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
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, 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
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


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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tulathromycin</td>
<td>217500-96-4</td>
<td>Not Listed</td>
<td>Xi; R36-R43</td>
<td>Eye Irrit. 2A (H319) Skin Sens. 1 (H317)</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)</td>
<td></td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>Xi; R36</td>
<td>Not Listed</td>
<td>**</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>HYDROCHLORIC ACID</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>T; R23; C; R35</td>
<td>Skin Corr.1B (H314) STOT SE 3 (H335)</td>
<td>**</td>
</tr>
</tbody>
</table>
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.
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
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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>OEL - TWA</th>
<th>OEL - TWAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Czech Republic</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900</td>
<td>2 ppm</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 ppm</td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Greece</td>
<td>5 ppm</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Hungary</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Italy</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>5 ppm</td>
<td>7.5 mg/m³</td>
</tr>
<tr>
<td>Latvia</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Lithuania</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Malta</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Netherlands</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Romania</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovakia</td>
<td>5 ppm</td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td>Slovenia</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Spain</td>
<td>5 ppm</td>
<td>7.6 mg/m³</td>
</tr>
<tr>
<td>Switzerland</td>
<td>2 ppm</td>
<td>3.0 mg/m³</td>
</tr>
</tbody>
</table>

**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.
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solution in multiple-dose vials
Odor: No data available
Molecular Formula: 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
 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
Flammability:
  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
11. TOXICOLOGICAL INFORMATION

**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)

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

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

**Genetic Toxicity:** (Study Type, Cell Type/Organism, Result)
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
- *Mysis bahia* (Mysid Shrimp) OECD LC50 48 Hours 20 mg/L
- *Cyprinodon variegatus* (Sheepshead Minnow) OECD LC50 48 Hours 20 mg/L
- *Onchorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours > 982 mg/L
- *Selenastrum capricornutum* (Green Alga) OECD EC-50 72 Hours 70 μg/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.
SAFETY DATA SHEET

Material Name: Draxxin (Tulathromycin) Solution for Injection
Revision date: 18-Sep-2013
Version: 3.1

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
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:
  - 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
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.

End of Safety Data Sheet