



SAFETY DATA SHEET

1. Identification

Product identifier	Elanco AH0206 Tylan 200 Tylosin Injection 200 MG/ML
Other means of identification	
Synonyms	Tylosin * Tylosin Base * 027892 Formulation * Tylan 200 Injection * Tylan 50 Injection * Tylan
Item Code	AF1400, AF1401, AF7200, AF7202, AH0137, AH0205, AH0206
Recommended use of the chemical and restrictions on use	
Recommended use	Veterinary Pharmaceutical
Restrictions on use	Not available.
Details of manufacturer or importer	
Manufacturer	
Company name	Elanco Australasia Pty Ltd. ACN: 076 745 198
Address	112 Wharf Road West Ryde, NSW 2114 Australia
Telephone	1800 226 324 (toll free)
e-mail	lilly_msds@lilly.com
Emergency phone number	Elanco Australasia 1800 226 324 (toll free)
24 hr emergency contact number	CHEMWATCH 1800 039 008 (spills and accidents)
24 hr emergency contact number (Local)	CHEMWATCH +61 2 9186 1132 (spills and accidents)

2. Hazard(s) identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

Health hazards

Sensitization, respiratory	Category 1	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Sensitization, skin	Category 1	May cause an allergic skin reaction.

Environmental hazards

Hazardous to the aquatic environment, acute hazard	Category 2	Toxic to aquatic life.
Hazardous to the aquatic environment, long-term hazard	Category 2	Toxic to aquatic life with long lasting effects.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains: Benzyl alcohol, Propylene glycol, Tylosin Base

Hazard pictograms



Signal word Danger

Hazard statements May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention Avoid breathing mist or vapour. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing. In case of inadequate ventilation wear respiratory protection.

Response IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. Wash contaminated clothing before reuse.

Storage Not available.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental label information Not applicable.

2.3. Other hazards None known.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Tylosin Base	1401-69-0	5 - 20
Propylene glycol	57-55-6	40 - 52
Benzyl alcohol	100-51-6	2 - 5

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

Description of necessary first aid measures

Inhalation Move to fresh air. Oxygen or artificial respiration if needed. Call a physician or poison control centre immediately.

Skin contact Wash off with soap and plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if irritation develops and persists.

Eye contact In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion If conscious, give the victim plenty of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control centre immediately.

Personal protection for first-aid responders In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Symptoms caused by exposure Allergic reactions in a manufacturing setting have been reported. Allergy symptoms may include skin rash, watery eyes, shortness of breath, nasal congestion, coughing, and wheezing. Accidental injection may cause pain and swelling at the site accompanied by anxiety.

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

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media Water. Carbon dioxide (CO₂). Dry chemical.

Unsuitable extinguishing media Not available.

Specific hazards arising from the chemical Fire or excessive heat may produce hazardous decomposition products.

Special protective equipment and precautions for fire fighters Wear self-contained breathing apparatus and protective clothing.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Avoid contact with skin, eyes and clothing. Wear suitable protective clothing, gloves and eye/face protection. See Section 8 for personal protective equipment.

For emergency responders Use personal protection recommended in Section 8 of the SDS.

Environmental precautions Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up Small Spillages:
Use absorbent/adsorbent material to solidify liquids. Clean up promptly by sweeping or vacuum.

Large Spillages:
Prevent further migration into the environment. Use absorbent/adsorbent material to solidify liquids. Collect in a non-combustible container for prompt disposal. Local authorities should be advised if significant spillages cannot be contained. Large spills due to traffic accidents, etc., should be reported immediately to CHEMWATCH and Elanco Animal Health for assistance.

Other issues relating to spills and releases Clean up in accordance with all applicable regulations.

7. Handling and storage

Precautions for safe handling Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. Keep away from heat and sources of ignition. Avoid release to the environment.

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.

Conditions for safe storage, including any incompatibilities Store in a cool place below 72F (22C). Keep the container tightly closed and dry. Store away from incompatible materials. Avoid contact with oxidising agents. Do not store in open or unlabelled containers.

8. Exposure controls and personal protection

Control parameters Lilly Exposure Guideline (LEG): <100 mcg/m³ 12 hour TWA (Tylosin Base)

Occupational exposure limits

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m ³	Total vapour and particulates.
		10 mg/m ³	Particulate.
		150 ppm	Total vapour and particulates.

