Complying to Regulation (EC) 1907/2006

Material Safety Data Sheet
Tilmodil 300 mg/ml Injection

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product identification

Product name(s): Tilmodil 300 mg/ml Injection
Product code(s): XVD 740

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: Veterinary medicinal product
Uses advised against: Not for human use. Refer to the product information leaflet
Reasons why uses advised against: Refer to the product information leaflet

1.3 Details of the supplier of the safety data sheet

Company name: Animalcare Limited
Address: 10 Great Northway
York Business Park
Nether Poppleton
York
YO26 6RB
United Kingdom

1.4 Emergency telephone number

Daytime: +44 (0) 1904 487687

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008: This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008: This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

Hazard pictograms: Not classified
Signal word: Not classified
Hazard statements: Not classified
Precautionary statements: Not classified
Supplemental information: Tilmodil 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

2.3 Other hazards

Hazard(s) not otherwise classified (HNOC): Injection of Tilmodil in humans has been associated with fatalities. Keep out of the reach of children. Do not use in automatically powered syringes. Exercise extreme caution to avoid accidental self-injection. In case of human injection, consult a physician immediately and apply ice or cold pack to the injection site while avoiding direct contact with the skin. Emergency medical telephone numbers are UK: 0844 892 0111; Ireland: 01 8379964; Germany: 030 19240; Belgium, Luxembourg: 070 245 245; The Netherlands: 030 274 88 88; Denmark: 035 31 55 55

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Substance name in the mixture	*CAS No*	*Quantity*
Tilmicosin	[137330-13-3]	30%
Propylene Glycol	[57-55-6]	25%
Phosphoric acid	[7664-38-2]	Proprietary
Water for injection	[7732-18-5]	Proprietary

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes: Hold eyes open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water

Ingestion: 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

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

Effects of Overexposure: Tilmodil 300 mg/ml - No allergic reactions in a manufacturing setting have been reported. Compounds of similar structure have been reported to cause transient alterations in heart rate. 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

4.3 Indication of any immediate medical attention and special treatment needed

Injection of Tilmodil in humans has been associated with fatalities. Keep out of the reach of children. Do not use in automatically powered syringes. Exercise extreme caution to avoid accidental self-injection. In case of human injection, consult a physician immediately and apply ice or cold pack to the injection site while avoiding direct contact with the skin. Emergency medical telephone numbers are UK: 0844 892 0111; Ireland: 01 8379964; Germany: 030 19240; Belgium, Luxembourg: 070 245 245; The Netherlands: 030 274 88 88; Denmark: 035 31 55 55

SECTION 5: FIRE- FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

Unsuitable extinguishing media: None known

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Not flammable or combustible

Hazardous combustion products: Decomposition products may include the following materials: Carbon oxides (CO_x), nitrogen oxides (NO_x)

5.3 Advice for fire-fighters

Special protective equipment for firefighters:	Use personal protective equipment
Further information:	Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:	Provide good ventilation. Prevent skin and eye contact
Advice for emergency responders:	If specialised clothing is required to deal with the spillage, take note of any information is section 8 on suitable and unsuitable materials

6.2 Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas. Do not allow to enter into surface water of drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Small spills:	Wear recommended personal protective equipment (see section 8- Exposure controls/personal Protection). Use absorbent towels or brooms to clean up spill. Wipe surface area clean with soap and water
Large spills:	Dike spilled material or otherwise contain material to ensure runoff does not reach a waterway

6.4 Reference to other sections

See Section 1 for emergency contact information
See section 8 for personal protection
See Section 13 for additional waste treatment information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling:	Avoid contact with eyes, skin or clothing. Do not breathe vapours or mist. Do not ingest. Do not smoke or eat while handling the product. Wash thoroughly after handling. The containers should be stored in their original boxes when not in use
Hygiene measures:	Wash thoroughly after handling

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:	Keep out of reach of children. Keep in the original packaging. Keep container tightly closed
Storage temperature:	Store below 25 ^{o}C and protect from light
Further information on storage conditions:	Keep in a dry, cool and well-ventilated place

7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use. NOT FOR HUMAN USE
Injection of this drug in humans can be lethal – Exercise extreme caution to avoid accidental self-injection and follow the administration instructions and the guidance below precisely
-This product should only be administered by a veterinary surgeon.
-Never carry a syringe loaded with Tilmodil with the needle attached. The needle should be connected to the syringe only when filling the syringe or administering the injection. Keep the syringe and needle separate at all other times.
-Do not use automatic injection equipment.
-Ensure that animals are properly restrained, including those in the vicinity.

