



Pulmotil Medicated Premix

Effective Date: 18-Nov-2003

Elanco Animal Health
Material Safety Data Sheet

Section 1 - Chemical Product and Company

Manufacturer:

Elanco Animal Health
Division of Eli Lilly and Company
2001 West Main St
PO Box 708
Greenfield, IN 46140

Manufacturer's Emergency Phone:

1-800-428-4441

CHEMTREC:

1-800-424-9300 (North America)

1-703-527-3887 (International)

Common Name: Pulmotil Medicated Premix

Chemical Name: Tylosin, 4A-O-de(2,6-dideoxy-3-C-methyl-alpha-L-ribo-hexopyranosyl)-20-deoxy-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.

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

Odor: No applicable information found

Emergency Overview



Special
A = Allergen

Emergency Overview Effective Date: 07-Sep-2001

Lilly Laboratory Labeling 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.

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: 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 CHEMTREC and Elanco Animal Health for assistance. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes. Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not

available, lightly mist material and remove by sweeping or wet wiping.

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

Odor: No applicable information found

Boiling Point: Not applicable

Melting Point: Not applicable

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

Vapor Density: No applicable information found

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

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

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

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

Eye Contact: 20% Tilimicosin 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: Tilimicosin 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: Tilimicosin 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: Tilimicosin phosphate - No effects identified in animal studies, except slight increase in offspring mortality at maternally toxic doses.

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

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

Section 12 - Ecological Information

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

Ecotoxicity Data: Tilimicosin

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 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

mold (*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: Tilimicosin

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)

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, molds, 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.

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

1-800-428-4441

1-317-276-2000

GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists

AIHA = American Industrial Hygiene Association

BEI = Biological Exposure Index

CAS Number = Chemical Abstract Service Registry Number

CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)

CHAN = Chemical Hazard Alert Notice

CHEMTREC = Chemical Transportation Emergency Center

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

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

Kow = Octanol/Water Partition Coefficient

LEG = Lilly Exposure Guideline

LEL = Lower Explosive Limit

MSDS = Material Safety Data Sheet

MSHA = Mine Safety and Health Administration

NA = Not Applicable, except in Section 14 where NA = North America

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

WEEL = Workplace Environmental Exposure Level (AIHA)