

SECTION 1: IDENTIFICATION**1.1. Product Identifier****Product Form:** Mixture**Product Name:** TilcoMed (Tilmicosin Injection, 300 mg/ml)**Synonyms:** Tilmicosin Formulation, Tilmicosin Phosphate Formulation**1.2. Intended Use of the Product** Veterinary use only**1.3. Name, Address, and Telephone of the Responsible Party****Company**

Bimeda-MTC Animal Health Inc.

420 Beaverdale Road

Cambridge, ON N3C 2W4

T 519.654.8055

F 519.654.8001

www.bimeda.com**1.4. Emergency Telephone Number****Emergency Number** : CHEMTREC International Emergency Phone: +1 703 527 3887

CHEMTREC 24-Hour Emergency Phone: 800 424 9300 (USA Only)

SECTION 2: HAZARDS IDENTIFICATION**2.1. Classification of the Substance or Mixture****Classification (GHS-US)**

Not classified

2.2. Label Elements**GHS-US Labeling** No labeling applicable**2.3. Other Hazards****Accidental injection of this drug in humans has been associated with fatalities.****2.4. Unknown Acute Toxicity (GHS-US)** No data available**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS****3.1. Substances**

Not applicable

3.2. Mixture

Name	Product Identifier	% (w/w)	Classification (GHS-US)
Tilmicosin	(CAS No) 137330-13-3	30	Not classified
Propylene glycol	(CAS No) 57-55-6	25	Not classified
Phosphoric acid	(CAS No) 7664-38-2	5 - 8	Met. Corr. 1, H290

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES**4.1. Description of First Aid Measures****General:** Never give anything by mouth to an unconscious person. If exposed or concerned: Get medical advice/attention. Call a POISON CENTER or doctor. TilcoMed 300 mg/ml contains tilmicosin phosphate 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. This product should only be administered by a veterinary surgeon.**Inhalation:** If inhaled, remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.**Skin Contact:** Remove/Take off immediately all contaminated clothing. Immediately flush skin with plenty of water for several minutes. Wash skin thoroughly with mild soap and water. Wash contaminated clothing before reuse. Get immediate medical advice/attention.

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Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

Ingestion: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor.

Injection: Call a physician or poison control center immediately. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water OR give 1-2 tablespoons syrup of ipecac and drink one or two glasses of water to induce vomiting. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of use.

Inhalation: Overexposure may be irritating to the respiratory system.

Skin Contact: Contact during a long period may cause slight irritation.

Eye Contact: Direct contact with eyes is likely irritating.

Ingestion: Ingestion is likely to be harmful or have adverse effects.

Injection: Clinical signs from accidental human injection include off taste in the mouth, nausea, headache, dizziness, rapid heart rate, chest pain, anxiety or lightheadedness. Local reactions such as injection site pain, bleeding, swelling or inflammation have been reported. Injection of this drug in humans has been associated with fatalities.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If you feel unwell, seek medical advice (show the label where possible).

Note to the Physician: The cardiovascular system is the target of toxicity, and this toxicity may be due to calcium channel blockade. Administration of intravenous calcium chloride should only be considered if there is positive confirmation of exposure to tilmicosin. In dog studies, tilmicosin induced a negative inotropic effect with consequent tachycardia, and a reduction in systemic arterial blood pressure and arterial pulse pressure. Do not give adrenalin or beta-adrenergic antagonists such as propranolol. In pigs, tilmicosin-induced lethality is potentiated by adrenaline. In dogs, treatment with intravenous calcium chloride showed a positive effect on the left ventricular inotropic state and some improvements in vascular blood pressure and tachycardia. Pre-clinical data and an isolated clinical report suggest that calcium chloride infusion may help to reverse tilmicosin-induced changes in blood pressure and heart rate in humans. Administration of dobutamine should also be considered due to its positive inotropic effects although it does not influence tachycardia.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. A heavy water stream may spread burning liquid.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but will burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Silicon oxides.

Other Information: Refer to Section 9 for flammability properties.

