SAFETY DATA SHEET



1. Identification

Product identifier Tylan Injection

Other means of identification

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

Synonyms Tylosin * Tylosin Base * 027892 Formulation * Tylan 200 Injection * Tylan 50 Injection * Tylan

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

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.

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

Precautionary statement

Prevention

P261 Avoid breathing mist or vapor,

P280 Wear protective gloves/eye protection/face protection.
P285 In case of inadequate ventilation wear respiratory protection.

Response

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

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

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

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

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

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.

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

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

Fire or excessive heat may produce hazardous decomposition products.

Special protective equipment and precautions for

firefighters

Wear self-contained breathing apparatus and protective clothing.

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.

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 values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

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 protection Other

Chemical-resistant gloves and impermeable body covering to minimize skin contact. 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.

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 Mustv.

Odor threshold No data available.

pН 8.5 - 10

Melting point/freezing point

No data available.

Initial boiling point and

No data available.

boiling range

No data available.

Flash point Evaporation rate

No data available.

Material name: Tylan Injection

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

(%)

Flammability limit -

upper (%)

No data available.

No data available.

Explosive limit - lower

Flammability 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)

Soluble.

Partition coefficient (n-octanol/water)

Not available.

Auto-ignition temperature Decomposition temperature 773.6 °F (412 °C) No data available.

Viscosity

No data available.

Other information

Density **Explosive properties Oxidizing properties**

No data available. No data available. No data available.

Percent volatile

No 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

Conditions to avoid

Material is stable under normal conditions. Hazardous polymerization does not occur.

Possibility of hazardous reactions

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 1 4 1

LD

Rabbit

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

Inhalation

LC50

Rat

> 1050 mg/m3, 1 hr 20% Tylosin Base Mixture. No deaths.

Material name: Tylan Injection

Product Species **Test Results** Oral 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.

CarcinogenicityAnimal 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 exposure

No effects identified in animal studies. (Tylosin Base)

Aspiration hazard 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 promeias)	460 mg/l, 96 hours
Tylosin Base (CAS 140)1-69 - 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)
	v.		> 2000 mg/kg, 14 days (Bobwhite)

Material name: Tylan Injection

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 mykiss)

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)

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

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

Transport hazard class(es)

9 Class Subsidiary risk Packing group III **Environmental hazards** Yes **ERG Code** 91

Not available.

Special precautions for

Other information

user

Passenger and cargo Allowed.

aircraft

Cargo aircraft only Allowed.

Material name: Tylan Injection

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 pollutant

Yes

EmS

F-A, S-F

Special precautions for

Not available.

user

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

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

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