# Elanco

# SAFETY DATA SHEET

#### 1. Identification

Product identifier Component TE-G, TE-IS, and TE-S Implants with Tylan

Other means of identification

Item Code AH0369, AH0508, AH0358, AH0973

Synonyms Component TE-G Implant with Tylan \* Component TE-IS Implant with Tylan \* Component TE-S

Implant with Tylan

Recommended use Veterinary Pharmaceutical

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)

Email: lilly\_msds@lilly.com

**Emergency Telephone** Elanco Product Technical Support / Human or Animal Exposure Reporting:

**Numbers:** 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 Serious eye damage/eye irritation Category 2B

Sensitization, respiratory

Sensitization, skin

Category 1

Carcinogenicity

Category 1A

Reproductive toxicity

Category 1A

Reproductive toxicity Effects on or via lactation

OSHA defined hazards Not classified.

Label elements



Signal word Danger

**Hazard statement** 

H317 May cause an allergic skin reaction.

H320 Causes eye irritation. H350 May cause cancer.

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

H360 May damage fertility or the unborn child. H362 May cause harm to breast-fed children.

**Precautionary statement** 

Prevention

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P261 Avoid breathing dust.

P263 P264 P270 P272 P280 P285	Avoid contact during pregnancy/while nursing. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection.
Response	
P302 + P352 P304 + P341	IF ON SKIN: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P363	Wash contaminated clothing before reuse.

Storage

Store locked up. P405

**Disposal** 

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

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information None.

# 3. Composition/information on ingredients

#### **Mixtures**

Chemical name	Common name and synonyms	CAS number	%
Trenbolone Acetate		10161-34-9	40 - 54
Tylosin Tartrate	Tylosin, (2R,3R)-2,3-dihydroxybutanedioate (salt) LSN 029510	1405-54-5	11 - 30
Estradiol		50-28-2	8 - 11
Other components below reportable levels			20 - < 30

#### **Composition comments**

This product consists of 2 to 7 Trenbolone Acetate and Estradiol Pellets packaged with a Tylosin Tartrate (Tylan) pellet as a single implant, with 20 implants encased in a single plastic cartridge belt that poses no exposure risk unless the belt is damaged.

#### 4. First-aid measures

Move to fresh air. Oxygen or artificial respiration if needed. Get medical attention immediately. Inhalation Immediately flush skin with plenty of water. Get medical attention if irritation persists after washing. Skin contact Remove contaminated clothing and shoes.

In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under Eye contact the eyelids, for at least 15 minutes. Get medical attention immediately.

Call a physician or poison control center immediately. If conscious, give the victim plenty of water Ingestion to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions.

May cause allergic skin reaction. May cause allergic respiratory reaction. Eye irritation. May cause **Most important** symptoms/effects, acute and cancer. May cause reproductive effects.

delayed Indication of immediate

medical attention and special treatment needed

**General information** 

The estradiol may aggravate pre-existing estrogen-dependent neoplasias including malignancies of the female reproductive organs and breast, thromboembolic diseases, impaired liver or kidney function, and pregnancy.

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. Show this safety data sheet to the doctor in attendance.

#### 5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing

None known.

media

Specific hazards arising from

the chemical

Hazardous decomposition products formed under fire conditions.

Special protective equipment and precautions for firefighters Wear self-contained breathing apparatus and protective clothing.

Fire fighting

equipment/instructions

Use water spray to cool unopened containers.

Water. Carbon dioxide (CO2). Dry chemical.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

Personal precautions. protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust and contact with skin and eyes. See Section 8 of the SDS for Personal Protective Equipment.

Methods and materials for containment and cleaning up If pellets remain intact, scoop or scrape up material into containers for disposal. If pellets are broken, contain dry material by lightly misting with water, followed by vacuuming. 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/wet material and remove by mopping or wet wiping.

Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance.

**Environmental precautions** 

Avoid discharge into drains, water courses or onto the ground. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

# 7. Handling and storage

Precautions for safe handling

NOT INTENDED FOR HUMAN USE.

Do not handle until all safety precautions have been read and understood. Pregnant or breastfeeding women must not handle this product. Wear appropriate personal protective equipment. Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.

Conditions for safe storage, including any incompatibilities Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.

