SAFETY DATA SHEET

Draxxin (Tulathromycin) Injectable Solution

Section 1. Identification

Product identifier : Draxxin (Tulathromycin) Injectable Solution

Other means of identification : Draxxin 100 mg/ml solution for injection
Draxxin Injectable Solution
Draxxin®
Tulathromycin sterile injectable solution

Product type : Liquid.

Relevant identified uses of the substance or mixture and uses advised against

Identified uses
Veterinary product used as antibiotic agent

Uses advised against
Not for human use

Supplier's details : Zoetis Canada Inc.
16740 Trans-Canada Highway
Kirkland, Quebec, H9H 4M7

1-800-461-0917
All Safety Data Sheets are available via our Zoetis Canada website at https://www.zoetis.ca/sds/sds.aspx

Emergency telephone number (with hours of operation) : CHEMTREC (24 hours): 1-800-424-9300

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

Rocky Mountain Poison & Drug Safety: 1-866-531-8896
Product support/Technical services: 1-888-963-8471

Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)

Section 2. Hazard identification

Classification of the substance or mixture : EYE IRRITATION - Category 2A
SKIN SENSITIZATION - Category 1

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : May cause an allergic skin reaction.
Causes serious eye irritation.

Precautionary statements

Section 2. Hazard identification

Prevention : Wear protective gloves. Wear eye or face protection. Avoid breathing vapor. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace.

Response : IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice or attention. Take off contaminated clothing and wash it before reuse. 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 or attention.

Storage : Not applicable.

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Supplemental label elements : Avoid accidental injection.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	Synonyms	% (w/w)	Identifiers	
propylene glycol	-	≥30 - ≤60	CAS: 57-55-6	
tulathromycin A	-	≥10 - ≤30	CAS: 217500-96-4	
Citric acid	Citric acid	≥1 - ≤5	CAS: 77-92-9	

Ranges if listed above for hazardous ingredient(s) are prescribed ranges. The actual concentration(s) or actual concentration range(s) are being withheld as a trade secret.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First-aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.

Section 4. First-aid measures

Ingestion : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

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

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous thermal decomposition products : Decomposition products may include the following materials:, carbon dioxide, carbon monoxide, nitrogen oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : Keep unnecessary personnel away.

For emergency responders : Keep unnecessary personnel away. If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Section 6. Accidental release measures

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill : Stop leak if without risk. Move containers from spill area. Absorb with an inert material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container. Avoid accidental injection.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Do not store above the following temperature: 30°C (86°F). Do not freeze. Prolonged exposure to higher temperatures may adversely affect potency. Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
propylene glycol	**CA Ontario Provincial (Canada, 6/2019)** TWA 8 hours: 10 mg/m³. Form: Aerosol only.. TWA 8 hours: 155 mg/m³. Form: Vapour fraction.. TWA 8 hours: 50 ppm. Form: Vapour fraction..
tulathromycin A	**Zoetis OEL (ZOETIS OEL)** TWA: 1 mg/m³.

Biological exposure indices

Section 8. Exposure controls/personal protection

No exposure indices known.

Control Banding Approach

Not available.

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Hand protection : Wear appropriate chemical resistant gloves. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment.

Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

Physical state : Liquid. [Solution]

Color : Colorless to slightly yellow

Odor : Not available.

Odor threshold : Not available.

pH : Not available.

Melting point/freezing point : Not available.

Boiling point or initial boiling point and boiling range : Not available.

Flash point : Not available.

Evaporation rate : Not available.

Flammability : Not available.

Lower and upper explosion limit/flammability limit : Not available.

Section 9. Physical and chemical properties

Vapor pressure : Not available.

Relative vapor density : Not available.

Relative density : Not available.

Solubility in water : Not available.

Partition coefficient: n-octanol/water : Not applicable.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Dynamic (room temperature): Not available.
Kinematic (room temperature): Not available.
Kinematic (40°C (104°F)): Not available.

