SAFETY DATA SHEET

1. Identification

Product identifier Tylan Injection

Other means of identification

AF1400, AF1401, AF7200, AF7202, AH0137, AH0205, AH0206 Item Code

Tylosin * Tylosin Base * 027892 Formulation * Tylan 200 Injection * Tylan 50 Injection * Tylan **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 Sensitization, respiratory Category 1

> Sensitization, skin Category 1

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement

H317 May cause an allergic skin reaction.

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

Precautionary statement

Prevention

Avoid breathing mist or vapor. P261

Wear protective gloves/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 skin irritation or rash occurs: Get medical advice/attention. P333 + P313

If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P342 + P311

Storage Not available.

Disposal

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

Material name: Tylan Injection SDS US 1/8 Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Not applicable.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Tylosin Base		1401-69-0	5 - 20
Benzyl Alcohol		100-51-6	2 - 5

Composition comments

Remaining components of this product are non-hazardous and/or are present at concentrations

below reportable levels.

4. First-aid measures

Inhalation Move to fresh air. Oxygen or artificial respiration if needed. Call a physician or poison control center

immediately.

Skin contact Wash off with soap and plenty of water. Take off contaminated clothing and wash before reuse.

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.

If conscious, give the victim plenty of water to drink. Never give anything by mouth to a victim who Ingestion

is unconscious or is having convulsions. Call a physician or poison control center immediately.

Most important

symptoms/effects, acute and

delayed

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. Accidental

injection may cause pain and swelling at the site accompanied by anxiety.

Indication of immediate medical attention and special

treatment needed

Accidental Injection: For accidental injection no specific treatment is needed other than symptomatic. Treat wound if necessary and consider need for tetanus immunization.

General information

In the case of accident or if you feel unwell, seek medical advice immediately (show the label

where possible).

5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing

media

Water. Carbon dioxide (CO2). Dry chemical.

Not available.

Specific hazards arising from

the chemical

Special protective equipment and precautions for

firefiahters

Wear self-contained breathing apparatus and protective clothing.

Fire or excessive heat may produce hazardous decomposition products.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothing. Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.

Methods and materials for containment and cleaning up Small Spillages:

Use absorbent/adsorbent material to solidify liquids. Clean up promptly by sweeping or vacuum.

Large Spillages:

Prevent further migration into the environment. Use absorbent/adsorbent material to solidify liquids, Collect in a non-combustible container for prompt disposal. Local authorities should be advised if significant spillages cannot be contained. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance.

Environmental precautions

Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes. Avoid

discharge into drains, water courses or onto the ground.

Material name: Tylan Injection SDS US

7. Handling and storage

Precautions for safe handling Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. Keep away from

heat and sources of ignition. Avoid release to the environment.

Do not mix with other injectable solutions as this may cause precipitation of the active ingredients. Do not administer to horses or other equines. Injection of tylosin in equines has been fatal.

Conditions for safe storage, including any incompatibilities

Store in a cool place below 72F (22C). Keep the container tightly closed and dry. Store away from incompatible materials. Avoid contact with oxidizing agents. Do not store in open or unlabelled containers.

8. Exposure controls/personal protection

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

Exposure guidelines Lilly Exposure Guideline (LEG): <100 mcg/m3 12 hour TWA (Tylosin Base)

Occupational exposure limits

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Туре	Value	
Benzyl Alcohol (CAS 100-51-6)	TWA	44.2 mg/m3	
,		10 ppm	

Biological limit valuesNo biological exposure limits noted for the ingredient(s).

biological limit values in biological exposure limits noted for the ingredient(s).

Appropriate engineeringControls
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 goggles/face shield.

Skin protection

Hand protectionChemical-resistant gloves and impermeable body covering to minimize skin contact. **Other**Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Respiratory protection Use an approved respirator. Select appropriate respirator for physical characteristics of material.

Select respirator with appropriate protection factor.

Thermal hazards Not available.

General hygiene considerations

Use good industrial hygiene practices in handling this material.

In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

race shield may not be required. Safety glasses are always required.

In production settings, airline-supplied, hood-type respirators are preferred. Shower and change

clothing if skin contact occurs.

Under normal use and handling conditions, wear goggles to protect eyes and wear impermeable gloves and protective equipment to avoid direct contact with skin. Wash thoroughly with soap and water after handling.

9. Physical and chemical properties

Appearance Viscous. Solution.

Physical state Liquid.
Form Liquid.
Color Yellow.
Odor Musty.

Odor threshold No data available.

pH 8.5 - 10

Melting point/freezing point No data available.

Initial boiling point and No data available.

boiling range

Flash point No data available.

Evaporation rate No data available.

Material name: Tylan Injection SDS US

4903 Version #: 02 Revision date: 10-01-2014 Issue date: 08-22-2014

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

pper/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) Soluble.

Partition coefficient Not available.
(n-octanol/water)

Auto-ignition temperature773.6 °F (412 °C)Decomposition temperatureNo data available.ViscosityNo data available.

Other information

DensityNo data available.Explosive propertiesNo data available.Oxidizing propertiesNo data available.Percent volatileNo data available.

Specific gravity 1.09

VOC (Weight %)No data available.

9.2. Other information

Minimum Ignition No data available.

Temperature

10. Stability and reactivity

Reactivity Not available.

