MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Tylosin Injection
Product No.: Not applicable
MSDS ID#: P138-955
GHS Product Identifier: Not applicable

Molecular Formula: Mixture, not applicable
Molecular Weight: Not applicable
CAS Number: Mixture, not applicable
Chemical Family: Vaccine

Manufacturer:
Boehringer Ingelheim Vetmedica, Inc.
2621 North Belt Hwy
St. Joseph, MO 64506-2002

Transportation Emergency: For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300
Outside USA and Canada: +1 703-527-3887
(collect calls accepted)

Medical Emergency (24HR): (866) 638-2226
Non-Emergency Telephone: (800) 821-7467

Intended Use: For use in the treatment of bovine respiratory complex and metritis and used in swine to treat swine arthritis.

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Antibiotic in a liquid solution, packaged in 500 mL bottle.
Color: Colorless to light yellow
Odor: Odorless

WARNING!
May be harmful if inhaled or swallowed.
Allergic reactions can occur.

For use in animals only.
Not for human use.

Precautionary Statements
Keep only in original container.
Keep at a temperature between 2 - 7°C.
Do not freeze.
Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.
Avoid contact with eyes, skin and clothing.
Wash thoroughly with soap and water after handling.
Wear suitable gloves and eye/face protection.
Spills: Cover with absorbent or contain. Collect and incinerate.
If swallowed, seek medical advice immediately and show this container or label.
In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
Keep out of reach of children.
Keep away from food, drink, and animal feedstuffs.

Potential Health Effects

Inhalation: Not expected to be an inhalation hazard with prescribed use.

Eye Contact: Not expected to be a hazard to the eye with prescribed use. Exposure to liquid in eye may cause mild transient eye irritation.

Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions. May cause skin sensitization by contact.

Ingestion: Not expected to be an ingestion hazard with prescribed use. Ingestion may cause nausea and systemic effects.

Injection: Swelling at injection site may occur

Chronic Health Effects: Possible hypersensitization (development of abnormal sensitivity).

Target Organ(s): Skin

OSHA Regulatory Status: Hazardous (exempt)

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Tylosin	215-754-8	1401-69-0	200 mg/mL	----	---
Propylene glycol	200-338-0	57-55-6	50 %	----	---
Benzyl alcohol	202-859-9	100-51-6	4 %	Xn; R20/22	---

Components not listed are not hazardous or are below reportable limits.

The full texts for all R-Phrases are displayed in Section 16, if applicable.

4 FIRST AID MEASURES

General: Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

Inhalation: Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

Eye Contact: Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

Skin Contact: Wash with soap and water. If skin irritation or rash occurs, seek medical advice. Wash contaminated clothing before reuse.

Ingestion: Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Injection: In case of accidental injection, wash the site thoroughly. Contact a physician immediately.

Note to Physician: For animal use only. Not for human use.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish with foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire & Explosion Hazards: None known

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, nitrogen oxides

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate personal protective equipment (See Section 8).

Spill Cleanup Methods: STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED: Absorb or cover with dry earth, sand or other non-combustible material. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

Environmental Precautions: Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

7 HANDLING AND STORAGE

Handling: HANDLING SIGNIFICANT QUANTITIES OF PRODUCT: Avoid contact with eyes, skin or clothing. Avoid accidental injection. Wash hand thoroughly after handling.

Storage: Keep only in the original container. Store between 2-8° C (36-46° F). Store out of direct sunlight. Keep from freezing.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

Chemical Name	Source	Type	Exposure Limits	Notes
Propylene glycol, aerosol only	AIHA	WEELs	10 mg/m^3	----
Benzyl alcohol	AIHA	WEELs	10 ppm	----

Where lower governmentally imposed exposure limits exist, such limits should take precedence.

Engineering Controls: Not generally required when handling vials or containers. Good ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Respiratory Protection: Not generally required when handling vials or containers. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.

Europe: Wear appropriate personal protective equipment according to the Council Directive 89/686/EEC (4) and the appropriate CEN standards.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely wear:

Eye Protection: Wear safety glasses with side shields (or goggles).

Hand Protection: Wear suitable gloves.

Skin Protection: Wear lab coat, apron or appropriate clothing to prevent skin contact.

