



SAFETY DATA SHEET

1. Identification

Product identifier Elanco AF0472 Pulmotil 200 Tilmicosin Phosphate Premix

Other means of identification

Synonyms

Pulmotil 200 Premix * 177370 Phosphate * Pulmotil 18 Type B Medicated Feed * Pulmotil 90 Type A Medicated Article * Tilmicosin Granules * Tilmicosin Premix * Tilmicosin Phosphate Premix * Tilmicosin on Ground Corn Cobs * Pulmotil 18 * Pulmoxtil Premix * Pulmotil Premix 20% * Pulmotil G200 Premix * Pulmotil 18 Type B * Pulmotil 100 * Pulmotil G100 Premix * Pulmotil * Pulmotil 50 * Pulmotil 40 * Pulmotil 20 * Pulmotil 10

Item Code

AF0462, AF0463, AF0464, AF0465, AF0472

Recommended use of the chemical and restrictions on use

Recommended use Veterinary Pharmaceutical

Restrictions on use Not available.

Details of manufacturer or importer

Manufacturer

Company name

Elanco Animal Health
A Division of Eli Lilly Australia Pty Ltd

Address

A.B.N. 39 000 233 992
112 Wharf Road, West Ryde, N.S.W. 2114, Australia

Telephone

(02) 9878 7777

Fax

(02) 9878 7720

e-mail

lilly_msds@lilly.com

Emergency phone number

Elanco Animal Health: 1800 226 324 (Toll free)
OR Poisons Information Centre: 131126 (Australia-wide)

24 hr emergency contact number

CHEMWATCH 1800 039 008 (spills and accidents)

24 hr emergency contact number (Local)

CHEMWATCH +61 2 9186 1132 (spills and accidents)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards

Not classified.

Health hazards

Serious eye damage/eye irritation Category 2

Sensitization, respiratory Category 1

Sensitization, skin Category 1

Specific target organ toxicity following repeated exposure Category 2

Environmental hazards

Hazardous to the aquatic environment, acute hazard Category 2

Hazardous to the aquatic environment, long-term hazard Category 2

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard Environment

Signal word

Danger

Hazard Statement(s) May cause an allergic skin reaction. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause damage to organs (Heart) through prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.

Precautionary Statement(s)

Prevention Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection.

Response IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. IF INHALED: If breathing is difficult, remove victim 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 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. Get medical advice/attention if you feel unwell. Wash contaminated clothing before reuse.

Storage Not available.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards which do not result in classification None known.

Supplemental information Not applicable.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
TILMICOSIN PHOSPHATE	137330-13-3	1 - 20
Excipient: Grain Dust	NA	80 - 99
Anti-dusting oil MINERAL OIL	8012-95-1	<= 3

Composition comments The anti-dusting oil reduces potential exposure under normal handling conditions of use. Excipients may include: Rice hulls. Soybean mill run. Corn cob grits. Defatted rice bran. Corn distillers grain.

4. First-aid measures

Description of necessary first aid measures

Inhalation Move to fresh air. Oxygen or artificial respiration if needed. Call a physician or poison control centre immediately.

Skin contact Wash off immediately with soap and plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if irritation develops and persists.

Eye contact Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion If conscious, give the victim plenty of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control centre immediately.

Personal protection for first-aid responders In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Symptoms caused by exposure Irritating to eyes. Allergic reactions in a manufacturing setting have been reported. Allergy symptoms may include skin rash, watery eyes, shortness of breath, nasal congestion, coughing, and wheezing. Compounds of similar structure have been reported to cause transient alterations in heart rate. (Tilmicosin Phosphate)

Medical attention and special treatment Treat symptomatically.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media Water. Carbon dioxide (CO2). Dry chemical.

Unsuitable extinguishing media	Not available.
Specific hazards arising from the chemical	Dust may form explosive mixture with air. Fire or excessive heat may produce hazardous decomposition products.
Special protective equipment and precautions for fire fighters	Wear self-contained breathing apparatus and protective clothing.
Hazchem Code	2Z

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Avoid contact with skin, eyes and clothing. Wear suitable protective clothing, gloves and eye/face protection. See Section 8 for personal protective equipment.
For emergency responders	Use personal protection recommended in Section 8 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up Small Spillages:
Do not sweep. Collect spill using a vacuum cleaner with a HEPA filter. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.

Large Spillages:
Should not be released into the environment. Remove sources of ignition. Collect in a non-combustible container for prompt disposal. Local authorities should be advised if significant spillages cannot be contained. Large spills due to traffic accidents, etc., should be reported immediately to CHEMWATCH and Elanco Animal Health for assistance.

Other issues relating to spills and releases Clean up in accordance with all applicable regulations.

