Date of preparation:
06 January 2015

SAFETY DATA SHEET

Tylovet Injection

Section 1: Identification of the Substance and Supplier

Product Name:	**Tylovet Injection**
ACVM Registration Number:	A10807
Pack sizes:	**100mL, 250mL**
Recommended 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 contol 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*).
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.
Tylovet Injection is approved pursuant to the HSNO Act 1996, **HSR002368.** The EPA website www.epa.govt.nz should be consulted for the full list of triggered controls and cited regulations.

Hazard Classifications:	6.4A Eye irritant
	6.5B Contact sensitiser (skin allergen)
	9.1A Aquatic ecotoxin
	9.2D Soil ecotoxin
Signal word:	**WARNING**
Hazard statements:	Causes serious eye irritation
	May cause an allergic skin reaction
	Very toxic to aquatic life
	Harmful to the soil environment
Precautionary statements:	Read label before use
	Wear protective gloves, clothing and eye protection
	Wash hands and exposed skin thoroughly after handling
	Contaminated work clothing should not be allowed out of the workplace
	Wash contaminated clothing 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/attention
	IF ON SKIN: Wash with plenty of soap and water
	If skin irritation or rash occurs: Get medical advice/attention Avoid release to the environment
	Collect spillage

Section 3: Composition / Information on Ingredients

Product Components:

Name	CAS Number	Concentration
Tylosin	1401-69-0	20%
Benzyl alcohol	100-51-6	4%

Non-hazardous components	N/A	76%

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.

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.

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.

Ingestion: If swallowed seek medical attention. DO NOT induce vomiting.

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: 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: 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 tylosin should handle the product carefully. Care should be taken to avoid self-injection.

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.

Contaminated work clothing should not be allowed out of the workplace. 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.
UN packing group III

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, 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:	Pale yellow to amber liquid
	Density:	1.05 – 1.10 g/cm^3
Information concerning the active ingredient:		
	pH of 2.5% aqueous solution:	8.5 – 10.5
	Solubility in water:	Slightly soluble
	Solubility in methylene chloride:	Freely soluble
	Solubility in ethanol:	Freely soluble
	Solubility in dilute solutions of mineral acids:	Soluble
	UV absorption:	Maximum at 290 nm

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: Water

Hazardous Decomposition Properties: Does not occur

Hazardous Polymerisation: Does not occur

Section 11: Toxicological Information

HSNO Classification: 6.4A, 6.5B

Acute toxicity (tylosin):

Species	Sex	Route	LD_{50}
Mouse	F	Oral	> 5000 mg/kg bw
Mouse	F	Intraperitoneal	594.1 mg/kg bw
Mouse	F	Subcutaneous	> 2500 mg/kg bw
Rat	M	Oral	> 5000 mg/kg bw
Dog	M&F	Oral	> 800 mg/kg bw

Acute toxicity (tylosin 200 mg/mL injectable formulation):

Species	Sex	Route	LD_{50}
Rat	M&F	Oral	> 0.5 mL/kg bw
Rabbit	M&F	Dermal	> 2.0 mL/kg bw

Chronic toxicity:

Target organ effects: Tylosin base – no effects identified in animal studies
Propylene glycol – no significant effects were reported in monkeys exposed to saturated vapour for 18 months or dogs administered 2000 mg/kg for 2 years.

Other effects: Tylosin base – salivation, diarrhea, vomiting.

Reproduction: Tylosin base – no effects identified in animal studies.
Propylene glycol – in animal studies, propylene glycol has been shown to interfere with reproduction.

Sensitisation: Tylosin base – guinea pig, positive contact sensitizer.

Mutagenicity: Tylosin base – mutagenic in one mammalian test system. Not mutagenic in bacterial cell tests and other mammalian cell tests. Unlikely to pose a genotoxic risk to man.
Propylene glycol – in vitro mutagenicity studies were negative. Animal mutagenicity studies were negative.

Carcinogenicity: Tylosin base – Not considered carcinogenic in animal studies conducted by Lilly Research Laboratories.
Benzyl alcohol – Two year carcinogenicity studies conducted by NTP demonstrated no evidence of carcinogenicity in mice and rats.
Propylene glycol – Multiple long-term dietary, inhalation and dermal studies demonstrated no evidence of carcinogenicity in mice, rabbits or rats.

Section 12: Environmental Information

HSNO Classification: 9.1A, 9.2D

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

Toxicity:

Blue-green algae (*Anabaena flos-aquae*) 72-hour median effective concentration EC_{50} (growth): 0.42 mg/L

Green algae (*Selensatrum capricornutum*) 72-hour median effective concentration EC_{50} (growth): 1.38 mg/L

Daphnia magna 48-hour median effective concentration EC_{50} (survival): 680 mg/L

Rainbow trout (*Oncorhynchys mykiss*) 96-hour median effective concentration EC_{50} (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 lethan concentration LC_{50}: ≥ 5000 mg/L

Enchytraeids (*Enchytraeus crypticus*) median lethal concentration LC_{50}: 3381 mg/L

Earthworms (*Apporectodea caliginosa*) median lethal concentration LC_{50}: > 5000 mg/L

Monocotyledon *Allium cepa* (onion) median effective concentration EC_{50} (shoot weight): 269.7 mg/kg

Dicotyledon *Raphanus sativus* (radish) median effective concentration EC_{50} (shoot weight): 271.9 mg/kg

Dicotyledon *Raphanus sativus* (radish) No observed effect concentration NOEC: 150 mg/kg

Persistence and degradability: Not persistent in the environment due to degradation and possible photolysis.

Bioaccumulative potential: 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)

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
UN Number	N/A
Proper Shipping Name	N/A
DG Class	N/A
Subsidiary Risk	N/A
Packing Group	III
HAZCHEM Code	N/A
Marine Pollutant	No

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 A10807 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 Tylovet 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: 06 January 2015
Due for revision within 5 years.

The SDS summarises, at the date of issue, AgriHealth's best knowledge of the health and safety hazard information. Although reasonable care has been taken in the preparation of this document, AgriHealth Ltd extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. AgriHealth Ltd urges the recipient of this SDS to study it carefully to become aware of, and understand, the hazards associated with the product as well as determine the suitability of the information for the intended purpose.