



Tylovet Premix

MATERIAL SAFETY DATA SHEET

April 2012

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1. IDENTIFICATION OF SUBSTANCE

Product Details

- Trade Name: **Tylovet 100**
- Chemical Name: Tylosin, phosphate (salt)
- Product Number: 4030
- Manufacturer: Biovet JSC, Peshtera, Bulgaria
- Supplier: Huvepharma Inc.
525 Westpark Drive, Suite 230
Peachtree City, GA 30269

2. COMPOSITION / DATA ON COMPONENTS

Chemical Characterization

- Description: Mixture of the Substances Listed Below:

<i>Ingredient</i>	<i>CAS</i>	<i>Concentration %</i>
Tylosin phosphate	1405-53-4	18 – 26
Excipients	NA	75 – 95
Anti-dusting Oil	NAIF	1 – 2

Excipients may include rice hulls, soybean mill run, soybean feed, starch, or limestone.

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

Exposure Guidelines

- Tylosin phosphate – 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 5 mg/m³ TWA (respirable) and 15 mg/m³ TWA (total). TLV 10 mg/m³ TWA.
- The anti-dusting oil reduces potential exposure under normal conditions of use.



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3. HAZARDS IDENTIFICATION

Appearance: Light tan granular meal

Physical State: Solid

Odor: Musty

Routes of Entry: Inhalation and skin contact

Effects of Overexposure: Allergic reactions to tylosin in a manufacturing setting have been reported. Allergy symptoms may include skin rash, watery eyes, shortness of breath, nasal congestion, coughing, and wheezing. Based on animal data, may be irritating to the eyes. Prolonged exposure to high concentrations of grain dust or limestone dust may cause irritation of the respiratory tract and mucous membranes.

Medical Conditions Aggravated by Exposure: Hypersensitivity to tylosin.

Carcinogenicity: Tylosin base – not listed by IARC, NTP, ACGIH, or OSHA. Not considered carcinogenic in animal studies.

4. FIRST AID MEASURES

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



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5. FIRE FIGHTING MEASURES

- **Flash Point:** Not applicable
- **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.

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.

7. HANDLING AND STORAGE

Storage Conditions: Store in a cool, dry place. Protect from moisture and heat. Product should not be used after date printed on the container.



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8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

See Section 2 for Exposure Guideline information. When mixing and handling, use protective clothing, impervious gloves, and dust respirator. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse with plenty of water.

- **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:** In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance:** Light tan granular meal
- **Odor:** Musty
- **Boiling Point:** Not applicable
- **Melting Point:** Not applicable
- **Specific Gravity:** Not applicable
- **pH value:** No applicable information found
- **Evaporation Rate:** No applicable information found
- **Water Solubility:** Insoluble
- **Vapor Density:** No applicable information found
- **Vapor Pressure:** No applicable information found

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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.

11. TOXICOLOGICAL INFORMATION

▪ **Acute Exposure**

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

- **Oral:** 22% Tylosin phosphate mixture – Rat, 500 mg/kg, no deaths or toxicity.
- **Skin:** 22% Tylosin phosphate mixture – Rabbit, 2000 mg/kg, no deaths or toxicity.
- **Inhalation:** Tylosin base – Rat, 2060 mg/m³ for 1 hour, no deaths or toxicity.
- **Skin Contact:** 22% Tylosin phosphate mixture – Rabbit, nonirritant
- **Eye Contact:** 22% Tylosin phosphate mixture – Rabbit, irritant

▪ **Chronic Exposure**

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

- **Target Organ Effects:** Tylosin base – No effects identified in animal studies.
- **Other Effects:** Tylosin base – Salivation, diarrhea, and vomiting after repeated large oral doses.
- **Reproduction:** Tylosin base – No effects identified in animal studies.
- **Sensitization:** Tylosin base – Guinea pig, positive contact sensitizer.
- **Mutagenicity:** Tylosin base – Mutagenic in one mammalian test system. Not mutagenic in bacterial cell tests and other mammalian cell tests. Unlikely to pose a genotoxic risk to man.



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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:** Tylosin base
 - Rainbow trout 96-hour median lethal concentration: > 300 mg/L
 - Bluegill 96-hour medial lethal concentration: > 300 mg/L
 - Daphnia magna 48-hour median effective concentration: > 300 mg/L
 - Bobwhite 14-day oral median lethal concentration: > 2000 mg/kg
 - Bobwhite 5-day dietary median lethal concentration: > 5000 ppm
 - Mallard 5-day dietary median lethal concentration: > 5000 ppm
 - Earthworm 14-day median lethal concentration: > 102.6 mg/kg
 - Green algae (*P. subcapitata*) 72-hour median effective concentration (growth): 0.22 mg/L
 - Seedling median effective concentration (growth): 43 mg/kg (tomato); 53 mg/kg (soybean); 140 mg/kg (oat)

- **Environmental Fate:** Tylosin base
 - Water Solubility (g/L): 5
 - Kow (pH 5, 7, 9): 5, 17, 17
 - Koc: 200 (sandy loom, pH 4.6); 1652 silt loom, pH 5.7); 2233 (sandy loom: pH 7.6)
 - UV-visible light absorption (nm): 282
 - Soil degradation half-life (100 ppm): 62 days (tylosin factor A); 37 days (tylosin factor D)
 - Soil degradation half-life (1 mg/kg; 4 soils): 50.3 to 105 days
 - Leaching in soil column: none

- **Environmental Summary:** Tylosin base – Practically nontoxic to fish, birds, earthworms, and aquatic invertebrates. Highly toxic to algae. No volatility expected. Not expected to bioconcentrate in aquatic organisms. Low mobility in soil. Not persistent in the environment due to degradation and possible photolysis.

13. DISPOSAL CONSIDERATIONS

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

Container Disposal: Packages may be burned or buried in accordance with environmental standards.



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14. TRANSPORT INFORMATION

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

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

Tylosin phosphate

TSCA – No

CERCLA – Not on this list

SARA 302 – Not on this list

SARA 313 – Not on this list

OSHA Substance Specific – No

16. OTHER INFORMATION

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:

HUVEPHARMA, Inc.

1-877-426-7765

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