



SAFETY DATA SHEET

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

Section 1. Identification of the material and the supplier

Product: **Pharmasin 100% Soluble**
 Pack size: 1kg, 5kg, 20kg, 25kg
 Product Use: For Turkeys, broiler chickens & replacement layers: As an aid in the prevention and treatment of chronic respiratory disease (CRD) caused by susceptible strains of *Mycoplasma gallisepticum* and/or *Mycoplasma synoviae*. For the treatment of necrotic enteritis caused by susceptible strains of *Clostridium perfringens*.
 For Pigs: For treatment of Porcine Intestinal Adenomatosis (Ileitis) associated with *Lawsonia intracellulari*.

Restriction of Use: Refer to Section 15
 New Zealand Supplier: **Agrihealth NZ Limited**
 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: 24 April 2025

Section 2. Hazards Identification

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

EPA Approval No: HSR002370

Pictograms



Signal Word: **DANGER**

GHS Category	Hazard Code	Hazard Statement
Serious eye damage/eye irritation Cat. 2	H319	Causes serious eye irritation
Respiratory sensitisation Cat. 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
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

Prevention Code	Prevention Statement
P103	Read carefully and follow all instructions
P261	Avoid breathing dust
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
P285	In case of inadequate ventilation wear respiratory protection

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
P304 + P341	IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
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.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician
P362+P364	Take off contaminated clothing and wash before reuse

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 tartrate	1000	1405-54-5

Section 4. First Aid Measures

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:	May cause allergy or asthma symptoms or breathing difficulties if inhaled
Skin:	May cause an allergic skin reaction
Eyes:	Causes serious eye irritation

Notes to doctor: Treat exposed patients symptomatically

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, dry powder or foam
Precautions for firefighters and special protective clothing	Do not attempt to take action without protective equipment. Self-contained breathing apparatus. Complete protective clothing.
HAZCHEM CODE	2Z

Section 6. Accidental Release Measures

Persons with a history of allergies, contact dermatitis, chronic rashes or respiratory problems should use special precautions to avoid skin contact or exposure to dust. Wear suitable protective equipment and a self-contained breathing apparatus. Evacuate all unnecessary personnel. Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust.

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

Carefully sweep the powder up and remove. Place material in a dry container and cover. Remove from the area. Flush spill area with water. Dispose of waste safely as per Section 13

Section 7. Handling and Storage**Precautions for Handling:**

- Read carefully and follow all instructions
- Avoid breathing dust
- Wash hands thoroughly after handling
- Contaminated work clothing should not be allowed out of the workplace and must be washed before reuse
- Avoid release to the environment
- Wear protective clothing as detailed in SDS Section 8
- Ensure good ventilation of the work station
- Avoid contact with skin and eyes
- Do not eat, drink or smoke when using this product
- Avoid formation of dust and aerosols
- Provide exhaust ventilation if dust is formed

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 in a dry place, away from direct heat or sunlight
- Keep container sealed when not in use
- Keep out of reach of children
- Store away from foodstuffs

Section 8. Exposure Controls / Personal Protection**WORKPLACE EXPOSURE STANDARDS (provided for guidance only)**

Substance	TWA		STEL	
	ppm	mg/m ³	ppm	mg/m ³

No ingredients have exposure limits

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

Provide local exhaust or general room ventilation. Ensure good ventilation of the work station.

Personal Protection Equipment

Eyes	Wear safety glasses
Hands	Wear suitable protective gloves. Wash hands after use
Skin	Suitable clothing to prevent skin contact
Respiratory	In case of inadequate ventilation wear respiratory protection
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	Solid, granules
Colour	White to light yellow
Odour	Specific
Odour Threshold	Not available
pH (2.5% Concentration)	5 – 7.2
Boiling Point	Not available
Melting Point	128 – 132°C
Freezing Point	Not available
Flash Point	Not available
Flammability	Not flammable
Upper and lower flammability limits	65 – 125 g/m ³ (lower limit) 2000 g/ m ³ (upper limit)
Vapour Pressure	As a high molecular weight solid, tylosin would be expected to have a negligible vapour pressure
Vapour Density	Not available
Density	Not available
Water Solubility	Freely soluble in water (5 mg/ml at 25°C) and methylene chloride; slightly soluble in ethanol; soluble in dilute solutions of mineral acids.
Partition Coefficient:	5; 17; 17 (pH 5, 7, 9).
Auto-ignition Temperature	500°C – 520°C
Decomposition Temperature	Not available
Kinematic Viscosity	Not available
Particle Characteristics	Not available

Temperature range of ignition in air	470°C - 520°C
Maximum pressure of explosion, MPa	66 – 86
Minimal energy of ignition, mJ	20.4

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	Under normal conditions of storage and use, decomposition products should not be produced.

Section 11. Toxicological Information

Acute Effects:

Swallowed	Not applicable
Dermal	Not applicable
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled
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	LD₅₀	Species	Test results
Pharmasin 100% Soluble	Oral	Rat	6000 mg/kg
Components	LD₅₀	Species	Test results
Tylosin tartrate	Oral	Rat	6500 mg/kg
	Intraperitoneal	Mouse	500 mg/kg
	Oral	Mouse	> 5000 mg/kg

Tylosin base:

Skin corrosion/irritation: Rabbit – causes slight dermal irritation
 Serious eye damage/irritation: Rabbit – causes serious eye irritation
 Respiratory or skin sensitisation: May cause allergy or asthma symptoms or breathing difficulties if inhaled

Germ cell mutagenicity:

In vitro mammalian cell mutagenicity – mouse lymphoma cells – Positive
 In vitro mammalian cell mutagenicity – Chinese hamster ovary (HGPRT+) cells – negative
 In vitro chromosome damage assay – Chinese hamster ovary cells – negative
 In vitro micronucleus – mouse – negative

Carcinogenicity: 1 year – rat – oral – 50mg/kg/day, NOEL – not carcinogenic
 2 year – rat – oral – not carcinogenic

Reproductive toxicity:

Reproductive toxicity:

Mouse– oral – 2-generation – no treatment related effects observed

Rat – oral – 3-generation – no treatment related effects observed

Teratogenicity:

Mouse – oral – 1000mg/kg b.w., NOEL – no effects observed

Rat – oral – 725mg/kg b.w., NOEL – no effects observed

STOT – single exposure – No data available

STOT – repeated exposure – No data available

Aspiration hazard – No data available

Section 12. Ecotoxicological Information

Very toxic to aquatic life with long lasting effects.

Product:	
Persistence and degradability	Log Kow: 5; 17; 17 (pH5,7,9) Water solubility: 5mg/ml
Bioaccumulation	Tylosin is unlikely to accumulate in soils over time.
Mobility in Soil	No data available
Other adverse effects	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.

TOXICITY:

- 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 (*Oncorhynchus mykiss*) 96-hour median effective concentration EC₅₀ (survival): > 100 mg/L
- Rainbow trout (*Oncorhynchus mykiss*) No observed effect concentration NOEC: 100 mg/L
- Macrophytes (*Myriophyllum 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 product by use. Dispose of product and packaging at an approved landfill or equivalent facility.

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	3077
Class - Primary	9
Packing Group	III
Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S (Tylosin tartrate)
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: **HSR002370**

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 kg
Emergency Response Plan (Schedule 5)	100 kg
Secondary Containment (Schedule 5)	100 kg
Restriction of Use	Only use for the intended purpose
ACVM Act and Regulations	
See www.foodsafety.govt.nz for registration conditions	A10039

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

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

Issue Date: 24 April 2025 Review Date: 24 April 2030