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m ³	Total vapour and particulates.
		10 mg/m ³	Particulate.
		150 ppm	Total vapour and particulates.

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m ³	Total vapour and particulates.
		10 mg/m ³	Particulate.
		150 ppm	Total vapour and particulates.

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines Lilly Exposure Guideline (LEG): <100 mcg/m³ 12 hour TWA (Tylosin Base)

Appropriate engineering controls	Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.
Individual protection measures, for example personal protective equipment (PPE)	
Eye/face protection	Wear goggles/face shield. (AS/NZS 1337)
Skin protection	
Hand protection	Chemical resistant gloves. (AS 2161)
Other	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Respiratory protection	Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor. (AS/NZS 1715)
Thermal hazards	Not available.
Hygiene measures	Use good industrial hygiene practices in handling this material.
	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.
	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.

9. Physical and chemical properties

Appearance	Viscous. Solution.
Physical state	Liquid.
Form	Liquid.
Colour	Yellow.
Odour	Musty.
Odour threshold	No data available.
pH	8.5 - 10
Melting point/freezing point	No data available.
Initial boiling point and boiling range	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	No data available.
Flammability limit - upper (%)	No data available.
Explosive limit - lower (%)	No data available.
Explosive limit – upper (%)	No data available.
Vapour pressure	No data available.
Vapour density	No data available.
Relative density	No data available.
Solubility(ies)	
Solubility (water)	Soluble.
Partition coefficient (n-octanol/water)	Not available.

Auto-ignition temperature 412 °C (773.6 °F)

Decomposition temperature No data available.

Viscosity No data available.

Other physical and chemical parameters

Density No data available.

Explosive properties Not explosive

Oxidising properties No oxidizing properties.

Percent volatile No data available.

Specific gravity 1.09

VOC No data available.

10. Stability and reactivity

Reactivity Not available.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions Hazardous polymerisation does not occur.

Conditions to avoid None known.

Incompatible materials Strong oxidising agents.

Hazardous decomposition products Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information

General information Not available.

11.1. Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

Product	Species	Test results
Elanco AH0206 Tylan 200 Tylosin Injection 200 MG/ML		
Acute		
Dermal		
LD	Rabbit	> 2140 mg/kg 20% Tylosin Base Mixture. No deaths or toxicity.
Inhalation		
LC50	Rat	> 1050 mg/m ³ , 1 hr 20% Tylosin Base Mixture. No deaths.
Oral		
LD	Rat	> 535 mg/kg 20% Tylosin Base Mixture. No deaths or toxicity.

Components	Species	Test results
Benzyl alcohol (CAS 100-51-6)		
Acute		
Dermal		
LD50	Rabbit	2000 mg/kg
Inhalation		
LD50	Rat	> 4178 mg/m ³ , 4 hr
Oral		
LD50	Rabbit	1940 mg/kg
Propylene glycol (CAS 57-55-6)		
Acute		
Dermal		
LD50	Rabbit	22 g/kg

Components	Species	Test results
Oral LD50	Rat	20.8 g/kg
Skin corrosion/irritation	Slightly irritating to the skin of rabbits. (20% formulation) (Tylosin Base) Remaining ingredients: No irritation. Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Rabbit: Slight irritation. (20% formulation) Based on available data, the classification criteria are not met.	
Respiratory sensitisation	Allergic reactions in a manufacturing setting have been reported.. (Tylosin Base)	
Skin sensitisation	Guinea pig: Causes sensitization. (Tylosin Base)	
Germ cell mutagenicity	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. (Tylosin Base) Based on available data, the classification criteria are not met.	
Carcinogenicity	Animal testing did not show any carcinogenic effects. (Tylosin Base) (Benzyl Alcohol) Based on available data, the classification criteria are not met.	
Reproductive toxicity	No effects identified in animal studies. (Tylosin Base) Developmental effects have been reported at doses toxic to the mother. (Benzyl Alcohol) Based on available data, the classification criteria are not met.	
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.	
Specific target organ toxicity - repeated exposure	No effects identified in animal studies. (Tylosin Base)	
Aspiration hazard	No aspiration toxicity classification.	
Mixture versus substance information	Not available.	
Other information	Salivation, diarrhea, and vomiting after repeated large oral doses. (Tylosin Base)	

12. Ecological information

Components	Species	Test results
Ecotoxicity	Toxic to aquatic life with long lasting effects.	
Benzyl alcohol (CAS 100-51-6)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 230 mg/l, 48 hr
Fish	LC50	Fathead minnow (Pimephales promelas) 460 mg/l, 96 hours
Propylene glycol (CAS 57-55-6)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 43500 mg/l, 48 hours
Fish	LC50	Rainbow trout,donaldson trout (Oncorhynchus mykiss) 51600 mg/l, 96 hours
Tylosin Base (CAS 1401-69-0)		
<i>Acute</i>		
	EC50	140 mg/kg (Oats, seedling) 53 mg/kg (Soybean, seedling) 43 mg/kg (Tomato, seedling)
	LC50	> 102.6 mg/kg, 14 days (Eisenia fetida, earthworm)
Other	EC50	Pseudokirchnerella subcapitata 0.22 mg/l, 72 hours (green algae) (average specific growth rate)
	LC50	Duck > 5000 mg/kg, 5 days (Anas platyrhynchos, Mallard) (Dietary)

Components	Species	Test results
	Quail	> 5000 mg/kg, 5 days (Bobwhite) (Dietary) > 2000 mg/kg, 14 days (Bobwhite)
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Daphnia magna > 300 mg/l, 48 hours (Water flea)
Fish	LC50	Bluegill (Lepomis macrochirus) > 300 mg/l, 96 hours Rainbow trout > 300 mg/l, 96 hours (Oncorhynchus mykiss)

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

Benzyl alcohol	1.1
Propylene glycol	-0.92
Tylosin Base	17 (pH 7 and 9) 5 (pH 5)

Mobility in soil Not available.

Other adverse effects Not available.

Ecotoxicological Properties

Drinking Water

Components	Test results
Tylosin Base	36 µg/l, (Lilly Aquatic Exposure Guideline)

Chronic Exposure of Aquatic Organisms

Components	Test results
Tylosin Base	99 µg/l, (Lilly Aquatic Exposure Guideline)

Acute Exposure of Aquatic Organisms

Components	Test results
Tylosin Base	220 µg/l, (Lilly Aquatic Exposure Guideline)

13. Disposal considerations

Disposal methods Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

General information Effective January 1, 2015 by Special Provision, UN3077 and UN3082 when packaged in inner packages of 5L / 5 KG or less are not subject to the dangerous goods regulations.

ADG

UN number	3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (Tylosin Base)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	Yes
Hazchem Code	D3Z
Special precautions for user	Not available.

Not classified as dangerous goods when transported by road or rail in packaging or receptacles not exceeding 500 kg (L) according to ADG 7 SP AU01.

RID

UN number	3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (Tylosin Base)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Packing group	III
Environmental hazards	Yes
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling. Read safety instructions, SDS and emergency procedures before handling.

IATA

UN number	3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (Tylosin Base)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	Yes
ERG Code	9L
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.

IMDG

UN number	3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tylosin Base)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

ADG; IATA; IMDG; RID



Marine pollutant



15. Regulatory information

Safety, health and environmental regulations

National regulations

APVMA approval number 36796
Poison Schedule 4

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Propylene glycol (CAS 57-55-6)

Low toxicity. General: Any use

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Benzyl alcohol (CAS 100-51-6)

10000 - 99999 TONNES See the regulation for additional information.

Propylene glycol (CAS 57-55-6)

10000 - 99999 TONNES See the regulation for additional information.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work.

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

List of abbreviations

LEG: Lilly Exposure Guideline

TWA: Time Weighted Average

References

Not available.

Information on evaluation method leading to the classification of mixture

Not available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
R36 Irritating to eyes.
R42/43 May cause sensitisation by inhalation and skin contact.
R50 Very toxic to aquatic organisms.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Harmful if swallowed.
Harmful in contact with skin.
May cause an allergic skin reaction.
Causes serious eye irritation.
Causes eye irritation.
Harmful if inhaled.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Very toxic to aquatic life with long lasting effects.

Lilly Lab Code

Health: 1
Fire: 1
Reactivity: 0
Special 1: A

Revision information

Hazard(s) identification: Classification of the substance or mixture
Physical & Chemical Properties: Multiple Properties

Disclaimer

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 MERCHANT ABILITY 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.

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