Tylovet® Premix
SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

1.1. Product Identifier:

Material name: **Tylosin phosphate**
Trade name: Tylovet 100, Tylovet 40, Tylovet 10
Product number: 2350

1.2. Manufacturer:

Biovet JSC
39 Petar Rakov Street
4550 Peshtera, Bulgaria

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: Veterinary antibiotic agent.
Restrictions on use: For animal use only. Not for human use.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the chemical:

Health: 2
Fire: 1
Reactivity: 0
Special: A

2.2. Signal word: Warning

2.3. Statement of hazard: Not applicable.

2.4. Precautionary statement(s): See First Aid Measures Section.

2.5. Description of any hazards not otherwise classified:
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.

Routes of Entry: Inhalation and skin contact.

Medical conditions aggravated by exposure: Hypersensitivity to tylosin.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	%
Tylosin phosphate	1405-53-4	7 - 26
Excipients	N/A	75 - 95
Anti-dusting Oil		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.

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: Irritant for eyes. Irritant for skin. Irritant for the respiratory tract.

Medical conditions aggravated by exposure: Hypersensitivity to tylosin.

4.3. Recommended immediate medical attention and special treatment needed:

Treat symptomatically. In case of hypersensitivity to the substance, avoid direct contact.

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:

Wear breathing apparatus and protective fire-fighting clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions and protective equipment: Wear protective equipment, including eye protection, to avoid exposure.

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

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters:

See Section 2 for exposure guideline information.

8.1. Exposure controls:
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.

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.

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Physical and chemical properties:

• Appearance:	Light tan granular meal
• Upper/lower flammability or explosive limits:	No data available
• Odor:	Musty
• Vapor pressure:	No applicable information found
• Odor threshold:	No data available
• Vapor density:	No applicable information found
• pH:	No applicable information found
• Relative density:	No data available
• Melting point/freezing point:	Not applicable
• Solubility(ies):	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:	Not applicable

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:
May react with strong oxidizing agents (e.g. peroxides, permanaganate, nitric acid, etc.).

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

10.3. Other:

- **Possibility of hazardous reactions:** None known.
- **Conditions to avoid:** None known.
- **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: Specific test data for the mixture is not available.
Ingestion: Specific test data for the mixture is not available.
Skin: Specific test data for the mixture is not available.
Eye: Specific test data for the mixture is not available.

Delayed, immediate, or chronic effects from short- and long-term exposure:
Inhalation: No information available.
Ingestion: No information available.
Skin: No information available.
Eye: No information available.

Sensitization: No information available.
Numerical measures of toxicity:

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.

Symptoms related to the physical, chemical and toxicological characteristics: None known.

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: Tylosin base

- Rainbow trout 96-hour median lethal concentration: > 300 mg/L
- Bluegill 96-hour median 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

12.2. Persistence and degradability:
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.

12.3. Bioaccumulation potential: No data available.

12.4. Mobility in soil: No data available.

12.5. Other adverse effects: No data available.

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.

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

SECTION 14: TRANSPORT INFORMATION

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

DOT regulations: Not regulated.

ICAO/IATA: 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 - 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

SECTION 16: OTHER INFORMATION

Prepared by: VJ

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End of Safety Data Sheet