

SAFETY DATA SHEETS

This SDS packet was issued with item:

078951322

N/A

SAFETY DATA SHEET



1. Identification

Product identifier	Draxxin (Tulathromycin) Injectable Solution
Other means of identification	
Synonyms	Draxxin® * Draxxin Injectable Solution * Tulathromycin sterile injectable solution * Draxxin 100 mg/ml solution for injection
Recommended use	Veterinary antibiotic agent
Recommended restrictions	Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

Supplier Not available.

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2A
	Sensitization, skin	Category 1
Environmental hazards	Not classified.	

Label elements



Signal word	Warning
Hazard statement	May cause an allergic skin reaction. Causes serious eye irritation.
Precautionary statement	
Prevention	Avoid breathing mist or vapour. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wear eye protection/face protection. Wear protective gloves.

Response	IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Tulathromycin		217500-96-4	10
1,2-Propylene Glycol		57-55-6	
Citric acid		77-92-9	**
Hydrochloric acid		7647-01-0	**

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments ** to adjust pH

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell. If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	Causes serious eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Mild skin irritation. May cause an allergic skin reaction. Dermatitis. Rash. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Alcohol resistant foam. Powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Ventilate the contaminated area. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Collect spill with an inert, non-combustible absorbent material and transfer to labeled container for disposal. Clean contaminated surface thoroughly. Prevent release to the environment.

Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Wear appropriate personal protective equipment. Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapour. Avoid accidental injection. Avoid prolonged exposure. Observe good industrial hygiene practices. Wash thoroughly after handling. Wash contaminated clothing before reuse. When using, do not eat, drink or smoke. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a cool, well-ventilated place. @ 15-30°C (59-86°F). Do not store in direct sunlight. Protect from light. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits

Zoetis

Components

Tulathromycin (CAS
217500-96-4)

Type

TWA

Value

1 mg/m³

US. ACGIH Threshold Limit Values

Components

Hydrochloric acid (CAS
7647-01-0)

Type

Ceiling

Value

2 ppm

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components

Hydrochloric acid (CAS
7647-01-0)

Type

Ceiling

Value

3 mg/m³

2 ppm

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components

Hydrochloric acid (CAS
7647-01-0)

Type

Ceiling

Value

2 ppm

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components

Hydrochloric acid (CAS
7647-01-0)

Type

Ceiling

Value

2 ppm

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components

1,2-Propylene Glycol (CAS
57-55-6)

Type

TWA

Value

155 mg/m³

Form

Vapor and aerosol.

10 mg/m³

Aerosol

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value	Form
Hydrochloric acid (CAS 7647-01-0)	Ceiling	50 ppm 2 ppm	Vapor and aerosol.

Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Hydrochloric acid (CAS 7647-01-0)	Ceiling	7.5 mg/m3 5 ppm

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)

Components	Type	Value
Hydrochloric acid (CAS 7647-01-0)	Ceiling	2 ppm

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	OEL Additional Information: Sensitizer
Control banding approach	Not available.
Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate. Eye wash fountain and emergency showers are recommended.
Individual protection measures, such as personal protective equipment	
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves. Impervious gloves.
Other	Wear suitable protective clothing. Wear impervious protective clothing to prevent skin contact - consider use of disposable clothing where appropriate.
Respiratory protection	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. 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.
Thermal hazards	Not applicable.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance	Clear. solution.
Physical state	Liquid.
Form	Liquid.
Colour	Colorless to slightly yellow
Odour	Not available.
Odour threshold	Not available.
pH	5.4
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties Not explosive.

Oxidising properties Not oxidising.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Heat, flames and sparks. Sunlight.

Incompatible materials Strong oxidising agents.

Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information**Information on likely routes of exposure**

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact May cause an allergic skin reaction.

1,2-Propylene Glycol

Species: Rabbit
Severity: Mild

Citric acid

Species: Rabbit
Severity: Mild

Tulathromycin

Species: Rabbit
Severity: Non-irritating

Eye contact Causes serious eye irritation.

1,2-Propylene Glycol

Species: Rabbit
Severity: Mild

Tulathromycin

Species: Rabbit
Severity: positive

Citric acid

Species: Rabbit
Severity: Severe

Ingestion Ingestion of large amounts may produce gastrointestinal disturbances including irritation, nausea, and diarrhoea. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Mild skin irritation. May cause an allergic skin reaction. Dermatitis. Rash. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

Information on toxicological effects

Acute toxicity Allergic reactions are possible.

