



Tylan 200 for Injection

Effective Date: 20 September 2011

Section 1 – Identification of the substance and supplier

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| Product Name: | Tylan 200 Injection |
| Manufacturer's Product Code: | AH0206 |
| UN number: | N/A |
| Proper Shipping Name: | N/A |
| Pack Size: | 100ml |
| Recommended use: | An injectable antibiotic for cattle, pigs, sheep and goats. |

NEW ZEALAND COMPANY DETAILS:

Elanco Animal Health
 (Division of Eli Lilly & Company (NZ) Limited)
 Level 1, 123 Ormiston Road
 Botany Junction, Auckland 2016
 Telephone: 09 523 9320
 (Mon-Fri, 8.30am – 5.00pm)
 0800 ELANCO (0800 352 626)
www.elanco.co.nz

NEW ZEALAND EMERGENCY PHONE:

National Poisons Centre:
 0800 POISON (0800 764 766)
 24 hours

CHEMCALL:
 0800 CHEMCALL (0800 243 622)
 24 hours

Section 2 - Hazards Identification

Classified as a hazardous substance according to the criteria in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001.

Tylan 200 for Injection is approved pursuant to the HSNO Act 1996, HSR002368. The EPA website www.epa.govt.nz should be consulted for the full list of triggered controls and cited regulations.

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| HSNO Classifications: | 6.4A Eye irritant |
| | 6.5B Skin allergen |
| | 9.1A Aquatic ecotoxin |
| | 9.2D Soil ecotoxin |

Signal word: WARNING

Hazard Statements: Causes eye irritation
 May cause an allergic skin reaction

Very toxic to aquatic life
Harmful to the soil environment

Precautionary Statements: Wear protective gloves, clothing, eye and face protection when handling
Wash hands and exposed skin thoroughly after handling
Contaminated work clothing should not be allowed out of the workplace
Wash contaminated clothing before reuse
Avoid release to the environment
Collect spillage
Read label before use
Keep out of reach of children

Section 3 - Composition / Information on Ingredients

| Chemical Name | CAS-No. | 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 |

Tylosin base:

Chemical Name: Tylosin
Alternate Chemical Name: Tylosin base

Section 4 - First Aid Measures

TREATMENT:

If swallowed: 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.

If inhaled: 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.

If on 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.

If in eyes: Rinse cautiously with water for several minutes.

Additional information: Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
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

Flash point: Not applicable
Lower explosion limit: Not known
Upper explosion limit: Not known
Auto-ignition: 412°C (774°F)
Suitable extinguishing media: Use water, carbon dioxide, dry chemical, foam, or Halon
Unsuitable extinguishing media: None known
Unusual Fire and Explosion Hazards: None known
Fire fighting precautions: May emit toxic fumes when exposed to heat or fire.
Hazchem code: N/A

Section 6 - Accidental Release Measures

Protective clothing and equipment: Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).
Environmental precautions: Prevent further migration into the environment. Do not allow material to enter waterways.
Procedure: Use absorbent material to solidify liquid. Sweep up or vacuum.
Emergency response assistance: For specialist advice in an emergency call 0800 CHEMCALL (0800 243 622) and Elanco Animal Health for assistance

Section 7 - Handling and Storage

Storage instructions: Keep out of reach of children. Store below 30°C.
Handling precautions: Wash hands and exposed skin thoroughly after handling.

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| 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. |
| Emergency response plan required: | 100L |
| Emergency containment required: | 100L |
| Signage required: | 100L |
| Approved Handler: | Not required |
| Packaging requirements: | Packing group III |

Section 8 - Exposure Controls / Personal Protection

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| Exposure limits or guidelines: | Tylosin base: LEG <math><100 \mu\text{g}/\text{m}^3\text{ TWA}</math> (12h) |
| | Propylene glycol: WEEL 50ppm TWA (total vapour and aerosol) 10 mg/m ³ TWA (8h) (aerosol only) |
| | Benzyl alcohol: WEEL 10ppm (44.2 mg/m ³) TWA |
| Engineering measures: | 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. |
| Personal protective equipment: | In a manufacturing setting, use protective clothing, impervious gloves, and approved respirator. Chemical goggles and/or face shield. 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

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| Appearance: | Yellow viscous solution |
| Physical state: | Liquid |
| Odour: | Faint musty |
| Boiling point: | No applicable information found |

