Date of preparation:
29 August 2022

SAFETY DATA SHEET

TilmoVet 300 Injection

Section 1: Identification of the Substance and Supplier

Product Name:	**TilmoVet 300 Injection**
Pack size:	**100mL vial**
Recommended Use:	For use in cattle for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida*, and other organisms sensitive to tilmicosin. For the treatment of footrot in sheep.
Company Details:	AgriHealth NZ Ltd Level 2, 89 Grafton Road, Grafton, Auckland 1010, New Zealand Phone: +64 9 215 1199 Website: www.agrihealth.co.nz
Emergency Telephone:	National Poisons Centre: 0800 764 766 (0800 POISON) Fire Service, Ambulance: Dial 111

Section 2: Hazards Identification

TilmoVet 300 Injection is assigned to the **Veterinary medicines (Limited pack size, finished dose) Group Standard 2020, HSR100757.**

Hazard Classifications:

Acute toxicity, oral Category 4

Skin sensitisation Category 1

Serious eye damage/eye irritation Category 2

Respiratory sensitization Category 1

Specific target organ toxicity, repeated exposure Category 2

Terrestrial vertebrate toxin

Priority identifier: **DANGER**

Hazard statements:

H302 Harmful if swallowed

H317 May cause an allergic skin reaction

H319 Causes serious eye irritation

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

H373 May cause damage to organs (heart) through prolonged or repeated exposure

Hazardous to terrestrial vertebrates

Precautionary statements:

P280	Wear protective gloves, eye and face protection
P285	In case of inadequate ventilation wear respiratory protection
P260	Do not breathe mist or spray
P264	Wash hands and exposed skin thoroughly after handling
P270	Do not eat, drink or smoke when using this product
P362+P364	Take off contaminated clothing and wash before reuse
P272	Contaminated work clothing should not be allowed out of the workplace
P301+P312	IF SWALLOWED: Call the National Poisons Centre 0800 764 766 or a doctor if you feel unwell
P330	Rinse mouth
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 or attention
P304+P340	IF INHALED: remove person to fresh air and keep comfortable for breathing
P342+P311	If experiencing respiratory symptoms: Call the National Poisons Centre 0800 764 766 or a doctor
P314	Get medical advice or attention if you feel unwell
P273	Avoid release to the environment
P391	Collect spillage
P501	Dispose of contents/container in accordance with local regulations

Section 3: Composition / Information on Ingredients

Name	CAS Number	Concentration
Tilmicosin	108050-54-0	30%
Phosphoric acid (concentrated)	7664-38-2	<10%
Propylene glycol	57-55-6	25%

Section 4: First Aid Measures

First Aid Measures: For advice contact the National Poisons Centre on 0800 POISON (0800 764 766) or a doctor, immediately.

General: People with known hypersensitivity to macrolides should avoid contact with the veterinary medicinal product. Contaminated clothing must be taken off. The person must receive immediate medical attention.

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

Ingestion: If swallowed seek medical attention. Rinse mouth with water.

Inhalation: Safely remove to fresh air. If breathing is difficult, ensure clear airway and give oxygen. If not breathing, begin cardiopulmonary resuscitation (CPR).

Skin Contact: If skin contact occurs remove contaminated clothing and wash skin with soap and water. If skin irritation, rash or symptoms occur or persist, consult a doctor.

Eyes: If eye contact occurs, flush eyes with water. If wearing contact lenses, remove only after initial rinse and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a doctor.

Workplace Facilities: No special facilities are required.

Required Instructions: Wear protective gloves, clothing and eye protection. Contaminated work clothing should not be allowed out of the work place. Wash contaminated clothing before reuse.

Notes for Medical Personnel: Treat exposed patients symptomatically.

Section 5: Fire Fighting Measures

Type of hazard: Non-flammable

Fire Hazard Properties: Under fire conditions this product may emit toxic and/or irritating fumes and gases such as carbon monoxide, carbon dioxide, nitrogen oxides, sulphur oxides.

Extinguishing Media and Methods: Water spray, dry powder, carbon dioxide, or foam

Hazchem Code: 2Z

Recommended Protective Clothing: Wear full protective clothing and self-contained breathing apparatus (SCBA)

Section 6: Accidental Release Measures

Emergency Procedures: Wear suitable protective clothing including eye protection. Restrict access to contaminated area. 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. Avoid contamination of water courses or sewers. Dispose of waste safely.

Section 7: Handling and Storage

Precautions for Safe Handling: Wear protective gloves, clothing, eye and face protection Avoid contact with skin and eyes. People with known hypersensitivity to macrolides should handle the product carefully. Care should be taken to avoid self-injection.

Regulatory Requirements: Signage is required for this substance when stored in quantities of **10,000L** or greater.

