

The logo for Elanco, featuring the word "ELANCO" in white, bold, uppercase letters on a blue rectangular background that is tilted slightly to the right.

**MATERIAL SAFETY DATA SHEET
PULMOTIL 200 PREMIX**

AF0472

Revision 3.5, 18 October 2006

STATEMENT OF HAZARDOUS NATURE:

"Hazardous according to criteria of Worksafe Australia"

Harmful; R42/43 May cause sensitisation by inhalation and skin contact.

Irritant; R36 Irritating to eyes.

Company Name and Address:

Elanco Animal Health

A Division of Eli Lilly Australia Pty Ltd

A.B.N. 39 000 233 992

112 Wharf Road, West Ryde, N.S.W. 2114, Australia

Contact Numbers:

Tel: (02) 9878 7777

Fax: (02) 9878 7720

Emergency Telephone Numbers:

Elanco Animal Health:

1800 226 324 (Toll free)

OR

Poisons Information Centre:

131126 (Australia-wide)

CHEMWATCH 1800 039 008 24 hour emergency contact number(spills and accidents)

Section 1 - Identification

Product Name: ElancoAF0472 Pulmotil 200 Tilmicosin Phosphate Premix

Other Names: Tilmicosin (as tilmicosin phosphate)

Manufacturer's Product Code: AF0472

UN Number: None allocated

Dangerous Goods Class/Subsidiary Risk: None allocated

Hazchem Code: None allocated

Poisons Schedule Number: S4

Pack Size and Container Type: 10 kg laminated printed bag.

Use:

Major Recommended Uses: For the control of pneumonia in swine, caused by *Actinobacillus pleuropneumoniae*, *Mycoplasma hyopneumoniae*, *Pasteurella multocida*, and other organisms sensitive to tilmicosin.

Major Recommended Method(s) of Application: Mixed in feed

Section 2 - Composition / Information on Ingredients

| Ingredient | CAS | Concentration % |
|----------------------|-------------|-----------------|
| Tilmicosin Phosphate | 137330-13-3 | 20 |
| Corn Cob Grits | NA | 80 |

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.

Section 3 - Hazards Identification

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

Physical State: Solid

Odor: No applicable information found

Emergency Overview

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

Caution Statement: Pulmotil 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.

Potential Signs and Symptoms of Occupational Exposure: Pulmotil - 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 Poisons Information Centre. Phone 13 1126 (Australia-wide). 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 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. Large spills due to traffic accidents, etc., should be reported immediately to Elanco Animal Health for assistance. Prevent spilled material from spreading onto adjacent land or into streams, ponds, or lakes. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

Section 7 - Handling and Storage

Storage: Store below 30°C (Room Temperature) in a dry place.

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

SPECIFIC SAFETY INSTRUCTIONS AS PER AUSTRALIAN REGISTERED LABEL¹:
Will irritate the eyes and skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. Do not inhale dust. When mixing wear elbow-length PVC gloves and goggles and if dust is present half-face respirator with dust cartridge or canister. If product in eyes, wash it out immediately with water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, goggles, respirator, and if rubber wash with detergent and warm water, and contaminated clothing.

ADDITIONAL INFORMATION PROVIDED BY MANUFACTURER:

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.

Other Handling 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

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.

¹ Handbook of First Aid Instructions and Safety Directions for Agricultural and Veterinary Chemicals (including Pesticides). Therapeutic Goods Administration

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

Animal Toxicity Data Single 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, labored breathing.

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

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

Animal Toxicity Data Repeat 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-hr median lethal concentration: 851 mg/L

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

Daphnia magna 48-hr 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 bacteria (*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, 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): 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

Disposal of bags: Shake bag empty into medicated feed. Puncture and bury empty bags in a local authority landfill. If not available bury the bag below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and roots. Empty bags and product should not be burned. Do not dispose of undiluted premix on site.

Protection of the environment: Sludge from waste treatment ponds must be disposed of in approved landfills for contaminated wastes. This product may accumulate in soils. DO NOT spread effluent containing tilmicosin on the same pastures or croplands in successive years. DO NOT allow wastes from pigs treated with tilmicosin to enter waterways. These wastes contain tilmicosin which is highly toxic to algae.

Section 14 - Transport Information

No special transport requirements necessary.

Section 15 - Other Information

Sections revised: Section 1 Chemwatch details

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.

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)
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
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
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)