

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 Veterinary Pharmaceutical
Recommended use	
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Company Name	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
Phone:	1-877-Elanco1 (1-877-352-6261)
Emergency Telephone:	Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973
Email:	elanco_sds@elanco.com
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.
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/protective clothing.
P285	In case of inadequate ventilation wear respiratory protection.
Response	
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position 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.
P363	Wash contaminated clothing before reuse.
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	Water. Carbon dioxide (CO2). Dry chemical.
Unsuitable extinguishing media	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

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	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).
Exposure guidelines		<100 mcg/m3 12 hour TWA (Tylosin Base)
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	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. 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.	

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 boiling range No data available.

Flash point No data available.

Evaporation rate No data available.

Flammability (solid, gas) Not applicable.

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)	Soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	773.6 °F (412 °C)
Decomposition temperature	No data available.
Viscosity	No data available.
Other information	
Density	No data available.
Explosive properties	Not explosive.
Oxidizing properties	No oxidizing properties.
Percent volatile	No data available.
Specific gravity	1.09
VOC	No data available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
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.
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Product	Species	Test Results
Tylan Injection		
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 Mixture. No deaths.
Oral		
LD	Rat	> 535 mg/kg 20% Tylosin Base Mixture. No deaths or toxicity.
Components	Species	Test Results
Benzyl Alcohol (CAS 100-51-6)		

Acute		
Dermal		
LD50	Rabbit	2000 mg/kg
Inhalation		
LD50	Rat	> 4178 mg/m3, 4 hr
Oral		
LD50	Rabbit	1940 mg/kg

Tylosin Base (CAS 1401-69-0)

Acute		
Dermal		
LD	Rabbit	> 2000 mg/kg

Components	Species	Test Results
Inhalation		
LC50	Rat	> 2060 mg/m ³ , 1 h
Oral		
LD	Rat	> 5000 mg/kg
LD50	Mouse	10 g/kg
Other		
LD50	Mouse	321 mg/kg (Intravenous) Tremors.
	Rat	600 mg/kg (Intravenous)
Skin corrosion/irritation	Slightly irritating to the skin of rabbits. (20% formulation) (Tylosin Base)	
Serious eye damage/eye irritation	Rabbit: Slight irritation. (20% formulation) 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.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)		
Not regulated.		
US. National Toxicology Program (NTP) Report on Carcinogens		
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) Based on available data, the classification criteria are not met.	
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.
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Components	Species	Test Results
Benzyl Alcohol (CAS 100-51-6)		
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 1401-69-0)		
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)

Components	Species	Test Results
Aquatic		
<i>Acute</i>		
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)
Terrestrial		
<i>Acute</i>		
	LC50	Duck > 5000 mg/kg, 5 days (Anas platyrhynchos, Mallard) (Dietary)
Other	LC50	Quail > 5000 mg/kg, 5 days (Bobwhite) (Dietary) > 2000 mg/kg, 14 days (Bobwhite)
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	
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 user	Not available.	

Other information

Passenger and cargo aircraft Allowed with restrictions.

Cargo aircraft only Allowed with restrictions.

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

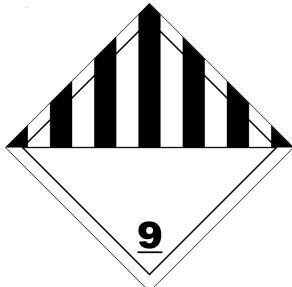
Marine pollutant Yes

EmS F-A, S-F

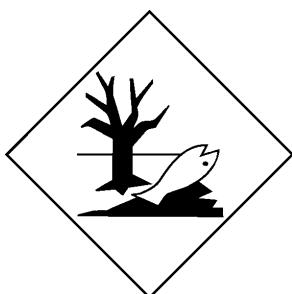
Special precautions for user Not available.

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

Not available.

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.

Toxic Substances Control Act (TSCA)

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 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**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.

US state regulations

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 02-03-2019

Version # 03

List of abbreviations TWA: Time Weighted Average

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For additional information contact:

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