

The logo for Elanco, featuring the word "ELANCO" in white, bold, sans-serif capital letters on a blue rectangular background that is tilted slightly to the right.

**MATERIAL SAFETY DATA SHEET
MICOTIL 300 INJECTION**

AH0230

Revision 4.0, 4 September 2007

STATEMENT OF HAZARDOUS NATURE:

"Hazardous according to criteria of Worksafe Australia"
Irritant; R43 May cause sensitisation by skin contact.

Company Name and Address:

Elanco Animal Health
A Division of Eli Lilly Australia Pty Ltd
A.B.N. 39 000 233 992
112 Wharf Road, West Ryde, N.S.W. 2114, Australia

Contact Numbers:

Tel: (02) 9878 7777

Fax: (02) 9878 7720

Emergency Telephone Numbers:

Elanco Animal Health:
1800 226 324 (Toll free)

OR

Poisons Information Centre:
13 1126 (Australia-wide)

CHEMWATCH 1800 039 008 24 hour emergency contact number (spills and accidents)

Section 1 - Identification

Product Name: Elanco AH0230 Micotil 300 Injection

Other Names: Tilmicosin

Manufacturer's Product Code: AH0230

UN Number: None allocated

Dangerous Goods Class/Subsidiary Risk: None allocated

Hazchem Code: None allocated

Poisons Schedule Number: S4

Pack Size and Container Type: 100 mL multidose amber bottles for subcutaneous injection in cattle only

Use:

Major Recommended Uses: For use in lot-fed cattle for the treatment of Bovine Respiratory Disease (BRD) associated with *Pasteurella haemolytica*, *Pasteurella multocida*, and other organisms susceptible to tilmicosin.

Major Recommended Method(s) of Application: For subcutaneous injection only in cattle.

Section 2 - Composition / Information on Ingredients

Ingredient	CAS	Concentration %
Tilmicosin Phosphate	137330-13-3	30
Inert Ingredients	NA	70

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

Exposure Guidelines: Tilmicosin - LEG <100 micrograms/m³ TWA for 12 hours.

Section 3 - Hazards Identification

Appearance: Clear yellow to amber-coloured solution

Physical State: Liquid

Odour: Faint characteristic sweet odour

Emergency Overview:

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

Caution Statement: Micotil 300 Injection 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.

Routes of Entry: Inhalation and skin contact.

Potential Signs and Symptoms of Occupational Exposure: Micotil 300 Injection - No allergic reactions in a manufacturing setting have been reported.

Tilmicosin phosphate powder - Allergic reactions in a manufacturing setting have been reported. Allergy symptoms may include skin rash, watery eyes, shortness of breath, nasal congestion, choking, coughing, and wheezing. Compounds of similar structure have been reported to cause transient alterations in heart rate.

NOT INTENDED FOR HUMAN USE.

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

Carcinogenicity: No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA.

Section 4 - First Aid Measures

Human Warnings

NOT FOR HUMAN USE.

Injection of MICOTIL Injection of Micotil 300 in humans has been associated with fatalities. Keep out of 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 doctor immediately and apply ice or cold pack to injection site while avoiding direct contact with the skin. Contact Poisons Information Centre on 13 1126 . Avoid contact with eyes. Do not massage injection site.

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.

Ingestion: Call a physician or Poisons Information Centre immediately. Phone 13 1126 (Australia-wide). If available, administer activated charcoal (6-8 heaping teaspoons) with two to 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.

NOTE TO DOCTOR:

The cardiovascular system is the target of toxicity and should be monitored closely. Cardiovascular toxicity may be due to calcium channel blockade. In dogs, administration of intravenous calcium offset Micotil-induced tachycardia and negative inotropy (decreased contractility). Dobutamine partially offset the negative inotropic effects induced by MICOTIL in dogs. Epinephrine potentiated lethality of MICOTIL in pigs. Beta-adrenergic antagonists, such as propranolol, exacerbated the negative inotropy of MICOTIL in dogs. This antibiotic persists in tissues for several days.

Section 5 - Fire Fighting Measures

Auto Ignition: 784°F (418°C)

Flash Point: Not applicable.

UEL: Not established.

LEL: Not flammable at temperatures up to 212°F (100°C). 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.

Section 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). Large spills due to traffic accidents, etc., should be reported immediately to Elanco Animal Health for assistance. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

Section 7 - Handling and Storage

Storage: Store below 30°C (Room Temperature). Protect from direct sunlight. Use all product within 90 days of opening and discard any unused portion.

