Date of preparation:
17 November 2015

SAFETY DATA SHEET

Pharmasin 100% Soluble

Section 1: Identification of the Substance and Supplier

Product Name:	**Pharmasin 100% Soluble**
ACVM Registration Number:	A10039
UN name and number:	**UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (tylosin tartrate, 100%)**
Pack sizes:	**100g, 200g, 1kg, 25kg**
Recommended Use:	For Turkeys, broiler chickens & replacement layers: As an aid in the prevention and treatment of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae.* For the treatment of necrotic enteritis caused by *Clostridium perfringens.* For Pigs: For treatment of Porcine Intestinal Adenomatosis (Ileitis) associated with *Lawsonia intracellularis.*
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.

Pharmasin 100% Soluble is approved pursuant to the HSNO Act 1996, **HSR002370.** 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
	6.5A Respiratory sensitiser
	6.5B Contact sensitiser (skin allergen)
	9.1A Aquatic ecotoxin
Signal word:	**DANGER**
Hazard statements:	Causes serious eye irritation
	May cause allergy or asthma symptoms or breathing difficulties if inhaled
	May cause an allergic skin reaction
	Very toxic to aquatic life
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
	Avoid breathing dust
	In case of inadequate ventilation wear respiratory protection
	IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.
	If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
	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 tartrate	1405-54-5	1000 g/kg

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.

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.

Inhalation: Remove to fresh air. If symptoms occur or persist, 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

Flame temperature: 500 - 520°C
Ignition temperature: 470 - 520°C
Explosion limits:
Lower concentration limit: 68 – 125 g/m^3
Upper concentration limit: > 2000 g/m^3
Maximum pressure of explosion: 66 – 86 MPa
Minimal energy of ignition: 20.4 mJ

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

Hazchem Code: 2Z

Recommended Protective Clothing: Wear respiratory protection. Use self-contained breathing apparatus (SCBA)

Section 6: Accidental Release Measures

Emergency Procedures: Wear suitable protective clothing. Restrict access to contaminated area. Prevent further spillage. Retrieve intact containers from site. Place damaged containers into containment devices. Sweep spilled product, taking care to avoid raising dust and place in sealable container for disposal. Wash the area with water and detergent. Absorb washings and place in the same sealable container 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 Avoid the formation of dust and aerosols. Avoid breathing dust. Provide exhaust ventilation if dust is formed
Regulatory Requirements:	An emergency response plan is required when stored in quantities of **100kg** or greater. Signage is required when stored in quantities of **1000kg** 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 in a dry place, away from direct heat or direct sunlight. Do not freeze. Keep container sealed when not in use. 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 inhalation of dust and contact with skin and eyes.
Exposure Standards outside the Workplace:	None set
Engineering Controls:	Ensure adequate ventilation. In case of inadequate ventilation wear respiratory protection.

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:	White to light yellow granule
	Melting Point:	Not applicable
	pH of 2.5% aqueous solution:	5.0 – 7.2
	Solubility in water:	Freely soluble
	UV absorption:	Maximum at 290nm

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: None known

Hazardous Reactions: None known

Section 11: Toxicological Information

HSNO Classification: 6.4A, 6.5A, 6.5B

Acute toxicity:

Rats:

LD_{50} p.o.: 6 5000 mg/kg b.w.

Mice:

LD_{50} i.p.: 500 mg/kg b.w.

LD_{50} p.o.: > 5000 mg/kg b.w.

Broiler Chickens:

Age of chickens (days)	Activity of the preparation in IU/mg	LD_{50} in mg/kg weight Mode of administration		
		intravenous	subcutaneous	oral
28 - 32	800	-	620	5100
42 - 45	800	-	740	5400
75 - 77	800	48		-
28	750	-		6000

Skin Contact: Rabbit, slight irritant

Eye Contact: Rabbit, irritant

Chronic toxicity:

- The long-term (30 days) intramuscular administration of tylosin tartrate at doses 120 and 1 200 mg/kg b.w. induced no manifestations of toxicity and lesions in the internal organs.

- The long-term intramuscular treatment of rats (90 days) with tylosin tartrate at a dose of 36 mg/kg b.w. induced no changes in the clinical-biochemical composition of blood nor in the structure of the internal organs.
- Tylosin tartrate, subcutaneously injected for a period of 20 days at a dose of 30 mg/kg b.w. induced no changes in appetite, behaviour, growth and morphological structure of internal organs of chicken-broilers. With the 42-day treatment at the same dose level, the antibiotic induced slight completely reversible degenerative changes in liver and kidneys. The dose levels of 90 and 150 mg/kg b.w administered for the same periods caused an increase in blood urea and activity of serum transaminases, with moderate destructive changes and increase in the relative weight of liver and kidneys being observed

Sensitization: Guinea pig, positive contact sensitizer.

Mutagenic effect:

- Tylosin tartrate administered at a concentration of 0.05% induced no mutagenic effect on the strains of *Salmonella typhi murium* TA 98 and TA 104 (Ames test).
- Tylosin tartrate administered per os a single time at doses of 500 and 1 000 mg/kg b.w. induced no mutagenic effect on the bone-marrow cells of mice (micronucleus-test).
- Tylosin tartrate did not exert mutagenic effect (MASH-test) after peroral administration to albino mice in the course of 5 days at a dose of 1 000 mg/kg b.w.

Teratogenic effect:
Tylosin tartrate introduced into the yolk sac of hen eggs on the 3rd day of incubation at levels of 2, 4 and 6 mg (= 1, 2 and 3 times ED_{50}), induced no embryotoxic and teratogenic effect and did not adversely affect the pre- and post-natal development of chickens.

Section 12: Environmental Information

HSNO Classification:	9.1A
Toxicity:	Highly toxic to algae. Practically non-toxic to fish, birds, earthworms and aquatic invertebrates.
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.

Other:

No effect on soil microbes was observed at the maximum predicted concentration (PEC) of tylosin in soil and only a very small effect was seen at 5 x the PEC indicating that tylosin tartrate is unlikely to pose a risk to soil microbes.

Predicted concentrations of tylosin in groundwater for tylosin tartrate indications were lower than 0.001 µg l^{-1}.

Tylosin is not classified as a PBT or vPvB substance.

It can therefore be concluded that use of tylosin tartrate in the treatment of turkeys, pigs, and broilers poses an acceptable risk to terrestrial and aquatic invertebrates, plants, microbes, fish and algae and groundwaters.

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	Classified as dangerous goods for transport under NZ Standard 5433:2007 Transport of Dangerous Goods on Land.
Air Transport	Classified as dangerous goods for transport under International Civil Aviation Organisation and International Air Transport Association regulations
Sea Transport	Classified as dangerous goods for transport under International Maritime Organisation regulations
UN Number	3077
Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (tylosin tartrate 100%)
DG Class	9
Subsidiary Risk	N/A
Packing Group	III
HAZCHEM Code	2Z
Marine Pollutant	Yes

The maximum quantity of this substance allowed for carriage on public service vehicles is 3kg.

Section 15: Regulatory Information

Regulatory Status:	Registered pursuant to the ACVM Act 1997, No A10039 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 **3kg** of Pharmasin 100% Soluble is sold or supplied.

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

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

Section 16: Other Information

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

Date of preparation: 17 November 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 NZ 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 NZ 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.