



SAFETY DATA SHEET

1. Identification

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

2. Hazard(s) identification

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



Signal word	Danger	
Hazard statement		
	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.
Precautionary statement		
Prevention		
	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.
Response		
	P302 + P352	IF ON SKIN: Wash with plenty of water.
	P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.

P337 + P313
P304 + P340
P342 + P311

If eye irritation persists: Get medical advice/attention.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

Storage

Not available.

Disposal

P501

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

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

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

4. First-aid measures

Inhalation

Move to fresh air. Oxygen or artificial respiration if needed. Get medical attention immediately.

Skin contact

Immediately flush skin with plenty of water. Remove contaminated clothing and shoes. 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

Immediately give large quantities of water to drink. Never give liquid to an unconscious person. Call a physician or poison control center immediately.

Most important symptoms/effects, acute and delayed

May cause allergic skin reaction. May cause allergic respiratory reaction. Eye irritation. Rash. Wheezing. Coughing.

Indication of immediate medical attention and special treatment needed

Treat symptomatically.

General information

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

Suitable extinguishing media

Water. Carbon dioxide (CO₂). Dry chemical.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Hazardous decomposition products formed under fire conditions.

Special protective equipment and precautions for firefighters

Wear self-contained breathing apparatus and protective clothing.

General fire hazards

Dust may form explosive mixture with air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear appropriate personal protective equipment.

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.

Environmental precautions

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

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/personal protection

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/m3 (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, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection

Chemical resistant gloves.

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.

Thermal hazards

Not available.

General hygiene considerations

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.

Color

Yellow

Odor

Odorless

Odor threshold

No data available

pH

4.5 - 7.2 (50% aqueous solution)

Melting point/freezing point

464 °F (240 °C)

Initial boiling point and boiling range

No data available.

Flash point

No data available.

Evaporation rate

No data available.

Flammability (solid, gas)

No test data available.

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.

Vapor pressure

No data available.

Vapor density

No data available.

Relative density

No data available.

Solubility(ies)

Solubility (water)

5 g/l

Partition coefficient (n-octanol/water)

17.000 (pH 7)

	17.000 (pH 9) 5.000 (pH 5)
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Viscosity	No data available.
Other information	
Density	No data available.
Explosive properties	Not explosive
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). For additional information contact the Chemical Hazards Laboratory.
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)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Inhalation		
LC50	Rat	> 600 mg/m3, 1 h
Oral		
LD50	Rat	> 6200 mg/kg

Skin corrosion/irritation	Rabbit: Slight irritation. Based on available data, the classification criteria are not met.
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Serious eye damage/eye irritation	Rabbit: Irritating. (cleared within 7 days)
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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.
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Carcinogenicity Animal testing did not show any carcinogenic effects. (as free base)

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

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)
Specific target organ toxicity - single exposure	This information is not available.
Specific target organ toxicity - repeated exposure	No significant target organ toxicity reported.
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)			
Acute	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)
	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
Chronic	LC50	Earthworms (Eisenia fetida)	> 102.6 mg/kg, 14 days
		Quail (Bobwhite quail)	> 2000 mg/kg, 14 days
	Aquatic		
Acute			
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)
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.		

Ecotoxicological Properties

Drinking Water

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

Chronic Exposure of Aquatic Organisms

Components

Tylosin Tartrate

Test Results

99 µg/l, (Lilly Aquatic Exposure Guideline)

Acute Exposure of Aquatic Organisms

Components

Tylosin Tartrate

Test Results

220 µg/l, (Lilly Aquatic Exposure Guideline)

13. Disposal considerations

Disposal instructions

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

Waste from residues / unused products

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.

DOT

Not regulated as dangerous goods.

IATA

UN number

UN3077

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

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

UN3077

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

Marine pollutant

Yes

EmS

F-A, S-F

Special precautions for user

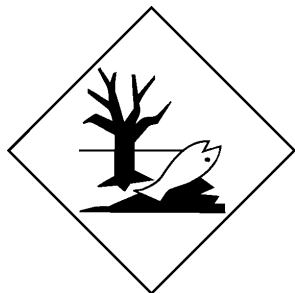
Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not available.

IATA; IMDG





15. Regulatory information

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

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 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

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.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

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

Country(s) or region	Inventory name	On inventory (yes/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	06-27-2016
Version #	03
Lilly Lab Code	Health: 2 Fire: 1 Reactivity: 1 Special 1: A
List of abbreviations	TWA: Time Weighted Average. LEG: Lilly Exposure Guideline
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: Elanco Animal Health 0011+1-877-352-6261 0011+1-800-428-4441
Revision information	This document has undergone significant changes and should be reviewed in its entirety.