



# MICOTIL 300

Effective Date: 23-Nov-2009

**Elanco Animal Health  
Material Safety Data Sheet**

## Section 1 - Chemical Product and Company

**Manufacturer:**

Elanco Animal Health  
Division of Eli Lilly and Company  
2001 West Main St  
PO Box 708  
Greenfield, IN 46140

**Manufacturer's Emergency Phone:**

1-800-722-0987

**CHEMTREC:**

1-800-424-9300 (North America)

1-703-527-3887 (International)

**Common Name:** MICOTIL 300

**Chemical Name:** Tylosin, 4A-O-de(2,6-dideoxy-3-C-methyl-a-L-ribo-hexopyranosyl)-20-deoxo-20-[(3R,5S)-3,5-dimethyl-1-

piperidinyl]-, phosphate (1:1) (salt)

**Synonym(s):** Tilmicosin Formulation; Tilmicosin Phosphate Formulation

**Trademarks(s):** Micotil; Micotil 300

**Lilly Item Code(s):** AH0230

NOT FOR HUMAN USE!

See attached glossary for abbreviations.

## Section 2 - Composition / Information on Ingredients

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration %</u>
Tilmicosin Phosphate	137330-13-3	30
Inert Ingredients	NA	70

**Exposure Guidelines:**

Tilmicosin - LEG <100 micrograms/m<sup>3</sup> TWA for 12 hours.

## Section 3 - Hazards Identification

**Appearance:** Clear yellow to amber-colored solution

**Physical State:** Liquid

**Odor:** Faint characteristic sweet

## Emergency Overview

Special  
A = Allergen

**Emergency Overview Effective Date:** 09-Dec-2003

**Lilly Laboratory Labeling Codes:**

**Health 1**

**Fire 1**

**Reactivity 0**

**Special A**

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

**Caution Statement:** MICOTIL 300 contains tilmicodin 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. Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

**Routes of Entry:** Inhalation and skin contact.

**Effects of Overexposure:** Micotil 300 - 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.

Tilmicodin 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.

NOT INTENDED FOR HUMAN USE.

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

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

## Section 4 - First Aid Measures

NOT FOR HUMAN USE!

Injection of MICOTIL 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 1-800-722-0987 or 1-317-276-2000. 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.

**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.

**Notes to Physician:** 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. Beta-adrenergic antagonists, such as propranolol, exacerbated the negative inotropy of Micotil in dogs. Epinephrine potentiated lethality of Micotil in pigs. This antibiotic persists in tissues for several days.

## Section 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.

## 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 CHEMTREC and 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 Conditions:** Store at 30 C (86 F) or below. Protect from direct sunlight. Product should not be used after the date printed on the container. A dating of 36 months is noted on the container.

**Additional Information:** Human Warnings: Not for human use. Injection of Micotil 300 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. Emergency medical telephone numbers are 1-800-722-0987 (Rocky Mountain Poison Control Center) or (317) 276-2000 (Eli Lilly and Company). Avoid contact with eyes.

## 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.

**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.

## Section 9 - Physical and Chemical Properties

**Appearance:** Clear yellow to amber-colored solution

**Odor:** Faint characteristic sweet

**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

**Vapor Density:** No applicable information found

**Vapor 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:** Will not occur.

## Section 11 - Toxicological Information

### Acute Exposure

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

#### Inhalation:

Micotil 300 - Rat, 2750 mg/m<sup>3</sup> for 4 hours, no deaths, reduced activity, labored breathing, blood in urine.

#### Subcutaneous:

Micotil 300 - 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 - 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 - Rabbit, slight irritant

**Eye Contact:**

Micotil 300 - 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 Micotil®300 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.

## Section 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 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**

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

**Container Disposal:** No special package disposal required.

**Section 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.

**Section 15 - Regulatory Information**

Below is selected regulatory information chosen primarily for possible Elanco Animal Health usage. This section is

not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

## **U.S. Regulations**

Tilimicosin phosphate

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

NADA Number: 140-929

## **EU Regulations**

### **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.

## **Section 16 - Other Information**

**MSDS Sections Revised:** Sections 14.

**NOT FOR HUMAN USE!** For accidental human exposure, call 1-800-722-0987. Refer to Human Warnings and Note to Physician on product label and Client Information Sheet dispensed with each bottle for further information.

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.

For additional information contact:

ELANCO Animal Health

1-800-428-4441

1-317-276-2000

### **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)

CHAN = Chemical Hazard Alert Notice  
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  
Kow = Octanol/Water Partition Coefficient  
LEG = Lilly Exposure Guideline  
LEL = Lower Explosive Limit  
MSDS = Material Safety Data Sheet  
MSHA = Mine Safety and Health Administration  
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)