



Tylan Premix

Effective Date: 18-Nov-2003

Elanco Animal Health Material Safety Data Sheet

Section 1 - Chemical Product and Company

Manufacturer:

Elanco Animal Health
Division of Eli Lilly and Company
2001 West Main St
PO Box 708
Greenfield, IN 46140

Manufacturer's Emergency Phone:

1-800-428-4441

CHEMTREC:

1-800-424-9300 (North America)

1-703-527-3887 (International)

Common Name: Tylan Premix

Chemical Name: Tylosin, phosphate (salt)

Synonym(s): 033840 Formulation; Tylosin Premix; Tylosin Phosphate Premix

Trademarks(s): Tylan 10 Premix; Tylan 20 Premix; Tylan 40 Premix; Tylan 50 Premix; Tylan 80 Premix; Tylan 100 Premix; Tylan

Lilly Item Code(s): AF0010; AF0020; AF0024; AF0026; AF0040; AF0042; AF0050; AF0055; AF0080; AF0090; AF0091; AF0099; AF0105; AH0042; MS8272; MS8274; MS8275; UC5318

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

Ingredient	CAS	Concentration %
Tylosin Phosphate	1405-53-4	1.7 - 24
Excipients	NA	75 - 95
Anti-dusting Oil	NAIF	1 - 2

Excipients may include rice hulls, soybean mill run, soybean feed, starch, or limestone.

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

Exposure Guidelines: Tylosin phosphate - LEG <100 micrograms/m³ TWA for 12 hours.

Grain dust - PEL 10 mg/m³ TWA. TLV 4 mg/m³ TWA for 8 or 12 hours (total). Lilly preferred exposure limit is TLV.

UK - Maximum Exposure Limit 10 mg/m³ TWA (total) (Sens).

Ireland - Occupational Exposure Limit 10 mg/m³ TWA (Sens).

Limestone dust - PEL 5 mg/m³ TWA (respirable) and 15 mg/m³ TWA (total). TLV 10 mg/m³ TWA.

UK - Exposure Standard 4 mg/m³ TWA (respirable) and 10 mg/m³ TWA (total).

Ireland - Occupational Exposure Limit 4 mg/m³ TWA (respirable) and 10 mg/m³ TWA (total).

France - Occupational Exposure Limit 10 mg/m³ (VME) TWA.

The anti-dusting oil reduces potential exposure under normal conditions of use.

Section 3 - Hazards Identification

Appearance: Light tan granular meal

Physical State: Solid

Odor: Musty

Emergency Overview



Special
A = Allergen

Emergency Overview Effective Date: 27-Nov-2001

Lilly Laboratory Labeling Codes:

Health 2

Fire 1

Reactivity 0

Special A

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

Caution Statement: Tylan Premix contains tylosin phosphate, 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.

Effects of Overexposure: 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. Prolonged exposure to high concentrations of grain dust or limestone dust may cause irritation of the respiratory tract and mucous membranes.

Medical Conditions Aggravated by Exposure: Hypersensitivity to tylosin.

Carcinogenicity: Tylosin base - 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: Not applicable

UEL: No applicable information found

LEL: No applicable information found

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.

Section 6 - Accidental Release Measures

Spills: Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). 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. Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping.

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.

Additional Exposure 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 handling.

Section 9 - Physical and Chemical Properties

Appearance: Light tan granular meal

Odor: Musty

Boiling Point: Not applicable

Melting Point: Not applicable

Specific Gravity: Not applicable

pH: No applicable information found

Evaporation Rate: No applicable information found

Water Solubility: Insoluble

Vapor Density: No applicable information found

Vapor Pressure: No applicable information found

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

Acute Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

Oral: 22% Tylosin phosphate mixture - Rat, 500 mg/kg, no deaths or toxicity.

Skin: 22% Tylosin phosphate mixture - Rabbit, 2000 mg/kg, no deaths or toxicity.

Inhalation: Tylosin base - Rat, 2060 mg/m³ for 1 hour, no deaths or toxicity.

Skin Contact: 22% Tylosin phosphate mixture - Rabbit, nonirritant

Eye Contact: 22% Tylosin phosphate mixture - Rabbit, irritant

Chronic Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

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

Other Effects: Tylosin base - Salivation, diarrhea, and vomiting after repeated large oral doses.

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 environmental data for the mixture or formulation. The environmental information for ingredient(s) or related material(s) 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 14-day median lethal concentration: > 102.6 mg/kg

Green algae (*P. subcapitata*) 72-hour median effective concentration (growth): 0.22 mg/L

Seedling median effective concentration (growth): 43 mg/kg (tomato); 53 mg/kg (soybean); 140 mg/kg (oat)

Environmental Fate: Tylosin base

Water Solubility (g/L): 5

Kow (pH 5, 7, 9): 5, 17, 17

Koc: 200 (sandy loam, pH 4.6); 1652 (silt loam, pH 5.7); 2233 (sandy loam; pH 7.6)

UV-visible light absorption (nm): 282

Soil degradation half-life (100 ppm): 62 days (tylosin factor A); 37 days (tylosin factor D)

Soil degradation half-life (1 mg/kg; 4 soils): 50.3 to 105 days

Leaching in soil column: none

Environmental Summary: Tylosin base - Practically nontoxic to fish, birds, earthworms, and aquatic invertebrates. Highly toxic to algae. 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: 99 micrograms/L

LAEG for Acute Exposure of Aquatic Organisms: 220 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: Packages may be burned or buried in accordance with environmental standards.

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 phosphate

TSCA - No

CERCLA - Not on this list.

SARA 302 - Not on this list.

SARA 313 - Not on this list.

OSHA Substance Specific - No

EU Regulations

EC Classification

Contains tylosin phosphate (C = 17 to 24%)

Xn (Harmful)

Xi (Irritant)

Risk Phrases

R 36 - Irritating to eyes.

R 42/43 - May cause sensitization by inhalation and skin contact.

Safety Phrases

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: Sections 1 and 16.

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

1-317-276-2000

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)

CHAN = Chemical Hazard Alert Notice

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
Kow = Octanol/Water Partition Coefficient
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)