

SAFETY DATA SHEETS

This SDS packet was issued with item:

078915355

N/A



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-deoxy-20-[(3R,5S)-3,5-dimethyl-1-piperidiny] -, 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. (Tilomicosin 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)		
Acute		
<i>Dermal</i>		
LD	Rabbit	> 1000 mg/kg (20% formulation)
<i>Oral</i>		
LD	Rat	> 500 mg/kg (20% formulation)

Components	Species	Test Results
Tilmicosin (CAS 108050-54-0)		
Acute		
<i>Dermal</i>		
LD	Rabbit	> 5000 mg/kg
<i>Inhalation</i>		
LC50	Rat	3800 mg/m3, 4 h
TILMICOSIN PHOSPHATE (CAS 137330-13-3)		
Acute		
<i>Dermal</i>		
LD	Rabbit	> 5000 mg/kg
<i>Inhalation</i>		
LC50	Rat	3800 mg/m3, 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.. (Tilmicosin 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.. (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.
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)			
Acute			
	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			
Acute			
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

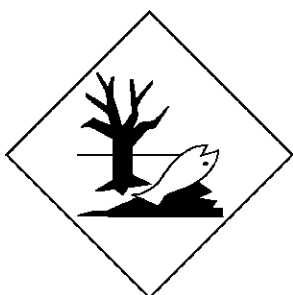
F-A, S-F

Special precautions for user

Not available.

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

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

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
00+1+317-276-2000
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



Pulmotil® Medicated Premix

Effective Date: 18-Nov-2003
Current as of: 25-Jan-2010

Elanco Animal Health
Material Safety Data Sheet

Section 1 - Chemical Product and Company

Manufacturer:

Elanco Animal Health
Division Eli Lilly Canada Inc.
150 Research Lane, Suite 120
Guelph, Ontario N1G 4T2

Emergency Phone: 1-800-265-5475

**FOR A DANGEROUS GOODS EMERGENCY
CALL CANUTEC AT THE 24-HOUR NUMBER
1-613-996-6666.**

Common Name: Pulmotil Medicated Premix

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

Synonym(s): 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

Trademarks(s): 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

Lilly Item Code(s): AF0461; AF0462; AF0463; AF0464; AF0465; AF0470; AF0472; MS8290; QA358V

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration %</u>
Tilmicosin Phosphate	137330-13-3	1 - 20
Excipients	NA	80 - 99
Anti-dusting Oil	NAIF	0 - 3

Each product contains one or more of the following excipients, ground corn cobs, soybean mill run, rice hulls, limestone, defatted rice bran, or corn distillers grain. Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

01/25/2010

Exposure Guidelines: Tilmicosin - LEG <100 micrograms/m³ TWA for 12 hours.

Grain dust - PEL 10 mg/m³ TWA. TLV 4 mg/m³ TWA for 8 or 12 hours (total). Lilly preferred exposure limit is TLV.

UK - Maximum Exposure Limit 10 mg/m³ TWA (total) (Sens).

Ireland - Occupational Exposure Limit 10 mg/m³ TWA (Sens).

Limestone dust - PEL 15 mg/m³ TWA (total dust) and 5 mg/m³ TWA (respirable fraction). TLV 10 mg/m³ TWA.

UK - Exposure Standard 10 mg/m³ TWA (total inhalable) and 4 mg/m³ TWA (respirable).

Ireland - Occupational Exposure Limit 10 mg/m³ TWA (total inhalable) and 5 mg/m³ TWA (respirable).

France - (Calcium carbonate) Occupational Exposure Limit 10 mg/m³ (VME) TWA.

The anti-dusting oil reduces potential exposure under normal conditions of use or in a foreseeable emergency.

Section 3 - Hazards Identification

Appearance: Yellowish-tan to reddish-tan free-flowing granules

Physical State: Solid

Odour: No applicable information found

Emergency Overview

Special
A = Allergen

Emergency Overview Effective Date: 07-Sep-2001

Lilly Laboratory Labelling Codes:

Health 2

Fire 1

Reactivity 0

Special A

Primary Physical and Health Hazards: Irritant (eyes). Severe Allergen. Heart Effects.