Chemical stability Material is stable under normal conditions. **Possibility of hazardous** Hazardous polymerization does not occur.

reactions

Conditions to avoid None known.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information

Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

 Product
 Species
 Test Results

 Tylan Injection (CAS Mixture)
 Acute

 Dermal
 LD
 Rabbit
 > 2140 mg/kg 20% Tylosin Base Mixture. No deaths or toxicity.

 Inhalation
 LC50
 Rat
 > 1050 mg/m3, 1 hr 20% Tylosin Base

Material name: Tylan Injection

Mixture. No deaths.

Product Species Test Results

Oral

Ora LD

Rat > 535 mg/kg 20% Tylosin Base Mixture. No

deaths or toxicity.

Skin corrosion/irritation Slightly irritating to the skin of rabbits. (20% formulation) (Tylosin Base)

Remaining ingredients: No irritation.

Serious eye damage/eye

Rabbit: Slight irritation. (20% formulation)

irritation

Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Respiratory sensitization Allergic reactions in a manufacturing setting have been reported.. (Tylosin Base)

Skin sensitization Guinea pig: Causes sensitization. (Tylosin 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. (Tylosin Base)

Based on available data, the classification criteria are not met.

Carcinogenicity Animal testing did not show any carcinogenic effects. (Tylosin Base) (Benzyl Alcohol)

Based on available data, the classification criteria are not met.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity No effects identified in animal studies. (Tylosin Base)

Developmental effects have been reported at doses toxic to the mother. (Benzyl Alcohol)

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 exposureAspiration hazard

No effects identified in animal studies. (Tylosin Base)

No aspiration toxicity classification.

Further information Salivation, diarrhea, and vomiting after repeated large oral doses. (Tylosin Base)

12. Ecological information

Ecotoxicity Toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Benzyl Alcohol (CAS 1	.00-51-6)		
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	230 mg/l, 48 hr
Fish	LC50	Fathead minnow (Pimephales promelas)	460 mg/l, 96 hours
Tylosin Base (CAS 140	01-69-0)		
Acute			
	EC50		140 mg/kg (Oats, seedling)
			53 mg/kg (Soybean, seedling)
			43 mg/kg (Tomato, seedling)
	LC50		> 102.6 mg/kg, 14 days (Eisenia fetida, earthworm)
Other	EC50	Pseudokirchnerella subcapitata	0.22 mg/l, 72 hours (green algae) (average specific growth rate)
	LC50	Duck	> 5000 mg/kg, 5 days (Anas platyrhynchos, Mallard) (Dietary)
		Quail	> 5000 mg/kg, 5 days (Bobwhite) (Dietary)
			> 2000 mg/kg, 14 days (Bobwhite)

Material name: Tylan Injection SDS US

 Components
 Species
 Test Results

 Aquatic
 Acute

 Crustacea
 EC50
 Daphnia magna
 > 300 mg/l, 48 hours (Water flea)

 Fish
 LC50
 Bluegill (Lepomis macrochirus)
 > 300 mg/l, 96 hours

 Rainbow Trout
 > 300 mg/l, 96 hours (Oncorhynchus)

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

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

Benzyl Alcohol 1.1

Tylosin Base 17 (pH 7 and 9)

5 (pH 5)

Mobility in soil No data available for this product.

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

mykiss)

Soil degradation half-life (1 mg/kg; 4 soils): 50.3 to 105 days (Tylosin Base)

Leaching in soil column: none (Tylosin Base)

Other adverse effects Not available.

Ecotoxicological Properties

Drinking Water

Components	Test Results	
Tylosin Base	36 μg/l, (Lilly Aquatic Exposure Guideline)	
Chronic Exposure of Aquatic Organisms		
Components	Test Results	
Tylosin Base	99 μg/l, (Lilly Aquatic Exposure Guideline)	
Acute Exposure of Aquatic Organisms		
Components	Test Results	
Tylosin Base	220 µg/l, (Lilly Aquatic Exposure Guideline)	

13. Disposal considerations

Disposal instructions Do not allow this material to drain into sewers/water supplies. 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 UN3082

UN proper shipping name Environmentally hazardous substance, liquid, n.o.s. (Tylosin Base)

Transport hazard class(es)

Class 9
Subsidiary risk Packing group III
Environmental hazards Yes
ERG Code 9L

Special precautions for Not available.

user

Other information

Passenger and cargo

aircraft

cargo Allowed.

Cargo aircraft only Allowed.

Material name: Tylan Injection sps us

IMDG

UN number UN3082

UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tylosin Base)

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



15. Regulatory information

US federal regulationsThis 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 listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 313 (TRI reporting)

Not regulated.

Material name: Tylan Injection

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

Benzyl Alcohol (CAS 100-51-6)

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

Not listed.

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

Benzyl Alcohol (CAS 100-51-6)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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
 08-22-2014

 Revision date
 10-01-2014

Version # 02

Lilly Lab Code Health: 1

Fire: 1 Reactivity: 0 Special 1: A

List of abbreviations LEG: Lilly Exposure Guideline

TWA: Time Weighted Average

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

Revision Information Physical & Chemical Properties: Multiple Properties

Toxicological Information: Toxicological Data Transport information: General information

GHS: Classification

Material name: Tylan Injection SDS US