SAFETY DATA SHEET

1. Identification

Product identifier Tylan Soluble

Other means of identification

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

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

May form combustible dust concentrations in air.

May cause an allergic skin reaction. H317

Causes eye irritation. H320

May cause allergy or asthma symptoms or breathing difficulties if inhaled. H334

Precautionary statement

Prevention

Avoid breathing dust/fume/gas/mist/vapors/spray. P261

Wear protective gloves/protective clothing/eye protection/face protection. P280

In case of inadequate ventilation wear respiratory protection. P285

Response

IF ON SKIN: Wash with plenty of soap and water. P302 + P352

If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. P304 + P341

IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician. P309 + P311

Not available. **Storage**

Material name: Tylan Soluble SDS US 1/8 **Disposal**

Dispose of contents/container in accordance with local/regional/national/international regulations. P501

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information

None.

3. Composition/information on ingredients

Mixtures

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

4. First-aid measures

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

Eye irritation. May cause allergic skin reaction. May cause allergic respiratory reaction. 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

Unsuitable extinguishing

media

Water. Carbon dioxide (CO2). Dry chemical.

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.

Material name: Tylan Soluble SDS US 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 Open handling is not recommended. Use appropriate control measures such as fume hood,

controls 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 Use an approved respirator.

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% agueous solution)

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

Initial boiling point and No data available.

boiling range

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 pressureNo data available.Vapor densityNo data available.Relative densityNo data available.

Solubility(ies)

Solubility (water) 5 g/l

Partition coefficient 17.000 (pH 7)

(n-octanol/water)

17.000 (pH 9) 5.000 (pH 5)

Auto-ignition temperature No data available.

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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 No data available.

explosion

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stabilityThis 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.

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)

Carcinogenicity Animal testing did not show any carcinogenic effects. (as free base)

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicityAnimal 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

This information is not available.

- single exposure

No significant target organ toxicity reported.

Specific target organ toxicity - repeated exposure

Aspiration hazard No aspiration toxicity classification

12. Ecological information

Ecotoxicity	Very toxic to aquatic life with long lasting effects.
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	Species	Test Results
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)
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)
EC50	Pseudokirchnerella subcapitata	0.22 mg/l (average specific growth rate) (as free base)
LC50	Earthworms (Eisenia fetida)	> 102.6 mg/kg, 14 days
	Quail (Bobwhite quail)	> 2000 mg/kg, 14 days
EC50	Daphnia magna	> 300 mg/l (as free base)
LC50	Bluegill (Lepomis macrochirus)	> 300 mg/l (as free base)
	Rainbow Trout	> 300 mg/l (as free base)
	EC50 EC50 EC50	EC50 Oats (Seedling) Soybean (Seedling) Tomato (Seedling) LC50 Duck (Mallard duck) Quail (Bobwhite quail) EC50 Pseudokirchnerella subcapitata LC50 Earthworms (Eisenia fetida) Quail (Bobwhite quail) EC50 Daphnia magna LC50 Bluegill (Lepomis macrochirus)

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

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

17, (pH 7) Tylosin Tartrate 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 Guildeline)	
Chronic Exposure of Aquatic Organisms		
Components	Test Results	
Tylosin Tartrate	99 μg/l, (Lilly Aquatic Exposure Guildeline)	
Acute Exposure of Aquatic Organisms		
Components	Test Results	
Tylosin Tartrate	220 μg/l, (Lilly Aquatic Exposure Guildeline)	

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

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 Allowed.

aircraft

Cargo aircraft only

Allowed.

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 pollutantYesEmSF-A, S-FSpecial precautions forNot available.

user

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

Transport in bulk according to This substance/mixture is not intended to be transported in bulk.

IATA; IMDG



Marine pollutant



Material name: Tylan Soluble SDS US

15. Regulatory information

US federal regulationsThis product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard,

29 CFR 1910.1200.

CERCLA/SARA Hazardous Substances - Not applicable.

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 listed.

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

Not regulated.

(SDWA)

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
United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No

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16. Other information, including date of preparation or last revision

 Issue date
 04-21-2014

 Revision date
 09-22-2014

Version # 02

Material name: Tylan Soluble SDS US

^{*}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).

Lilly Lab Code Health: 2

Fire: 1 Reactivity: 1 Special 1: A

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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 00+1+877-352-6261 00+1-800-428-4441

Revision Information Hazard(s) identification: Storage

Stability and reactivity: Hazardous decomposition products

Transport information: General information

GHS: Classification

Material name: Tylan Soluble SDS US