SAFETY DATA SHEET

According to
HSNO Hazardous Substances (Safety Data Sheets) Notice 2017

Section 1. Identification of the material and the supplier

Product:	**Tylovet Injection**
Pack size:	100mL, 250mL
Product Use:	In cattle: For the treatment and control of acute mastitis, metritis, respiratory infections, foot-rot (necrotic pododermatitis), calf diphtheria. In pigs: For the treatment and control of swine dysentery and enteritis associated with the presence of *Campylobacter coli* and other organisms sensitive to tylosin, swine erysipelas, pneumonia and arthritis due to Mycoplasma. In sheep and goats: For the treatment of the early stages of peracute and acute contagious agalactia caused by *Mycoplasma agalactiae* and caprine pleuropneumonia caused by *Mycoplasma mycoides var capri* (*M capri*).
Restriction of Use:	Refer to Section 15
New Zealand Supplier:	**Agrihealth NZ Ltd**
Address:	Level 2, 89 Grafton Road, Auckland 1010
Telephone:	+64 9 215 1199
Emergency No:	**0800 764 766 (National Poisons Centre)**
Date of SDS Preparation:	18 March 2025

Section 2. Hazards Identification

This substance is hazardous according to the EPA Hazardous Substances (Classification) Notice 2020

EPA Approval No: Veterinary Medicines - Limited Pack Size, Finished Dose – HSR100757

Pictograms

Signal Word: **Warning**

GHS Category	Hazard Code	Hazard Statement
Serious eye damage/eye irritation Cat. 2	H319	Causes serious eye irritation
Skin sensitisation Cat. 1	H317	May cause an allergic skin reaction

Hazardous to the aquatic environment acute Cat. 1	H400	Very toxic to aquatic life
Hazardous to the aquatic environment chronic Cat. 1	H410	Very toxic to aquatic life with long lasting effects
Hazardous to soil organisms	H423	Hazardous to soil organisms

Prevention Code	**Prevention Statement**
P103	Read carefully and follow all instructions
P261	Avoid breathing vapours
P264	Wash hands thoroughly after handling
P272	Contaminated work clothing should not be allowed out of the workplace
P273	Avoid release to the environment
P280	Wear protective clothing as detailed in SDS Section 8

Response Code	**Response Statement**
P101	If medical advice is needed, have product container or label at hand
P391	Collect spillage
P302 + P352	IF ON SKIN: Wash with plenty of water
P305 + P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention
P337 + P313	If eye irritation persists: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash before reuse.
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

Disposal Code	**Disposal Statement**
P501	Dispose of according to Local Regulations or Authorities

Section 3. Composition / Information on Hazardous Ingredients

Ingredients	**Concentration w/w%**	**CAS NUMBER.**
Tylosin	20	1401-69-0
Propylene Glycol	45-55	57-55-6
Benzyl Alcohol	3-5	100-51-6
Non-hazardous ingredients	Bal to 100%	Proprietary

Section 4. First Aid Measures

General: Tylosin may induce irritation. Macrolides, such as tylosin, may also cause hypersensitivity (allergy) following injection, inhalation or contact with skin or eye. Hypersensitivity to tylosin may lead to cross reactions to other macrolides and vice versa. Allergic reactions to these substances may occasionally be serious and therefore direct contact should be avoided.

Accidental self-injection: Care should be taken to avoid accidental self-injection. If injection occurs, seek medical attention immediately.

Routes of Exposure:

If in Eyes Rinse cautiously with water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice.