-Do not work alone when using Tilmodil.
-In case of human injection SEEK IMMEDIATE MEDICAL ATTENTION and take the vial or the package insert with you. Apply a cold pack (not ice directly) to the injection site.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. At this time, the other constituents have no known exposure limits

Substance name in the mixture	*Type*	*Value*
Tilmicosin:	TWA	<100 µg/m^3

8.2 Exposure controls

Engineering measures: Laboratory fume hood or local exhaust ventilation

Individual protection measures:

Hygiene measures: No specific measures identified

Eye/face protection: Chemical goggles and/or face shield

Skin/body protection: 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

Hand protection: 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 protection: Use an approved respirator

Environmental exposure controls: Consider the provision of containment around storage vessels

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance Liquid
Colour: Clear, yellow/brown
Odour: None
Odour threshold: No data available
pH: 6
Density: No data available
Melting point: No data available
Boiling point: No data available
Flash point: 418 ^{o}C
Evaporation rate: No data available
Flammability: No data available
Water solubility: No data available
Partition coefficient: No data available
Auto-ignition temperature: No data available
Thermal decomposition: No data available
Viscosity: No data available
Vapour pressure: No data available
Vapour density: No data available
Explosive properties: No data available
Oxidizing properties: The substance or mixture is not classified as oxidizing

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.)

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

10.4 Conditions to avoid

Avoid contact with incompatible materials

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

May emit toxic fumes when heated to decomposition

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Tilmicosin LD_{50} 855 mg/kg (Rat, oral) Tilmodil 300 mg/ml 0.5 ml/kg (Rabbit, skin) – No deaths or toxicity Tilmodil 300 mg/ml 2750 mg/m^3 4 hours (Rat, inhalation) – No deaths, reduced activity, labored breathing, blood in urine Target organ effects: Tilmicosin phosphate - The heart is the target of toxicity in laboratory and domestic animals given Tilmodil 300 mg/ml by oral or parenteral routes. The primary cardiac effects are increased heart rate (tachycardia) and decreased contractility (negative inotropy). Cardiovascular toxicity may be due to calcium channel blockade
Chronic toxicity:	No data available
Skin irritation/sensitization:	Tilmodil 300 mg/ml Rabbit – slight irritant
Reproductive toxicity:	Tilmicosin phosphate - Slight increase in offspring mortality at maternally toxic doses
Carcinogenicity:	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No drug related carcinogenic/tumorigenic effects based on animal data
Mutagenicity:	Tilmicosin - Not mutagenic in bacterial or mammalian cells

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Tilmicosin
Rainbow trout 96-hour median lethal concentration: 851 mg/L
Bluegill 96-hour median lethal concentration: 716 mg/L
Daphnia magna 48-hour median effective concentration: 57.3 mg/L
Bobwhite 5-day dietary median lethal concentration: > 4820 ppm
Mallard 5-day dietary median lethal concentration: > 4710 ppm
Earthworm 28-day median lethal concentration: > 918 mg/Kg

Green algae (S. capricornutum) median effective concentration: 0.354 mg/L (average specific growth rate)
Plant growth in soil for most species unaffected at 100 mg/L
Microorganisms:
fungus (Chaetomium globosum): MIC > 1000 mg/L
mold (Aspergillus flavus): MIC > 1000 mg/L
soil bacteria (Comamonas acidovorans): MIC = 250 mg/L
N-fixing bact. (Azotobacter chroococcum): MIC = 5 mg/L
blue-green algae (Nostoc sp.): MIC = 0.5 mg/L

12.2 Persistence and degradability

Tilmicosin
Log Kow: <1, <1, 2.6 (pH 5, 7, 9)
Adsorption coefficients (K): 129,181, 318 (sandy loam, loam, clay loam)
Water solubility (g/L): 566, 7.7 (pH 7, 9)
Photolysis half-life (hours): 0.84, 0.82, 0.82 (pH 5, 7, 9)
Photolysis rate constant (1/hours): 0.83, 0.84, 0.84 (pH 5, 7, 9)
Hydrolysis half-life (days): >= 365, >= 365, 156 (pH 5, 7, 9)
Hydrolysis rate constant (1/hours): 0.0001853 (pH 9)
Aerobic biodegradation: none measured after 64 days (sandy loam, loam, clay loam)
Anaerobic biodegradation: none measured after 73 days
Decline in loam soil: 45.9% after 52 weeks
Decline in clay loam soil: none after 52 weeks

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

SECTION 14: TRANSPORT INFORMATION

DOT: Not Regulated
IMO:
UN Number 3082
Description of the goods Environmentally hazardous substance, liquid, n.o.s. (tilmicosin phosphate)
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 (UN3082) when shipping under ADR.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This product has been authorised under the provisions of Directive 2001/82/EC

15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out

SECTION 16: OTHER INFORMATION

For animal treatment only

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

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