Elanco

SAFETY DATA SHEET

1. Identification

Product identifier Tylan Soluble

Other means of identification

Item CodeAF1320, AH0670, AF1298, AF1310, AF1300, AF1317SynonymsTylosin, (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 Elanco Product Technical Support / Human or Animal Exposure Reporting:

CHEMTREC: 1-800-424-9300

Numbers: 1-888-545-5973

Transportation Emergency

Telephone: (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.

H317 May cause an allergic skin reaction.

H320 Causes eye irritation.

H334 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 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.

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

InhalationMove to fresh air. Oxygen or artificial respiration if needed. Get medical attention immediately.Skin contactImmediately 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.

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

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

Indication of immediate medical attention and special

medical attention and special treatment needed

General information

Treat symptomatically.

Wheezing. Coughing.

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

None known.

Specific hazards arising from the chemical

Special protective equipment

and precautions for firefighters

Hazardous decomposition products formed under fire conditions.

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.

Water. Carbon dioxide (CO2). Dry chemical.

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

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

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

LEG = Lilly Exposure Guideline 12 hour TWA <100 ug/m3 (Tylosin Tartrate) **Exposure guidelines**

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.

Respirator selection must be based on known or anticipated exposure levels, the hazards of the Respiratory protection

product and the safe working limits of the respirator. Select appropriate respirator for physical

characteristics of material. Select respirator with appropriate protection factor.

Not available. Thermal hazards

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. Solid. Physical state Powder. **Form** Color Yellow Odor Odorless

Odor threshold No data available

4.5 - 7.2 (50% agueous solution)

464 °F (240 °C) Melting point/freezing point Initial boiling point and boiling No data available.

range

Flash point No data available. No data available. **Evaporation rate** 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.

No data available. Explosive limit - lower (%) Explosive limit - upper (%) No data available. Vapor pressure No data available. Vapor density No data available. Relative density No data available.

Solubility(ies)

5 g/l Solubility (water)

Partition coefficient 17.000 (pH 7)

(n-octanol/water)

17.000 (pH 9) 5.000 (pH 5)

Auto-ignition temperatureNo data available.Decomposition temperatureNo data available.ViscosityNo 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

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)	
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Inhalation		
LC50	Rat	> 600 mg/m3, 1 h
Oral		
LD50	Rat	> 6200 mg/kg
Chin composion/invitation	Babbit: Clight irritation	

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)

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.

Animal testing did not show any effects on fertility. Animal testing did not show any effects on Reproductive toxicity

foetal development. (as free base)

Specific target organ toxicity - single exposure

This information is not available.

Specific target organ toxicity - repeated

No significant target organ toxicity reported.

exposure **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	n 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)		
Acute					
	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)		
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)		

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

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

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

Soil degradation half-life (100 ppm): 62 days (tylosin factor A); 37 days (tylosin factor D) Mobility in soil

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)

Not available. Other adverse effects

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.

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

UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Tylosin Tartrate)

Transport hazard class(es)

9 Class Subsidiary risk Ш Packing group **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

UN3077 **UN** number

UN proper shipping name

Transport hazard class(es)

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tylosin Tartrate)

9 **Class** Subsidiary risk Ш Packing group

Environmental hazards

Marine pollutant Yes **EmS** F-A, S-F Special precautions for user Not available. Not available.

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

the IBC Code

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.

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

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)*

CanadaDomestic Substances List (DSL)NoCanadaNon-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

*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 informationThis document has undergone significant changes and should be reviewed in its entirety.

Material name: Tylan Soluble sps us

5220 Version #: 03 Revision date: 06-27-2016 Issue date: 04-21-2014