If on Skin	Take off contaminated clothing and wash before reuse. Wash skin with plenty of soap and water. If skin irritation or rash occurs: get medical advice/attention.
If Swallowed	Wash out mouth thoroughly with water. Do not induce vomiting. Never give anything to the mouth of an unconscious person. Call the National Poisons Centre 0800 764 766 or a doctor/physician for advice.
If Inhaled	Remove person to fresh air. Remove contaminated clothing and loosen remaining clothing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Most important symptoms and effects, both acute and delayed symptoms:

Ingestion: Not applicable
Inhalation: Not applicable
Skin: May cause an allergic skin reaction
Eyes: Causes serious eye irritation

Section 5. Fire Fighting Measures

Hazard Type	Non-Flammable
Hazards from products	May emit toxic fumes under fire conditions. They are: carbon monoxide, carbon dioxide, nitrogen oxides, and sulphur oxides.
Suitable Extinguishing media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Precautions for firefighters and special protective clothing	As with all fires, evacuate personnel to save area. Fire fighters should use self- contained breathing equipment and protective clothing.
HAZCHEM CODE	**3Z**

Section 6. Accidental Release Measures

People with known hypersensitivity to tylosin should handle the product carefully. Care should be taken to avoid self-injection. Wear protective gear as detailed in Section 8. Evacuate all unnecessary personnel. Avoid contact with skin and eyes.

Prevent further spillage, and prevent spilled material from flowing onto adjacent land or into waterways.

Retrieve intact containers from site. Place damaged containers into containment devices. Clean the contaminated area with new sponges soaked in water. Place the spillage including sponges into sealable containers for disposal. Dispose of waste safely as per Section 13.

Section 7. Handling and Storage

Precautions for Handling:

- Read carefully and follow all instructions
- Avoid breathing vapours
- Wash hands thoroughly after handling
- Contaminated work clothing should not be allowed out of the workplace
- Avoid release to the environment
- Wear protective clothing as detailed in SDS Section 8
- Avoid contact with skin and eyes
- People with known hypersensitivity to tylosin should handle the product carefully. Care should be taken to avoid self-injection
- Allergic reactions to macrolide antibiotics may occasionally be serious and therefore direct contact should be avoided

- Do not handle the product if you are allergic to ingredients in the product

Precautions for Storage:

- Store away from incompatible materials listed in Section 10
- Store in a cool, well-ventilated place
- Store <25˚C
- Store in the original container away from direct heat or sunlight
- Do not freeze
- Keep out of reach of children

Section 8. Exposure Controls / Personal Protection

WORKPLACE EXPOSURE STANDARDS (provided for guidance only)

Substance	TWA ppm	TWA mg/m³	STEL ppm	STEL mg/m³
Propane-1,2-diol, Vapour and particulates [57-55-6]	150	474	-	-

Workplace Exposure Standard – Time Weighted Average (WES-TWA). The time-weighted average exposure standard designed to protect the worker from the effects of long-term exposure. Workplace Exposure Standard – Short-Term Exposure Limit (WESSTEL). The 15-minute average exposure standard. Applies to any 15- Minute period in the working day and is designed to protect the worker against adverse effects of irritation, chronic or irreversible tissue change, or narcosis that may increase the likelihood of accidents. The WES-STEL is not an alternative to the WES-TWA; both the short-term and time-weighted average exposures apply. Workplace Exposure Standards and Biological Exposure Indices Nov 2023 14TH EDITION.

Engineering Controls

No special requirements.

Personal Protection Equipment

Eyes	Wear safety glasses
Hands	Wear suitable protective gloves
Skin	Suitable clothing to prevent skin contact
Respiratory	Not required
General	Wash hands with soap and water before breaks and after work. Avoid release to the environment. Do not eat, drink or smoke when using this product

Section 9. Physical and Chemical Properties

Appearance	Liquid
Colour	Pale yellow to amber-coloured
Odour	Characteristic
Odour Threshold	Not available
pH (2.5% w/v solution)	8.5 – 10.5
Boiling Point	Not available
Melting Point	137 – 143°C
Freezing Point	Not available
Flash Point	Not available
Flammability	Not flammable
Explosive Limits	Not available
Vapour Pressure	Not available
Vapour Density	Not available
Density	From 1.050 – 1.100 g/cm³

Water Solubility	Slightly soluble in water Freely soluble in methylene chloride Freely soluble in ethanol Soluble in dilute solutions of mineral acids
Partition Coefficient n-octanol/water	5; 17; 17 (pH 5, 7, 9)
Auto-ignition Temperature	Not available
Decomposition Temperature	Not available
Kinematic Viscosity	Not available
UV absorption	Maximum of 290 nm

