

# SAFETY DATA SHEET



Revision date: 18-Sep-2013

Version: 1.1

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

### Product Identifier

**Material Name:** Draxxin 25 (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

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:** H317 - May cause an allergic skin reaction

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**Precautionary Statements:** P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P272 - Contaminated work clothing should not be allowed out of the workplace  
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)	2.5
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/m<sup>3</sup>, Sensitizer

#### Propylene glycol

Australia TWA 150 ppm  
474 mg/m<sup>3</sup>  
10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 150 ppm  
470 mg/m<sup>3</sup>  
10 mg/m<sup>3</sup>  
Latvia OEL - TWA 7 mg/m<sup>3</sup>  
Lithuania OEL - TWA 7 mg/m<sup>3</sup>

#### HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit: 2 ppm  
Australia PEAK 5 ppm  
7.5 mg/m<sup>3</sup>  
Austria OEL - MAKs 5 ppm  
8 mg/m<sup>3</sup>  
Belgium OEL - TWA 5 ppm  
8 mg/m<sup>3</sup>  
Bulgaria OEL - TWA 8.0 mg/m<sup>3</sup>  
5 ppm

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 8 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m <sup>3</sup>
Germany (DFG) - MAK	2 ppm 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 8 mg/m <sup>3</sup>
Netherlands OEL - TWA	8 mg/m <sup>3</sup>
Vietnam OEL - TWAs	5 mg/m <sup>3</sup>
Poland OEL - TWA	5 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>
Slovenia OEL - TWA	5 ppm 8 mg/m <sup>3</sup>
Spain OEL - TWA	5 ppm 7.6 mg/m <sup>3</sup>
Switzerland OEL -TWAs	2 ppm 3.0 mg/m <sup>3</sup>

#### 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.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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

<b>Physical State:</b>	Solution in multiple-dose vials	<b>Color:</b>	Colorless to slightly yellow
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	5.4
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	No data available

No data available

#### Tulathromycin

Measured 7.0 Log P -1.41

<b>Decomposition Temperature (°C):</b>	No data available.
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<b>Evaporation Rate (Gram/s):</b>	No data available
<b>Vapor Pressure (kPa):</b>	No data available
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available
<b>Viscosity:</b>	No data available

#### Flammability:

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

<b>Polymerization:</b>	Will not occur
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### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	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.

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### 11. TOXICOLOGICAL INFORMATION

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

##### **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

##### **HYDROCHLORIC ACID**

Rat Oral LD 50 238-277 mg/kg

##### **Tulathromycin**

Rat Oral LDmin. > 2000 mg/kg

Rabbit Dermal LD50 > 2000 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)

##### **Citric acid**

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

##### **Propylene glycol**

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

##### **Tulathromycin**

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Positive

Skin Sensitization - GPMT Guinea Pig Severe

#### 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

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### 11. TOXICOLOGICAL INFORMATION

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)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus Chromosome Aberration	Rat	Negative
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	Negative

#### 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)



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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.

**Toxicity:**

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

**Tulathromycin**

<i>Daphnia magna</i> (Water Flea)	OECD	EC50	48 Hours	64 mg/L
<i>Mysidopsis bahia</i> (Mysid Shrimp)	OECD	LC50	48 Hours	20 mg/L
<i>Cyprinodon variegatus</i> (Sheepshead Minnow)	OECD	LC50	48 Hours	20 mg/L
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	OECD	LC50	96 Hours	> 982 mg/L
<i>Selenastrum capricornutum</i> (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.

### 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.

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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 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**

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

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### 15. REGULATORY INFORMATION

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
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	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  
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage  
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation  
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

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.

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**End of Safety Data Sheet**