Handling Practices: Avoid skin contact. Wash hands and exposed skin before meals and after use. Do not eat, drink or smoke while using.

Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

Conditions for Safe Storage: Store below 25°C. Store in the original container, away from direct heat or direct sunlight. Keep out of reach of children.

Packaging: Store in original container, away from foodstuffs.

Section 8: Exposure Control / Personal Protection

Workplace Exposure Standards: None set

Application in the Workplace: Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent contact with skin, and prevent self-injection.

Personal Protection: Wear protective gloves, eye safety glasses and protective clothing and face protection. Do not eat, drink or smoke when using this product. Wash hands with soap and water before breaks and after work. Keep away from foodstuffs and beverages.

Section 9: Physical and Chemical Properties

Product Properties:

Appearance:	Clear amber yellow liquid
Odour:	Characteristic
Odour threshold:	NDA
pH:	4.0 – 5.0
Melting point/freezing point:	NDA
Initial boiling point and boiling range:	NDA
Flash point:	NDA
Evaporation rate:	NDA
Flammability (solid, gas):	NDA
Upper/lower flammability or explosive limits:	NDA
Vapour pressure:	NDA
Vapour density:	NDA
Relative density:	NDA
Decomposition temperature:	NDA
Viscosity:	NDA
Explosive properties:	NDA
Oxidising properties:	NDA

Information concerning the active ingredient:

Solubility:	slightly soluble in water; slightly soluble in n-hexane; soluble in dilute solutions of mineral acids
Partition coefficient n-octanol/water:	Tilmicosin - from -2.5 (pH 5) to 2.6 (pH 9)
Auto-ignition temperature:	Tilmicosin - 280°C (dust layer)

Section 10: Stability and Reactivity

Stability of the Substance:	Stable under normal conditions of use and storage
Conditions to Avoid:	Avoid heat, light and moisture
Material to Avoid:	Strong oxidizing agents
Hazardous decomposition products:	Carbon monoxide, carbon dioxide, nitrogen oxides, sulphur oxides

Section 11: Toxicological Information

Acute toxicity:

Components		**Species**	**Test results**
Tilmicosin (CAS 108050-54-0)	Oral LD_{50}	Rat	2200 mg/kg bw
	Subcutaneous LD_{50}	Rat	212 mg/kg bw
	Subcutaneous LD_{50}	Mouse	97 mg/kg bw (male) 109 mg/kg bw (female)
	Inhalation LD_{50}	Rat	560 mg/m^3 (1 hour)
	Dermal LD_{50}	Rabbit	> 5000 mg/kg bw
Phosphoric acid, concentrated (CAS 7664-38-2)	Oral LD_{50}	Rat	1.53 g/kg bw
	Dermal LD_{50}	Rabbit	2.74 g/kg bw
Propylene glycol (CAS 57-55-6)	Intraperitoneal LD_{50}	Mouse	9.72 g/kg bw
	Intravenous LD_{50}	Mouse	6.63 g/kg bw
	Oral LD_{50}	Mouse	22.0 g/kg bw
	Subcutaneous LD_{50}	Mouse	17.34 g/kg bw
	Intramuscular LD_{50}	Rat	0.01 g/kg bw
	Intraperitoneal LD_{50}	Rat	6.66 g/kg bw
	Intravenous LD_{50}	Rat	6.42 g/kg bw
	Oral LD_{50}	Rat	0.02 g/kg bw
	Subcutaneous LD_{50}	Rat	22.5 g/kg bw

Skin corrosion/irritation: Tilmicosin - Rabbit – slight irritant effect

Serious eye damage/irritation: Tilmicosin - Rabbit – causes serious eye irritation

Respiratory or skin sensitisation: Tilmicosin - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Tilmicosin - Guinea pig – does not cause skin sensitisation.

Germ cell mutagenicity (Tilmicosin)

Reverse mutation Salmonella	Negative	
Reverse mutation Escherichia coli	Negative	
Forward mutation Mouse lymphoma cells	Negative	
Forward mutation Chinese hamster ovary cells	Negative	
Unscheduled DNA synthesis assay Primary cultures of rat hepatocytes		Negative
Sister chromatid exchange assay Chinese hamster bone marrow		Negative
Chromosome abberations Rat bone marrow	Negative	

Carcinogenicity (Tilmicosin):

1 Year – Rat - Oral	Effects on heart (tachycardia and dilatation) and kidneys (nephrosis) and relative weight of organs (heart, liver, kidney)

1 Year - Dog - Oral	4 mg/kg b.w., NOEL

Reproductive toxicity (Tilmicosin):

Reproductive toxicity	
Rat, oral 2-generation	10 mg/kg b.w., NOEL No treatment related effects observed
Teratogenicity	
Rat, Oral	10 mg/kg b.w., NOEL No effects observed

STOT-single exposure: NDA

STOT-repeated exposure: NDA

Aspiration hazard: NDA

Section 12: Environmental Information

No data is available for the formulated product. The following information relates to tilmicosin.