Section 10. Stability and Reactivity

Stability of Substance	This product is stable under normal conditions of use
Possibility of hazardous reactions	No data available
Conditions to Avoid	High temperature, moisture, direct sunlight
Incompatible Materials	Water
Hazardous Decomposition Products	Does not occur

Section 11. Toxicological Information

Acute Effects:

Swallowed	Not applicable
Dermal	Not applicable
Inhalation	Not applicable
Eye	Causes serious eye irritation
Skin	May cause an allergic skin reaction

Chronic Effects:

Carcinogenicity	Not applicable
Reproductive Toxicity	Not applicable
Germ Cell Mutagenicity	Not applicable
Aspiration	Not applicable
STOT/SE	Not applicable
STOT/RE	Not applicable

Acute toxicity:

Mixture		**Species**	**Test results**
Pharmasin 200 mg/ml solution for injection (CAS Not applicable)	Acute Oral LD50	Rat	>0.5 ml/kg b.w
	Acute Dermal LD50	Rabbit	>2.0 ml/kg b.w
Components		**Species**	**Test results**
Tylosin (CAS 1401-69-0)	Acute Oral LD50	Mouse	> 5 g/kg
	Acute i.p. LD50	Mouse	0.594 g/kg
	Acute s.c. LD50	Mouse	>2.5 g/ kg
	Acute Oral LD50	Rat	>5 g/kg b.w (male)
	Acute Oral LD50	Dog	>0.8 g/kg b.w
Benzyl alcohol (CAS 100-51-6)	Acute IV LD50	Mouse	0.32 g/kg
	Acute Oral LD50	Mouse	1.36 g/kg b.w.
	Acute IP LD50	Rat	0.4 g/kg b.w.
	Acute IV LD50	Rat	0.05 g/kg b.w
	Acute Oral LD50	Rat	1.23 g/kg b.w.
Propylene glycol (CAS 57-55-6)	Acute, IP LD50	Mouse	9.72 g/kg b.w.
	Acute, i.v. LD50	Mouse	6.63 g/kg b.w.
	Acute, Oral LD50	Mouse	22.0 g/kg b.w.
	Acute, s.c. LD50	Mouse	17.34 g/kg b.w.

Acute, i.m. LD50	Rat	0.01 g/kg b.w.
Acute, IP LD50	Rat	6.66 g/kg b.w.
Acute, i.v. LD50	Rat	6.42 g/kg b.w.
Acute, Oral LD50	Rat	0.02 g/kg b.w.
Acute, s.c. LD50	Rat	22.5 g/kg b.w.

Section 12. Ecotoxicological Information

Very toxic to aquatic life with long lasting effects. Hazardous to soil organisms.

Product:	
Persistence and degradability	Not persistent in the environment due to degradation and possible photolysis
Bioaccumulation	Tylosin is unlikely to accumulate in soils over time pKa: 7.73 Water solubility (25°C): 5 g/L Log Kow: 0.36, 1.18, 1.36 (pH 5, 7, 9)
Mobility in Soil	Tylosin is unlikely to accumulate in soils over time
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

TOXICITY

The below data are for the active substance tylosin:

- Blue-green algae (*Anabaena flos-aquae*) 72-hour median effective concentration EC50 (growth): 0.42 mg/L
- Green algae (*Selensatrum capricornutum*) 72-hour median effective concentration EC50 (growth): 1.38 mg/L
- *Daphnia magna* 48-hour median effective concentration EC50 (survival): 680 mg/L
- Rainbow trout (*Oncorhynchys mykiss)* 96-hour median effective concentration EC50 (survival): > 100 mg/L
- Rainbow trout (*Oncorhynchys mykiss)* No observed effect concentration NOEC: 100 mg/L
- Macrophytes (*Myriphyllum spicatum)* 14-day median effective concentration (growth): > 3 mg/L
- Macrophytes (*Lemna gibba)* 14-day median effective concentration (growth): > 3 mg/L
- Collembolans (*Folsomia fimetaria*) median lethal concentration LC50: ≥ 5000 mg/L
- Enchytraeids (*Enchytraeus crypticus*) median lethal concentration LC50: 3381 mg/L
- Earthworms (*Apporectodea caliginosa*) median lethal concentration LC50: > 5000 mg/L
- Monocotyledon *Allium cepa* (onion) median effective concentration EC50 (shoot weight): 269.7 mg/kg
- Dicotyledon *Raphanus sativus* (radish) median effective concentration EC50 (shoot weight): 271.9 mg/kg
- Dicotyledon *Raphanus sativus* (radish) No observed effect concentration NOEC: 150 mg/kg

