Complying to 91/155/EC, 93/112/EC

Material Safety Data Sheet

Tilmoxan 250mg/ml Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name Tilmoxan 250mg/ml Injection

Supplier
MICROWISE

11516 DONNA DR Tampa FL 33637 USA
Phone: +18133301934

EMAIL;- www.microwise9@gmail.com
info@microwise.us

2. HAZARDS IDENTIFICATION

Emergency Overview

Primary Physical and Health Hazards: Severe Allergen. Heart Effects.

Caution Statement: Tilmoxan 250mg/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.

Effects of Overexposure: Tilmoxan 250mg/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.

NOT INTENDED FOR HUMAN USE.

Medical Conditions Aggravated by Exposure: Sensitivity to tilmicosin and/or tylosin.

Carcinogenicity: No carcinogenicity data found.

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3. COMPOSITION / INFORMATION ON COMPONENTS

Ingredient	CAS	Concentration %
Tilmicosin	137330-13-3	30
Propylene Glycol	57-55-6	25
Phosphoric acid	7664-38-2	pH = 6

4. FIRST AID MEASURES

Injection of TilMOXAN 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*.

Avoid contact with eyes.

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.

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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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.

NOTE TO THE PHYSICIAN

Injection of tilmicosin in humans has been associated with fatalities.

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.

As tilmicosin persists in tissues for several days, the cardiovascular system should be closely monitored and supportive treatment provided.

Physicians treating patients exposed to this compound are advised to discuss clinical management with the National Poison Information Service on

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.

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5. FIRE FIGHTING MEASURES

Auto Ignition: 418°C (784°F)

Flash Point: Not applicable.

UEL: Not established.

LEL: Not flammable at temperatures up to 100°C (212°F). No ignition up to 20.0% volume in air.

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: None known.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

6. ACCIDENTAL RELEASE MEASURES

Spills: Prevent further migration into the environment. Use absorbent/adsorbent material to solidify liquids. Sweep up or vacuum. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

7. HANDLING AND STORAGE

Storage Conditions: Do not store above 25°C. Protect from light.

Once opened use the remaining solution within 28 days. Discard unused material.

Additional Information:

Injection of this drug in humans can be lethal – Exercise extreme caution to avoid and accidental self-injection 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 Tilmoxan 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 Tiloxan.
- 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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

See Section 2 for Exposure Guideline information.

Respiratory Protection: Use an approved respirator.

Eye Protection: Chemical goggles and/or face shield.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: 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.

Additional Exposure Precautions: 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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear yellowish to brown-yellowish solution.

Odor: Faint characteristic sweet.

Boiling Point: No applicable information found.

Melting Point: Not applicable.

Specific Gravity: No applicable information found.

pH: 6

Evaporation Rate: No applicable information found.

Water Solubility: Soluble.

Vapor Density: No applicable information found.

Vapor Pressure: No applicable information found.

10. STABILITY AND REACTIVITY

Stability: Stable at normal temperatures and pressures.

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

Hazardous Decomposition: May emit toxic fumes when heated to decomposition.

Hazardous Polymerization: Will not occur

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11. TOXICOLOGICAL INFORMATION

Acute Exposure

Data for tilmicosin phosphate and Tilmoxan 250mg/ml are reported as indicated.

Oral:

Tilmicosin phosphate - Rat (fasted), median lethal dose 855 mg/kg, reduced activity, incoordination, drooping eyelids, soft stools, whole body thin, distended abdomen.

Skin:

TILMOXAN 250 mg/ml - Rabbit, 0.5 ml/kg, no deaths or toxicity.

Inhalation:

TILMOXAN 250mg/ml - Rat, 2750 mg/m^3 for 4 hours, no deaths, reduced activity, labored breathing, blood in urine.

Subcutaneous:

TILMOXAN 250 mg /ml - Rat, median lethal dose 318 mg/kg, reduced activity, leg weakness, hunched posture.

Tilmoxan phosphate - Rat, median lethal dose 185 mg/kg, coma, lethargy, incoordination, reduced activity.

Intramuscular:

TILMOXAN 250 mg/ml - Monkey, a single dose of 10 mg/kg caused no signs of toxicity. A single dose of 20 mg/kg caused vomiting, and 30 mg/kg caused the death of the only monkey tested.

Swine, intramuscular injection of 10 mg/kg caused increased respiration, emesis, and a convulsion, 20 mg/kg resulted in mortality in 3 of 4 pigs, and 30 mg/kg caused the death of all 4 pigs tested.

Skin Contact:

Tilmoxan 250mg/ml - Rabbit, slight irritant.

Eye Contact:

Tilmoxan 250mg/ml - Rabbit, slight irritant.

Chronic Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

Target Organ Effects:

Tilmicosin phosphate - The heart is the target of toxicity in laboratory and domestic animals given Tilmoxan250 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.

Other Effects:

Tilmicosin phosphate - Increased adrenal and kidney weights, increased cell size in adrenal cortex, mucosal edema of the gallbladder, and subretinal fluid accumulation. Decreased food consumption and body weight gains, slightly decreased urine pH, occult blood in urine, increased serum alanine transaminase.

Reproduction:

Tilmicosin phosphate - Slight increase in offspring mortality at maternally toxic doses.

Sensitization:

Tilmicosin phosphate - Guinea pig, not a contact sensitizer.

Mutagenicity:

Tilmicosin - Not mutagenic in bacterial or mammalian cells.

12. ECOLOGICAL INFORMATION

No environmental data for the mixture or formulation. The environmental information for ingredient(s) or related material(s) are presented.

Ecotoxicity Data:

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

Environmental Fate:

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

Environmental Summary:

Tilmicosin - Practically nontoxic to fish, birds, earthworms, fungus, molds, soil bacteria, and most plants. Slightly toxic to aquatic invertebrates. Moderately toxic to nitrogen-fixing bacteria. Highly toxic to green algae and bluegreen algae. No volatility expected. Low potential to bioconcentrate in aquatic organisms. Low mobility in soil. Persistent in the soil environment. Persistence in the aquatic environment not expected due to rapid photolysis.

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13. DISPOSAL CONSIDERATIONS

Waste Disposal: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Container Disposal: No special package disposal required.

14. TRANSPORT INFORMATION

Regulatory Organizations:

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.

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15. REGULATORY INFORMATION

EC Classification

Xn (Harmful)

N (Dangerous for the Environment)

Risk Phrases

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

R 50 - Very toxic to aquatic organisms.

Safety Phrases

S 36/37 - Wear suitable protective clothing and gloves.

S 61 - Avoid release to the environment. Refer to special instructions/Safety data sheets.

16. OTHER INFORMATION

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.