

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 | 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 |
| Recommended use | Veterinary Pharmaceutical |
| Recommended restrictions | None known. |
| Manufacturer/Importer/Supplier/Distributor information | |
| Company Name | Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US |
| Phone: | 1-877-Elanco1 (1-877-352-6261) |
| Emergency Telephone: | Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973 |
| Email: | elanco_sds@elanco.com |
| 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 | |
| H319 | May form combustible dust concentrations in air. |
| H334 | Causes serious eye irritation. |
| H317 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H373 | May cause an allergic skin reaction. |
| | May cause damage to organs (Heart) through prolonged or repeated exposure. |
| Precautionary statement | |
| Prevention | |
| P261 | Avoid breathing dust. |
| P280 | Wear protective gloves/eye protection/face protection. |
| P285 | In case of inadequate ventilation wear respiratory protection. |
| Response | |

P304 + P340
P342 + P311
P302 + P352
P333 + P313

IF INHALED: Remove person to fresh air and keep comfortable for breathing.
If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
IF ON SKIN: Wash with plenty of water.
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 | <= 6 |
| 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

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

Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. May cause damage to organs (Heart) through prolonged or repeated exposure.
Compounds of similar structure have been reported to cause transient alterations in heart rate. (Tilimicosin Phosphate)

Indication of immediate medical attention and special treatment needed

Treat symptomatically.

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**Occupational exposure limits****U.S. - OSHA
Components**

| Components | Type | Value | Form |
|-----------------------|------|----------------------|--------------|
| Excipient: Grain Dust | TWA | 10 mg/m ³ | (grain dust) |

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

| Components | Type | Value | Form |
|----------------------------------|------|----------------------|----------------------|
| Anti-dusting oil (CAS 8012-95-1) | PEL | 5 mg/m ³ | Mist. |
| Calcium Carbonate (CAS 471-34-1) | PEL | 5 mg/m ³ | Respirable fraction. |
| | | 15 mg/m ³ | Total dust. |

**ACGIH
Components**

| Components | Type | Value | Form |
|-----------------------|------|---------------------|--------------|
| Excipient: Grain Dust | TWA | 4 mg/m ³ | (grain dust) |

**US. ACGIH Threshold Limit Values
Components**

| Components | Type | Value | Form |
|----------------------------------|------|---------------------|---------------------|
| Anti-dusting oil (CAS 8012-95-1) | TWA | 5 mg/m ³ | Inhalable fraction. |

**US. NIOSH: Pocket Guide to Chemical Hazards
Components**

| Components | Type | Value | Form |
|----------------------------------|------|----------------------|-------------|
| Anti-dusting oil (CAS 8012-95-1) | STEL | 10 mg/m ³ | Mist. |
| | TWA | 5 mg/m ³ | Mist. |
| Calcium Carbonate (CAS 471-34-1) | TWA | 5 mg/m ³ | Respirable. |
| | | 10 mg/m ³ | Total |

Biological limit values

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

Exposure guidelines

12 hour TWA <100 ug/m³ (Tilmicosin)

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.

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. 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 | |
| Density | No data available. |
| Dust explosion properties | |
| Pmax | 8.6 bar ASTM E1226 |
| Kst | 204 bar.m/s ASTM E 1226 |
| St class | 2 |

| | |
|---|--|
| Minimum ignition energy (MIE) - dust cloud | 3 - 10 mJ ASTM E2019 (without inductance) (4.7% moisture) (100% < 75 um) |
| Explosive properties | Not explosive. |
| Oxidizing properties | No oxidizing properties. |
| Percent volatile | No data available. |
| VOC | No data available. |

10. Stability and reactivity

| | |
|---|--|
| Reactivity | Not water reactive. |
| 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 Based on available data, the classification criteria are not met.

| Product | Species | Test Results |
|--|---|---|
| Pulmotil Medicated Premix | | |
| Acute | | |
| Dermal | | |
| LD | Rabbit | > 1000 mg/kg (20% formulation) |
| Oral | | |
| LD | Rat | > 500 mg/kg (20% formulation) |
| Components | Species | Test Results |
| Tilimicosin (CAS 108050-54-0) | | |
| Acute | | |
| Dermal | | |
| LD | Rabbit | > 5000 mg/kg |
| Inhalation | | |
| LC50 | Rat | 3800 mg/m ³ , 4 h |
| Oral | | |
| LD50 | Rat | 855 mg/kg (fasted) (Tilimicosin Phosphate) |
| TILMICOSIN PHOSPHATE (CAS 137330-13-3) | | |
| Acute | | |
| Dermal | | |
| LD | Rabbit | > 5000 mg/kg |
| Inhalation | | |
| LC50 | Rat | 3800 mg/m ³ , 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/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. (Tilimicosin)
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.

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 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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.

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.
(Tilimicosin Phosphate)

12. Ecological information

Ecotoxicity Toxic to aquatic life with long lasting effects.

| Components | | Species | Test Results |
|-------------------------------|------|--------------------------------|---|
| Tilimicosin (CAS 108050-54-0) | | | |
| <i>Acute</i> | | | |
| | LC50 | | > 918 mg/kg, 28 day (Earthworm (Eisenia fetida)) |
| Other | 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 |

| Components | Species | Test Results | |
|--|---|--|--|
| Terrestrial | | | |
| <i>Acute</i> | | | |
| | LC50 | Duck | > 4710 ppm, 5 day <i>Anas platyrhynchos</i> (Mallard), Dietary |
| Other | LC50 | Quail | > 4820 ppm, 5 day <i>Colinus virginianus</i> (Bobwhite), Dietary |
| 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

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.

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

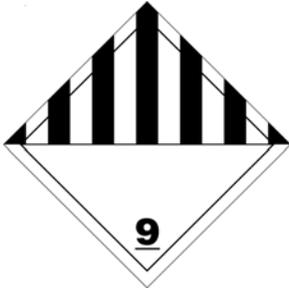
Allowed with restrictions.

Cargo aircraft only

Allowed with restrictions.

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 | Not available. |

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.

Toxic Substances Control Act (TSCA)**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 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**Classified hazard categories**

Combustible dust
Serious eye damage or eye irritation
Respiratory or skin sensitization
Specific target organ toxicity (single or repeated exposure)

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.

US state regulations

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.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

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

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

Revision date 01-23-2019

Version # 03

List of abbreviations
LC50: Lethal Concentration 50%.
LD50: Lethal Dose 50%.
LEG: Lilly Exposure Guideline.
TWA: Time Weighted Average Value.

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 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
0011+1-877-352-6261
0011+1-800-428-4441



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.

01/25/2010

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

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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: Tilmicosin - 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): Tilmicosin
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.

U.S. Regulations

Tilmicosin 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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