Do not allow to enter waterways.

Section 13. Disposal Considerations

Disposal Method:

Preferably dispose of the product by use. Otherwise dispose of contents/container in accordance with local/national/international regulations.

Precautions or methods to avoid: Avoid contamination of any water supply with product or empty container.

Section 14. Transport Information

This product is classified as a Dangerous Good for transport in NZ ; NZS 5433:2020 and SNZ HB 5433:2021

Road, Rail, Sea and Air Transport

UN No	3082
Class - Primary	9
Packing Group	III
Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S (Tylosin)
Marine Pollutant	Yes
Special Provisions	If the product's individual container is below 5L/kg, it can be transported as a non-DG as long as the product packaging is still labelled as per DG requirements and the driver is given safety information in accordance with Chapter 3.4 of the UNRTDG.

Section 15. Regulatory Information

This substance is classified hazardous according to the EPA Hazardous Substances (Classification) Notice 2020

EPA Approval No: **Veterinary Medicines – Limited Pack Size, Finished Dose – HSR100757**

HSW (HS) Regulations 2017	**Trigger Quantity**
Certified Handler	Not required
Location Certificate	Not required
Tracking Trigger Quantities (Schedule 26)	Not required
Signage Trigger Quantities (Schedule 3)	100 L
Emergency Response Plan (Schedule 5)	100 L
Secondary Containment (Schedule 5)	100 L
Restriction of Use	Only use for the intended purpose
ACVM Act and Regulations	
See www.foodsafety.govt.nz for registration Conditions	**A10807**

Section 16. Other Information

Glossary

Cat	Category
EC_{50}	Median effective concentration.
EEL	Environmental Exposure Limit.
EPA	Environmental Protection Authority
HSNO	Hazardous Substances and New Organisms.
HSW	Health and Safety at Work.
LC_{50}	Lethal concentration that will kill 50% of the test organisms inhaling or ingesting it.
LD_{50}	Lethal dose to kill 50% of test animals/organisms.

LEL	Lower explosive level.
OSHA	American Occupational Safety and Health Administration.
TEL	Tolerable Exposure Limit.
TLV	Threshold Limit Value-an exposure limit set by responsible authority.
UEL	Upper Explosive Level
WES	Workplace Exposure Limit

References:

1. EPA Hazardous Substances (Safety Data Sheets) Notice 2017
2. Workplace Exposure Standards and Biological Exposure Indices Nov 2023 14th edition.
3. Assigning a hazardous substance to a HSNO Approval (Aug 2013).
4. Transport of Dangerous goods on land NZS 5433:2020
5. HSW (Hazardous Substances) Regulations 2017

Disclaimer

This document has been prepared by TCC (NZ) Ltd and serves as the suppliers Safety Data Sheet ('SDS'). It is based on information concerning the product which has been provided to TCC (NZ) Ltd or obtained from third party sources and is believed to represent the current state of knowledge as to the appropriate safety and handling precautions for the product at the time of issue. Further clarification regarding any aspect of the product should be obtained directly from the manufacturer. While TCC (NZ) have taken all due care to include accurate and up-to-date information in this SDS, it does not provide any warranty as to accuracy or completeness. As far as lawfully possible, TCC (NZ) Ltd accept no liability for any loss, injury or damage (including consequential loss) which may be suffered or incurred by any person as a consequence of their reliance on the information contained in this SDS

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Please contact the New Zealand distributor, if further information is required.

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