Tilmovet Medicated Premix

MATERIAL SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF SUBSTANCE

Product Details

- Trade Names: **Tilmovet 90, Tilmovet 18**
- Chemical Name: Tylosin, 4A-O-de(2,6-dideoxy-3-C-methyl-alpha-L-ribo-hexopyranosyl)-20-deoxo-20-[(3R,5S)-3,5-dimethyl-1-pipeidinyl], phosphate (1:1)(salt)
- Manufacturer: Biovet JSC, Peshtera, Bulgaria
- Supplier: Huvepharma Inc.
  525 Westpark Drive, Suite 230
  Peachtree City, GA 30269

SECTION 2: COMPOSITION / DATA ON COMPONENTS

Chemical Characterization:

Ingredient	*CAS*	*Concentration %*
Tilmicosin Phosphate	137330-13-3	1 - 20
Excipients	NA	80 - 99
Anti-dusting Oil	NAIF	0 - 3

Products 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).
- Limestone dust – PEL 15 mg/m3 TWA (total dust) and 5 mg/m3 TWA (respirable fraction). TLV 10 mg/m3 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

- **Classification System:** The classification was made according to the latest editions of international substances lists, and from company and regulatory data.

  Health 2 Fire 1 Reactivity 0 Special A=allergen

- **Primary Physical and Health Hazards:** Irritant (eyes). Severe allergen. Heart effects.
- **Caution Statement:** Tilmovet 90 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:**
  - Tilmovet 90 - 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, 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 or 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 Huvepharma 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 date printed on the container. Warehouse: 10 to 40 °C (45 to 104 °F).

SECTION 8: EXPOSURE CONTROLS AND 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 and 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 value:** 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% 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% Tylosin 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

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 – ECOTOXOLOGICAL EFFECTS

No environmental data for the mixture or formulation. The environmental information 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 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: 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, 0.82, 0.82 (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. Persistent in the aquatic environment not expected due to rapid photolysis.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

SECTION 14: TRANSPORT INFORMATION

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

SECTION 15: REGULATIONS

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.

US 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

SECTION 16: OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Contact: Huvepharma, Inc. 770–486–7212