



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-piperidinyl]-, phosphate (1:1) (salt) * Tilmicosin Formulation * Tilmicosin Phosphate Formulation |
| 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 | 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. |
| 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 mist or vapor. |
| P284 | In case of inadequate ventilation wear respiratory protection. |
| P272 | Contaminated work clothing should not be allowed out of the workplace. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| Response | |
| P304 + P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| P342 + P311 | If experiencing respiratory symptoms: Call a POISON CENTER/doctor. |
| P362 + P364 | Take off contaminated clothing and wash it before reuse. |
| 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 |

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 | 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 | (Micotil 300) 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. (Tilmicosin Phosphate) 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. |
| 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. Dry chemical. 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. 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.

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

Biological limit values

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

Exposure guidelines

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

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.

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 | No data available. |

10. Stability and reactivity

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|------------------------------------|--|
| Reactivity | Not water reactive. |
| 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

| Product | Species | Test Results |
|--------------|---------|---|
| Micotil 300 | | |
| <u>Acute</u> | | |
| 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. |

| Product | Species | Test Results |
|---------|---------|--|
| | 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 Slightly irritating to the eyes of rabbits. Based on available data, the classification criteria are not met. |
| 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. Due to lack of data the classification is not possible. |
| 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 | 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.

| Components | Species | | Test Results |
|------------------------------|---------|--------------------------------|---|
| Tilmicosin (CAS 108050-54-0) | | | |
| <i>Acute</i> | LC50 | | > 918 mg/kg, 28 day (Earthworm (Eisenia fetida)) |
| Other | 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 |
| Terrestrial | | | |
| <i>Acute</i> | | | |
| | LC50 | Duck | > 4710 ppm, 5 day Anas platyrhynchos (Mallard), Dietary |
| Other | LC50 | Quail | > 4820 ppm, 5 day Colinus virginianus (Bobwhite), Dietary |

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 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 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

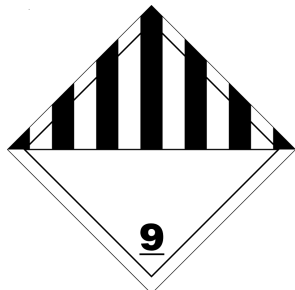
UN number UN3082
UN proper shipping name Environmentally hazardous substance, liquid, n.o.s. (TILMICOSIN PHOSPHATE)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards Yes
ERG Code 9L
Special precautions for user Not available.
Other information
Passenger and cargo aircraft Allowed with restrictions.
Cargo aircraft only Allowed with restrictions.

IMDG

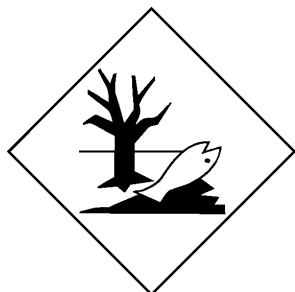
UN number UN3082
UN proper shipping name Environmentally hazardous substances, liquid, n.o.s. (TILMICOSIN PHOSPHATE)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards
Marine pollutant Yes
EmS F-A, S-F
Special precautions for user Not available.

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.

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)**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.

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 03-19-2019

Version # 12

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 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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