



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** Elanco AF1300 Tylan Tylosin Tartrate Soluble

### Other means of identification

**Synonyms** Tylosin, (2R,3R)-2,3-dihydroxybutanedioate (salt)  
**Item Code** AF1320, AH0670, AF1298, AF1310, AF1300, AF1317

### 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

Elanco Australasia 1800 226 324 (toll free)

#### number

#### 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 substance has been assessed and/or tested for its physical, health and environmental hazards and the following classifier applies.

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

#### Health hazards

Serious eye damage/eye irritation	Category 2	Causes serious eye irritation.
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 1	Very toxic to aquatic life.
Hazardous to the aquatic environment, long-term hazard	Category 1	Very toxic to aquatic life with long lasting effects.

### 2.2. Label elements

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

**Contains:** Tylosin Tartrate

#### Hazard pictograms



<b>Signal word</b>	Danger
<b>Hazard statements</b>	May cause an allergic skin reaction. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Very toxic to aquatic life with long lasting effects.
<b>Precautionary statements</b>	
<b>Prevention</b>	Avoid breathing dust. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection.
<b>Response</b>	IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. Wash contaminated clothing before reuse.
<b>Storage</b>	Not available.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Supplemental label information</b>	None.
<b>2.3. Other hazards</b>	None known.

### 3. Composition/information on ingredients

#### Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Tylosin Tartrate Tylosin, (2R,3R)-2,3-dihydroxybutanedioate (salt) LSN 029510	1405-54-5	100

### 4. First-aid measures

#### Description of necessary first aid measures

<b>Inhalation</b>	Move to fresh air. Oxygen or artificial respiration if needed. Get medical attention immediately.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	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.
<b>Ingestion</b>	Immediately give large quantities of water to drink. Never give liquid to an unconscious person. Call a physician or poison control centre immediately.
<b>Personal protection for first-aid responders</b>	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
<b>Symptoms caused by exposure</b>	Eye irritation. May cause allergic skin reaction. May cause allergic respiratory reaction. Rash. Wheezing. Coughing.
<b>Medical attention and special treatment</b>	Treat symptomatically.

### 5. Fire-fighting measures

#### Extinguishing media

<b>Suitable extinguishing media</b>	Water. Carbon dioxide (CO <sub>2</sub> ). Dry chemical.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	Hazardous decomposition products formed under fire conditions.
<b>Special protective equipment and precautions for fire fighters</b>	Wear self-contained breathing apparatus and protective clothing.
<b>Hazchem Code</b>	2Z

**General fire hazards** Dust may form explosive mixture with air.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel** Wear appropriate personal protective equipment.

**For emergency responders** Keep unnecessary personnel away.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Do not discharge into drains, water courses or onto the ground.

**Methods and materials for containment and cleaning up** Collect dust using a vacuum cleaner equipped with HEPA filter. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping. Wear appropriate protective equipment and clothing during clean-up.

Large spills due to traffic accidents, etc., should be reported immediately to CHEMWATCH and Elanco Animal Health for assistance.

## 7. Handling and storage

**Precautions for safe handling** Keep formation of airborne dusts to a minimum. Avoid contact with eyes, skin, and clothing. Do not breathe dust. Use only with adequate ventilation. Wear personal protective equipment. Wash hands thoroughly after handling.

**Conditions for safe storage, including any incompatibilities** Keep container tightly closed in a dry and well-ventilated place.

## 8. Exposure controls and personal protection

**Control parameters** LEG = Lilly Exposure Guideline 12 hour TWA <100 ug/m<sup>3</sup> (Tylosin Tartrate)

**Occupational exposure limits** No exposure limits noted for ingredient(s).

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

**Exposure guidelines** LEG = Lilly Exposure Guideline 12 hour TWA <100 ug/m<sup>3</sup> (Tylosin Tartrate)

**Appropriate engineering controls** Open handling is not recommended. 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 safety glasses with side shields (or goggles). (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

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

**Appearance** Powder.

**Physical state** Solid.

**Form** Powder.

**Colour** Yellow

**Odour** Odourless.

**Odour threshold** No data available

**pH** 4.5 - 7.2 (50% aqueous solution)

**Melting point/freezing point** 240 °C (464 °F)

<b>Initial boiling point and boiling range</b>	No data available.
<b>Flash point</b>	No data available.
<b>Evaporation rate</b>	No data available.
<b>Flammability (solid, gas)</b>	No test data available.

#### Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	No data available.
<b>Flammability limit - upper (%)</b>	No data available.
<b>Explosive limit - lower (%)</b>	No data available.
<b>Explosive limit – upper (%)</b>	No data available.

<b>Vapour pressure</b>	No data available.
<b>Vapour density</b>	No data available.
<b>Relative density</b>	No data available.

#### Solubility(ies)

<b>Solubility (water)</b>	5 g/l
<b>Partition coefficient (n-octanol/water)</b>	17.000 (pH 7)
	17.000 (pH 9)
	5.000 (pH 5)

<b>Auto-ignition temperature</b>	No data available.
<b>Decomposition temperature</b>	No data available.
<b>Viscosity</b>	No data available.

#### Other physical and chemical parameters

<b>Density</b>	No data available.
<b>Explosive properties</b>	Not explosive
<b>Oxidising properties</b>	No oxidizing properties.
<b>Potential for dust explosion</b>	No data available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	This material should not be packaged or stored above the following temperature: 95 °C. This temperature is based on a laboratory test (ARC) and assumes near atmospheric pressures and quantities of less than 500 kg (1100 lb) or 208 L (55 gal). For additional information contact the Chemical Hazards Laboratory.
<b>Possibility of hazardous reactions</b>	Hazardous polymerisation does not occur.
<b>Conditions to avoid</b>	Excessive heat.
<b>Incompatible materials</b>	Strong oxidising agents.
<b>Hazardous decomposition products</b>	Hazardous decomposition products formed under fire conditions.

