



# Tylan Soluble

Effective Date: 23-Nov-2009

Elanco Animal Health  
Material Safety Data Sheet

## Section 1 - Chemical Product and Company

**Manufacturer:**

Elanco Animal Health  
Division of Eli Lilly and Company  
2001 West Main St  
PO Box 708  
Greenfield, IN 46140

**Manufacturer's Emergency Phone:**

1-800-428-4441

**CHEMTREC:**

1-800-424-9300 (North America)

1-703-527-3887 (International)

**Common Name:** Tylan Soluble

**Chemical Name:** Tylosin, (2R,3R)-2,3-dihydroxybutanedioate (salt)

**Synonym(s):** 027892 tartrate; Tylan soluble powder with lactose; Tylosin tartrate soluble; Tylan soluble with 1% glucose; Tylosin tartrate; Tylosin

**Trademarks(s):** Tylan

**Lilly Item Code(s):** AF1298; AF1300; AF1310; AF1317; AF1320; AH0670; PO378

See attached glossary for abbreviations.

## Section 2 - Composition / Information on Ingredients

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration %</u>
Tylosin Tartrate	1405-54-5	> 49

**Exposure Guidelines:** LEG <100 micrograms/m<sup>3</sup> TWA for 12 hours.

## Section 3 - Hazards Identification

**Appearance:** Light to medium yellow granular powder

**Physical State:** Solid

**Odor:** Odorless

### Emergency Overview

Emergency Overview Effective Date: 15-Jan-1999

Lilly Laboratory Labeling Codes:

Health 2

Fire 1

Reactivity 0

Special A

**Primary Physical and Health Hazards:** Irritant (eyes). Severe Allergen.

**Caution Statement:** Tylan Soluble is tylosin tartrate, may be irritating to the eyes, and is classified as a severe allergen because repeated unprotected exposures are likely to cause allergic reactions.

**Routes of Entry:** Inhalation and skin contact.

**Effects of Overexposure:** Allergic reactions to tylosin in a manufacturing setting have been reported. Allergy symptoms may include skin rash, watery eyes, shortness of breath, nasal congestion, coughing, and wheezing. Based on animal data, may be irritating to the eyes.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to tylosin.

**Carcinogenicity:** Not listed by IARC, NTP, ACGIH, or OSHA. Tylosin was not considered carcinogenic in animal studies conducted by Lilly Research Laboratories.

## Section 4 - First Aid Measures

**Eyes:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately.

**Skin:** Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

**Inhalation:** Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

**Ingestion:** Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

## Section 5 - Fire Fighting Measures

**Flash Point:** No applicable information found

**UEL:** No applicable information found

**LEL:** No applicable information found

**Minimum Ignition Temperature of Dust Layer:** 380 C (716 F)

**Extinguishing Media:** Use water, carbon dioxide, dry chemical, foam, or Halon.

**Unusual Fire and Explosion Hazards:** As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

**Hazardous Combustion Products:** May emit toxic fumes when exposed to heat or fire.

## Section 6 - Accidental Release Measures

**Spills:** Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes. Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping.

## Section 7 - Handling and Storage

**Storage Conditions:** Store in a cool, dry place. Protect from moisture and heat. Product should not be used after the date printed on the container.

## Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

When mixing and handling, use protective clothing, impervious gloves, and dust respirator. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse with plenty of water.

**Respiratory Protection:** Use an approved respirator.

**Eye Protection:** Chemical goggles and/or face shield.

**Ventilation:** Laboratory fume hood or local exhaust ventilation.

**Other Protective Equipment:** 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.

**Additional Exposure Precautions:** 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.

## Section 9 - Physical and Chemical Properties

**Appearance:** Light to medium yellow granular powder

**Odor:** Odorless

**Boiling Point:** No applicable information found

**Melting Point:** 240 C (464 F)

**Specific Gravity:** No applicable information found

**pH:** 4.5 to 7.2 (aqueous 50/50)

**Evaporation Rate:** No applicable information found

**Water Solubility:** Soluble  
**Vapor Density:** No applicable information found  
**Vapor Pressure:** No applicable information found

## Section 10 - Stability and Reactivity

**Stability:** Stable at normal temperatures and pressures.

**Incompatibility:** May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

**Hazardous Decomposition:** May emit toxic fumes when heated to decomposition.

**Hazardous Polymerization:** Will not occur.

## Section 11 - Toxicological Information

### Acute Exposure

**Oral:** Rat, 6200 mg/kg, no deaths or toxicity.

**Skin:** Rabbit, 2000 mg/kg, no deaths or toxicity.

**Inhalation:** Rat, 600 mg/m<sup>3</sup> for 1 hour, no deaths.

**Skin Contact:** Rabbit, slight irritant

**Eye Contact:** Rabbit, irritant

### Chronic Exposure

The toxicity data for the material or related material(s) are presented.

**Target Organ Effects:** Tylosin base - No effects identified in animal studies.

**Reproduction:** Tylosin base - No effects identified in animal studies.

**Sensitization:** Tylosin base - Guinea pig, positive contact sensitizer.

**Mutagenicity:** Tylosin base - 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.

## Section 12 - Ecological Information

The environmental data for the material or related material(s) are presented.