Reference to Other Sections

Refer to section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all unnecessary exposure. Avoid all contact with skin, eyes, or clothing. Do not breathe vapor, mist or spray. Do not allow prolonged contact with metals.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

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Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Evacuate unnecessary personnel. Stop leak if safe to do so. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clear up spills immediately and dispose of waste safely. Spills should be contained with mechanical barriers. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container tightly closed. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers. Metals.

Maximum Storage Period: Once opened use the remaining solution within 28 days

Storage Temperature: ≤ 25 °C

7.3. Specific End Use(s)

Veterinary use only

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established Exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), OSHA (PEL), Canadian provincial governments, or the Mexican government.

Propylene glycol (57-55-6)		
Ontario	OEL TWA (mg/m ³)	10 mg/m ³ (for assessing the visibility in a work environment where 1,2-Propylene glycol aerosol is present-aerosol only)
Ontario	OEL TWA (ppm)	50 ppm (aerosol and vapor)
Phosphoric acid (7664-38-2)		
USA ACGIH	ACGIH TWA (mg/m ³)	1 mg/m ³
USA ACGIH	ACGIH STEL (mg/m ³)	3 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	1 mg/m ³
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	1 mg/m ³
USA NIOSH	NIOSH REL (STEL) (mg/m ³)	3 mg/m ³
USA IDLH	US IDLH (mg/m ³)	1000 mg/m ³
Alberta	OEL STEL (mg/m ³)	3 mg/m ³
Alberta	OEL TWA (mg/m ³)	1 mg/m ³
British Columbia	OEL STEL (mg/m ³)	3 mg/m ³
British Columbia	OEL TWA (mg/m ³)	1 mg/m ³
Manitoba	OEL STEL (mg/m ³)	3 mg/m ³
Manitoba	OEL TWA (mg/m ³)	1 mg/m ³
New Brunswick	OEL STEL (mg/m ³)	3 mg/m ³
New Brunswick	OEL TWA (mg/m ³)	1 mg/m ³

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Newfoundland & Labrador	OEL STEL (mg/m ³)	3 mg/m ³
Newfoundland & Labrador	OEL TWA (mg/m ³)	1 mg/m ³
Nova Scotia	OEL STEL (mg/m ³)	3 mg/m ³
Nova Scotia	OEL TWA (mg/m ³)	1 mg/m ³
Nunavut	OEL STEL (mg/m ³)	3 mg/m ³
Nunavut	OEL TWA (mg/m ³)	1 mg/m ³
Northwest Territories	OEL STEL (mg/m ³)	3 mg/m ³
Northwest Territories	OEL TWA (mg/m ³)	1 mg/m ³
Ontario	OEL STEL (mg/m ³)	3 mg/m ³
Ontario	OEL TWA (mg/m ³)	1 mg/m ³
Prince Edward Island	OEL STEL (mg/m ³)	3 mg/m ³
Prince Edward Island	OEL TWA (mg/m ³)	1 mg/m ³
Québec	VECD (mg/m ³)	3 mg/m ³
Québec	VEMP (mg/m ³)	1 mg/m ³
Saskatchewan	OEL STEL (mg/m ³)	3 mg/m ³
Saskatchewan	OEL TWA (mg/m ³)	1 mg/m ³
Yukon	OEL STEL (mg/m ³)	3 mg/m ³
Yukon	OEL TWA (mg/m ³)	1 mg/m ³

8.2. Exposure Controls

Appropriate Engineering Controls: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Avoid all unnecessary exposure. Protective goggles.



Materials for Protective Clothing: Corrosionproof clothing.

Hand Protection: Wear chemically resistant protective gloves.

Eye Protection: Chemical goggles.

Skin and Body Protection: Wear suitable protective clothing. Wash contaminated clothing before reuse.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn.

Environmental Exposure Controls: Do not allow the product to be released into the environment.

