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]-p-hosphate (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
- Address: 2500 Innovation Way, Greenfield, IN 46140, US
- Phone: 1-877-Elanco1 (1-877-352-6261)
- Email: lilly_msds@lilly.com
- Emergency Telephone: 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

<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>30</td>
</tr>
<tr>
<td>Other components below reportable levels</td>
<td></td>
<td></td>
<td>70</td>
</tr>
</tbody>
</table>

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)
Soluble.

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.

Material name: Micotil 300
4899 Version #: 03 Revision date: 03-03-2015 Issue date: 08-15-2014
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.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micotil 300</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>Rabbit</td>
<td>0.5 ml/kg No mortality. No toxicity.</td>
</tr>
<tr>
<td>LD</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Inhalation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC</td>
<td>Rat</td>
<td>2750 mg/m3, 4 hr No mortality.</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monkey</td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>Swine</td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>318 mg/kg Subcutaneous: reduced activity, leg weakness, hunched posture.</td>
</tr>
</tbody>
</table>

**Components**
Tilmicosin Phosphate (CAS 137330-13-3)

| **Acute** |         |              |
| Dermal   | Rabbit  | > 5000 mg/kg |
| LD       |         |              |
| **Inhalation** |   | 3800 mg/m3, 4 h |
| LC50     | Rat     |              |
| **Oral** |         | 855 mg/kg (fasted) |
| 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. (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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.

Reproductive toxicity
Slight increase in offspring mortality at maternally toxic doses. (Tilmicosin Phosphate)

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.

<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></td>
<td>LC50</td>
<td>&gt; 918 mg/kg, 28 day (Earthworm (Eisenia fetida))</td>
</tr>
<tr>
<td>Other</td>
<td>LC50</td>
<td>&gt; 4710 ppm, 5 day Anas platyrhynchos (Mallard), Dietary</td>
</tr>
<tr>
<td></td>
<td>Duck</td>
<td>&gt; 4820 ppm, 5 day Colinus virginianus (Bobwhite), Dietary</td>
</tr>
<tr>
<td></td>
<td>Quail</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MIC</td>
<td>&gt; 1000 mg/l Mold (Aspergillus flavus)</td>
</tr>
<tr>
<td></td>
<td>Micro-organisms</td>
<td>&gt; 1000 mg/l Fungus (Chaetomium globosum)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>250 mg/l Soil bacteria (Comamonas acidovaorans)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 mg/l N-fixing bacteria (Azotobacter chroococcum)</td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algae</td>
<td>EC50</td>
<td>0.354 mg/l (Selenastrum capricornutum, average specific growth rate)</td>
</tr>
<tr>
<td></td>
<td>MIC</td>
<td>0.5 mg/l (Blue-green algae)</td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>57.3 mg/l, 48 hours</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>716 mg/l, 96 hr</td>
</tr>
<tr>
<td></td>
<td>Bluegill (Lepomis macrholirus)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oncorhynchus mykiss</td>
<td>851 mg/l, 96 hours</td>
</tr>
</tbody>
</table>
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

IATA; IMDG

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

<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>

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

Revision Information
Physical & Chemical Properties: Multiple Properties
Regulatory Information: Other
Other information, including date of preparation or last revision: Disclaimer
GHS: Classification