7. Handling and storage

Precautions for safe handling Avoid contact with eyes, skin, and clothing. Minimise dust generation and accumulation. Wash hands thoroughly after handling. Keep away from heat and sources of ignition. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities Store at temperatures between: 10 to 40 C (50 to 104 F).
Keep container tightly closed in a dry and well-ventilated place. Store away from strong oxidizers.
Do not store in open or unlabelled containers.

8. Exposure controls and personal protection

Control parameters Lilly Exposure Guideline (LEG): 12 hour TWA <100 ug/m3 (Tilimicosin)

Occupational exposure limits

ACGIH

Components	Type	Value	Form
Excipient: Grain Dust	TWA	4 mg/m3	(grain dust)

United Kingdom Components

Components	Type	Value	Form
Excipient: Grain Dust	STEL	30 mg/m3	inhalable fraction (grain dust)
	TWA	10 mg/m3	inhalable fraction (grain dust)

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines Lilly Exposure Guideline (LEG): 12 hour TWA <100 ug/m3 (Tilimicosin)

Appropriate engineering controls Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection Wear goggles/face shield. (AS/NZS 1337)

Skin protection

Hand protection Chemical resistant gloves. (AS 2161)

Other	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Respiratory protection	Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor. (AS/NZS 1715)
Thermal hazards	Not available.
Hygiene measures	NOT INTENDED FOR HUMAN USE. Use good industrial hygiene practices in handling this material.
	In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.
	Under normal use and handling conditions, wear goggles to protect eyes and wear impermeable gloves and protective equipment to avoid direct contact with skin. Wash thoroughly with soap and water after handling.

9. Physical and chemical properties

Appearance	Solid.
Physical state	Solid.
Form	Dry flowable granules.
Colour	Yellow to Red.
Odour	No data available.
Odour threshold	No data available.
pH	5.5 - 7 (50% aqueous)
Melting point/freezing point	No data available.
Initial boiling point and boiling range	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability (solid, gas)	No test data available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	No data available.
Flammability limit - upper (%)	No data available.
Explosive limit - lower (%)	No data available.
Explosive limit – upper (%)	No data available.
Vapour pressure	No data available.
Vapour density	No data available.
Relative density	No data available.
Solubility(ies)	
Solubility (water)	No data available.
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Viscosity	No data available.
Other physical and chemical parameters	
Explosive properties	Not explosive
Oxidising properties	No oxidizing properties.
Percent volatile	No data available.
VOC (Weight %)	No data available.

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	Hazardous polymerisation does not occur.
Conditions to avoid	None known.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information

Product	Species	Test results
Elanco AF0472 Pulmotil 200 Tilmicosin Phosphate Premix		
<u>Acute</u>		
Dermal		
LD	Rabbit	> 1000 mg/kg (20% formulation)
Oral		
LD	Rat	> 500 mg/kg (20% formulation)
Components	Species	Test results
Tilmicosin (CAS 108050-54-0)		
<u>Acute</u>		
Dermal		
LD	Rabbit	> 5000 mg/kg
Inhalation		
LC50	Rat	3800 mg/m3, 4 h
Oral		
LD50	Rat	855 mg/kg (fasted) (Tilmicosin Phosphate)
TILMICOSIN PHOSPHATE (CAS 137330-13-3)		
<u>Acute</u>		
Dermal		
LD	Rabbit	> 5000 mg/kg
Inhalation		
LC50	Rat	3800 mg/m3, 4 h
Oral		
LD50	Rat	855 mg/kg (fasted)
Other		
LD50	Rat	> 185 mg/kg Subcutaneous: coma, lethargy, incoordination, reduced activity.
Skin corrosion/irritation	Rabbit: Slight irritation. (20% formulation) Based on available data, the classification criteria are not met.	
Serious eye damage/irritation	Rabbit: Irritating. (20% formulation) (cleared within 7 days)	
Respiratory or skin sensitisation		
Respiratory sensitisation	No allergic reactions in a manufacturing setting have been reported. (Pulmotil Medicated Premix) Allergic reactions in a manufacturing setting have been reported.. (Tilmicosin Phosphate) Grain dusts may cause sensitization by inhalation.	
Skin sensitisation	No allergic reactions in a manufacturing setting have been reported. (Pulmotil Medicated Premix) Did not cause sensitization on laboratory animals. Allergic reactions in a manufacturing setting have been reported.. (Tilmicosin Phosphate)	
Germ cell mutagenicity	In vitro and in vivo tests did not show mutagenic effects. (Tilmicosin) Remaining ingredients: Not classified. Based on available data, the classification criteria are not met.	