Ecotoxicity:

- Rainbow trout 96-hour median lethal concentration: 851 mg/L
- Bluegill 96-hour median lethal concentration: 716 mg/L
- Daphnia magna 48-hour median effective concentration: 57.3 mg/L
- Bobwhite 5-day dietary median lethal concentration: > 4820 ppm
- Mallard 5-day dietary median lethal concentration: > 4710 ppm
- Earthworm 28-day median lethal concentration: > 918 mg/Kg
- Green algae (S. capricornutum) median effective concentration: 0.354 mg/L (average specific growth rate)
- Plant growth in soil for most species unaffected at 100 mg/L.

Microorganisms:

- Fungus (Chaetomium globosum): MIC > 1000 mg/L
- Mould (Aspergillus flavus): MIC > 1000 mg/L
- Soil bacteria (Comamonas acidovorans): MIC = 250 mg/L
- N-fixing bact. (Azotobacter chroococcum): MIC = 5 mg/L
- Blue-green algae (Nostoc sp.): MIC = 0.5 mg/L

Conclusion: Practically nontoxic to fish, birds, earthworms, fungus, moulds, soil bacteria, and most plants. Slightly toxic to aquatic invertebrates. Moderately toxic to nitrogen-fixing bacteria. Highly toxic to green algae and blue-green algae.

Persistence and degradability (tilmicosin):

Log Kow: <1, <1, 2.6 (pH 5, 7, 9)

Adsorption coefficients (K): 129, 181, 318 (sandy loam, loam, clay loam)

Water solubility (g/L): 566, 7.7 (pH 7, 9)
Photolysis half-life (hours): 0.84, 0.82, 0.82 (pH 5, 7, 9)
Photolysis rate constant (1/hours): 0.83, 0.84, 0.84 (pH 5, 7, 9)
Hydrolysis half-life (days): >= 365, >= 365, 156 (pH 5, 7, 9)
Hydrolysis rate constant (1/hours): 0.0001853 (pH 9)
Aerobic biodegradation: none measured after 64 days (sandy loam, loam, clay loam)
Anaerobic biodegradation: none measured after 73 days
Decline in loam soil: 45.9% after 52 weeks
Decline in clay loam soil: none after 52 weeks

Conclusion: No volatility expected. Low potential to bioconcentrate in aquatic organisms. Low mobility in soil. Persistent in the soil environment. Persistence in the aquatic environment not expected due to rapid phytolysis. Therefore, tilmicosin does not meet the criteria for a "persistent" compound.

Bioaccumulation potential: "bioaccumulative" compound.	Tilmicosin does not meet the criteria for a
Mobility in soil:	Tilmicosin has low mobility in soil.
PBT and VPVB assessment:	Tilmicosin is not classified as a PBT or vPvB substance

No other adverse environmental effects (e.g. ozone depletion, photochemical oxone creation potential, endocrine disruption, global warming potential) are expected from this component

Section 13: Disposal Considerations

Disposal Information: Preferably dispose of the product by use. Otherwise dispose of product and packaging at an approved landfill or other approved facility. Avoid contamination of any water supply with product or empty container.

Section 14: Transport Information

Land Transport	Not classified as dangerous goods for transport under NZ Standard 5433:2007 Transport of Dangerous Goods on Land, ADR/RID.
Air Transport	Not classified as dangerous goods for transport under International Civil Aviation Organisation and International Air Transport Association regulations (IATA/ICAO)

Sea Transport	Not classified as dangerous goods for transport under International Maritime Organisation regulations (IMDG/IMO)
UN Number	N/A
Proper Shipping Name	N/A
DG Class	N/A
Subsidiary Risk	N/A
Packing Group	N/A
HAZCHEM Code	N/A
Marine Pollutant	No

Section 15: Regulatory Information

Regulatory Status: Registered pursuant to the ACVM Act 1997, No A11195
See www.foodsafety.govt.nz for registration conditions
Restricted Veterinary Medicine
For use only under the authority or prescription of a veterinarian

TilmoVet 300 Injection is assigned to the **Veterinary medicines (Limited pack size, finished dose) Group Standard 2020, HSR100757.** See epa.govt.nz for details.

Classified as hazardous according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

Section 16: Other Information

Additional Information: For product information see the AgriHealth website: www.agrihealth.co.nz

Date of preparation: 29 August 2022
Due for revision within 5 years.