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| pH: | 8.0 – 10.0 |
| Solubility: | Soluble |
| Specific Gravity: | 1.09 |
| Flammability: | Not flammable |

Section 10 - Stability and Reactivity

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| Stability: | Stable at normal temperatures and pressures |
| Conditions to avoid: | None known |
| Incompatible materials: | May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.). |
| Hazardous decomposition products: | May emit toxic fumes when heated to decomposition |
| Hazardous reactions | Hazardous polymerisation does not occur |

Section 11 - Toxicological Information

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

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| Acute oral toxicity | 20% Tylosin base mixture: | Rat, 535 mg/kg, no deaths or toxicity |
| Acute inhalation toxicity | 20% Tylosin base mixture: | Rat, 1050 mg/m ³ for 1 hour, no deaths |
| Acute dermal toxicity | 20% Tylosin base mixture: | Rabbit, 2140 mg/kg, no deaths or toxicity |
| Skin irritation | 20% Tylosin base mixture: | Rabbit, slight irritant |
| Eye irritation | 20% Tylosin base mixture: | Rabbit, slight irritant |
| Sensitisation | Tylosin base: | Guinea pig, positive contact sensitizer |
| Repeated dose toxicity | Tylosin base: | No effects identified in animal studies. Other effects salivation, diarrhoea, vomiting. |
| | Propylene glycol: | No significant effects were reported in monkeys exposed to saturated vapour for 18 months or dogs administered 2000mg/kg for 2 years |
| Reproductive toxicity | Tylosin base: | No effects identified in animal studies |
| | Propylene glycol: | In animal studies, has been shown not to interfere with reproduction |

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| Carcinogenicity | Tylosin base: | Not considered carcinogenic in animal studies conducted by Lilly Research Laboratories |
| | Propylene glycol: | Multiple long term dietary, inhalation, and dermal studies demonstrated no evidence of carcinogenicity in mice, rabbits, or rats. |
| | Benzyl alcohol: | Two-year carcinogenicity studies conducted by NTP demonstrated no evidence of carcinogenicity in mice and rats. |
| 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 data available for mixture. Data for ingredients or related materials are presented.

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| Toxicity to fish | Tylosin base: LC ₅₀ / 96h / Rainbow Trout : >300 mg/L LC ₅₀ / 96h / Bluegill : >300 mg/L |
| Toxicity to algae | Tylosin base: EC ₅₀ /72h (growth)/ Pseudokirchneriella subcapitata: 0.22 mg/L |
| Toxicity to daphnia | Tylosin base: EC ₅₀ / 48 h / Daphnia magna : >300 mg/L |
| Toxicity to earthworms | Tylosin base: LC ₅₀ / 14d / Earthworm : >102.6 mg/kg |
| Toxicity to birds | Tylosin base: LC ₅₀ / 14d oral / Bobwhite : >2000 mg/kg LC ₅₀ / 5d dietary / Bobwhite : >5000 ppm LC ₅₀ / 5d dietary / Mallard : >5000 ppm |

Any other relevant information available Tylosin base: Seedling median effective concentration (growth): 43 mg/kg (tomato); 53 mg/kg (soybean); 140 mg/kg (oat)

Water Solubility (g/L): 5

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

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

Section 13 - Disposal Considerations

Preferably dispose of product by use. Otherwise dispose of product as part of an approved chemical disposal program. Dispose of packaging at an approved landfill facility.

Section 14 - Transport Information

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| Land Transport | Not regulated |
| Air Transport | Not regulated |
| Sea Transport | Not regulated |
| UN Number | Not assigned |
| Proper Shipping Name | Not assigned |
| DG Class | Not assigned |
| Subsidiary Risk | Not assigned |
| Packing Group | The packaging for this substance must conform to the packaging requirements as specified in Schedule 4 of the Hazardous Substances (Packaging) Regulations 2001 (PS4). |
| HAZCHEM Code | 3Z |
| Marine Pollutant | No |

The maximum quantity of this substance allowed for carriage on public transport is 0.5L.

Section 15 - Regulatory Information

Tylan 200 for Injection is approved pursuant to the ACVM Act 1997 (A907). See www.foodsafety.govt.nz for registration conditions.

A Safety Data Sheet must be provided whenever 1L of Tylan 200 for Injection is sold or supplied.

Section 16 – Other Information

This SDS is effective as of 20 September 2011.

Sections updated or revised:

Formatting of entire document. ACVM website updated.

Due for revision within 5 years.

Further information

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:
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0800 352 626