

MSDS for: PULMOTIL 18 TYPE B MEDICATED FEED

Material Safety Data Sheet
PULMOTIL 18 TYPE B MEDICATED FEED
EFFECTIVE DATE: 04/01/97

SECTION I CHEMICAL PRODUCT AND COMPANY

See SECTION XVI for abbreviations.

MANUFACTURER: ELANCO ANIMAL HEALTH
Division of Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

EMERGENCY PHONE: 317-276-2000

CHEMTREC: 800-424-9300

COMMON NAME: PULMOTIL 18 TYPE B MEDICATED FEED

SYNONYMS: Tilmicosin; Tilmicosin Premix; Tilmicosin Granules;
Tilmicosin Phosphate.

TRADE NAME(S): Pulmotil 18; Pulmotil; Pulmotil 18 Type B

ITEM CODE(S): AF0463

ADDITIONAL INFORMATION: PULMOTIL 18 is a Type B medicated feed used
to make a Type C medicated feed for use in swine for the control
of bacterial pneumonia caused by Actinobacillus pleuropneumonia
and Pasteurella multocida.

SECTION II COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT	CONCENTRATION (%)
Tilmicosin phosphate CAS #137330-13-3	4
Anti-dusting oil CAS # NAIF	2.5
Excipients CAS # NAIF	93.5

Contains no hazardous components (one percent or greater) or
carcinogens (one-tenth percent or greater) not listed above.

Excipients may include ground corn cobs, soybean mill run, rice
hulls, limestone, defatted rice bran, or corn distillers grain.

EXPOSURE GUIDELINES:

PULMOTIL 18 TYPE B MEDICATED FEED: PEL and TLV not established

TILMICOSIN PHOSPHATE: LEG < 100 micrograms/m³ TWA for 12 hours

GRAIN DUST: PEL not established. TLV 4 mg/m³

Aerosol exposure should be no greater than the grain dust
TLV of 4 mg/m³. Users should restrict dust levels to
the grain dust TLV of 4 mg/m³ which should be
achievable under normal operating conditions. The
anti-dusting oil reduces potential exposure under
normal conditions of use or in a foreseeable
emergency.

LIMESTONE DUST: PEL not established. TLV 10 mg/m³

Aerosol exposure should be no greater than the nuisance dust
TLV of 10 mg/m³. Users should restrict dust levels to
the nuisance dust TLV of 10 mg/m³ which should be
achievable under normal operating conditions. The

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

SECTION III HAZARDS IDENTIFICATION

APPEARANCE: Yellowish-tan to reddish-tan free-flowing granular.

PHYSICAL STATE: Solid

ODOR: NAIF

EMERGENCY OVERVIEW:

LILLY LABORATORY LABELING CODES:

HEALTH: 2

FIRE: 1

REACTIVITY: 0

SPECIAL: A = Allergen

PRIMARY PHYSICAL AND HEALTH HAZARDS: Irritant (eyes). Severe allergen. Heart effects.

CAUTION STATEMENT: PULMOTIL 18 TYPE B MEDICATED FEED 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 damage.

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ROUTES OF ENTRY: Inhalation and skin contact.

POTENTIAL SIGNS AND SYMPTOMS OF OCCUPATIONAL EXPOSURE:

TILMICOSIN PHOSPHATE POWDER: Allergy 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.

PULMOTIL 18: No allergic reactions in a manufacturing setting have been reported. Based on animal data, this material may be irritating to the eyes.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Sensitivity to Tilmicosin and/or tylosin.

CARCINOGENICITY: Not listed as carcinogenic by IARC, NCI/NTP, ACGIH, or OSHA.

SECTION IV 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: Call a physician or Poison Control Center immediately. If available, administer activated charcoal (6-8 heaping teaspoonfuls) with two or three glasses of water OR give 1-2 tablespoons syrup of ipecac and drink one or two glasses of

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water to INDUCE VOMITING. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

SECTION V FIREFIGHTING MEASURES

AUTOIGNITION: 374 deg. F (190 deg. C) (dust layer)

FLASH POINT: N/A

UEL: N/A

LEL: 0.90 oz/cu. ft (dust layer)

EXTINGUISHING MEDIA: Use water, carbon dioxide, dry chemical, foam or Halon.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None known; however, 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 heated to decomposition.

SECTION VI ACCIDENTAL RELEASE MEASURES

SPILLS: Do not contaminate any body of water. For spills, sweep up and place the material, and any damaged unusable containers, in landfill in accordance with applicable regulations. Large spills due to traffic accidents, etc. should be reported immediately to CHEMTREC and ELI LILLY AND COMPANY for assistance. Prevent spilled material from spreading onto adjacent land or into streams, ponds or lakes.

SECTION VII HANDLING AND STORAGE

SEE SECTION VIII FOR APPROPRIATE PERSONAL PROTECTIVE EQUIPMENT.

STORAGE TEMPERATURE: Store at room temperature.

SECTION VIII EXPOSURE CONTROLS/PERSONAL PROTECTION

SEE SECTION II FOR EXPOSURE GUIDELINES.

