AgriHealth
Evidence based vet medicines

Date of preparation:
13 July 2016

SAFETY DATA SHEET

Tilmovet 300 Injection

Section 1: Identification of the Substance and Supplier

Product Name:	**Tilmovet 300 Injection**
ACVM Registration Number:	A11195
Pack sizes:	**25mL, 50mL, 100mL**
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 Unit 1.2, 89 Grafton Road, Grafton, Auckland 1010, New Zealand Phone: +64 9 215 1199 Fax: +64 9 984 9455 Website: www.agrihealth.co.nz
Emergency Telephone:	National Poisons Centre: 0800 764 766 (0800 POISON) Fire Service, Ambulance: Dial 111

Section 2: Hazards Identification

Classified as a hazardous substance according to the criteria in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001.
Tilmovet 300 Injection is approved pursuant to the HSNO Act 1996, **HSR100757.** The EPA website www.epa.govt.nz should be consulted for the full list of triggered controls and cited regulations.

Hazard Classifications:	6.1E	Acute toxin
	6.3A	Skin irritant
	6.4A	Eye irritant

	6.9B Target organ toxin
	9.1A Aquatic ecotoxin
	9.3C Terrestrial vertebrate ecotoxin
Signal word:	**WARNING**
Hazard statements:	May be harmful if swallowed
	Keep out of reach of children
	Read label before use
	Causes skin irritation
	Causes eye irritation.
	Very toxic to aquatic life
	Harmful to terrestrial vertebrates
Precautionary statements:	Wear protective gloves
	Take off contaminated clothing and wash before reuse
	Wash hands and exposed skin thoroughly after handling. Do not eat, drink or smoke when using this product.
	Call the National Poisons Centre 0800 764 766 or a doctor/physician if exposed or you feel unwell.
	IF ON SKIN: Wash with plenty of soap and water
	If skin irritation 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.
	If medical advice is needed, have product container or label at hand.
	Injection in humans has been associated with fatalities. Exercise extreme caution to avoid accidental self-injection. Do not work alone when using TilmoVet. Do not use in automatically powered injectors or syringes. Do not carry a syringe loaded with TilmoVet with the needle attached, except for filling the syringe or for administration to the animal. Remove needle at all other times.
	In case of human injection, consult a physician immediately and apply ice or cold pack to the injection site.
	Store locked up. Avoid release to the environment. Collect spillage

Section 3: Composition / Information on Ingredients

Product Components:

Name	CAS Number	Concentration
Tilmicosin	108050-54-0	30%
Non-hazardous components	N/A	70%

N/A = not applicable or not available

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.

IF ON SKIN: Wash with plenty of soap and water

If skin irritation 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.

Injection in humans has been associated with fatalities. Exercise extreme caution to avoid accidental self-injection. Do not work alone when using TilmoVet. Do not use in automatically powered injectors or syringes. Do not carry a syringe loaded with TilmoVet with the needle attached, except for filling the syringe or for administration to the animal. Remove needle at all other times.

In case of human injection, consult a physician immediately and apply ice or cold pack to the injection site.

Workplace Facilities: No special facilities are required.

Required Instructions: Wear protective gloves. Wash contaminated clothing before reuse.

Notes for Medical Personnel: The cardiovascular system is the target of toxicity (possibly due to calcium channel blockade) and should be monitored closely. In dogs, administration of intravenous calcium offset tilmicosin-induced tachycardia and negative inotrophy (decreased contractility). Dobutamine partially offset the negative inotrophic effects in dogs. Beta-adrenergic antagonists, such as propranolol, exacerbated the negative inotrophy of tilmicosin in dogs, and should not be used. Adrenaline potentiated lethality of tilmicosin in pigs and should not be used. Tilmicosin persists in tissues for several days. Monitor the cardiovascular system and provide supportive treatment.

