Elanco Animal Health
Material Safety Data Sheet

Section 1 - Chemical Product and Company

Manufacturer:
Elanco Animal Health
Division of Eli Lilly and Company
Four Parkwood, Suite 125
500 East 96th Street
Indianapolis, IN 46240

Emergency Phone:
1-317-276-2000

CHEMTREC:
1-800-424-9300 (North America)
1-703-527-3887 (International)

Common Name: Tylan Soluble

CAS Number(s): 1405-54-5
Chemical Name: Tylosin, (2R,3R)-2,3-dihydroxybutanedioate (salt)
Chemical Family: Macrolide antibiotic
Chemical Formula: C46 H77 N O17 . x C4 H6 O6
Molecular Weight: 1066.2
Synonym(s): Tylosin Tartrate; Tylosin; 027892 Tartrate; Tylosin Tartrate Soluble; EL-810; EL810; Elanco-T 20
Tradename(s): Tylan
Lilly Serial Number(s): 029510
Lilly Item Code(s): AF1300; AF1310; AF1313; AF1317; AF1320; PO378

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

<table>
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<tr>
<th>Ingredient</th>
<th>CAS</th>
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<td>Tylosin Tartrate</td>
<td>1405-54-5</td>
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Exposure Guidelines: LEG <100 micrograms/m3 TWA for 12 hours.

Section 3 - Hazards Identification

Appearance: Light to medium yellow granular powder
Physical State: Solid
Odor: Odorless
Emergency Overview

Emergency Overview Effective Date: 15-Jan-1999

Lilly Laboratory Labeling Codes:
Health 2  Fire 1  Reactivity 0  Special A

Primary Physical and Health Hazards: Irritant (eyes). Severe Allergen.

Caution Statement: Tylan Soluble is tylosin tartrate, may be irritating to the eyes, and is classified as a severe allergen because repeated unprotected exposures are likely to cause allergic reactions.

Routes of Entry: Inhalation and skin contact.

Potential Signs and Symptoms of Occupational Exposure: Allergic reactions to tylosin in a manufacturing setting have been reported. Allergy symptoms may include skin rash, watery eyes, shortness of breath, nasal congestion, coughing, and wheezing. Based on animal data, may be irritating to the eyes.

Medical Conditions Aggravated by Exposure: Hypersensitivity to tylosin.

Carcinogenicity: Tylosin - Not listed by IARC, NTP, ACGIH, or OSHA. Not considered carcinogenic in animal studies conducted by Lilly Research Laboratories.

Section 4 - First Aid Measures

Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Section 5 - Fire Fighting Measures
Flash Point: NA
UEL: NAIF
LEL: No ignition up to 0.605 oz/cu ft

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

Additional Information: Minimum Ignition Temperature of Dust Layer: 380 C (716 F)

Section 6 - Accidental Release Measures

Spills: Contain dry material by lightly misting with water, followed by sweeping up or vacuuming. Vacuuming may disperse dust if appropriate dust collection filter is not part of the vacuum. Be aware of potential for dust explosion when using electrical equipment. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

Section 7 - Handling and Storage

Storage Conditions: Store in a cool, dry place. Protect from moisture and heat. Product should not be used after the date printed on the container.

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information. When mixing and handling, use protective clothing, impervious gloves, and dust respirator. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse with plenty of water.

Respiratory Protection: Use an approved respirator.

Eye Protection: Chemical goggles and/or face shield.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: 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.

Other Handling Precautions: In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

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
Section 9 - Physical and Chemical Properties

Boiling Point: NA
Melting Point: NA
Specific Gravity: NA
pH: 4.5 - 7.2 (aqueous 50/50)
Evaporation Rate: NA
Water Solubility: Soluble
Vapor Density: NA
Vapor Pressure: NA

Section 10 - Stability and Reactivity

Stability: Stable at normal temperatures and pressures.