Carcinogenicity	No ingredients present at 0.1% (one-tenth percent) or greater are listed by IARC, NTP, ACGIH, or OSHA. Due to lack of data the classification is not possible.
Reproductive toxicity	Slight increase in offspring mortality at maternally toxic doses. (Tilimicosin Phosphate) Remaining ingredients: Not classified. Based on available data, the classification criteria are not met.
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Heart effects (increased heart weight and size, heart muscle degeneration characterized by small areas of cell death, severe and persistent increase in heart rate with changes in electrocardiogram ST, Q, and T wave forms occurred generally at higher oral or injection doses where some mortality occurred), liver effects (increased liver weight and enzyme activity). (Tilimicosin Phosphate)
Aspiration hazard	No aspiration toxicity classification.
Other information	Increased adrenal and kidney weights, increased cell size in adrenal cortex, mucosal edema of the gallbladder, and subretinal fluid accumulation. Decreased food consumption and body weight gains, slightly decreased urine pH, occult blood in urine, increased serum alanine transaminase. (Tilimicosin Phosphate)

12. Ecological information

Ecotoxicity		Toxic to aquatic life with long lasting effects.	
Components	Species		Test results
Tilmicosin (CAS 108050-54-0)			
<i>Acute</i>	LC50		> 918 mg/kg, 28 day (Earthworm (Eisenia fetida))
Other	LC50	Duck	> 4710 ppm, 5 day Anas platyrhynchos (Mallard), Dietary
		Quail	> 4820 ppm, 5 day Colinus virginianus (Bobwhite), Dietary
	MIC	Micro-organisms	> 1000 mg/l Mold (Aspergillus flavus) > 1000 mg/l Fungus (Chaetomium globosum) 250 mg/l Soil bacteria (Comamonas acidovaorans) 5 mg/l N-fixing bacteria (Azotobacter chroococcum)
Aquatic			
<i>Acute</i>			
Algae	EC50	Algae	0.354 mg/l (Selenastrum capricornutum, average specific growth rate)
	MIC	Algae	0.5 mg/l (Blue-green algae)
Crustacea	EC50	Daphnia magna	57.3 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	716 mg/l, 96 hr
		Oncorhynchus mykiss	851 mg/l, 96 hours
Persistence and degradability	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		
Bioaccumulative potential	No data available for this product.		

**Partition coefficient
n-octanol / water (log
Kow)**

Tilmicosin

< 1 (pH 5)

< 1 (pH 7)

2.6 (pH 9)

Mobility in soil

Not available.

Other adverse effects

Not available.

Ecotoxicological Properties

Drinking Water

Components

Test results

Tilmicosin

280 µg/l, (Lilly Aquatic Exposure Guideline)

Chronic Exposure of Aquatic Organisms

Components

Test results

Tilmicosin

54 µg/l, (Lilly Aquatic Exposure Guideline)

Acute Exposure of Aquatic Organisms

Components

Test results

Tilmicosin

354 µg/l, (Lilly Aquatic Exposure Guideline)

13. Disposal considerations

Disposal methods

Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

General information

Effective January 1, 2015 by Special Provision, UN3077 and UN3082 when packaged in inner packages of 5L / 5 KG or less are not subject to the dangerous goods regulations.

ADG

UN number

3077

UN proper shipping name

Environmentally hazardous substance, solid, n.o.s. (TILMICOSIN PHOSPHATE)

Transport hazard class(es)

Class

9

Subsidiary risk

-

Packing group

III

Environmental hazards

Yes

Hazchem Code

2Z

Special precautions for user

Not available.

Not classified as dangerous goods when transported by road or rail in packaging or receptacles not exceeding 500 kg (L) according to ADG 7 SP AU01.

RID

UN number

3077

UN proper shipping name

Environmentally hazardous substance, solid, n.o.s. (TILMICOSIN PHOSPHATE)

Transport hazard class(es)

Class

9

Subsidiary risk

-

Label(s)

9

Packing group

III

Environmental hazards

Yes

Special precautions for user

Not available.

IATA

UN number

3077

UN proper shipping name

Environmentally hazardous substance, solid, n.o.s. (TILMICOSIN PHOSPHATE)

Transport hazard class(es)

Class

9

Subsidiary risk	-
Packing group	III
Environmental hazards	Yes
ERG Code	9L
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

IMDG

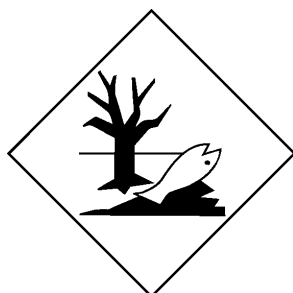
UN number	3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (TILMICOSIN PHOSPHATE)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

ADG; IATA; IMDG; RID



Marine pollutant



15. Regulatory information

Safety, health and environmental regulations

National regulations APVMA approval number 46076
Poison Schedule 4

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work.

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information**Issue date**

28-September-2015

Key abbreviations or acronyms used

LEG: Lilly Exposure Guideline
TWA: Time Weighted Average

Disclaimer

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health
0011+1-877-352-6261
0011+1-800-428-4441

Revision Information

Product and Company Identification: Alternate Trade Names
Physical & Chemical Properties: Multiple Properties
GHS: Classification