

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/m³ 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/m³ 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

Product identifier Micotil 300

Other means of identification

Item Code AH0230

Synonyms 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

Recommended use Veterinary Pharmaceutical

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company Name Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140
US

Phone: 1-877-Elanco1 (1-877-352-6261)

Emergency Telephone: Elanco Product Technical Support / Human or Animal Exposure Reporting:
1-888-545-5973

Email: elanco_sds@elanco.com

Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300
(Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Sensitization, respiratory	Category 1
Sensitization, skin	Category 1
Specific target organ toxicity, repeated exposure	Category 2

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement

H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H373	May cause damage to organs (Heart) through prolonged or repeated exposure.

Precautionary statement

Prevention

P261	Avoid breathing mist or vapor.
P284	In case of inadequate ventilation wear respiratory protection.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Response

P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
P362 + P364	Take off contaminated clothing and wash it before reuse.
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

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

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	(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.
Indication of immediate medical attention and special treatment needed	(Tilmicosin Phosphate) 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. 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. Dry chemical. Carbon dioxide (CO2).
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.
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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. 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.

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**Biological limit values**

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

Exposure guidelines

12 hour TWA <100 ug/m3 (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.

Skin protection**Hand protection**

Wear appropriate chemical resistant gloves.

Other

Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Respiratory protection

Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor.

Thermal hazards

Not available.

General hygiene considerations

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**Appearance**

Solution.

Physical state

Liquid.

Form

Liquid.

Color

Yellow to Amber.

Odor

faint sweet odor

Odor threshold

No data available.

pH

5.5 - 6.5 (aqueous 50/50)

Melting point/freezing point

No data available.

Initial boiling point and boiling range

No data available.

Flash point

No data available.

Evaporation rate

No data available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	No data available.
Flammability limit - upper (%)	No data available.
Explosive limit - lower (%)	20 %
Explosive limit - lower (%) temperature	212 °F (100 °C)
Explosive limit - upper (%)	No data available.
Vapor pressure	No data available.
Vapor density	No data available.
Relative density	No data available.
Solubility(ies)	
Solubility (water)	Soluble.
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	784.4 °F (418 °C)
Decomposition temperature	No data available.
Viscosity	No data available.
Other information	
Density	No data available.
Explosive properties	No data available.
Oxidizing properties	No data available.
Percent volatile	No data available.
VOC	No data available.

10. Stability and reactivity

Reactivity	Not water reactive.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information**Information on toxicological effects****Acute toxicity**

Product	Species	Test Results
Micotil 300		
<u>Acute</u>		
Dermal		
LD	Rabbit	0.5 ml/kg No mortality. No toxicity.
Inhalation		
LC	Rat	2750 mg/m3, 4 hr No mortality.
Other		
	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.

Product	Species	Test Results
	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)		
<u>Acute</u>		
Dermal		
LD	Rabbit	> 5000 mg/kg
Inhalation		
LC50	Rat	3800 mg/m3, 4 h
Oral		
LD50	Rat	855 mg/kg (fasted)
Other		
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 Slightly irritating to the eyes of rabbits. Based on available data, the classification criteria are not met.	
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)	
Skin sensitization	May cause an allergic skin reaction. Did not cause sensitization on laboratory animals. Allergic reactions in a manufacturing setting have been reported. (Tilmicosin Phosphate)	
Germ cell mutagenicity	In vitro and in vivo tests did not show mutagenic effects. (Tilmicosin) Based on available data, the classification criteria are not met.	
Carcinogenicity	No carcinogenicity data available for this product. Not listed by IARC, NTP, ACGIH or OSHA. Due to lack of data the classification is not possible.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)		
Not regulated.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	Slight increase in offspring mortality at maternally toxic doses. (Tilmicosin Phosphate) Based on available data, the classification criteria are not met.	
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.	
Specific target organ toxicity - repeated exposure	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.	
Aspiration hazard	No aspiration toxicity classification	
Further information	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	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
Terrestrial			
Acute			
	LC50	Duck	> 4710 ppm, 5 day Anas platyrhynchos (Mallard), Dietary
Other	LC50	Quail	> 4820 ppm, 5 day Colinus virginianus (Bobwhite), Dietary
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)		
accumulative 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			
Not available.			

Ecotoxicological Properties

Drinking Water

Components	Test Results
Tilimicosin	280 µg/l, (Lilly Aquatic Exposure Guideline)

Chronic Exposure of Aquatic Organisms

Components	Test Results
Tilimicosin	54 µg/l, (Lilly Aquatic Exposure Guideline)

Acute Exposure of Aquatic Organisms

Components	Test Results
Tilimicosin	354 µg/l, (Lilly Aquatic Exposure Guideline)

13. Disposal considerations

Disposal instructions 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	Not available.
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.

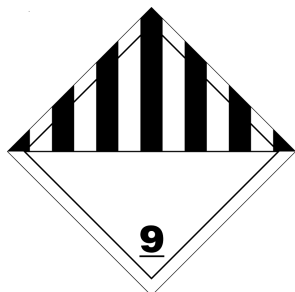
IMDG

UN number	UN3082
UN proper shipping name	Environmentally hazardous substances, liquid, n.o.s. (TILMICOSIN PHOSPHATE)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Not available.

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.

Toxic Substances Control Act (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 1910.1001-1052)

Not regulated.

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

US state regulations**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** 03-19-2019**Version #** 12**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 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.

For additional information contact:

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