Section 1 - Identification of the Substanc e/Mixture and Supplier

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AUSTRALIA
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Product Identifier:	**Draxxin Injectable Solution**
APVMA Approval No:	60018
Other names:	None
Chemical family:	Tulathromycin injectable solution
Recommended Use:	For the treatment of respiratory infections in cattle and pigs
Restrictions on use	For veterinary use only
Emergency Phone:	**1800 814 883 (all hours)**

Section 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

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.

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.

Section 3 - Composition/Information on Ingredients

Hazardous

Ingredients	CAS No	Conc,%	GHS Classification
Tulathromycin	217500-96-4	10	Eye Irrit. 2A (H319) Skin Sens. 1 (H317) Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)
Citric acid	77-92-9	**	Not Listed
Propylene glycol	57-55-6	*	Not Listed
HYDROCHLORIC ACID	7647-01-0	**	Skin Corr.1B (H314) STOT SE 3 (H335)
Monothioglycerol	96-27-5	*	Not Listed
Water	7732-18-5	*	Not Listed

Additional Information:
** to adjust pH
* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non-hazardous ingredients are also possible.

Section 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 None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

Section 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 firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 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

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.

Section 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

Section 8 - Exposure Controls and 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

HYDROCHLORIC ACID

Australia PEAK	5 ppm 7.5 mg/m³

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.

Section 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

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

Section 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

Section 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
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

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)

Section 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

Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Section 14 - Transport Information

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

Not regulated for transport under ADG, IATA or IMDG regulations.

Section 15 - Regulatory Information

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

Monothioglycerol
Australia (AICS): Present

Citric acid
Australia (AICS): Present

Propylene glycol
Australia (AICS): Present

Water
Australia (AICS): Present

HYDROCHLORIC ACID
Australia (AICS): Present

Poison Schedule: Schedule 4

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Acronyms:

ADG Code Australian Code for the Transport of Dangerous Goods by Road and Rail (7th edition)

AICS	Australian Inventory of Chemical Substances
SWA	Safe Work Australia, formerly ASCC and NOHSC
CAS number	Chemical Abstracts Service Registry Number
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
IARC	International Agency for Research on Cancer
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
R-Phrase	Risk Phrase
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

This version issued: 21 September 2021 and is valid for 5 years from this date
Supersedes: Revision issued 01 Oct 2016

Revision History:

Date of Revision	Reason
19 Nov 2015	Update to Zoetis address
01 Oct 2016	Update precautionary statements minor formatting changes.
21 Sep 2021	Periodical revision

Contact Points:

Zoetis	**1800 814 883**
Police and Fire Brigade:	**Dial 000**

If ineffective: **Dial Poisons Information Centre**
(13 11 26 from anywhere in Australia)

THIS SDS SUMMARISES OUR CURRENT AND BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION ABOUT THE PRODUCT DETAILED IN THIS SDS, AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE FOR THE RECOMMENDED USE. EACH USER OF THE PRODUCT MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THEIR OWN WORKPLACE. IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT ZOETIS.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document “Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice” (December 2011)

End of Safety Data Sheet