Caution Statement: Pulmotil Medicated Premix contains tilmicosin phosphate, may be irritating to the eyes, and is classified as a severe allergen because repeated unprotected exposures are likely to cause allergic reactions. Effects of exposure may include changes in heart rate/rhythm and heart tissue changes.

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: Pulmotil Medicated Premix - No allergic reactions in a manufacturing setting have been reported. Based on animal data, may be irritating to the eyes.

01/25/2010

Tilmicosin phosphate powder - Allergic reactions in a manufacturing setting have been reported. Allergy symptoms may include skin rash, watery eyes, shortness of breath, nasal congestion, choking, coughing, and wheezing. Compounds of similar structure have been reported to cause transient alterations in heart rate.

Grain dust - Prolonged exposure to grain dust may result in irritation of the respiratory tract, mucous membranes, eyes, and skin.

NOT INTENDED FOR HUMAN USE.

Medical Conditions Aggravated by Exposure: Sensitivity to tilmicosin and/or tylosin.

Carcinogenicity: No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA.

Section 4 - First Aid Measures

Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Section 5 - Fire Fighting Measures

Flash Point: No applicable information found

UEL: No applicable information found

LEL: No applicable information found

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

Spills: Contain dry material by lightly misting with water, followed by sweeping up or vacuuming. Vacuuming may disperse dust if appropriate dust collection filter is not part of the vacuum. Be aware of potential for dust explosion when using electrical equipment. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Large spills due to traffic accidents, etc., should be reported immediately to CANUTEC and Elanco Animal Health for assistance. **FOR A DANGEROUS GOOD EMERGENCY CALL CANUTEC AT THE 24-HOUR NUMBER 1-613-996-6666.** Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

Section 7 - Handling and Storage

Storage Conditions: Store at room temperature. Product should not be used after the date printed on the container. Warehouse: 10 to 40 C (45 to 104 F).

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

Respiratory Protection: Use an approved respirator.

Eye Protection: Chemical goggles and/or face shield.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: 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.

Additional Exposure Precautions: 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.

NOT INTENDED FOR HUMAN USE.

Section 9 - Physical and Chemical Properties

Appearance: Yellowish-tan to reddish-tan free-flowing granules

Odour: No applicable information found

Boiling Point: Not applicable

Melting Point: Not applicable

01/25/2010

Specific Gravity: No applicable information found

pH: 5.5-7.0 (50% aqueous)

Evaporation Rate: No applicable information found

Water Solubility: Tilmicosin phosphate - Soluble

Inert ingredients - Insoluble

Vapour Density: No applicable information found

Vapour Pressure: No applicable information found

Section 10 - Stability and Reactivity

Stability: Stable at normal temperatures and pressures.

Incompatibility: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

Hazardous Decomposition: May emit toxic fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Acute Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

Oral: 20% Tilmicosin phosphate formulation - Rat, 500 mg/kg, no deaths or toxicity. Tilmicosin phosphate - Rat (fasted), median lethal dose 855 mg/kg, reduced activity, incoordination, drooping eyelids, soft stools, whole body thin, distended abdomen.

Skin: 20% Tilmicosin phosphate formulation - Rabbit, 1000 mg/kg, no deaths.

Inhalation: Tilmicosin - Rat, median lethal concentration 3800 mg/m³ for 4 hours, reduced activity, laboured breathing.

Skin Contact: 20% Tilmicosin phosphate formulation - Rabbit, slight irritant

Eye Contact: 20% Tilmicosin phosphate formulation - Rabbit, irritant

Chronic Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

Target Organ Effects: Tilmicosin phosphate - 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).

Other Effects: Tilmicosin phosphate - 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.

Reproduction: Tilmicosin phosphate - No effects identified in animal studies, except slight increase in offspring mortality at maternally toxic doses.

Sensitization: Tilmicosin phosphate - Guinea pig, not a contact sensitizer.

Mutagenicity: Tilmicosin - Not mutagenic in bacterial or mammalian cells.

Section 12 - Ecological Information

No environmental data for the mixture or formulation. The environmental data for ingredient(s) or related material(s) are presented.

Ecotoxicity Data: Tilmicosin

Rainbow trout 96-hour median lethal concentration: 851 mg/L

Bluegill 96-hour median lethal concentration: 716 mg/L

Daphnia magna 48-hour median effective concentration: 57.3 mg/L

Bobwhite quail 5-day dietary median lethal concentration: > 4820 ppm

Mallard 5-day dietary median lethal concentration: > 4710 ppm

Earthworm 28-day median lethal concentration: > 918 mg/Kg

Green algae (*S. capricornutum*) median effective concentration: 0.354 mg/L (average specific growth rate)

Plant growth in soil for most species unaffected at 100 mg/L

Microorganisms:

fungus (*Chaetomium globosum*): MIC > 1000 mg/L

mould (*Aspergillus flavus*): MIC > 1000 mg/L

soil bacteria (*Comamonas acidovorans*): MIC = 250 mg/L

N-fixing bact. (*Azotobacter chroococcum*): MIC = 5 mg/L

blue-green algae (*Nostoc* sp.): MIC = 0.5 mg/L

Environmental Fate: Tilmicosin

Log Kow: <1, <1, 2.6 (pH 5, 7, 9)

Adsorption coefficients (K): 129, 181, 318 (sandy loam, loam, clay loam)

Water solubility (g/L): 566, 7.7 (pH 7, 9)

Photolysis half-life (hours): 0.84, 0.82, 0.82 (pH 5, 7, 9)

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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

Environmental Summary: Tilimicosin - Practically nontoxic to fish, birds, earthworms, fungus, moulds, soil bacteria, and most plants. Slightly toxic to aquatic invertebrates. Moderately toxic to nitrogen-fixing bacteria. Highly toxic to green algae and blue-green algae. No volatility expected. Low potential to bioconcentrate in aquatic organisms. Low mobility in soil. Persistent in the soil environment. Persistence in the aquatic environment not expected due to rapid photolysis.

Lilly Aquatic Exposure Guideline (LAEG): Tilimicosin

LAEG for Drinking Water: 280 micrograms/L

LAEG for Chronic Exposure of Aquatic Organisms: 54 micrograms/L

LAEG for Acute Exposure of Aquatic Organisms: 354 micrograms/L

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Container Disposal: No special package disposal required.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Elanco Animal Health usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

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U.S. Regulations

Tilimicosin phosphate

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

EU Regulations

EC Classification:

Xn (Harmful)

Xi (Irritant)

Risk Phrases:

R 36 - Irritating to eyes.

R 42/43 - May cause sensitization by inhalation and skin contact.

Safety Phrases:

S 26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

Section 16 - Other Information

MSDS Sections Revised: Sections 1 and 16.

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 MERCHANTABILITY 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

1-800-265-5475

GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists

AIHA = American Industrial Hygiene Association

BEI = Biological Exposure Index

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CANUTEC = Canadian Transport Emergency Center
CAS Number = Chemical Abstract Service Registry Number
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN = Chemical Hazard Alert Notice
DOT = Department of Transportation
EC = European Community
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
EPA = Environmental Protection Agency
EU = European Union
HEPA = High Efficiency Particulate Air (Filter)
IARC = International Agency for Research on Cancer
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association
IEG = Lilly Interim Exposure Guideline
IMO = International Maritime Organization
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
MSHA = Mine Safety and Health Administration
NA = Not Applicable
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline
STEL = Short Term Exposure Limit
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations
U.S. = United States
WEEL = Workplace Environmental Exposure Level (AIHA)

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