



Tylan Injection

Effective Date: 24-Mar-2005

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 Injection

Chemical Name: Tylosin

Synonym(s): Tylosin; Tylosin Base; 027892 Formulation

Trademarks(s): Tylan 200 Injection; Tylan 50 Injection; Tylan

Lilly Item Code(s): AF1400; AF1401; AF7200; AF7202; AH0137; AH0205; AH0206; UC5071; UC5072; UC5080; UC5104; UC5113; UC5114; UC5119; UC5120; UC5121; UC5122; UC5124; UC5125; UC5201; UC5202; UC5203; UC5204; UC5205; UC5206; UC5211; UC5212; UC5213; UC5214; UC5215; UC5216; UC5217; UC5218; UC5219; UC5220; UC5221; UC5222; UC5223; UC5224; UC5225; UC5226; UC5228; UC5229; UC5230; UC5231; UC5232; UC5233; UC5234; UC5235; UC5236; UC5237; UC5238; UC5239; UC5240; UC5241; UC5247; UC5248; UC5249; UC5250; UC5251; UC5252; UC5253; UC5254; UC5255; UC5256; UC5257; UC5258; UC5259; UC5260; UC5261; UC5262; UC5263; UC5264; UC5265; UC5266; UC5267; UC5268; UC5269; UC5271; UC5273; UC5276; UC5277; UC5278; UC5280; UC5283; UC5284; UC5285; UC5286; UC5287; UC5288; UC5289; UC5298

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

Ingredient	CAS	Concentration %
Tylosin Base	1401-69-0	5 - 20
Propylene Glycol	57-55-6	40 - 52
Benzyl Alcohol	100-51-6	2 - 5
Water	7732-18-5	25 - 37

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater)

not listed above.

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

Propylene glycol - WEEL 50 ppm TWA (total vapor and aerosol), 10 mg/m³ (aerosol only) TWA for 8 hours.

UK - Exposure Standard 10 mg/m³ TWA (particulates), 150 ppm (474 mg/m³) TWA (vapor and particulates).

Ireland - Occupational Exposure Limit 10 mg/m³ TWA (particulates) 150 ppm (470 mg/m³) TWA (total vapor and particulates).

Benzyl alcohol - WEEL 10 ppm (44.2 mg/m³) TWA.

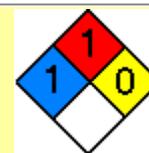
Section 3 - Hazards Identification

Appearance: Yellow viscous solution

Physical State: Liquid

Odor: Faint musty

Emergency Overview



Special
A = Allergen

Emergency Overview Effective Date: 19-Jan-2000

Lilly Laboratory Labeling Codes:

Health 1

Fire 1

Reactivity 0

Special A

Primary Physical and Health Hazards: Severe Allergen.

Caution Statement: Tylan Injection contains tylosin base 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. Accidental injection may cause pain and swelling at the site accompanied by anxiety. No lasting ill effects have been reported. May be slightly irritating to the eyes and skin.

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.

Benzyl alcohol - Not listed by IARC, NTP, ACGIH, or OSHA. Two-year carcinogenicity studies conducted by NTP demonstrated no evidence of carcinogenicity in mice and rats.

Propylene glycol - Not listed by IARC, NTP, ACGIH, or OSHA. Multiple long term dietary, inhalation, and dermal studies demonstrated no evidence of carcinogenicity in mice, rabbits, or rats.

Section 4 - First Aid Measures

Eyes: Flush eyes with plenty of water. Get medical attention.

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.

Additional Information: Accidental Injection: For accidental injection no specific treatment is needed other than symptomatic. Treat wound if necessary and consider need for tetanus immunization.

Section 5 - Fire Fighting Measures

Auto Ignition: 412 C (774 F)

Flash Point: No applicable information found

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: None known.

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

Section 6 - Accidental Release Measures

Spills: Do not contaminate any body of water. Clean up spill using suitable absorbent material. Place it and damaged unusable containers in landfill in accordance with applicable regulations. 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.

Section 7 - Handling and Storage

Material Handling Precautions: Do not mix with other injectable solutions as this may cause precipitation of the active ingredients. Do not administer to horses or other equines. Injection of tylosin in equines has been fatal.

Storage Conditions: Store at 22 C (72 F) or below. 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.

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: Yellow viscous solution

Odor: Faint musty

Boiling Point: No applicable information found

Melting Point: Not applicable

Specific Gravity: 1.09

pH: 8-10

Evaporation Rate: No applicable information found

Water Solubility: Soluble

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

Toxicity data for a 20% tylosin base formulation with propylene glycol and benzyl alcohol are presented.

Oral: 20% Tylosin base mixture - Rat, 535 mg/kg, no deaths or toxicity.

Skin: 20% Tylosin base mixture - Rabbit, 2140 mg/kg, no deaths or toxicity.

Inhalation: 20% Tylosin base mixture - Rat, 1050 mg/m³ for 1 hour, no deaths.

Skin Contact: 20% Tylosin base mixture - Rabbit, slight irritant

Eye Contact: 20% Tylosin base mixture - Rabbit, slight irritant

Chronic Exposure

Toxicity data for tylosin base are presented.

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

Propylene glycol - No significant adverse effects were reported in monkeys exposed to saturated vapor for 18 months or dogs administered 2000 mg/kg for 2 years.

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

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

Propylene glycol - In animal studies, has been shown not to interfere with reproduction.

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.

Propylene glycol - In vitro mutagenicity studies were negative. Animal mutagenicity studies were negative.

Section 12 - Ecological Information

No environmental data for the mixture or formulation. The environmental information for ingredient(s) or related material(s) are presented.

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.

Propylene glycol - Practically non-toxic to aquatic organisms. Material is not expected to bioconcentrate in aquatic organisms. Material may leach from soil into groundwater. Material is expected to be degraded by microorganisms. Biodegradation is expected to be achievable in secondary waste water treatment plant. Material is not expected to readily evaporate; however, once in the atmosphere it is expected to rapidly degrade (within minutes to hours).

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: 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

TSCA - No

CERCLA - Not on this list.

SARA 302 - Not on this list.

SARA 313 - Not on this list.

OSHA Substance Specific - No

NADA No. 12-965

Remaining Ingredients

TSCA - Yes

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

Xn (Harmful)

Risk Phrases

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

Safety Phrases

S 36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

Section 16 - Other Information

MSDS Sections Revised: Sections 1, 2, and 7

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)