# 8. Exposure controls/personal protection

#### Occupational exposure limits

Lilly (LEG) Components	Туре	Value	Form
Estradiol (CAS 50-28-2)	Excursion Limit	0.075 ug/m3	(30 minutes)
,	TWA (12hrs)	0.025 ug/m3	,
	TWA (8hrs)	0.04 ug/m3	
Trenbolone Acetate (CAS 10161-34-9)	TWA (12hrs)	0.05 ug/m3	
,	TWA (8hrs)	0.07 ug/m3	
iological limit values	No biological exposure limits noted for the ingredient(s).		
xposure guidelines	Lilly Exposure Guideline (LEG): 12 hour TWA <100 ug/m3 (Tylosin Tartrate)		

Appropriate engineering controls

Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, isolator (eg. glovebag, glovebox), or closed material transfer systems.

#### 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.

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

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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. If material is handled in a fume hood or ventilated enclosure, consider using redundant respiratory protection.

Thermal hazards Not available.

General hygiene considerations

The intact implant is not considered hazardous under normal handling procedures.

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.

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** 

Physical state Solid.

**Form** Solid. Cylindrical pellets packaged as an implant.

Color Blue (Tylosin Tartrate)

Light yellow (Component TE-S)

Odor Odorless

**Odor threshold** No data available pН No data available. No data available. Melting point/freezing point Initial boiling point and boiling No data available.

range

Flash point No data available. No data available. **Evaporation rate** No test data available. Flammability (solid, gas)

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. No data available. Vapor pressure No data available. Vapor density No data available. Relative density

Solubility(ies)

(Tylosin Tartrate), soluble, (Component TE), insoluble Solubility (water)

**Partition coefficient** (n-octanol/water)

No data available.

No data available. **Auto-ignition temperature Decomposition temperature** No data available.

No data available. **Viscosity** 

Other information

No data available. Density Not explosive. **Explosive properties** 

Oxidizing properties No oxidizing properties. Potential for dust

explosion

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 Hazardous polymerization does not occur.

reactions

**Conditions to avoid**Contact with incompatible materials. None known.

**Species** 

Incompatible materials Strong oxidizing agents.

**Hazardous decomposition** 

products

Hazardous decomposition products formed under fire conditions.

**Test Results** 

#### 11. Toxicological information

#### Information on toxicological effects

# Acute toxicity Components

Estradiol (CAS 50-28-2)		
<u>Acute</u>		
Dermal		
LD	Rabbit	> 100 mg/kg No deaths or toxicity.
Oral		
LD	Rat	> 500 mg/kg No deaths.
Trenbolone Acetate (CAS 10161-34-9)		
<u>Acute</u>		
Oral		
LD	Rat	> 5000 mg/kg
LD50	Mouse	2700 mg/kg
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
Skin corrosion/irritation	Due to partial or complete lack of data the classification is not possible.	
Serious eye damage/eye irritation	Causes eye irritation. (Tylosin Tartrate) (cleared within 7 days)	
Respiratory or skin sensitization	n	
Respiratory sensitization	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Skin sensitization	May cause an allergic skin reaction.	
Germ cell mutagenicity	Negative in bacterial cells. Induced micronuclei but not chromosomal aberrations, aneuploidy, or sister chromatid exchanges in in-vitro human cell assays. Induced aneuploidy and unscheduled DNA synthesis but did not induce DNA strand breaks or sister chromatid exchanges in in-vitro rodent cell assays. Did not induce chromosomal aberrations in bone marrow cells of mice treated in-vivo. (Estradiol)	
Results in genetic toxicity assays (in vitro): Negative (Trenbolone Acetate)		e (Trenbolone Acetate)

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

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 Tartrate, as free base)

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#### Carcinogenicity

May cause cancer. IARC Group 1 (sufficient evidence of carcinogenicity in humans). Estrogen-only menopausal therapy is carcinogenic to humans (Group 1) (Estradiol)

IARC has not classified trenbolone acetate for carcinogenicity. NTP and OSHA have not listed trenbolone as a human carcinogen. Androgens as a class are considered probable human carcinogens.

Animal testing did not show any carcinogenic effects. (Tylosin Tartrate, as free base)

# IARC Monographs. Overall Evaluation of Carcinogenicity

Estradiol (CAS 50-28-2) 1 Carcinogenic to humans.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

#### US. National Toxicology Program (NTP) Report on Carcinogens

Estradiol (CAS 50-28-2) Known To Be Human Carcinogen.

Reproductive toxicity May cause harm to breastfed babies. May damage fertility or the unborn child.