Human Warnings – User Safety

NOT FOR HUMAN USE. Keep out of reach of children. Micotil must be administered by appropriately trained personnel who are using techniques designed to reduce the risk of accidental self injection. Properly restrain animals prior to administration. Do not administer Micotil if the animal cannot be restrained.

While this product is well tolerated by cattle, there is a risk of severe injury to humans associated with accidental self-injection. Injection of this drug in humans has been associated with fatalities. Care should be taken to avoid needle-stick injury when injecting this product. Exercise extreme caution to avoid accidental self-injection. Keep a protective cover on needles until ready to use. Never carry a loaded syringe in pocket or clothing. Do not use in automatically powered syringes.

Section 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.

Other Handling 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.

Section 9 - Physical and Chemical Properties

Appearance: Clear yellow to amber-coloured solution

Physical State: Liquid

Odor: Faint characteristic sweet odour

Boiling Point: No applicable information found.

Melting Point: Not applicable.

Specific Gravity: No applicable information found.

pH: 5.5 to 6.5 (aqueous 50/50).

Evaporation Rate: No applicable information found.

Water Solubility: Soluble.

Vapour Density: No applicable information found.

Vapour Pressure: No applicable information found.

Section 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: Not known to occur.

Section 11 - Toxicological Information

Animal Toxicity Data Single Exposure

Data for tilmicosin phosphate and Micotil 300 Injection 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: Micotil 300 Injection - Rabbit, 0.5 mL/kg, no deaths or toxicity.

Inhalation: Micotil 300 Injection - Rat, 2750 mg/m³ for 4 hours, no deaths, reduced activity, labored breathing, blood in urine.

Subcutaneous: Micotil 300 Injection - Rat, median lethal dose 318 mg/kg, reduced activity, leg weakness, hunched posture.

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

Intramuscular: Micotil 300 Injection - 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: Micotil 300 Injection - Rabbit, slight irritant.

Eye Contact: Micotil 300 Injection - Rabbit, slight irritant.

Animal Toxicity Data Repeat Exposure

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

Target Organ Effects: Tilmicosin phosphate - Heart effects (increased heart weight and size, heart muscle degeneration characterized by small areas of cell death, severe and persistent increase in heart rate with changes in electrocardiogram ST, Q, and T wave forms occurred generally at higher oral or injection doses where some mortality occurred), liver effects (increased liver weight and enzyme activity).

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 - No effects identified in animal studies, except slight increase in offspring mortality at maternally toxic doses.

Sensitization: Tilmicosin phosphate - Not a contact sensitizer in guinea pigs.

Mutagenicity: Tilmicosin - Not mutagenic in bacterial or mammalian cells.

Section 12 - Ecological Information

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

Ecotoxicity Data: Tilmicosin

Rainbow trout 96-hr median lethal concentration: 851 mg/L

Bluegill 96-hr median lethal concentration: 716 mg/L

Daphnia magna 48-hr 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 blue-green 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.

Lilly Aquatic Exposure Guideline (LAEG): Tilmicosin

LAEG for Drinking Water: 280 micrograms/L

LAEG for Chronic Exposure of Aquatic Organisms: 54 micrograms/L

LAEG for Acute Exposure of Aquatic Organisms: 354 micrograms/L

Section 13 - Disposal Considerations

Disposal: Dispose of empty container by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled "sharps" container.

Section 14 - Transport Information

No special transport requirements necessary.

Section 15 - Other Information

Sections revised: Header and Footer: R. Pagination changed to page number only. Section 1: Added CHEMWATCH contact details. Italicised species names in Major recommended uses. Section 15: Deleted contact point details. (moved to section 1)

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

GLOSSARY

ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association
BEI = Biological Exposure Index
CAS Number = Chemical Abstract Service Registry Number
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHEMTREC = Chemical Transportation Emergency Center
DOT = Department of Transportation
EC = European Community
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
EPA = Environmental Protection Agency
HEPA = High Efficiency Particulate Air (Filter)
IARC = International Agency for Research on Cancer
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association
IEG = Lilly Interim Exposure Guideline
IMO = International Maritime Organization
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline
STEL = Short Term Exposure Limit
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations
WEEL = Workplace Environmental Exposure Level (AIHA)