



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Tylan Soluble</b>
<b>Other means of identification</b>	
<b>Item Code</b>	AF1320, AH0670, AF1298, AF1310, AF1300, AF1317
<b>Synonyms</b>	Tylosin, (2R,3R)-2,3-dihydroxybutanedioate (salt)
<b>Recommended use</b>	Veterinary Pharmaceutical
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name</b>	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
<b>Phone:</b>	1-877-Elanco1 (1-877-352-6261)
<b>Emergency Telephone:</b>	Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973
<b>Email:</b>	elanco_sds@elanco.com
<b>Transportation Emergency Telephone:</b>	CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Serious eye damage/eye irritation	Category 2B
	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
<b>OSHA defined hazards</b>	Combustible dust	

### Label elements



<b>Signal word</b>	Danger
<b>Hazard statement</b>	
H317	May form combustible dust concentrations in air.
H320	May cause an allergic skin reaction.
H334	Causes eye irritation.
	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>Precautionary statement</b>	
<b>Prevention</b>	
P261	Avoid breathing dust.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P272	Contaminated work clothing should not be allowed out of the workplace.
P284	In case of inadequate ventilation wear respiratory protection.
<b>Response</b>	
P302 + P352	IF ON SKIN: Wash with plenty of water.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

<b>Storage</b>	Not available.
<b>Disposal</b>	
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	None.

### 3. Composition/information on ingredients

#### Substances

Chemical name	Common name and synonyms	CAS number	%
Tylosin Tartrate	Tylosin, (2R,3R)-2,3-dihydroxybutanedioate (salt) LSN 029510	1405-54-5	100

**Composition comments** The full text for all H-statements is displayed in section 16.

### 4. 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 center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	May cause allergic skin reaction. May cause allergic respiratory reaction. Eye irritation. Rash. Wheezing. Coughing.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically.
<b>General information</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.

### 5. Fire-fighting measures

<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 firefighters</b>	Wear self-contained breathing apparatus and protective clothing.
<b>General fire hazards</b>	Dust may form explosive mixture with air.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Wear appropriate personal protective equipment.
<b>Methods and materials for containment and cleaning up</b>	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.
<b>Environmental precautions</b>	Prevent further leakage or spillage if safe to do so. Do not discharge into drains, water courses or onto the ground.

### 7. Handling and storage

<b>Precautions for safe handling</b>	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.
<b>Conditions for safe storage, including any incompatibilities</b>	Keep container tightly closed in a dry and well-ventilated place.

## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	This substance has no PEL, TLV, or other recommended exposure limit.
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	12 hour TWA <100 ug/m <sup>3</sup> (Tylosin Tartrate)
<b>Appropriate engineering controls</b>	Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
<b>Skin protection</b>	
<b>Hand protection</b>	Chemical resistant gloves.
<b>Other</b>	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
<b>Respiratory protection</b>	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.
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	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

<b>Appearance</b>	Powder.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder
<b>Color</b>	Yellow
<b>Odor</b>	Odorless
<b>Odor threshold</b>	No data available
<b>pH</b>	4.5 - 7.2 (50% aqueous solution)
<b>Melting point/freezing point</b>	464 °F (240 °C)
<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.
<b>Upper/lower flammability or explosive limits</b>	
<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>Vapor pressure</b>	No data available.
<b>Vapor density</b>	No data available.
<b>Relative density</b>	No data available.
<b>Solubility(ies)</b>	
<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 information

Density	No data available.
Explosive properties	Not explosive.
Molecular weight	916.11 g/mol
Oxidizing properties	No oxidizing properties.
Potential for dust explosion	No data available.

## 10. Stability and reactivity

Reactivity	Not water reactive.
Chemical stability	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).
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Excessive heat.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.

## 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

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/m <sup>3</sup> , 1 h
<b>Oral</b>		
LD50	Rat	> 6200 mg/kg

**Skin corrosion/irritation** Rabbit: Slight irritation.  
Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Rabbit: Irritating. (cleared within 7 days)

#### Respiratory or skin sensitization

**Respiratory sensitization** 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.

**Skin sensitization** Guinea pig: Causes sensitization. (as free 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. (as free base)  
Based on available data, the classification criteria are not met.

**Carcinogenicity** Animal testing did not show any carcinogenic effects. (as free base)  
Based on available data, the classification criteria are not met.

#### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

#### US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

**Reproductive toxicity** Animal testing did not show any effects on fertility. Animal testing did not show any effects on foetal development. (as free base)  
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 significant target organ toxicity reported.  
Based on available data, the classification criteria are not met.

**Aspiration hazard** No aspiration toxicity classification

## 12. Ecological information

**Ecotoxicity** Very toxic to aquatic life with long lasting effects.

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

### LILLY AQUATIC EXPOSURE GUIDELINES:

#### Tylosin Tartrate

Acute LAEG (at the edge of the acute mixing zone): 220 µg/l

Chronic LAEG (at the edge of the chronic mixing zone): 99 µg/l

Drinking water LAEG (at the point where surface water is taken for drinking water): 36 µg/l

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

**Bioaccumulative potential** Not available.

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

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

**Mobility in soil** 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

#### 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.

## 13. Disposal considerations

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

## 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.

**DOT**

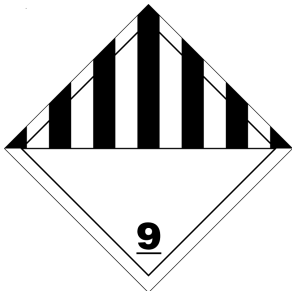
Not regulated as dangerous goods.

**IATA**

<b>UN number</b>	UN3077
<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>	UN3077
<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.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not available.

**IATA; IMDG****Marine pollutant****15. Regulatory information**

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**Toxic Substances Control Act (TSCA)****TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

<b>Classified hazard categories</b>	Combustible dust Serious eye damage or eye irritation Respiratory or skin sensitization
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**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	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, including date of preparation or last revision****Issue date** 04-21-2014**Revision date** 02-04-2019**Version #** 04**List of abbreviations** TWA: Time Weighted Average Elanco OEL: Elanco Occupational Exposure Limit.**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 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:  
Elanco Animal Health  
0011+1-877-352-6261  
0011+1-800-428-4441