**Ecotoxicity Data:**

Tylosin base

Rainbow trout 96-hour median lethal concentration: > 300 mg/L

Bluegill 96-hour median lethal concentration: > 300 mg/L

Daphnia magna 48-hour median effective concentration: > 300 mg/L

Bobwhite 14-day oral median lethal concentration: > 2000 mg/kg

Bobwhite 5-day dietary median lethal concentration: > 5000 ppm

Mallard 5-day dietary median lethal concentration: > 5000 ppm

Earthworm 14-day median lethal concentration: > 102.6 mg/kg

Green algae (*P. subcapitata*) 72-hour median effective concentration (growth): 0.22 mg/L

Seedling median effective concentration (growth): 43 mg/kg (tomato); 53 mg/kg (soybean); 140 mg/kg (oat)

**Environmental Fate:**

Tylosin base

Water Solubility (g/L): 5

Kow (pH 5, 7, 9): 5, 17, 17

Koc: 200 (sandy loam, pH 4.6); 1652 (silt loam, pH 5.7); 2233 (sandy loam; pH 7.6)

UV-visible light absorption (nm): 282

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

**Environmental Summary:**

Tylosin base - Practically nontoxic to fish, birds, earthworms, and aquatic invertebrates. Highly toxic to algae. No volatility expected. Not expected to bioconcentrate in aquatic organisms. Low mobility in soil. Not persistent in the environment due to degradation and possible photolysis.

**Lilly Aquatic Exposure Guideline (LAEG):**

Tylosin base

LAEG for Drinking Water: 36 micrograms/L

LAEG for Chronic Exposure of Aquatic Organisms: 99 micrograms/L

LAEG for Acute Exposure of Aquatic Organisms: 220 micrograms/L

## Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

**Container Disposal:** No special package disposal required.

## Section 14 - Transport Information

**Regulatory Organizations:**

**DOT:** Not Regulated

**IMO:**

UN Number	:	3077
Description of the goods	:	Environmentally hazardous substance, solid, n.o.s.
Class	:	9
Packaging group	:	III
Labels	:	9
Marine pollutant	:	yes

**Additional Information:** This material is considered to be an Environmentally Hazardous Substance according to the criteria set forth in the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) and is regulated as a Hazard Class 9 (UN3077 or UN3082) when shipping under ADR.

## Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Elanco Animal Health usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

### U.S. Regulations

- TSCA - No
- CERCLA - Not on this list
- SARA 302 - Not on this list
- SARA 313 - Not on this list
- OSHA Substance Specific - No

NADA Number: 13-076

### EU Regulations

#### EC Classification

- Xn (Harmful)
- Xi (Irritant)
- N (Dangerous for the Environment)

#### Risk Phrases

- R 36 - Irritating to eyes.
- R 42/43 - May cause sensitization by inhalation and skin contact.
- R 50 - Very toxic to aquatic organisms.

#### Safety Phrases

- S 25 - Avoid contact with eyes.
- S 26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- S 36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

## Section 16 - Other Information

**MSDS Sections Revised:** Section 14

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 MERCHANTABILITY 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  
1-800-428-4441  
1-317-276-2000

### **GLOSSARY:**

ACGIH = American Conference of Governmental Industrial Hygienists  
AIHA = American Industrial Hygiene Association  
BEI = Biological Exposure Index  
CAS Number = Chemical Abstract Service Registry Number  
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)  
CHAN = Chemical Hazard Alert Notice  
CHEMTREC = Chemical Transportation Emergency Center  
DOT = Department of Transportation  
EC = European Community  
EINECS = European Inventory of Existing Chemical Substances  
ELINCS = European List of New Chemical Substances  
EPA = Environmental Protection Agency  
HEPA = High Efficiency Particulate Air (Filter)  
IARC = International Agency for Research on Cancer  
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association  
IEG = Lilly Interim Exposure Guideline  
IMO = International Maritime Organization  
Kow = Octanol/Water Partition Coefficient  
LEG = Lilly Exposure Guideline  
LEL = Lower Explosive Limit  
MSDS = Material Safety Data Sheet  
MSHA = Mine Safety and Health Administration  
NA = Not Applicable, except in Section 14 where NA = North America  
NADA = New Animal Drug Application  
NAIF = No Applicable Information Found  
NCI = National Cancer Institute  
NIOSH = National Institute for Occupational Safety and Health  
NOS = Not Otherwise Specified  
NTP = National Toxicology Program  
OSHA = Occupational Safety and Health Administration  
PEL = Permissible Exposure Limit (OSHA)  
RCRA = Resource Conservation and Recovery Act  
RQ = Reportable Quantity  
RTECS = Registry of Toxic Effects of Chemical Substances  
SARA = Superfund Amendments and Reauthorization Act

STEG = Lilly Short Term Exposure Guideline  
STEL = Short Term Exposure Limit  
TLV = Threshold Limit Value (ACGIH)  
TPQ = Threshold Planning Quantity  
TSCA = Toxic Substances Control Act  
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted  
UEL = Upper Explosive Limit  
UN = United Nations  
WEEL = Workplace Environmental Exposure Level (AIHA)