

SAFETY DATA SHEET



1. Identification

Product identifier	Draxxin 25 (Tulathromycin) Injectable Solution
Other means of identification	
Synonyms	Draxxin® 25 * Draxxin 25 Injectable Solution * Tulathromycin sterile injectable solution * Draxxin 25 mg/ml solution for injection
Recommended use	Veterinary antibiotic agent
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	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 (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Sensitization, skin	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Warning	
Hazard statement	May cause an allergic skin reaction.	
Precautionary statement		
Prevention	Avoid breathing mist or vapor. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.	
Response	If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.	
Storage	Store away from incompatible materials.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	None known.	
Supplemental information	None.	

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Propylene glycol		57-55-6	50
Tulathromycin		217500-96-4	2.5
Citric acid		77-92-9	<1
Hydrochloric acid		7647-01-0	**
Sodium hydroxide		1310-73-2	**

Composition comments

** to adjust pH

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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 center 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

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. 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 (CO₂).

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 vapor. 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 vapor. 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**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis**Components****Type****Value**

Tulathromycin (CAS
217500-96-4)

TWA

1 mg/m3

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**Components****Type****Value**

HYDROCHLORIC ACID
(CAS 7647-01-0)

Ceiling

7 mg/m3

SODIUM HYDROXIDE
(CAS 1310-73-2)

PEL

5 ppm

2 mg/m3

US. ACGIH Threshold Limit Values**Components****Type****Value**

HYDROCHLORIC ACID
(CAS 7647-01-0)
SODIUM HYDROXIDE
(CAS 1310-73-2)

Ceiling

2 ppm

Ceiling

2 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards**Components****Type****Value**

HYDROCHLORIC ACID
(CAS 7647-01-0)

Ceiling

7 mg/m3

SODIUM HYDROXIDE
(CAS 1310-73-2)

Ceiling

5 ppm

2 mg/m3

US. Workplace Environmental Exposure Level (WEEL) Guides**Components****Type****Value****Form**

Propylene glycol (CAS
57-55-6)

TWA

10 mg/m3

Aerosol.

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.
Color	Colorless to slightly yellow
Odor	Not available.
Odor 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.
Vapor pressure	Not available.
Vapor 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.

Oxidizing properties Not oxidizing.

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 oxidizing 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.

Citric acid Species: Rabbit
Severity: Mild

Propylene glycol Species: Rabbit
Severity: Mild

Tulathromycin Species: Rabbit
Severity: Non-irritating

Eye contact Direct contact with eyes may cause temporary irritation.

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 diarrhea. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. 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
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
Propylene glycol (CAS 57-55-6)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	20800 mg/kg

Components	Species	Test Results
Oral		
LD50	Mouse	24900 mg/kg
	Rat	22000 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	Direct contact with eyes may cause temporary irritation.	
Eye Contact		
Propylene glycol	Species: Rabbit	Severity: Mild
Tulathromycin	Species: Rabbit	Severity: Positive
Citric acid	Species: Rabbit	Severity: Severe
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	May cause an allergic skin reaction.	
Skin sensitization		
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

Mutagenicity
Tulathromycin

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.

IARC Monographs. Overall Evaluation of Carcinogenicity

Hydrochloric acid (CAS 7647-01-0) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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.

Components	Species	Test Results
Hydrochloric acid (CAS 7647-01-0)		
Aquatic		
Fish	LC50	Western mosquitofish (Gambusia affinis) 282 mg/l, 96 hours

Components	Species		Test Results
Propylene glycol (CAS 57-55-6)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	710 mg/l, 96 hours
Sodium hydroxide (CAS 1310-73-2)			
Aquatic			
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	34.59 - 47.13 mg/l, 48 hours
Fish	LC50	Western mosquitofish (Gambusia affinis)	125 mg/l, 96 hours
Tulathromycin (CAS 217500-96-4)			
	EC50	Daphnia magna (Water Flea)	64 mg/L, 48 Hours
		Selenastrum capricornutum (Green Alga)	70 µg/l, 72 Hours (ErC50)
	IC50	Polytox	19 mg/L
	LC50	Cyprinodon variegatus (Sheepshead Minnow)	20 mg/L, 48 Hours
		Mysidopsis bahia (Mysid Shrimp)	20 mg/L, 48 Hours
		Oncorhynchus mykiss (Rainbow Trout)	> 982 mg/L, 96 Hours
Persistence and degradability	No data is available on the degradability of this product.		
Bioaccumulative potential	No data available.		
Partition coefficient n-octanol / water (log Kow)			
Tulathromycin	-1.41, (Measured Log P @ pH 7.0)		
Mobility in soil	No data available.		
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.		

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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
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

DOT	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

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Hydrochloric acid (CAS 7647-01-0)

Listed.

Sodium hydroxide (CAS 1310-73-2)

Listed.

SARA 304 Emergency release notification

Hydrochloric acid (CAS 7647-01-0)

5000 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes

Delayed Hazard - No

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
Hydrochloric acid	7647-01-0	5000	500		

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Hydrochloric acid (CAS 7647-01-0)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Hydrochloric acid (CAS 7647-01-0)

Safe Drinking Water Act

Not regulated.

(SDWA)

Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2) and Chemical Code Number

Hydrochloric acid (CAS 7647-01-0)

6545

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

Hydrochloric acid (CAS 7647-01-0)

20 %WV

DEA Exempt Chemical Mixtures Code Number

Hydrochloric acid (CAS 7647-01-0)

6545

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Hydrochloric acid (CAS 7647-01-0)

Sodium hydroxide (CAS 1310-73-2)

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

Country(s) or region	Inventory name	On inventory (yes/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
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, including date of preparation or last revision

Issue date	05-19-2017
Version #	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	This document has undergone significant changes and should be reviewed in its entirety.