## 11. Toxicological information

<b>General information</b>	Not available.
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### 11.1. Information on toxicological effects

Components	Species	Test results
Tylosin Tartrate (CAS 1405-54-5)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rabbit	> 2000 mg/kg
<b>Inhalation</b>		
LC50	Rat	> 600 mg/m3, 1 h
<b>Oral</b>		
LD50	Rat	> 6200 mg/kg
<b>Skin corrosion/irritation</b>	Rabbit: Slight irritation. Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Rabbit: Irritating. (cleared within 7 days)	
<b>Respiratory sensitisation</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled. 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.	
<b>Skin sensitisation</b>	Guinea pig: Causes sensitization. (as free base)	
<b>Germ cell mutagenicity</b>	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. (as free base) Based on available data, the classification criteria are not met.	
<b>Carcinogenicity</b>	Animal testing did not show any carcinogenic effects. (as free base)	
<b>Reproductive toxicity</b>	Animal testing did not show any effects on fertility. Animal testing did not show any effects on foetal development. (as free base)	
<b>Specific target organ toxicity - single exposure</b>	This information is not available.	
<b>Specific target organ toxicity - repeated exposure</b>	No significant target organ toxicity reported.	
<b>Aspiration hazard</b>	No aspiration toxicity classification	
<b>Mixture versus substance information</b>	Not available.	
<b>Other information</b>	Not available.	

## 12. Ecological information

Components	Species	Test results	
Tylosin Tartrate (CAS 1405-54-5)			
	EC50	Oats (Seedling)	140 mg/kg (Growth, as free base)
		Soybean (Seedling)	53 mg/kg (Growth, as free base)
		Tomato (Seedling)	43 mg/kg (Growth, as free base)
<i>Acute</i>	LC50	Duck (Mallard duck)	> 5000 mg/kg, 5 days (dietary, as free base)
		Quail (Bobwhite quail)	> 5000 mg/kg, 5 days (dietary, as free base)
Other	EC50	Pseudokirchnerella subcapitata	0.22 mg/l (average specific growth rate) (as free base)
<i>Chronic</i>	LC50	Earthworms (Eisenia fetida)	> 102.6 mg/kg, 14 days
		Quail (Bobwhite quail)	> 2000 mg/kg, 14 days

Components		Species	Test results
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Daphnia magna	> 300 mg/l (as free base)
Fish	LC50	Bluegill ( <i>Lepomis macrochirus</i> )	> 300 mg/l (as free base)
		Rainbow trout	> 300 mg/l (as free base)

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

#### Bioaccumulative potential

##### Partition coefficient n-octanol / water (log Kow)

Tylosin Tartrate 17, (pH 7)  
17, (pH 9)  
5, (pH 5)

**Mobility in soil** Not available.

##### Adsorption

##### Soil/sediment sorption - log Koc

Tylosin Tartrate 1652 Silt Loom (pH 5.7)  
200 Sandy Loom (pH 4.6)  
2233 Sandy Loom (pH 7.6)

**Other adverse effects** Not available.

#### Ecotoxicological Properties

##### Drinking Water

##### Components

Tylosin Tartrate 36 µg/l, (Lilly Aquatic Exposure Guideline)

##### Chronic Exposure of Aquatic Organisms

##### Components

Tylosin Tartrate 99 µg/l, (Lilly Aquatic Exposure Guideline)

##### Acute Exposure of Aquatic Organisms

##### Components

Tylosin Tartrate 220 µg/l, (Lilly Aquatic Exposure Guideline)

### 13. Disposal considerations

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

**Residual waste** Dispose of in accordance with local 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** 3077  
**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Tylosin Tartrate)  
**Transport hazard class(es)**  
**Class** 9  
**Subsidiary risk** -  
**Packing group** III  
**Environmental hazards** Yes  
**Hazchem Code** 2Z  
**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**

<b>UN number</b>	3077
<b>UN proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (Tylosin tartrate)
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Label(s)</b>	9
<b>Packing group</b>	III
<b>Environmental hazards</b>	Yes
<b>Special precautions for user</b>	Not available.

**IATA**

<b>UN number</b>	3077
<b>UN proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (Tylosin Tartrate)
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>Environmental hazards</b>	Yes
<b>ERG Code</b>	9L
<b>Special precautions for user</b>	Not available.
<b>Other information</b>	
<b>Passenger and cargo aircraft</b>	Allowed with restrictions.
<b>Cargo aircraft only</b>	Allowed with restrictions.

**IMDG**

<b>UN number</b>	3077
<b>UN proper shipping name</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tylosin Tartrate)
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	Yes
<b>EmS</b>	F-A, S-F
<b>Special precautions for user</b>	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 40217  
Poison Schedule 4

#### **Australia Medicines & Poisons Appendix A**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix B**

Poisons schedule number not allocated.

#### **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)**

Not listed.



**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 Regulation (EC) 1272/2008 (CLP Regulation) as amended and respective national laws implementing EC directives.

**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)	Yes
Korea	Existing Chemicals List (ECL)	No
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**

Not available.

**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**

R36 Irritating to eyes.

R42/43 May cause sensitisation by inhalation and skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

May cause an allergic skin reaction.

Causes serious eye irritation.

Causes eye irritation.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
Very toxic to aquatic life with long lasting effects.

**Lilly Lab Code**

Health: 2  
Fire: 1  
Reactivity: 1  
Special 1: A

**Revision information**

Hazard(s) identification: Hazard statements  
Hazard(s) identification: Response

**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.

For additional information contact:  
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