



**MATERIAL SAFETY DATA SHEET  
TYLAN 200 INJECTION**

**AH0206**

Revision 3.6, 22 November 2006

**STATEMENT OF HAZARDOUS NATURE:**

"Hazardous according to criteria of Worksafe Australia"  
Irritant; R43 May cause sensitisation by skin contact.

**Company Name and Address:**

Elanco Animal Health  
A Division of Eli Lilly Australia Pty Ltd  
A.B.N. 39 000 233 992  
112 Wharf Road, West Ryde, N.S.W. 2114, Australia

**Contact Numbers:**

Tel: (02) 9878 7777  
Fax: (02) 9878 7720

**Emergency Telephone Numbers:**

Elanco Animal Health:  
1800 226 324 (Toll free)  
OR  
Poisons Information Centre:  
131126 (Australia-wide)

24 hour emergency contact number, CHEMWATCH **1800 039 008** ( spills and accidents)

**Section 1 - Identification**

Product Name: ElancoAH0206 Tylan 200 Tylosin Injection 200 mg/mL

Other Names: Tylosin, Tylan Injection

Manufacturer's Product Code: AH0206

UN Number: None allocated

Dangerous Goods Class/Subsidiary Risk: None allocated

Hazchem Code: None allocated

Poisons Schedule Number: S4

Pack Size and Container Type: Multidose vial of 100 mL in 50% propylene glycol

**Use:**

Major Recommended Uses: For the treatment of tylosin susceptible bacterial and mycoplasmal infections in cattle and pigs.

Major Recommended Method(s) of Application: Inject intramuscularly or by slow intravenous injection.

## Section 2 - Composition / Information on Ingredients

Ingredient	CAS	Concentration %
Tylosin Base	1401-69-0	20
Benzyl Alcohol	100-51-6	4
Propylene Glycol	57-55-6	50
Water	7732-18-5	26

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/m<sup>3</sup> TWA for 12 hours.  
 Propylene glycol - WEEL 50 ppm (total vapour and aerosol), 10 mg/m<sup>3</sup> (aerosol only) TWA for 8 hours.  
 Benzyl alcohol - WEEL 10 ppm (44.2 mg/m<sup>3</sup>) TWA.

## Section 3 - Hazards Identification

Appearance: Yellow viscous solution

Physical State: Liquid

Odor: Faint, musty

Emergency Overview

Primary Physical and Health Hazards: Severe Allergen.

Caution Statement: TYLAN 200 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.

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. Accidental injection may cause pain and swelling at the site accompanied by anxiety. No lasting ill effects have been reported. Based on animal data for a 20% tylosin base mixture, may be slightly irritating to the eyes and skin.

Medical Conditions Aggravated by Exposure: Hypersensitivity to tylosin.

Carcinogenicity: Tylosin - Not listed by IARC, NTP, ACGIH, or OSHA. Not considered to be 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 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 Poisons Information Centre. Phone 13 1126 (Australia-wide). 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. Large spills due to traffic accidents, etc., should be reported immediately to 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**

**Handling Precautions:** Do not mix TYLAN 200 Injection 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:** Store below 25°C (Air Conditioning). Use all product within 90 days of opening and discard any unused portion.

## **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.

**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 handling.

## **Section 9 - Physical and Chemical Properties**

**Appearance:** Yellow viscous solution

**Odour:** 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

### Animal Toxicity Data Single 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/m<sup>3</sup> for 1 hour, no deaths.

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

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

### Animal Toxicity Data Repeat 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 vapour for 18 months or dogs administered 2000 mg/kg for 2 years.

Other Effects: Tylosin base - Salivation, diarrhea, and 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**

Disposal of containers and needles: Dispose of empty container by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled "sharps" container.

## **Section 14 - Transport Information**

No special transport requirements necessary.

## **Section 15 - Other Information**

Sections revised: Header and Footer: Removed automatic print date from header. Pagination changed to page number only. Added CHEMWATCH contact details.. Section 15: Deleted contact point details.

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.

## 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  
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)