



SAFETY DATA SHEET

1. Identification

Product identifier

Pulmotil Medicated Premix

Other means of identification

Item Code

AF0462, AF0463, AF0464, AF0465, AF0472

Synonyms

Tylosin, 4A-O-de(2,6-dideoxy-3-C-methyl-alpha-L-ribo-hexopyranosyl)-20-deoxo-20-[(3R,5S)-3,5-dimethyl-1-piperidinyl]-, phosphate (1:1)(salt) * 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

Recommended use

Veterinary Pharmaceutical

Recommended restrictions

None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company Name

Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140
US

Phone:

1-877-Elanco1 (1-877-352-6261)

Email:

lilly_msds@lilly.com

Emergency Telephone Numbers:

Elanco Product Technical Support / Human or Animal Exposure Reporting:
1-888-545-5973
Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300
(Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards

Not classified.

Health hazards

Serious eye damage/eye irritation Category 2B
Sensitization, respiratory Category 1
Sensitization, skin Category 1
Specific target organ toxicity, repeated exposure Category 2

OSHA defined hazards

Combustible dust

Label elements



Signal word

Danger

Hazard statement

H317

May form combustible dust concentrations in air.

H320

May cause an allergic skin reaction.

H334

Causes eye irritation.

H373

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause damage to organs (Heart) through prolonged or repeated exposure.

Precautionary statement

Prevention

P280 Wear protective gloves/eye protection/face protection.
P285 In case of inadequate ventilation wear respiratory protection.
P261 Avoid breathing dust/fume.

Response

P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

Storage

Not available.

Disposal

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
TILMICOSIN PHOSPHATE		137330-13-3	1 - 20
Excipient: Grain Dust		NA	80 - 99
Calcium Carbonate		471-34-1	0 - 6
Anti-dusting oil	MINERAL OIL	8012-95-1	0 - 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

Inhalation

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

Most important symptoms/effects, acute and delayed

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)

Indication of immediate medical attention and special treatment needed

None known.

General information

In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. Fire-fighting measures

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 firefighters

Wear self-contained breathing apparatus and protective clothing.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothing. Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.

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 CHEMTREC and Elanco Animal Health for assistance.

Environmental precautions

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

7. Handling and storage

Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Minimize 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/personal protection

Exposure guidelines

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

Occupational exposure limits

ACGIH

Components

Type

Value

Form

Excipient: Grain Dust (CAS NA)

TWA

4 mg/m3

(grain dust)

US. ACGIH Threshold Limit Values

Components

Type

Value

Form

Anti-dusting oil (CAS 8012-95-1)

TWA

5 mg/m3

Inhalable fraction.

U.S. - OSHA

Components

Type

Value

Form

Excipient: Grain Dust (CAS NA)

TWA

10 mg/m3

(grain dust)

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components

Type

Value

Form

Anti-dusting oil (CAS 8012-95-1)

PEL

5 mg/m3

Mist.

Calcium Carbonate (CAS 471-34-1)

PEL

5 mg/m3

Respirable fraction.

15 mg/m3

Total dust.

US. NIOSH: Pocket Guide to Chemical Hazards

Components

Type

Value

Form

Anti-dusting oil (CAS 8012-95-1)

STEL

10 mg/m3

Mist.

Calcium Carbonate (CAS 471-34-1)

TWA

5 mg/m3

Mist.

TWA

5 mg/m3

Respirable.

10 mg/m3

Total

Biological limit values

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

Appropriate engineering controls

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

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear goggles/face shield.
Skin protection	
Hand protection	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Other	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Respiratory protection	Use an approved respirator. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor.
Thermal hazards	Not available.
General hygiene considerations	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.
Color	Yellow to Red.
Odor	No data available.
Odor 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.
Vapor pressure	No data available.
Vapor 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 information	
Explosive properties	Not explosive
Oxidizing 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 polymerization does not occur.
Conditions to avoid None known.
Incompatible materials Strong oxidizing agents.
Hazardous decomposition products Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Product	Species	Test Results
Pulmotil Medicated Premix (CAS Mixture)		
<i>Acute</i>		
<i>Dermal</i>		
LD	Rabbit	> 1000 mg/kg (20% formulation)
<i>Oral</i>		
LD	Rat	> 500 mg/kg (20% formulation)
Components	Species	Test Results
Tilimicosin (CAS 108050-54-0)		
<i>Acute</i>		
<i>Dermal</i>		
LD	Rabbit	> 5000 mg/kg
<i>Inhalation</i>		
LC50	Rat	3800 mg/m ³ , 4 h
TILMICOSIN PHOSPHATE (CAS 137330-13-3)		
<i>Acute</i>		
<i>Dermal</i>		
LD	Rabbit	> 5000 mg/kg
<i>Inhalation</i>		
LC50	Rat	3800 mg/m ³ , 4 h
<i>Oral</i>		
LD50	Rat	855 mg/kg (fasted)
<i>Other</i>		
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/eye irritation Rabbit: Irritating. (20% formulation) (cleared within 7 days)

Respiratory or skin sensitization

Respiratory sensitization No allergic reactions in a manufacturing setting have been reported. (Pulmotil Medicated Premix)
Allergic reactions in a manufacturing setting have been reported.. (Tilimicosin Phosphate)
Grain dusts may cause sensitization by inhalation.

Skin sensitization 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.. (Tilimicosin 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.
IARC Monographs. Overall Evaluation of Carcinogenicity	
Anti-dusting oil (CAS 8012-95-1)	3 Not classifiable as to carcinogenicity to humans.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	
Reproductive toxicity	Slight increase in offspring mortality at maternally toxic doses. (Tilmicosin 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). (Tilmicosin Phosphate)
Aspiration hazard	No aspiration toxicity classification.
Further 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. (Tilmicosin Phosphate)

12. Ecological information

Ecotoxicity

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 acidovorans) 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 No data 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 instructions Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

UN number UN3077

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 UN3077

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
Special precautions for user

F-A, S-F
Not available.

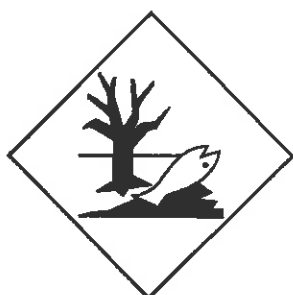
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

This substance/mixture is not intended to be transported in bulk.

IATA; IMDG



Marine pollutant



15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Anti-dusting oil (CAS 8012-95-1)
Calcium Carbonate (CAS 471-34-1)

US. New Jersey Worker and Community Right-to-Know Act

Anti-dusting oil (CAS 8012-95-1)
Calcium Carbonate (CAS 471-34-1)

US. Pennsylvania Worker and Community Right-to-Know Law

Anti-dusting oil (CAS 8012-95-1)
Calcium Carbonate (CAS 471-34-1)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	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, including date of preparation or last revision

Issue date 08-20-2014

Version # 01

Lilly Lab Code Health: 2
Fire: 1
Reactivity: 0
Special 1: A

List of abbreviations LEG: Lilly Exposure Guideline
TWA: Time Weighted Average

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For additional information contact:
Elanco Animal Health
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00+1-800-428-4441

Revision Information Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Toxicological Information: Toxicological Data
Ecological Information: Ecotox Property Data
Regulatory Information: Safety Phrases
GHS: Classification