

Tylovet® Soluble

SAFETY DATA SHEET

Revised: June 2015

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SECTION 1: IDENTIFICATION

1.1. Product Identifier:

Trade names: Tylovet Soluble
Chemical name: Tylosin, (2R,3R)-2,3-dihydroxybutanedioate (salt)
Product number: 2220-1B (20x100g)
2220-1D (100x100g)

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: Not for human use.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Appearance: Light tan granular meal

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

2.2. Signal word: Warning

2.3. Statement of hazard:

Tylovet Soluble is tylosin tartrate, may be irritating to the eyes, and is classified as a severe allergen because repeated unprotected exposures are likely to cause allergic reactions.

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

2.5. Description of any hazards not otherwise classified:

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.

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Routes of Exposure: Inhalation and skin contact

Medical conditions aggravated by exposure: Hypersensitivity to tylosin.

Carcinogenicity: Not listed by IARC, NTP, ACGIH or OSHA

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	%
Tylosin tartrate	1405-54-5	100%

Exposure Guidelines:

100 micrograms/m³ TWA for 12 hours

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.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16.

SECTION 4: FIRST-AID MEASURES

4.1. First aid measures:

- **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.
- **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.

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- 4.2. Most important symptoms and effects, both acute and delayed:** In case of hypersensitivity to the substance, avoid direct contact.

Symptoms and effects of exposure: Irritant for eyes. Irritant for skin. Irritant for the respiratory tract.

Medical conditions aggravated by exposure: For those individuals sensitive to 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:

Minimum ignition temperature of dust layer: 380°C (716°F).

Hazardous combustion products: 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.

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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, 25°C (77°F). (Excursion permitted to 40°C (104°F). Avoid moisture. 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: White to light yellow granules
- Upper/lower flammability or explosive limits: No data available
- Odor: No data available
- Vapor pressure: No applicable information found
- Odor threshold: No data available
- Vapor density: No applicable information found
- pH: 5.0 to 7.2 (2.5% aqueous)
- Relative density: No data available
- Melting point/freezing point: 240°C (464°F)
- Solubility(ies): Soluble
- Initial boiling point and boiling range: No applicable information found
- 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:**

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:****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: No information available.

Numerical measures of toxicity:

Acute exposure:

Oral:	Rat	6200 mg/kg, no deaths or toxicity
Skin:	Rabbit	2000 mg/kg, no deaths or toxicity
Inhalation:	Rat	600 mg/m ³ for 1 hour, no deaths
Skin Contact:	Rabbit	slight irritant
Eye Contact:	Rabbit	irritant

Chronic exposure:

The toxicity data for the material or related material(s) are presented.

Target Organ Effects: Tylosin Base – no effects identified in animal studies

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:

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 loam, pH 4.6); 1652 silt loam, pH 5.7); 2233 (sandy loam: 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.

Aquatic Exposure Guideline (AEG): Tylosin Base

- AEG for Drinking Water: 36 micrograms/L
- AEG for Chronic Exposure of Aquatic Organisms: 99 micrograms/L
- AEG for Acute Exposure of Aquatic Organisms: 220 micrograms/L

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 Disposal: Waste should be incinerated or sent to an approved landfill.

Container disposal: No special package disposal required.

SECTION 14: TRANSPORT INFORMATION

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

DOT regulations: Not regulated

IMO: UN Number 3077

Description of the goods: Environmentally hazardous substance, solid, n.o.s.

Class: 9

Packaging group: III

Labels: 9

Marine pollutant: Yes

Additional Information: This material is considered to be an Environmentally Hazardous Substance according to the criteria set forth in the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) and is regulated as a Hazard Class 9 (UN3077 or UN3082) when shipping under ADR.

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

ANADA Number: 200-473

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EU Regulations

EC Classification:

Xn (Harmful)

Xi (Irritant)

N (Dangerous for the Environment)

Risk Phrases:

R 36 – Irritating to eyes

R 42/43 – May cause sensitization by inhalation and skin contact

R 50 – Very toxic to aquatic organisms

Safety Phrases:

S 25 – Avoid contact with eyes

S 26 – In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 36/37/39 – Wear suitable protective clothing, gloves and eye/face protection

SECTION 16: OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

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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