Specific target organ toxicity -

single exposure

**Aspiration hazard** 

Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity -

Due to partial or complete lack of data the classification is not possible.

repeated exposure

No aspiration toxicity classification

# 12. Ecological information

**Ecotoxicity** Very toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Estradiol (CAS 50-28-	-2)		
Chronic			
Other	NOEC	Pseudokirchnerella subcapitata	>= 0.523 mg/l, 72 h
Aquatic			
Acute			
Algae	EC50	Algae	> 3.1 mg/l, 72 h (Desmodesmus subspicatus)
Crustacea	EC50	Water flea (Daphnia magna)	2.87 mg/l, 48 h
Fish	LC50	Medaka, high-eyes (Oryzias latipes)	460 μg/l, 72 h
Chronic			
Crustacea	NOEC	Water flea (Daphnia magna)	0.2 mg/l, 48 h
Fish	LC50	Medaka, high-eyes (Oryzias latipes)	0.002 μg/l, 96 h
Trenbolone Acetate (0	CAS 10161-34-9)		
Aquatic			
Crustacea	NOEC	Daphnia magna	0.58 mg/l, 48 h
Acute			
Crustacea	EC50	Daphnia magna	1.34 mg/l, 48 h
Tylosin 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
	LOGO	Lattiwoffis (Lisetila fetida)	- 102.0 mg/kg, 14 days

**Species** Components **Test Results** 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)

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

The product contains potentially bioaccumulating substances.

Partition coefficient n-octanol / water (log Kow)

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

Mobility in soil 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

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)

Other adverse effects Not available.

**Ecotoxicological Properties** 

**Drinking Water** 

Components	Test Results	
Estradiol	0.00022 μg/l, (Lilly Aquatic Exposure Guideline)	
Tylosin Tartrate	36 μg/l, (Lilly Aquatic Exposure Guildeline)	
Chronic Exposure of Aquatic Organisms		
Components	Test Results	
Estradiol	0.0009 μg/l, (Lilly Aquatic Exposure Guideline)	
Tylosin Tartrate	99 μg/l, (Lilly Aquatic Exposure Guildeline)	
Acute Exposure of Aquatic Organisms		
Components	Test Results	
Estradiol	0.009 μg/l, (Lilly Aquatic Exposure Guideline)	
ylosin Tartrate 220 µg/l, (Lilly Aquatic Exposure Guildeline)		

#### 13. Disposal considerations

**Disposal methods/information** Dispose of contents/container in accordance with local/regional/national/international regulations.

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

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 UN3077

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

Transport hazard class(es)

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

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Other information

Passenger and cargo

aircraft

Allowed with restrictions.

Allowed with restrictions. Cargo aircraft only

**IMDG** 

**UN** number UN3077

**UN** proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Trenbolone Acetate, Tylosin

Tartrate)

Transport hazard class(es)

Class 9 Subsidiary risk Ш Packing group

**Environmental hazards** 

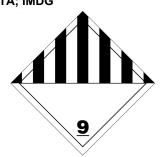
Marine pollutant Yes F-A, S-F **EmS** 

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

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

Not applicable.

IATA; IMDG



#### Marine pollutant



#### 15. Regulatory information

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication **US federal regulations** 

Standard, 29 CFR 1910.1200.

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on 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 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Immediate Hazard - Yes **Hazard categories** 

Delayed Hazard - Yes Fire Hazard - No 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 WARNING: This product contains a chemical known to the State of California to cause cancer and

birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Estradiol (CAS 50-28-2) Listed: January 1, 1988

US - California Proposition 65 - CRT: Listed date/Developmental toxin

Estradiol (CAS 50-28-2) Listed: April 1, 1990

#### International Inventories

Country(s) or regionInventory nameOn inventory (yes/no)\*CanadaDomestic Substances List (DSL)NoCanadaNon-Domestic Substances List (NDSL)NoUnited States & Puerto RicoToxic Substances Control Act (TSCA) InventoryNo

# 16. Other information, including date of preparation or last revision

 Issue date
 03-17-2015

 Revision date
 03-06-2017

Version # 02 Lilly Lab Code He

Health: 2 Fire: 1 Reactivity: 0 Special 1: C Special 2: R

> Special 3: P Special 4: A

**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 information** Product and Company Identification: Alternate Trade Names

Hazard(s) identification: Prevention Hazard(s) identification: Response

Exposure controls/personal protection: Exposure guidelines

Toxicological information: Carcinogenicity

Toxicological information: Respiratory sensitization

Toxicological information: Skin contact

GHS: Classification

Material name: Component TE-G, TE-IS, and TE-S Implants with Tylan 4375 Version #: 02 Revision date: 03-06-2017 Issue date: 03-17-2015

<sup>\*</sup>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).