Particle characteristics

Pmax : Not available.

Kst : Not available.

Min. Ignition Temperature (Dust) : Not available.

Minimum ignition energy (MIE) - dust cloud : Not available.

Median particle size : Not applicable.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : Do not freeze. Avoid exposure to light, sunlight and elevated temperatures. Prolonged exposure to higher temperatures may adversely affect potency.

Incompatible materials : This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.

Remarks : Strong oxidizing agents

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result
propylene glycol	**Rabbit - Dermal - LD50** 20800 mg/kg **Mouse - Oral - LD50** 24900 mg/kg **Rat - Oral - LD50** 22000 mg/kg **Rat - Oral - LD50** 20 g/kg

Section 11. Toxicological information

	Rabbit - Dermal - LD50 20800 mg/kg
tulathromycin A	**Rabbit - Dermal - LD50** >2000 mg/kg
Citric acid	**Rat - Oral - LD50** 3000 mg/kg

Conclusion/Summary [Product] : Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Skin corrosion/irritation

Product/ingredient name	Result
propylene glycol	**Child - Skin - Moderate irritant** Duration of treatment/exposure: 96 hours Amount/concentration applied: 30 % C **Human - Skin - Mild irritant** Duration of treatment/exposure: 168 hours Amount/concentration applied: 500 mg **Human - Skin - Moderate irritant** Duration of treatment/exposure: 72 hours Amount/concentration applied: 104 mg I **Woman - Skin - Mild irritant** Duration of treatment/exposure: 96 hours Amount/concentration applied: 30 %
tulathromycin A	**Rabbit - Skin - Mild irritant**
Citric acid	**Rabbit - Skin - Mild irritant** Duration of treatment/exposure: 24 hours Amount/concentration applied: 500 mg **Rabbit - Skin - Moderate irritant** Amount/concentration applied: 0.5 Ml

Conclusion/Summary [Product] : Causes mild skin irritation.

Serious eye damage/eye irritation

Product/ingredient name	Result
propylene glycol	**Rabbit - Eyes - Mild irritant** Duration of treatment/exposure: 24 hours Amount/concentration applied: 500 mg **Rabbit - Eyes - Mild irritant** Amount/concentration applied: 100 mg
tulathromycin A	**Rabbit - Eyes - Irritant**
Citric acid	**Rabbit - Eyes - Severe irritant** Duration of treatment/exposure: 24 hours Amount/concentration applied: 750 ug

Conclusion/Summary [Product] : Causes serious eye irritation.

Respiratory corrosion/irritation

Not available.

Conclusion/Summary [Product] : Due to partial or complete lack of data the classification is not possible.

Respiratory or skin sensitization

Product/ingredient name	Result

Section 11. Toxicological information

tulathromycin A	**Guinea pig - skin** Result: Sensitizing

Skin

Conclusion/Summary [Product] : May cause an allergic skin reaction.

Respiratory

Conclusion/Summary [Product] : Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity (single exposure)

Not applicable.

Specific target organ toxicity (repeated exposure)

Not applicable.

Aspiration hazard

Not applicable.

Information on the likely routes of exposure

Not available.

Potential acute health effects

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

Potential chronic health effects

Product/ingredient name	Result
tulathromycin A	**Sub-chronic - Rat - Oral - NOAEL** 15 mg/kg [3 months] **Sub-chronic - Dog - Oral - NOEL** 5 mg/kg [3 months] **Chronic - Dog - Oral - NOAEL** 5 mg/kg [7 days per week] [1 years] **Sub-acute - Dog - Oral - NOAEL** 15 mg/kg [7 days per week] [1 minutes] **Sub-acute - Rat - Oral - NOAEL** 50 mg/kg [7 days per week] [1 minutes]

General : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

Germ cell mutagenicity

Product/ingredient name	Result

Section 11. Toxicological information

tulathromycin A

In vitro - Bacteria
OECD 471 [Bacterial Reverse Mutation Test]
Result: Negative
In vitro - Mammalian-Animal
OECD 473 [In vitro Mammalian Chromosomal Aberration Test]
Result: Negative
In vitro - Mammalian-Human
OECD 473 [In vitro Mammalian Chromosomal Aberration Test]
Result: Negative
In vitro - Mammalian-Animal
OECD 476 [In vitro Mammalian Cell Gene Mutation Test]
Result: Negative
In vivo - Mammalian-Animal
OECD 474 [Mammalian Erythrocyte Micronucleus Test]
Result: Negative

Conclusion/Summary [Product] : Due to partial or complete lack of data the classification is not possible.

Carcinogenicity

Not available.

Conclusion/Summary [Product] : Due to partial or complete lack of data the classification is not possible.

Reproductive toxicity

Product/ingredient name	Result
tulathromycin A	**Rat - Oral** 200 mg/kg Effects: NOAEL No effects at maximum dose. Developmental: Negative **Rabbit - Oral** 50 mg/kg Effects: NOAEL No effects at maximum dose. Developmental: Negative **Rat - Oral** OECD 416 [Two-Generation Reproduction Toxicity Study] 50 mg/kg Effects: NOAEL No effects at maximum dose. Developmental: Negative

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Draxxin (Tulathromycin) Injectable Solution	166666.8	N/A	N/A	N/A	N/A
propylene glycol	20000	20800	N/A	N/A	N/A
tulathromycin A	N/A	2500	N/A	N/A	N/A
Citric acid	3000	N/A	N/A	N/A	N/A

Other information

In the event of accidental injection, an allergic reaction may occur.

Section 12. Ecological information

Toxicity

Product/ingredient name	Result
propylene glycol	**Acute - LC50 - Fresh water** Crustaceans - Water flea - *Ceriodaphnia dubia* Age: <24 hours 1020 mg/l [48 hours] Effect: Mortality **Acute - LC50 - Fresh water** Fish - Fathead minnow - *Pimephales promelas* Age: ≤7 days 710 mg/l [96 hours] Effect: Mortality
Citric acid	**Acute - LC50 - Marine water** Crustaceans - Green crab - *Carcinus maenas* - Adult 160 mg/l [48 hours] Effect: Mortality

Conclusion/Summary [Product] : No known significant effects or critical hazards. Avoid release to the environment.

Persistence and degradability

Not available.

Conclusion/Summary [Product] : Not available.

Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
propylene glycol	-1.07	-	Low
tulathromycin A	-1.41	-	Low
Citric acid	-1.8	-	Low

Mobility in soil

Soil/Water partition coefficient : Not available.

Other adverse effects

No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : 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. The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered

Section 13. Disposal considerations

when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	TDG Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15. Regulatory information

Canadian lists

Canadian NPRI : None of the components are listed.

CEPA Toxic substances : None of the components are listed.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia : Not determined.

Canada : Not determined.

China : Not determined.

Eurasian Economic Union : **Russian Federation inventory**: All components are listed or exempted.

Japan : **Japan inventory (CSCL)**: Not determined.
Japan inventory (ISHL): Not determined.

New Zealand : Not determined.

Section 15. Regulatory information

Philippines : Not determined.

Republic of Korea : Not determined.

Taiwan : Not determined.

Thailand : Not determined.

Turkey : Not determined.

United States : Not determined.

Viet Nam : All components are listed or exempted.

Section 16. Other information

History

Date of issue/Date of revision : 11/7/2025

Date of previous issue : 5/27/2025

Version : 1.01

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
DOT = Department of Transportation
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
HPR = Hazardous Products Regulations
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
IMO = International Maritime Organization
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
N/A = Not available
SGG = Segregation Group
TDG = Transportation of Dangerous Goods
UN = United Nations

Procedure used to derive the classification

Classification	Justification
EYE IRRITATION - Category 2A	Calculation method
SKIN SENSITIZATION - Category 1	Calculation method

References : Not available.

Notice to reader

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.