



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-piperidiny]-, phosphate (1:1) (salt) * Tilmicosin Formulation * Tilmicosin Phosphate Formulation
Recommended use	Veterinary Pharmaceutical
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	
Company Name	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
Phone:	1-877-Elanco1 (1-877-352-6261)
Email:	lilly_msds@lilly.com
Emergency Telephone Numbers:	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

Physical hazards	Not classified.	
Health hazards	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
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	
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.
Precautionary statement	
Prevention	
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 (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.

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/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	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 (Weight %) No data available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
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 Harmful if swallowed.

Product	Species	Test Results
Micotil 300		
Acute		
Dermal		
LD	Rabbit	0.5 ml/kg No mortality. No toxicity.
Inhalation		
LC	Rat	2750 mg/m ³ , 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.
	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)		
Acute		
Dermal		
LD	Rabbit	> 5000 mg/kg
Inhalation		
LC50	Rat	3800 mg/m ³ , 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: 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)

Skin sensitization	May cause an allergic skin reaction. Did not cause sensitization on laboratory animals. Allergic reactions in a manufacturing setting have been reported.. (Tilimicosin Phosphate)
Germ cell mutagenicity	In vitro and in vivo tests did not show mutagenic effects. (Tilimicosin) 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.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	
Reproductive toxicity	Slight increase in offspring mortality at maternally toxic doses. (Tilimicosin 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. (Tilimicosin Phosphate)

12. Ecological information

Ecotoxicity Very toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Tilimicosin (CAS 108050-54-0)			
<i>Acute</i>			
	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			
<i>Acute</i>			
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

Subsidiary risk -
Packing group III
Environmental hazards
Marine pollutant Yes
EmS F-A, S-F
Special precautions for user 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 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:

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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