Components	Species	Test results
1,2-Propylene Glycol (CAS 57-55-6)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	20800 mg/kg
Oral		
LD50	Mouse	24900 mg/kg
	Rat	22000 mg/kg
Citric acid (CAS 77-92-9)		
<u>Acute</u>		
Oral		
LD50	Rat	3000 mg/kg
Hydrochloric acid (CAS 7647-01-0)		
<u>Acute</u>		
Oral		
LD50	Rat	238 - 277 mg/kg
Tulathromycin (CAS 217500-96-4)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD	Rat	> 2000 mg/kg (Minimum Lethal Dose)
<u>Chronic</u>		
Oral		
NOAEL	Dog	5 mg/kg/day, 1 years (Target organs: Liver, Male reproductive system)
<u>Subacute</u>		
Oral		
NOAEL	Dog	15 mg/kg/day, 1 months (Target organs: Liver)
	Rat	50 mg/kg/day, 1 months (Target organs: Liver, Blood)
<u>Subchronic</u>		
Oral		
NOAEL	Rat	15 mg/kg/day, 3 months (Target organs: Liver)
NOEL	Dog	5 mg/kg/day, 3 months (Target organs: Liver)
Skin corrosion/irritation		
Prolonged skin contact may cause temporary irritation.		
Serious eye damage/eye irritation		
Causes serious eye irritation.		
<u>Eye contact</u>		
1,2-Propylene Glycol	Species: Rabbit	Severity: Mild
Tulathromycin	Species: Rabbit	Severity: positive

Eye contact

Citric acid

Species: Rabbit

Severity: Severe

Respiratory or skin sensitisation**Canada - Alberta OELs: Irritant**

Hydrochloric acid (CAS 7647-01-0)

Irritant

Respiratory sensitisation

Not a respiratory sensitizer.

Skin sensitisation

May cause an allergic skin reaction.

Skin sensitisation

Tulathromycin

GPMT

Species: Guinea Pig

Severity: Severe

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Tulathromycin

Bacterial Mutagenicity (Ames)

Result: negative

Species: Salmonella

In Vitro Chromosome Aberration

Result: negative

Species: Chinese Hamster Ovary (CHO) cells

In Vitro Chromosome Aberration

Result: negative

Species: Human lymphocytes

In Vitro Mammalian Cell Mutagenicity

Result: negative

Species: Chinese Hamster Ovary (CHO) cells

In Vivo Micronucleus Chromosome Aberration

Result: negative

Species: Rat

Carcinogenicity

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

ACGIH Carcinogens

Hydrochloric acid (CAS 7647-01-0)

A4 Not classifiable as a human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Hydrochloric acid (CAS 7647-01-0)

Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Hydrochloric acid (CAS 7647-01-0)

3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity

This product is not expected to cause reproductive or developmental effects.

Developmental effects

Tulathromycin

200 mg/kg/day Embryo / Fetal Development, No effects at maximum dose

Result: NOAEL

Species: Rat

Organ: Oral

50 mg/kg/day Embryo / Fetal Development, No effects at maximum dose

Result: NOAEL

Species: Rabbit

Organ: Oral

Reproductivity
Tulathromycin

50 mg/kg/day 2 Generation Reproductive Toxicity, Paternal toxicity; No effects on reproductive parameters or neonatal development at any dose level.
Result: NOAEL
Species: Rat
Organ: Oral

Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not an aspiration hazard.
Chronic effects	Prolonged inhalation may be harmful.
Further information	Caution - Pharmaceutical agent. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.
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Components	Species	Test results
1,2-Propylene Glycol (CAS 57-55-6)		
Aquatic		
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) > 10000 mg/l, 48 hours
Fish	LC50	Fathead minnow (<i>Pimephales promelas</i>) 710 mg/l, 96 hours
Hydrochloric acid (CAS 7647-01-0)		
Aquatic		
Fish	LC50	Western mosquitofish (<i>Gambusia affinis</i>) 282 mg/l, 96 hours
Tulathromycin (CAS 217500-96-4)		
	EC50	<i>Daphnia magna</i> (Water Flea) 64 mg/l, 48 Hours
		<i>Selenastrum capricornutum</i> (Green Alga) 70 µg/l, 72 Hours (ErC50)
	IC50	Polytox 19 mg/l
	LC50	<i>Cyprinodon variegatus</i> (Sheepshead Minnow) 20 mg/l, 48 Hours
		<i>Mysidopsis bahia</i> (Mysid Shrimp) 20 mg/l, 48 Hours
		<i>Oncorhynchus mykiss</i> (Rainbow Trout) > 982 mg/l, 96 Hours

Persistence and degradability	No data is available on the degradability of this product.
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Bioaccumulative potential	No data available.
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Partition coefficient n-octanol / water (log Kow)

Tulathromycin	-1.41, (Measured Log P @ pH 7.0)
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Mobility in soil	No data available.
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Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.
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13. Disposal considerations

Disposal instructions	Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.
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Local disposal regulations	Dispose in accordance with all applicable regulations.
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Hazardous waste code	None known.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

TDG

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Ontario. Toxic Substances. Toxic Reduction Act, 2009. Regulation 455/09 (July 1, 2011)

Hydrochloric acid (CAS 7647-01-0)

Precursor Control Regulations

Hydrochloric acid (CAS 7647-01-0)

Class B

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date 19-May-2017

Version No. 01

Disclaimer 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. The information in the sheet was written based on the best knowledge and experience currently available.

Revision information Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties