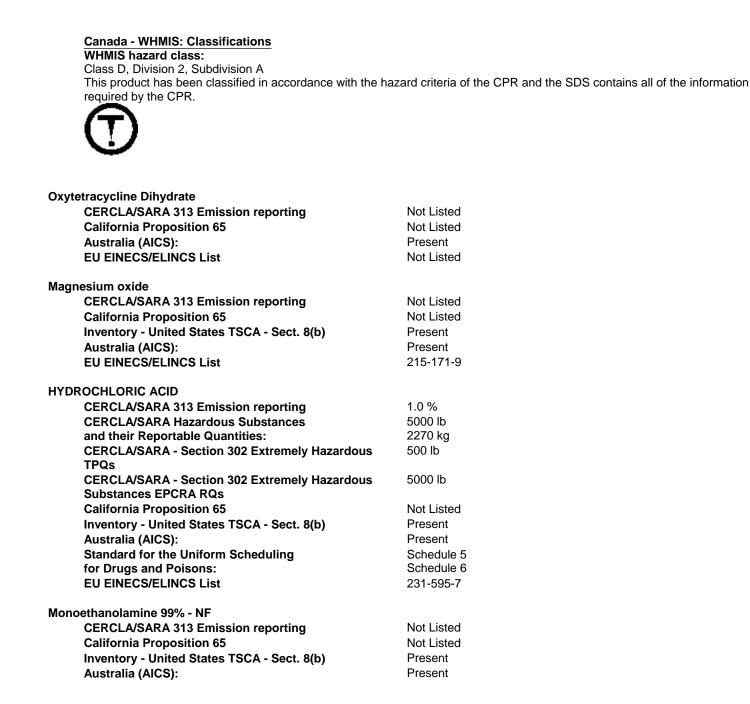
## U.S. DOT Reportable Quantity (RQ), 49 CFR 172.101 Appendix A:

HYDROCHLORIC ACID	
CERCLA/SARA Hazardous Substances	
and their Reportable Quantities:	

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# **15. REGULATORY INFORMATION**

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture



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# **15. REGULATORY INFORMATION**

Standard for the Uniform Scheduling for Drugs and Poisons:

### EU EINECS/ELINCS List

### 2-Pyrrolidone

CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List Not Listed Not Listed Present Present

Schedule 4

Schedule 5

Schedule 6

205-483-3

210-483-1

# **16. OTHER INFORMATION**

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled Reproductive toxicity-Cat.1A; H360 - May damage fertility or the unborn child Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Toxic to reproduction: Category 1 T - Toxic C - Corrosive Xn - Harmful 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:	The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.
Reasons for Revision:	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information.
Prepared by:	Toxicology and Hazard Communication Zoetis Global Risk Management

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.

End of Safety Data Sheet