SAFETY DATA SHEET

1. Identification

Product identifier: Pulmotil AC

Other means of identification:
- Item Code: AH0470, MS8291
- Synonyms: 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

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:
- Serious eye damage/eye irritation Category 2
- 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:
- P280: Wear protective gloves/eye protection/face protection.
- P285: In case of inadequate ventilation wear respiratory protection.

Response:
- P304 + P340 + P338: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P314: Get medical advice/attention if you feel unwell.
If experiencing respiratory symptoms: Call a POISON CENTER/doctor. Not available.

Disposal
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>TILMICOSIN PHOSPHATE</td>
<td></td>
<td>137330-13-3</td>
<td>25</td>
</tr>
</tbody>
</table>

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
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
Treat symptomatically.

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
Alcohol resistant foam. Water fog. 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. 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. Collect in a non-combustible container for prompt disposal.
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 at room temperature. Do not store in open or unlabelled containers.

8. Exposure controls/personal protection

Occupational exposure limits
This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.

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

Exposure guidelines
12 hour TWA <100 ug/m3 (Tilmicosin)

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
Chemical resistant gloves.

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

Other

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. 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
Not available.

pH
3.5 - 5.5

Melting point/freezing point
Not available.

Initial boiling point and boiling range
Not available.

Flash point
Not available.

Evaporation rate
Not available.

Flammability (solid, gas)
No test data available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)
Not available.

Flammability limit - upper (%)
Not available.

Explosive limit - lower (%)
Not available.

Explosive limit - upper (%)
Not available.
Vapor pressure Not available.
Vapor density Not available.
Relative density Not available.
Solubility(ies)
  Solubility (water) Soluble
Partition coefficient (n-octanol/water) Not available.
Auto-ignition temperature Not available.
Decomposition temperature Not available.
Viscosity Not available.
Other information
  Explosive properties Not explosive.
  Oxidizing properties The substance or mixture is not classified as oxidizing.

10. Stability and reactivity
Reactivity Not water reactive.
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

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tilmicosin (CAS 108050-54-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD</td>
<td>Rabbit</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td>Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>Rat</td>
<td>3800 mg/m3, 4 h</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>855 mg/kg (fasted) (Tilmicosin Phosphate)</td>
</tr>
<tr>
<td>TILMICOSIN PHOSPHATE (CAS 137330-13-3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD</td>
<td>Rabbit</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td>Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>Rat</td>
<td>3800 mg/m3, 4 h</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>855 mg/kg (fasted)</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 185 mg/kg Subcutaneous: coma, lethargy, incoordination, reduced activity.</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation Rabbit: No irritation. (Tilmicosin)
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)
Based on available data, the classification criteria are not met.

Carcinogenicity
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
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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50 Other</td>
<td>Micro-organisms</td>
<td>&gt; 918 mg/kg, 28 day (Earthworm (Eisenia fetida))</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MIC Other</td>
<td>Micro-organisms</td>
<td>&gt; 1000 mg/l Mold (Aspergillus flavus)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC50 Algae</td>
<td>Algae</td>
<td>0.354 mg/l (Selenastrum capricornutum, average specific growth rate)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC50 Crustacea</td>
<td>Daphnia magna</td>
<td>57.3 mg/l, 48 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50 Fish</td>
<td>Bluegill (Lepomis macrochirus) Oncorhynchus mykiss</td>
<td>716 mg/l, 96 hr</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Terrestrial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50 Other</td>
<td>Duck</td>
<td>&gt; 4710 ppm, 5 day Anas platyrhynchos (Mallard), Dietary</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MIC Other</td>
<td>Quail</td>
<td>&gt; 4820 ppm, 5 day Colinus virginianus (Bobwhite), Dietary</td>
</tr>
</tbody>
</table>

Material name: Pulmotil AC
4822 Version #: 05 Revision date: 03-28-2019 Issue date: 08-19-2014
### 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

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tilmicosin</td>
<td>280 µg/l, (Lilly Aquatic Exposure Guideline)</td>
</tr>
</tbody>
</table>

#### Chronic Exposure of Aquatic Organisms

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tilmicosin</td>
<td>54 µg/l, (Lilly Aquatic Exposure Guideline)</td>
</tr>
</tbody>
</table>

#### Acute Exposure of Aquatic Organisms

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tilmicosin</td>
<td>354 µg/l, (Lilly Aquatic Exposure Guideline)</td>
</tr>
</tbody>
</table>

### 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 with restrictions.
  - Cargo aircraft only: Allowed with restrictions.

#### IMDG

- **UN number**: UN3082
- **UN proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (TILMICOSIN PHOSPHATE) (Tilmicosin)
- **Transport hazard class(es)**
  - **Class**: 9
  - **Subsidiary risk**: -
  - **Packing group**: III
  - **Environmental hazards**: Yes
  - **Marine pollutant**: Yes
Special precautions for user
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
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.

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)
Classified hazard categories
Serious eye damage or eye irritation
Respiratory or skin sensitization
Specific target organ toxicity (single or repeated exposure)

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.

Material name: Pulmotil AC
4822 Version #: 05 Revision date: 03-28-2019 Issue date: 08-19-2014
International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*“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               03-28-2019
Version #                   05

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