SAFETY DATA SHEET

1. Identification

Product identifier **Pulmotil AC**

Other means of identification

Item Code AH0470, MS8291

Synonyms Tylosin, 4A-O-de(2,6-dideoxy-3-C-methyl-alpha-L-ribo-hexopyran osyl)-20-deoxo-20-[(3R,5S)-3,5-dimethyl-1-piperidinyl]-, phosphate (1:1) (salt) * Tilmicosin Phosphate Aqueous Concentrate * Tilmicosin Solution * Pulmusol * Tilmicosin Drinking Water Medication * Tilmicosin Aqueous Concentrate * Pulmotil * Pulmotil AC

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	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

H317	May cause an allergic skin reaction.
H319	Causes serious 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

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

P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P304 + P341	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a positior comfortable for breathing.
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) None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
TILMICOSIN PHOSPHATE		137330-13-3	25
Additional components are either non-hazardous and/or below required disclosure limits.			75

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

Eye contact Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion If conscious, give the victim plenty of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control center immediately.

Most important symptoms/effects, acute and delayed Irritating to eyes. 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.
Compounds of similar structure have been reported to cause transient alterations in heart rate. (Tilmicosin Phosphate)

Indication of immediate medical attention and special treatment needed None known.

General information In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. Fire-fighting measures

Suitable extinguishing media Water fog. Dry chemical. Foam. 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.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. See Section 8 of the SDS for Personal Protective Equipment. Avoid contact with skin, eyes and clothing. Wear suitable protective clothing, gloves and eye/face protection.

Methods and materials for containment and cleaning up	Local authorities should be advised if significant spillages cannot be contained. Remove sources of ignition. 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. Sweep up or vacuum up spillage and collect in suitable container for disposal. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills in original containers for re-use. For waste disposal, see section 13 of the SDS. Collect in a non-combustible container for prompt disposal. Large Spillages: Small Spillages: Use absorbent/adsorbent material to solidify liquids. Prevent further migration into the environment. Use absorbent/adsorbent material to solidify liquids. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

7. Handling and storage

Precautions for safe handling	Keep away from heat and sources of ignition. Wash hands thoroughly after handling. Avoid release to the environment. Avoid contact with eyes, skin, and clothing.
Conditions for safe storage, including any incompatibilities	Keep container tightly closed in a dry and well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Store at room temperature. Do not store in open or unlabelled containers.

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Exposure guidelines	Lilly Exposure Guideline (LEG): 12 hour TWA <100 ug/m3 (Tilmicosin)
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear goggles/face shield.
Skin protection	
Hand protection	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Other	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Respiratory protection	Use an approved respirator. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor.
Thermal hazards	Not available.
General hygiene considerations	NOT INTENDED FOR HUMAN USE. Use good industrial hygiene practices in handling this material. 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	Sweet. Pungent.
Odor threshold	No data available.
pH	3.5 - 5.5
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)	No test data available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	No data available.
Flammability limit - upper (%)	No data available.
Explosive limit - lower (%)	No data available.
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	No data available.
Decomposition temperature	No data available.
Viscosity	No data available.
Other information	
Density	No data available.
Explosive properties	Not explosive
Oxidizing properties	No data available.
Percent volatile	No data available.
VOC (Weight %)	No data available.
9.2. Other information	
Minimum Ignition Temperature	No data available.

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	None known.
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

Components	Species	Test Results
Tilmicosin (CAS 108050-54-0)		
Acute		
Dermal		
LD	Rabbit	> 5000 mg/kg
Inhalation		
LC50	Rat	3800 mg/m3, 4 h
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: No irritation (Tilmicosin)
Remaining ingredients: Not classified.
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Rabbit: Irritating. (cleared within 7 days) (Tilmicosin)

Respiratory or skin sensitization

Respiratory sensitization Allergic reactions in a manufacturing setting have been reported. (Tilmicosin Phosphate)

Skin sensitization No allergic reactions in a manufacturing setting have been reported. (Pulmotil Aqueous Concentrate) 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)
Remaining ingredients: Not classified.
Based on available data, the classification criteria are not met.

Carcinogenicity No ingredients present at 0.1% (one-tenth percent) or greater are 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. (Tilmicosin Phosphate)
Remaining ingredients: Not classified.
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 Heart effects (increased heart weight and size, heart muscle degeneration characterized by small areas of cell death, severe and persistent increase in heart rate with changes in electrocardiogram ST, Q, and T wave forms occurred generally at higher oral or injection doses where some mortality occurred), liver effects (increased liver weight and enzyme activity). (Tilmicosin Phosphate)

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	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

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 Not available.

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	Not available.
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

IMDG

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	
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 This substance/mixture is not intended to be transported in bulk.

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.

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 08-19-2014
Revision date 09-30-2014
Version # 02

Lilly Lab Code	Health: 2 Fire: 0 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. For additional information contact: Elanco Animal Health 00+1+317-276-2000 00+1-800-428-4441 The information in the sheet was written based on the best knowledge and experience currently available.
Revision Information	Hazard(s) identification: Hazard statement Accidental release measures: Personal precautions, protective equipment and emergency procedure s Physical & Chemical Properties: Multiple Properties Transport information: General information GHS: Classification