Hygiene Measures: Eye bath, washing facilities

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: Colorless to light yellow
Odor: Odorless
Odor Threshold: No data available

Physical State: Antibiotic in a liquid solution, packaged in 500 mL bottle.
pH: 7.5
Melting Point: No data available
Freezing Point: No data available
Boiling Point: No data available
Flash Point: No data available
Flammability Limit – Upper (%): No data available
Flammability Limit – Lower (%): No data available
Evaporation rate: No data available
Vapor Pressure: No data available
Vapor Density (Air=1): No data available
Specific Gravity: 1.06
Solubility: Soluble in water (cold and hot)
Partition Coefficient (n-Octanol/water): No data available
Autoignition Temperature: No data available
Decomposition Temperature: No data available

10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Excessive heat, freezing

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: Carbon oxides, nitrogen oxides

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

11 TOXICOLOGICAL INFORMATION

Specified Substances

Acute Toxicity:

Chemical Name	Test Results
Tylosin	Oral (rat) LD50: > 5000 mg/kg
Propylene glycol	Administration into eye, rabbit, 500 mg/24 H; Mild irritation Administration onto skin, human, 500mg/7D; Mild irritation Oral (rat) LD50: 20,000 mg/kg Dermal (rabbit) LD50: > 20,000 mg/kg
Benzyl alcohol	Administration onto skin, rabbit,100 mg/24H: Moderate irritation Oral (rat) LD50: 1660 mg/kg Dermal (rabbit) LD50: 2,000 mg/kg Inhalation (rat) LC50: > 500 mg/m^3

Chronic Toxicity – Possible hypersensitization (development of abnormal sensitivity).

Listed Carcinogens: None listed.

12 ECOLOGICAL INFORMATION

Ecotoxicity: No data available
Persistence and degradability: No data available
Mobility in soil: No data available
Other adverse effects: No data available

Germany WGK: Propylene glycol: ID No: 280; Class 1: Slightly water-endangering. Benzyl alcohol: ID No: 216; Class 1: Slightly water-endangering.

13 DISPOSAL CONSIDERATIONS

General Information: Dispose of in accordance with local, state, federal, national or international regulations.

Disposal Methods: No specific disposal method required. Do not empty into drains. Dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by disposal.

RCRA Information: Not applicable

14 TRANSPORT INFORMATION

DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15 REGULATORY INFORMATION

Canadian Controlled Products Regulations: This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

WHMIS Classification: Non-controlled

Inventory Status

This material **is** listed on the following inventories: AICS, EINECS, KECI and NZIoC.

This material is **not** listed on the following inventories: TSCA, DSL, IECSC, ENCS and PICCS. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

Canada CEPA Schedule 1 – None listed

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4): None listed.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): None listed.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): None listed.

SARA Title III

Section 302 Extremely Hazardous Substances (40 CFR 355, Appendix A): None listed.

Section 311/312 (40 CFR 370):

X	Acute (Immediate)		Chronic (Delayed)		Fire		Reactive		Pressure Generating

Section 313 Toxic Release Inventory (40 CFR 372): None listed.

State Regulations

California: Restricted Drug (California) – Use Only as Directed
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): None listed.
Massachusetts Right-To-Know List: Benzyl alcohol
Minnesota Hazardous Substances List: Propylene glycol; Benzyl alcohol
New Jersey Right-To-Know List: Propylene glycol
Pennsylvania Right-To-Know List: Propylene glycol; Benzyl alcohol
Rhode Island Right-To-Know List: Propylene glycol.

European Regulations
Austria MAK List (Annex I): None listed.
Denmark (Annex 3.6): None listed.
Germany (Dangerous Substances Ordinance 2004, Annex III): Benzyl alcohol
Norway (List of Dangerous Substance): Benzyl alcohol
Sweden (Annex 3): None listed.
Switzerland (Toxins List 1): Propylene glycol; Benzyl alcohol

16 OTHER INFORMATION

Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1	1	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	1	1	0	N/A

* – Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

EU Symbol and R Phrase Definitions:
Xn – Harmful
R20/22 – Harmful by inhalation and if swallowed.

ABBREVIATIONS:
BIV – Boehringer Ingelheim Vetmedica, Inc.
N/A – Not applicable
N/E – Not established
ppm – parts per million

References:

1. Tylosin Injection MSDS and Label
2. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
3. GHS Manual

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