Incompatibility: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

Hazardous Decomposition: May emit toxic fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Animal Toxicity Data Single Exposure

Oral: Rat, 6200 mg/kg, no deaths or toxicity.

Skin: Rabbit, 2000 mg/kg, no deaths or toxicity.

Inhalation: Rat, 600 mg/m3 for 1 hour, no deaths.

Skin Contact: Rabbit, slight irritant

Eye Contact: Rabbit, irritant

Animal Toxicity Data Repeat Exposure

No data are available for Tylan Soluble. Toxicity data for tylosin base are presented.

Target Organ Effects: Tylosin base - No effects identified in animal studies.

Other Effects: Tylosin base - Salivation, diarrhea, vomiting.

Reproduction: Tylosin base - No effects identified in animal studies.

Sensitization: Tylosin base - Guinea pig, positive contact sensitizer.
Mutagenicity: Tylosin base - Mutagenic in one mammalian test system. Not mutagenic in bacterial cell tests and other mammalian cell tests. Unlikely to pose a genotoxic risk to man.

Section 12 - Ecological Information

No data are available for this material. Ecological data for tylosin base are presented.

Ecotoxicity Data: Tylosin base
Rainbow trout 96-hour median lethal concentration: > 300 mg/L
Bluegill 96-hour median lethal concentration: > 300 mg/L
Daphnia magna 48-hour median effective concentration: > 300 mg/L
Bobwhite 14-day oral median lethal concentration: > 2000 mg/kg
Bobwhite 5-day dietary median lethal concentration: > 5000 ppm
Mallard 5-day dietary median lethal concentration: > 5000 ppm
Earthworm 28-day median lethal concentration: > 102.6 mg/kg

Environmental Fate: Tylosin base
Log Kow: 1.7
Water solubility (g/L): 5
Light absorption in ethanol (nm): 282
Soil degradation half-life (days): 62 for tylosin factor A, 37 for tylosin factor D
Soil leaching: none measured

Environmental Summary: Tylosin base - Practically nontoxic to fish, birds, earthworms, and aquatic invertebrates. No volatility expected. Not expected to bioconcentrate in aquatic organisms. Low mobility in soil. Not persistent in the environment due to degradation and possible photolysis.

Lilly Aquatic Exposure Guideline (LAEG): Tylosin base
LAEG for Drinking Water: 36 micrograms/L
LAEG for Chronic Exposure of Aquatic Organisms: 2500 micrograms/L
LAEG for Acute Exposure of Aquatic Organisms: 5000 micrograms/L

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Container Disposal: No special package disposal required.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated
ICAO/IATA: Not Regulated
IMO: Not Regulated
Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Elanco Animal Health usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:
Tylosin tartrate
TSCA - No
CERCLA - Not on this list.
SARA 302 - Not on this list.
SARA 313 - Not on this list.
OSHA Substance Specific - No

NADA Number: 13-076

EC Classification and Risk and Safety Phrases:
EC Classification:
Xi (Irritant)

Risk Phrases:
R 36/37/38 - Irritating to eyes, respiratory system and skin.
R 42/43 - May cause sensitization by inhalation and skin contact.

Safety Phrases:
S 22 - Do not breathe dust.
S 24/25 - Avoid contact with skin and eyes.
S 26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

Section 16 - Other Information

MSDS Sections Revised: Section 1.

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
1-800-428-4441
GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association
BEI = Biological Exposure Index
CAS Number = Chemical Abstract Service Registry Number
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHEMTREC = Chemical Transportation Emergency Center
DOT = Department of Transportation
EC = European Community
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
EPA = Environmental Protection Agency
HEPA = High Efficiency Particulate Air (Filter)
IARC = International Agency for Research on Cancer
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association
IEG = Lilly Interim Exposure Guideline
IMO = International Maritime Organization
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
MSHA = Mine Safety and Health Administration
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline
STEL = Short Term Exposure Limit
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations
WEEL = Workplace Environmental Exposure Level (AIHA)