



SAFETY DATA SHEET

1. Identification

Product identifier	Elanco AH0230 Micotil 300 Injection (Tilmicosin)
Other means of identification	
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]-,p hosphate (1:1) (salt) * Tilmicosin Formulation * Tilmicosin Phosphate Formulation
Item Code	AH0230
Recommended use of the chemical and restrictions on use	
Recommended use	Veterinary Pharmaceutical
Restrictions on use	Not available.
Details of manufacturer or importer	
Manufacturer	
Company name	Elanco Animal Health A Division of Eli Lilly Australia Pty Ltd
Address	A.B.N. 39 000 233 992 112 Wharf Road, West Ryde, N.S.W. 2114, Australia
Telephone	(02) 9878 7777
Fax	(02) 9878 7720
e-mail	lilly_msds@lilly.com
Emergency phone number	Elanco Animal Health: 1800 226 324 (Toll free) OR Poisons Information Centre: 131126 (Australia-wide)
24 hr emergency contact number	CHEMWATCH 1800 039 008 (spills and accidents)
24 hr emergency contact number (Local)	CHEMWATCH +61 2 9186 1132 (spills and accidents)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 2
	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
	Specific target organ toxicity following repeated exposure	Category 2
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 1
	Hazardous to the aquatic environment, long-term hazard	Category 1

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard Exclamation mark Environment

Signal word

Danger

Hazard Statement(s) Harmful if swallowed. May cause an allergic skin reaction. Causes eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause damage to organs (Heart) through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

Precautionary Statement(s)

Prevention Do not handle until all safety precautions have been read and understood. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection.

Response IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell. IF ON SKIN: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed: Call a POISON CENTRE or doctor/physician. Specific treatment (see this label). Rinse mouth. If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. Take off contaminated clothing and wash it before reuse.

Storage Not available.

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

Other hazards which do not result in classification Injection of Micotil 300 in humans has been associated with fatalities.

Supplemental information None.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Tilimicosin Phosphate	137330-13-3	30
Other components below reportable levels		70

4. First-aid measures

Description of necessary first aid measures

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

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

Personal protection for first-aid responders Not available.

Symptoms caused by exposure 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. Call a poison control centre immediately. 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. (Tilimicosin Phosphate)

Medical attention and special treatment	<p>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.</p> <p>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.</p>
--	--

5. Fire-fighting measures

Extinguishing media	
Suitable extinguishing media	Alcohol resistant foam. Water fog. Dry chemical. Dry chemical powder. Carbon dioxide (CO ₂).
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 fire fighters	Wear self-contained breathing apparatus and protective clothing.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Hazchem Code	3Z
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	
For non-emergency personnel	Avoid inhalation of vapours or mists. See Section 8 for personal protective equipment. Avoid contact with skin, eyes and clothing.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
Environmental precautions	Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.
Methods and materials for containment and cleaning up	<p>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.</p> <p>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.</p>

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. Call a poison control centre immediately. Avoid contact with eyes.
Conditions for safe storage, including any incompatibilities	Store in a well-ventilated place. Keep at temperature not exceeding 30°C. Avoid moisture. Protect against direct sunlight. Avoid contact with oxidising agents.

8. Exposure controls and personal protection

Control parameters	Follow standard monitoring procedures.
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 ³ (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, for example personal protective equipment (PPE)

Eye/face protection	Wear chemical goggles. Use face shield in case of splash risk. (AS/NZS 1337)
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves. (AS 2161)
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. (AS/NZS 1715)
Thermal hazards	Not available.
Hygiene measures	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.
Colour	Yellow to Amber.
Odour	faint sweet odor
Odour 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	100 °C (212 °F)
Explosive limit – upper (%)	No data available.
Vapour pressure	No data available.
Vapour 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	418 °C (784.4 °F)
Decomposition temperature	No data available.
Viscosity	No data available.

Other physical and chemical parameters

Density	No data available.
Explosive properties	No data available.
Oxidising 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 polymerisation does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information

Product	Species	Test results
Elanco AH0230 Micotil 300 Injection (Tilmicosin)		
Acute		
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.
	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/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/irritation	Rabbit: Causes eye irritation. (cleared within 7 days)
Respiratory or skin sensitisation	
Respiratory sensitisation	Allergic reactions in a manufacturing setting have been reported.. (Tilmicosin Phosphate)
Skin sensitisation	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.
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	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
Other 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)			
<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 acidovorans) 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 for this product.

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

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

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.

ADG

UN number 3082
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
Hazchem Code D3Z
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Not classified as dangerous goods when transported by road or rail in packaging or receptacles not exceeding 500 kg (L) according to ADG 7 SP AU01.

RID

UN number 3082

UN proper shipping name	Environmentally hazardous substances, liquid, n.o.s. (TILMICOSIN PHOSPHATE)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Packing group	III
Environmental hazards	Yes
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IATA

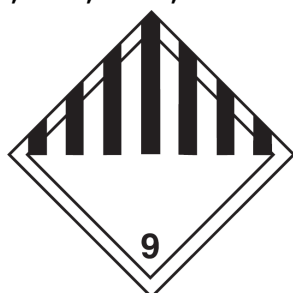
UN number	3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (TILMICOSIN PHOSPHATE)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	Yes
ERG Code	9L
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

IMDG

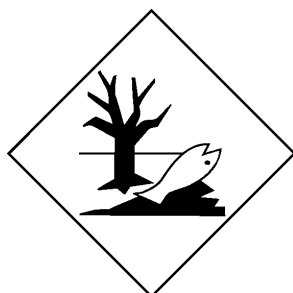
UN number	3082
UN proper shipping name	Environmentally hazardous substances, liquid, n.o.s. (TILMICOSIN PHOSPHATE)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

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

ADG; IATA; IMDG; RID



Marine pollutant



15. Regulatory information

Safety, health and environmental regulations

National regulations APVMA approval number 45653
Poison Schedule 4

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	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

Issue date

25-September-2015

Key abbreviations or acronyms used

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.

For additional information contact:

Elanco Animal Health
0011+1-877-352-6261
0011+1-800-428-4441

Revision Information

Product and Company Identification: Alternate Trade Names
Exposure controls and personal protection: Control parameters
Physical & Chemical Properties: Multiple Properties