Section 5: Fire Fighting Measures

Type of hazard:	Non-flammable
Fire Hazard Properties:	This material is assumed to be combustible. When heated to decomposition no toxic fumes are emitted.
Extinguishing Media and Methods:	Water spray, dry powder, carbon dioxide, or foam
Hazchem Code:	N/A
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 Avoid contact with skin and eyes. Exercise extreme caution to avoid accidental self-injection. Do not work alone when using TilmoVet. Do not use in automatically powered injectors or syringes. Do not carry a syringe loaded with TilmoVet with the needle attached, except for filling the syringe or for administration to the animal. Remove needle at all other times. In case of human injection, consult a physician immediately and apply ice or cold pack to the injection site.
Regulatory Requirements:	An emergency response plan is required when stored in quantities of **100L** or greater. Secondary containment is required when stored in quantities of **100L** or greater.

	Signage is required for this substance when stored in quantities of **100L** 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. Wash contaminated clothing before reuse.
Approved Handlers:	Not required
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 eyes, and prevent self-injection.
Exposure Standards outside the Workplace:	None set

Personal Protection: Wear protective gloves. 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 liquid
	Density:	0.15 – 0.30 g/cm^3
	pH:	5.5 – 6.5
Information concerning the active ingredient:		
	Solubility in water:	Slightly soluble
	Solubility in n-hexane:	Slightly soluble

Section 10: Stability and Reactivity

Stability of the Substance:	Stable under normal conditions of use and storage
Conditions to Avoid:	Avoid heat and light
Material to Avoid:	None known
Hazardous Decomposition Properties:	Does not occur
Hazardous Polymerisation:	Does not occur

Section 11: Toxicological Information

HSNO Classification: 6.1E, 6.3A, 6.4A, 6.9B

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

Acute toxicity:

Oral administration:	Rat, >3000 mg/kg; neither intoxication nor death occurs
Inhalation:	Rat, 560mg/m^3 for 1 hour, no death occurs, local irritation
Skin contact:	Rabbit, slight irritant effect
Eye contact:	Rabbit, eye-irritating
Other effects:	Salivation, diarrhoea and vomiting after administration of high doses of tilmicosin. Attacks the cardiac blood circulation. Tilmicosin is irritating to the eyes and may cause allergic reaction. Avoid contact.

Chronic toxicity:

Reproductive and teratogenic effects:	No teratogenic effect. No adverse effects were observed in reproductivity of 3 generations.
Sensitisation:	Guinea pig, sensitising effect
Carcinogenic effects:	Not registered as carcinogenic according to OSHA, ACGIH, NSI/NTP and IARC
Other effects:	Potential hypersensitivity; leucopaenia, urticarial, eosinophilia, gastrointestinal disturbances, diarrhoea. Allergic reactions and allergic contact dermatitis (skin eruptions). Allergic symptoms may include ski eruptions, lacrimation, suffocation, coughing and wheezing. It disturbs immunological indices. No cumulative properties.
Aggravated medical conditions:	Persons with hypersensitive skin, liver or renal impairments may be subject to increased risk to this material. This should not be a problem when appropriate procedures are used to minimize the exposure. In case of self-injection seek immediate medical attention.

Section 12: Environmental Information

HSNO Classification: 9.1A, 9.3C

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

Environmental Fate: 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

Environmental Summary: Tilmicosin - 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. 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.

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.
Air Transport	Not classified as dangerous goods for transport under International Civil Aviation Organisation and International Air Transport Association regulations
Sea Transport	Not classified as dangerous goods for transport under International Maritime Organisation regulations
Marine Pollutant	Yes

The maximum quantity of this substance allowed for carriage on public service vehicles is 1L.

Section 15: Regulatory Information

Regulatory Status:	Registered pursuant to the ACVM Act 1997, No A11195 See www.foodsafety.govt.nz for registration conditions
HSNO and ACVM Controls:	Refer to section 2
List Exposure Limits:	None set

An SDS must be provided whenever **1L** of Tilmovet 300 Injection is sold or supplied.

An emergency response plan is required when stored in quantities of **100L** or greater.
Secondary containment is required when stored in quantities of **100L** or greater.

Signage is required for this substance when stored in quantities of **100L** or greater.

Section 16: Other Information

Additional Information:	For product information see the AgriHealth website: www.agrihealth.co.nz
Date of preparation:	13 July 2016

Due for revision within 5 years.