# Tilmovet®
**SAFETY DATA SHEET**



## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier:

**Material name:** **Tilmicosin phosphate**
Trade names: Tilmovet 90, Tilmovet 18
Product number: 2395-3D, 2400

### 1.2. Manufacturer:

Tilmovet 90: Biovet JSC
39 Petar Rakov Street
4550 Peshtera, Bulgaria

Tilmovet 18: Huvepharma Inc.
3360 Maury Avenue
St. Louis, MO 63116

**Supplier:**
Huvepharma, Inc.
525 Westpark Drive, Suite 230
Peachtree City, GA 30269
Telephone: 1-770-486-7212
Emergency telephone: 1-877-994-4883
Contact e-mail: customerservice@huvepharma.us

### 1.3. Relevant identified uses and any restrictions:

Intended use: For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.
Restrictions on use: For animal use only. Not for human use.

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the chemical:
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

**2.2. Signal word:** Warning

**2.3. Statement of hazard:** Not applicable.

**2.4. Precautionary statement(s):**. Tilmovet 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.

### 2.5. Description of any hazards not otherwise classified:

Primary physical and health hazards: Irritant (eyes). Severe allergen. Heart effects.

Caution statement: Tilmovet 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 - 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 3: COMPOSITION / INFORMATION ON INGREDIENTS

**Hazardous**

| Ingredient | CAS Number | % |
|---|---|---|
| Tilmicosin Phosphate | 137330-13-3 | 1 - 20 |
| Excipients | N/A | 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.

Additional information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

## SECTION 4: FIRST-AID MEASURES

### 4.1. First aid measures:

- **Eye contact:** Hold eyelids open and flush with a gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately.
- **Skin contact:** 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.
- **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.
- **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.

### 4.2. Most important symptoms and effects, both acute and delayed:

**Symptoms and effects of exposure:**
- Tilmovet - 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.

**Medical conditions aggravated by exposure:** Sensitivity to tilmicosin and/or Tylosin.

**4.3. Recommended immediate medical attention and special treatment needed:** Treat symptomatically.

## SECTION 5: FIRE-FIGHTING MEASURES

**5.1. Extinguishing media:**
Use water, carbon dioxide, dry chemical foam, or Halon.
Flash point: No applicable information found.
UEL: No applicable information found.
LEL: No applicable information found.

**5.2. Specific hazards arriving from the substance or mixture:**
May emit toxic fumes when exposed to heat or fire.
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.

**5.3. Advice for firefighters:** Personnel should be evacuated to a safe area, as with all fires. Firefighters should use self-contained breathing equipment and protective clothing. Ventilation in the room should be shut down. As with all organic material, material is assumed combustible at high temperatures. It is advisable to ground mechanical equipment in contact with dry material in order to dissipate any potential build-up of static electricity.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

**6.1. Personal precautions and protective equipment:** Wear coveralls, safety glasses, impervious gloves and approved dust mask when handling product.

**6.2. Emergency procedures:**
Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

**6.3. Methods and materials for containment:**
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.

**6.4. Cleanup procedures:**

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

**7.1. Precautions for safe handling:** Handle with care.

**7.2. Conditions for safe storage, including any incompatibilities:**
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 / PERSONAL PROTECTION

**Control Parameters:**

See Section 2 for exposure guideline information.

**8.1. Exposure controls:** Avoid ingestion. The handling of this product should be avoided by individuals with known hypersensitivity to macrolide antibiotics. Avoid direct contact with skin. Wear coveralls, safety glasses and impervious gloves when mixing and handling product. Wear an approved dust mask. If you develop symptoms after exposure, seek medical attention and show product label.

**8.2. Engineering controls:**
Ventilation: Laboratory fume hood or local exhaust ventilation.

**8.3. Personal protective measures:**
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.
Respiratory: Use an approved respirator.
Eyes: Chemical goggles and/or face shield.

**8.4. Special requirements for PPE, protective clothing or respirators:**

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.

NOT INTENDED FOR HUMAN USE

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Physical and chemical properties:

| | |
|---|---|
| • Appearance: | Yellowish-tan and reddish-tan, free-flowing granules |
| • Upper/lower flammability or explosive limits: | No data available |
| • Odor: | No applicable information found |
| • Vapor pressure: | No applicable information found |
| • Odor threshold: | No data available |
| • Vapor density: | No applicable information found |
| • pH: | 5.5-7.0 (50% aqueous) |
| • Relative density: | No data available |
| • Melting point/freezing point: | Not applicable |
| • Solubility(ies): | Tilmicosin phosphate: soluble<br>Inert ingredients: insoluble |
| • Initial boiling point and boiling range: | Not applicable |
| • Flash point: | No data available |
| • Evaporation rate: | No applicable information found |
| • Flammability (solid, gas): | No data available |
| • Partition coefficient: n-octanol/water: | No data available |
| • Auto-ignition temperature: | No data available |
| • Decomposition temperature: | No data available |
| • Viscosity: | No data available |
| • Specific gravity: | No applicable information found |

## SECTION 10: STABILITY AND REACTIVITY

**10.1. Reactivity:** None known.

**10.2. Chemical stability:**
Stable at normal temperatures and pressures.

**10.3. Other:**

- **Possibility of hazardous reactions:** Avoid strong oxidizing agents (i.e. peroxides, permanganates, perchlorates, nitric acid, etc.) may react with this compound. It is sensitive to concentrated solution of strong acids and alkali, provoking degradation.
- **Conditions to avoid:**
No decompositions if used according to specifications.
- **Incompatible material:**
May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).
- **Hazardous decomposition products:**
May emit toxic fumes when heated to decomposition.
- **Hazardous polymerization:**
Will not occur.

## SECTION 11: TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects General Information:**
The information included in this section describes the potential hazards of the active ingredient(s).

**Routes of exposure:**
Inhalation
Ingestion
Skin
Eye

**Delayed, immediate, or chronic effects from short- and long-term 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.

**Numerical measures of toxicity:**
No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

| | |
|---|---|
| Inhalation: | Tilmicosin - Rat, median lethal concentration - 3800 mg/m3 for 4 hours, reduced activity, labored breathing. |
| Ingestion: | 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. 20% Tilmicosin phosphate formulation – Rabbit - slight irritant |
| Eye: | 20% Tilmicosin phosphate formulation – Rabbit - irritant |

**Symptoms related to the physical, chemical and toxicological characteristics:**
The product is not subject to classification according to internally approved calculation methods for preparations. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## SECTION 12: ECOLOGICAL INFORMATION

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

### 12.1. Toxicity

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

### 12.2. Persistence and degradability:

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.

**12.3. Bioaccumulation potential:** Low potential to bioconcentrate in acquatic organisms.

**12.4. Mobility in soil:** Low mobility in soil.

**12.5. Other adverse effects:** 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.

## SECTION 13: DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## SECTION 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

DOT regulations: Not regulated

Air transport ICAO-TI and IATA-DGR: Not regulated

IMO: Not regulated

## SECTION 15: REGULATORY INFORMATION

**Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture**

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

Prepared by: VJ

Issuing date: 6/08/2015

Revision: 1

Huvepharma, Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet