

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078384716

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078384690 078384708 078434715 078434723



## 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 tilmicotin 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.

Tilmicotin 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 tilmicotin 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 tilmicotin phosphate and Micotil 300 are reported as indicated.

#### Oral:

Tilmicotin 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.

Tilmicotin 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)



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Micotil 300</b>
<b>Other means of identification</b>	
<b>Item Code</b>	AH0230
<b>Synonyms</b>	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) * Tilmicosin Formulation * Tilmicosin Phosphate Formulation
<b>Recommended use</b>	Veterinary Pharmaceutical
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Manufacturer</b>	
<b>Company Name</b>	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
<b>Phone:</b>	1-877-Elanco1 (1-877-352-6261)
<b>Email:</b>	lilly_msds@lilly.com
<b>Emergency Telephone Numbers:</b>	Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973 Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 2B
	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
	Specific target organ toxicity, repeated exposure	Category 2
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger
<b>Hazard statement</b>	
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H320	Causes eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H373	May cause damage to organs (Heart) through prolonged or repeated exposure.
<b>Precautionary statement</b>	
<b>Prevention</b>	
P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P280	Wear protective gloves/eye protection/face protection.
P285	In case of inadequate ventilation wear respiratory protection.

**Response**

P321	Specific treatment (see this label).
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P330	Rinse mouth.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P304 + P341	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P362 + P364	Take off contaminated clothing and wash it before reuse.
P307 + P311	IF exposed: Call a POISON CENTER or doctor/physician.
P314	Get medical advice/attention if you feel unwell.

**Storage**

Not available.

**Disposal**

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazard(s) not otherwise classified (HNOC)**

Injection of Micotil 300 in humans has been associated with fatalities.

**Supplemental information**

None.

**3. Composition/information on ingredients****Mixtures**

Chemical name	Common name and synonyms	CAS number	%
Tilmicosin Phosphate		137330-13-3	30
Other components below reportable levels			70

**4. First-aid measures****Inhalation**

Move to fresh air. Oxygen or artificial respiration if needed. Call a physician or poison control center immediately.

**Skin contact**

Wash off immediately with soap and plenty of water. Get medical attention if irritation develops and persists. Take off contaminated clothing and wash before reuse.

**Eye contact**

Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Call a physician or poison control center immediately.

**Ingestion**

Call a physician or poison control center immediately. Give several glasses of water. Never give anything by mouth to a victim who is unconscious or is having convulsions.

**Most important symptoms/effects, acute and delayed**

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.

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. (Micotil 300)

Allergic reactions in a manufacturing setting have been reported. Allergy symptoms may include skin rash, watery eyes, shortness of breath, nasal congestion, coughing, and wheezing. (Tilmicosin Phosphate)

**Indication of immediate medical attention and special treatment needed**

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.

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.

## 5. Fire-fighting measures

**Suitable extinguishing media**

Alcohol resistant foam. Water fog. Dry chemical. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**Unsuitable extinguishing media**

Do not use water jet as an extinguisher, as this will spread the fire.

**Specific hazards arising from the chemical**

Fire or excessive heat may produce hazardous decomposition products.

**Special protective equipment and precautions for firefighters**

Wear self-contained breathing apparatus and protective clothing.

**Fire fighting equipment/instructions**

Move containers from fire area if you can do so without risk.

**Specific methods**

Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards**

No unusual fire or explosion hazards noted.

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**

Do not breathe mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. See Section 8 of the SDS for Personal Protective Equipment. Avoid contact with skin, eyes and clothing.

**Methods and materials for containment and cleaning up**

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

**Environmental precautions**

Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

## 7. Handling and storage

**Precautions for safe handling**

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 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 (Rocky Mountain Poison Control Center) or 1-800-428-4441 (Elanco). Avoid contact with eyes.

Avoid contact with eyes.

**Conditions for safe storage, including any incompatibilities**

Store in a well-ventilated place. Keep at temperature not exceeding 30°C / 86°F. Avoid moisture. Protect against direct sunlight. Avoid contact with oxidizing agents.

## 8. Exposure controls/personal protection

**Occupational exposure limits**

No exposure limits noted for ingredient(s).

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Exposure guidelines**

Lilly Exposure Guideline (LEG): 12 hour TWA <100 ug/m<sup>3</sup> (Tilmicosin)

**Appropriate engineering controls**

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

Wear chemical goggles. Use face shield in case of splash risk.

<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves.
<b>Other</b>	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
<b>Respiratory protection</b>	Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor.
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	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.
	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.

## 9. Physical and chemical properties

<b>Appearance</b>	Solution.
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Color</b>	Yellow to Amber.
<b>Odor</b>	faint sweet odor
<b>Odor threshold</b>	No data available.
<b>pH</b>	5.5 - 6.5 (aqueous 50/50)
<b>Melting point/freezing point</b>	No data available.
<b>Initial boiling point and boiling range</b>	No data available.
<b>Flash point</b>	No data available.
<b>Evaporation rate</b>	No data available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	No data available.
<b>Flammability limit - upper (%)</b>	No data available.
<b>Explosive limit - lower (%)</b>	20 %
<b>Explosive limit - lower (%) temperature</b>	212 °F (100 °C)
<b>Explosive limit - upper (%)</b>	No data available.
<b>Vapor pressure</b>	No data available.
<b>Vapor density</b>	No data available.
<b>Relative density</b>	No data available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Soluble.
<b>Partition coefficient (n-octanol/water)</b>	No data available.
<b>Auto-ignition temperature</b>	784.4 °F (418 °C)
<b>Decomposition temperature</b>	No data available.
<b>Viscosity</b>	No data available.
<b>Other information</b>	
<b>Density</b>	No data available.
<b>Explosive properties</b>	No data available.
<b>Oxidizing properties</b>	No data available.
<b>Percent volatile</b>	No data available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Fire or excessive heat may produce hazardous decomposition products.

## 11. Toxicological information

### Information on toxicological effects

**Acute toxicity** Harmful if swallowed.

Product	Species	Test Results
Micotil 300		
<b>Acute</b>		
<b>Dermal</b>		
LD	Rabbit	0.5 ml/kg No mortality. No toxicity.
<b>Inhalation</b>		
LC	Rat	2750 mg/m3, 4 hr No mortality.
<b>Other</b>		
	Monkey	Intramuscular: 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: 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.
LD50	Rat	318 mg/kg Subcutaneous: reduced activity, leg weakness, hunched posture.

Components	Species	Test Results
Tilmicosin Phosphate (CAS 137330-13-3)		
<b>Acute</b>		
<b>Dermal</b>		
LD	Rabbit	> 5000 mg/kg
<b>Inhalation</b>		
LC50	Rat	3800 mg/m3, 4 h
<b>Oral</b>		
LD50	Rat	855 mg/kg (fasted)
<b>Other</b>		
LD50	Rat	> 185 mg/kg Subcutaneous: coma, lethargy, incoordination, reduced activity.

**Skin corrosion/irritation** Rabbit: Slight irritation.  
Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Rabbit: Causes eye irritation. (cleared within 7 days)

### Respiratory or skin sensitization

**Respiratory sensitization** May cause allergy or asthma symptoms or breathing difficulties if inhaled. Allergic reactions in a manufacturing setting have been reported.. (Tilmicosin Phosphate)

<b>Skin sensitization</b>	May cause an allergic skin reaction. Did not cause sensitization on laboratory animals. Allergic reactions in a manufacturing setting have been reported.. (Tilmicosin Phosphate)
<b>Germ cell mutagenicity</b>	In vitro and in vivo tests did not show mutagenic effects. (Tilmicosin) Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	No carcinogenicity data available for this product. Not listed by IARC, NTP, ACGIH or OSHA.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	
Not listed.	
<b>Reproductive toxicity</b>	Slight increase in offspring mortality at maternally toxic doses. (Tilmicosin Phosphate) Based on available data, the classification criteria are not met.
<b>Specific target organ toxicity - single exposure</b>	Due to lack of data the classification is not possible.
<b>Specific target organ toxicity - repeated exposure</b>	May cause damage to organs through prolonged or repeated exposure. 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.
<b>Aspiration hazard</b>	No aspiration toxicity classification
<b>Further information</b>	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. (Tilmicosin Phosphate)

