SAFETY DATA SHEETS

This SDS packet was issued with item:

078695541

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

078695525

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).

078912799

SAFETY DATA SHEET

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

Product Identifier

Material Name: Draxxin (Tulathromycin) Solution for Injection

Trade Name: DRAXXIN
Synonyms: Tulathromycin 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

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 Control 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
Contact E-Mail: VMIPSrecords@zoetis.com

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

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to slightly yellow solution in multiple-dose vials

Classification of the Substance or Mixture

GHS - Classification

Serious Eye Damage/Eye Irritation: Category 2A
Skin Sensitization: Category 1

EU Classification:

EU Indication of danger: Irritant

EU Symbol: Xi
EU Risk Phrases:
R43 - May cause sensitization by skin contact.

Label Elements

Signal Word: Warning
Hazard Statements: H319 - Causes serious eye irritation
H317 - May cause an allergic skin reaction

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Precautionary Statements:

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P264 - Wash hands thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P272 - Contaminated work clothing should not be allowed out of the workplace
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Short Term: Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

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.

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	%
Tulathromycin	217500-96-4	Not Listed	Xi;R36-R43	Eye Irrit. 2A (H319) Skin Sens. 1 (H317) Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)	10
Citric acid	77-92-9	201-069-1	Xi; R36	Not Listed	**
Propylene glycol	57-55-6	200-338-0	Not Listed	Not Listed	*
HYDROCHLORIC ACID	7647-01-0	231-595-7	T; R23 C; R35	Skin Corr.1B (H314) STOT SE 3 (H335)	**

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Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Monothioglycerol	96-27-5	202-495-0	Not Listed	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	Not Listed	*

Additional Information: ** to adjust pH
* Proprietary
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: May emit toxic fumes of oxides of carbon and nitrogen.

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.

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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: Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. 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 accidental injection. Minimize generating airborne mists and vapors. Avoid breathing mist or aerosols. 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.

Tulathromycin

Zoetis OEL TWA 8-hr	1mg/m³, Sensitizer

Propylene glycol

Australia TWA	150 ppm 474 mg/m³ 10 mg/m³
Ireland OEL - TWAs	150 ppm 470 mg/m³ 10 mg/m³
Latvia OEL - TWA	7 mg/m³
Lithuania OEL - TWA	7 mg/m³

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m³
Austria OEL - MAKs	5 ppm 8 mg/m³
Belgium OEL - TWA	5 ppm 8 mg/m³
Bulgaria OEL - TWA	8.0 mg/m³ 5 ppm
Cyprus OEL - TWA	5 ppm 8 mg/m³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
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

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:	Wear impervious gloves to prevent skin contact.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Wear impervious protective clothing to prevent skin contact - consider use of disposable clothing where appropriate.
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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution in multiple-dose vials	**Color:**	Colorless to slightly yellow
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: 5.4
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
No data available
Tulathromycin
Measured 7.0 Log P -1.41
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
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: Toxicological properties of the formulation have not been investigated. The information included in this section describes the potential hazards of the individual ingredients.

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

Tulathromycin
Rat Oral LDmin. > 2000 mg/kg

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11. TOXICOLOGICAL INFORMATION

Rabbit Dermal LD50 > 2000 mg/kg

Citric acid
Rat Oral LD50 3000 mg/kg

Propylene glycol
Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Tulathromycin
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Positive
Skin Sensitization - GPMT Guinea Pig Severe

Citric acid
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

Tulathromycin
1 Month(s) Rat Oral 50 mg/kg/day NOAEL Liver, Blood
3 Month(s) Rat Oral 15 mg/kg/day NOAEL Liver
1 Month(s) Dog Oral 15 mg/kg/day NOAEL Liver
3 Month(s) Dog Oral 5 mg/kg/day NOEL Liver
1 Year(s) Dog Oral 5 mg/kg/day NOAEL Liver, Male reproductive system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Tulathromycin
2 Generation Reproductive Toxicity Rat Oral 50 mg/kg/day NOAEL Paternal toxicity
2 Generation Reproductive Toxicity Rat Oral 100 mg/kg/day NOAEL Neonatal toxicity, Fertility
Embryo / Fetal Development Rat Oral 200 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rabbit Oral 50 mg/kg/day NOAEL No effects at maximum dose

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

Tulathromycin
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vivo Micronucleus Chromosome Aberration Rat Negative
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
In Vitro Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative

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11. TOXICOLOGICAL INFORMATION

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Tulathromycin
Daphnia magna (Water Flea) OECD EC50 48 Hours 64 mg/L
Mysidopsis bahia (Mysid Shrimp) OECD LC50 48 Hours 20 mg/L
Cyprinodon variegatus (Sheepshead Minnow) OECD LC50 48 Hours 20 mg/L
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 982 mg/L
Selenastrum capricornutum (Green Alga) OECD EC-50 72 Hours 70 ug/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Tulathromycin
Polytox IC-50 19 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available
Tulathromycin
Measured 7.0 Log P -1.41

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.

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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

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



Tulathromycin

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

Monothioglycerol

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	202-495-0

Citric acid

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	201-069-1

Propylene glycol

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	200-338-0

Water

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15. REGULATORY INFORMATION

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
EU EINECS/ELINCS List	231-791-2

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

Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

T - Toxic
C - Corrosive
Xi - Irritant

R23 - Toxic by inhalation.
R35 - Causes severe burns.
R36 - Irritating to eyes.
R43 - May cause sensitization by skin contact.

Data Sources: The data contained in this MSDS 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.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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End of Safety Data Sheet

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