SAFETY DATA SHEETS

This SDS packet was issued with item:

078912908

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078912917 078949231 078949233 078949234

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078912897

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, Primamycin
Synonyms: TM LA; TMLA; LA-200, Primamycin LA Injectable Solution
Chemical Family: 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.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

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

Contact E-Mail: VMIPSrecords@zoetis.com

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

Label Elements

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

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
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	%
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 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

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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 / 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

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 of sun and away from heat, sparks, and flame. Protect from light and freezing. Store as directed by product packaging.

Storage Temperature: At or below 25°C (77°F)

Specific end use(s): Veterinary antibiotic agent

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Oxytetracycline Dihydrate

Zoetis OEL TWA 8-hr	500 µg/m^3

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 OEL - 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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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	5 ppm 8.0 mg/m^3
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 OEL - TWAs	5 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 ppm 8 mg/m^3
Romania OEL - TWA	5 ppm 8 mg/m^3
Slovakia OEL - TWA	5 ppm 8.0 mg/m^3

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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	2.5 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 OEL - TWAs	8 mg/m^3

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
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

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

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

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: Direct sunlight, excessive heat, sparks or open flame
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: 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

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

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. 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) 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.

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

HYDROCHLORIC ACID
CERCLA/SARA Hazardous Substances and their Reportable Quantities: 5000 lb
2270 kg

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15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A
This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



Oxytetracycline Dihydrate

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

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

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

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

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15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4 Schedule 5 Schedule 6
EU EINECS/ELINCS List	205-483-3

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

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

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