## 12. Ecological information

Ecotoxicity		Very toxic to aquatic life with long lasting effects.	
Components		Species	Test Results
Tilmicosin (CAS 108050-54-0)			
Acute			
	LC50		> 918 mg/kg, 28 day (Earthworm (Eisenia fetida))
Other	LC50	Duck	> 4710 ppm, 5 day Anas platyrhynchos (Mallard), Dietary
		Quail	> 4820 ppm, 5 day Colinus virginianus (Bobwhite), Dietary
	MIC	Micro-organisms	> 1000 mg/l Mold (Aspergillus flavus) > 1000 mg/l Fungus (Chaetomium globosum) 250 mg/l Soil bacteria (Comamonas acidovaorans) 5 mg/l N-fixing bacteria (Azotobacter chroococcum)
Aquatic			
Acute			
Algae	EC50	Algae	0.354 mg/l (Selenastrum capricornutum, average specific growth rate)
	MIC	Algae	0.5 mg/l (Blue-green algae)
Crustacea	EC50	Daphnia magna	57.3 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	716 mg/l, 96 hr
		Oncorhynchus mykiss	851 mg/l, 96 hours

**Persistence and degradability** 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  
 (Tilmicosin)

**Bioaccumulative potential** No data available for this product.

**Partition coefficient n-octanol / water (log Kow)**

Tilmicosin < 1 (pH 5)  
 < 1 (pH 7)  
 2.6 (pH 9)

**Mobility in soil** No data available.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

**Ecotoxicological Properties**

**Drinking Water**

**Components**

**Test Results**

Tilmicosin 280 µg/l, (Lilly Aquatic Exposure Guideline)

**Chronic Exposure of Aquatic Organisms**

**Components**

**Test Results**

Tilmicosin 54 µg/l, (Lilly Aquatic Exposure Guideline)

**Acute Exposure of Aquatic Organisms**

**Components**

**Test Results**

Tilmicosin 354 µg/l, (Lilly Aquatic Exposure Guideline)

**13. Disposal considerations**

**Disposal instructions** Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

**14. Transport information**

**General information** Effective January 1, 2015 by Special Provision, UN3077 and UN3082 when packaged in inner packages of 5L / 5 KG or less are not subject to the dangerous goods regulations.

**DOT**

Not regulated as dangerous goods.

**IATA**

**UN number** UN3082

**UN proper shipping name** Environmentally hazardous substance, liquid, n.o.s. (TILMICOSIN PHOSPHATE)

**Transport hazard class(es)**

**Class** 9

**Subsidiary risk** -

**Packing group** III

**Environmental hazards** Yes

**ERG Code** 9L

**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.

**Other information**

**Passenger and cargo aircraft** Allowed.

**Cargo aircraft only** Allowed.

**IMDG**

**UN number** UN3082

**UN proper shipping name** Environmentally hazardous substances, liquid, n.o.s. (TILMICOSIN PHOSPHATE), Yes

**Transport hazard class(es)**

**Class** 9



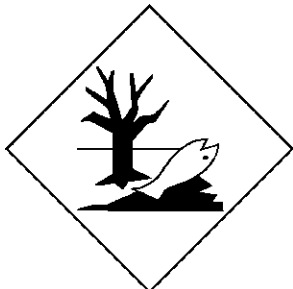
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	Yes
<b>EmS</b>	F-A, S-F
<b>Special precautions for user</b>	Read safety instructions, SDS and emergency procedures before handling.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not available.

**IATA; IMDG**



**Marine pollutant**



## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.  
One or more components are not listed on TSCA.

### **TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

### **CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

### **SARA 304 Emergency release notification**

Not regulated.

### **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

### **Superfund Amendments and Reauthorization Act of 1986 (SARA)**

#### **Hazard categories**

Immediate Hazard - Yes  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

#### **SARA 313 (TRI reporting)**

Not regulated.

### **Other federal regulations**

#### **Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

#### **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

#### US state regulations

**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

**US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not listed.

**US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

#### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

**Issue date** 08-15-2014

**Revision date** 03-03-2015

**Version #** 03

**Lilly Lab Code** Health: 2  
Fire: 1  
Reactivity: 0  
Special 1: A

#### List of abbreviations

LEG: Lilly Exposure Guideline

TWA: Time Weighted Average

#### Disclaimer

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 MERCHANT ABILITY 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.

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#### Revision Information

Physical & Chemical Properties: Multiple Properties

Regulatory Information: Other

Other information, including date of preparation or last revision: Disclaimer

GHS: Classification