



# 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.

**Exposure Guidelines:** Tilmicosin - LEG <100 micrograms/m<sup>3</sup> TWA for 12 hours.

Grain dust - PEL 10 mg/m<sup>3</sup> TWA. TLV 4 mg/m<sup>3</sup> TWA for 8 or 12 hours (total). Lilly preferred exposure limit is TLV.

UK - Maximum Exposure Limit 10 mg/m<sup>3</sup> TWA (total) (Sens).

Ireland - Occupational Exposure Limit 10 mg/m<sup>3</sup> TWA (Sens).

Limestone dust - PEL 15 mg/m<sup>3</sup> TWA (total dust) and 5 mg/m<sup>3</sup> TWA (respirable fraction). TLV 10 mg/m<sup>3</sup> TWA.

UK - Exposure Standard 10 mg/m<sup>3</sup> TWA (total inhalable) and 4 mg/m<sup>3</sup> TWA (respirable).

Ireland - Occupational Exposure Limit 10 mg/m<sup>3</sup> TWA (total inhalable) and 5 mg/m<sup>3</sup> TWA (respirable).

France - (Calcium carbonate) Occupational Exposure Limit 10 mg/m<sup>3</sup> (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.

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

**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/m<sup>3</sup> 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)

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



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)