Consumer Exposure Controls: Do not eat, drink or smoke during use

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear yellowish to brown-yellowish solution.
Odor	: Faint characteristic sweet.
Odor Threshold	: Not available
pH	: 6
Evaporation Rate	: Not available
Melting Point	: Not available
Freezing Point	: Not available
Boiling Point	: Not available
Flash Point	: Not available
Auto-ignition Temperature	: 418 °C (784 °F)
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Lower Flammable Limit	: Not available

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Upper Flammable Limit : Not available

Vapor Pressure : Not available
Relative Vapor Density at 20 °C : Not available
Relative Density : Not available
Specific Gravity : Not available
Solubility : Water: Soluble
Partition Coefficient: N-Octanol/Water : Not available
Viscosity : Not available
Explosion Data – Sensitivity to Mechanical Impact : Not expected to present an explosion hazard due to mechanical impact.
Explosion Data – Sensitivity to Static Discharge : Not expected to present an explosion hazard due to static discharge.

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).
10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
10.4. Conditions to Avoid: Direct sunlight. Extremely high or low temperatures. Incompatible materials. Prolonged contact with metallic substances.
10.5. Incompatible Materials: Strong acids. Strong bases. Strong oxidizers. Metals.
10.6. Hazardous Decomposition Products: Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity: Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

pH: 6

Serious Eye Damage/Irritation: Not classified

pH: 6

Respiratory or Skin Sensitization: Not

classified **Germ Cell Mutagenicity:** Not

classified **Teratogenicity:** Not available

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

General: Not expected to present a significant hazard under anticipated conditions of use.

Inhalation: Overexposure may be irritating to the respiratory

system. **Skin Contact:** Contact during a long period may cause slight

irritation. **Eye Contact:** Direct contact with eyes is likely irritating.

Ingestion: Ingestion is likely to be harmful or have adverse effects.

Injection: Clinical signs from accidental human injection include off taste in the mouth, nausea, headache, dizziness, rapid heart rate, chest pain, anxiety or lightheadedness. Local reactions such as injection site pain, bleeding, swelling or inflammation have been reported. Injection of this drug in humans has been associated with fatalities.

Chronic Symptoms: None expected under normal conditions of use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Propylene glycol (57-55-6)	
LD50 Oral Rat	20000 mg/kg
LD50 Dermal Rabbit	20800 mg/kg
Phosphoric acid (7664-38-2)	

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LD50 Oral Rat	1530 mg/kg
LD50 Dermal Rabbit	2740 mg/kg
LC50 Inhalation Rat	> 850 mg/m ³ (Exposure time: 1 h)

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity No additional information available

Propylene glycol (57-55-6)	
LC50 Fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

12.2. Persistence and Degradability

TilcoMed (Tilmicosin Injection, 300 mg/ml)	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

TilcoMed (Tilmicosin Injection, 300 mg/ml)	
Bioaccumulative Potential	Not established.
Propylene glycol (57-55-6)	
BCF Fish 1	< 1
Log Pow	-0.92

12.4. Mobility in Soil Not available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains; dispose of this material and its container in a safe way.

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

- 14.1. In Accordance with DOT Not regulated for transport
- 14.2. In Accordance with IMDG Not regulated for transport
- 14.3. In Accordance with IATA Not regulated for transport
- 14.4. In Accordance with TDG Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

TilcoMed (Tilmicosin Injection, 300 mg/ml)	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
Propylene glycol (57-55-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.
Phosphoric acid (7664-38-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Not available


15.3. Canadian Regulations

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WHMIS Classification	Class E - Corrosive Material
	
Propylene glycol (57-55-6)	
Listed on the Canadian DSL (Domestic Substances List) Listed on the Canadian IDL (Ingredient Disclosure List)	
IDL Concentration 1 %	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria
Phosphoric acid (7664-38-2)	
Listed on the Canadian DSL (Domestic Substances List) Listed on the Canadian IDL (Ingredient Disclosure List)	
IDL Concentration 1 %	
WHMIS Classification	Class E - Corrosive Material

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 13/03/2015

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Met. Corr. 1	Corrosive to metals Category 1
H290	May be corrosive to metals

Party Responsible for the Preparation of This Document

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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