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: 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: When mixing and handling, use protective clothing, impervious gloves, and a NIOSH-approved dust mask. Operators should wash thoroughly with soap and water after handling.

SECTION IX PHYSICAL AND CHEMICAL PROPERTIES

BOILING POINT: N/A

MELTING POINT: N/A

SPECIFIC GRAVITY: N/A

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pH: 5.5-7 (aqueous 50/50)

EVAPORATION RATE: NAIF

WATER SOLUBILITY:

TILMICOSIN PHOSPHATE: Soluble

INERT INGREDIENTS: Insoluble

VAPOR DENSITY: NAIF

VAPOR PRESSURE: NAIF

SECTION X 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 XI TOXICOLOGICAL INFORMATION

ANIMAL TOXICITY DATA SINGLE EXPOSURE: Data for the active ingredient, tilmicosin, and a 20% tilmicosin phosphate formulation are reported as indicated.

ORAL:

20% TILMICOSIN PHOSPHATE FORMULATION, RAT: 500 mg/kg, no deaths or toxicity.

SKIN:

20% TILMICOSIN PHOSPHATE FORMULATION, RABBIT: 1000 mg/kg, no deaths.

INHALATION:

TILMICOSIN - RAT: Median lethal concentration 3200-4400 mg/m³ for four 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: Data for the active ingredient, tilmicosin phosphate, are reported.

TARGET ORGAN EFFECTS:

TILMICOSIN PHOSPHATE: Based on studies in dogs, rats, and cattle, 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. Increased adrenal, kidney, and liver weights, increased cell size in adrenal cortex, lymphoid depletion, increased enzyme activity, mucosal edema of the gallbladder, and subretinal fluid accumulation were seen at higher oral or injection doses where some mortality occurred and were likely secondary effects of stress resulting from high doses.

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OTHER EFFECTS:

TILMICOSIN PHOSPHATE: Decreased food consumption and body weight gains, slightly decreased urine pH, occult blood in urine, increased serum alanine transaminase.

REPRODUCTION:

TILMICOSIN PHOSPHATE: Not teratogenic or fetotoxic. No impairment of reproductive capacity. Slight increase in offspring mortality at maternally toxic doses.

SENSITIZATION:

TILMICOSIN PHOSPHATE: Guinea pig, not a contact sensitizer.

MUTAGENICITY:

TILMICOSIN PHOSPHATE: Not mutagenic in bacterial or mammalian cells.

SECTION XII ECOLOGICAL INFORMATION

Specific ecological data are not yet available. Please refer to SECTION VI for information regarding accidental releases and SECTION XV for regulatory reporting.

SECTION XIII DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Dispose of any cleanup materials and waste residue according to applicable Federal, State and Local regulations.
CONTAINER DISPOSAL: No special package disposal required.

SECTION XIV TRANSPORT INFORMATION

REGULATORY ORGANIZATIONS:

DOT: Not regulated
ICAO: Not regulated
IMO: Not regulated

SECTION XV REGULATORY INFORMATION

CLASSIFICATION AND LABELING FOR SHIPMENT TO THE EUROPEAN COMMUNITY (EC COUNCIL DIRECTIVE 67/548/EEC):

CLASSIFICATION: Harmful, Xn

RISK PHRASES:

R36: Irritating to the eyes.
R42/43: May cause sensitization by inhalation and skin contact.

SAFETY PHRASES:

S24/25: Avoid contact with skin and eyes.
S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.

NADA NUMBER: 141-064

SECTION XVI OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All

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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: 800-428-4441

GLOSSARY (ABBREVIATIONS USED IN THIS MATERIAL SAFETY DATA SHEET):

ACGIH: American Conference of Governmental Industrial Hygienists
BEI: Biological Exposure Index
CAS #: Chemical Abstract Service Registry Number
CERCLA: Comprehensive Environmental Response Compensation and Liability Act (of 1980).
CHEMTREC: Chemical Transportation Emergency Center
CWA: Clean Water Act
DOT: Department of Transportation
EP: Extraction Procedure as defined under RCRA regulations.
EPA: Environmental Protection Agency
HEPA: High Efficiency Particulate Filter (Filter)
HSDB: Hazardous Substance Data Base
IARC: International Agency for Research on Cancer
ICAO: International Civil Aviation Organization
IEG: Lilly Interim Exposure Guidelines
IMO: International Maritime Organization
LEG: Lilly Exposure Limit
LEL: Lower Explosive Limit
MSDS: Material Safety Data Sheet
N/A: Not applicable, except in SECTION XIV where NA = North America
NADA: New Animal Drug Application
NAIF: No applicable information found
NCI/NTP: National Cancer Institute/National Toxicology Program
NOS: Not otherwise classified
OHS: Occupational Health Services
OSHA: Occupational Safety and Health Administration
PEL: Permissible Exposure Limit
RCRA: Resource Conservation and Recovery Act.
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
TSCA: Toxic Substances Control Act
TWA: Time Weighted Average/8 Hours Unless Otherwise Noted
UEL: Upper Explosive Limit
UN: United Nations