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

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 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.

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

H350 May cause cancer.

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	Avoid contact during pregnancy/while nursing.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/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 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	
P405	Store locked up.
Disposal	
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

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

Inhalation Move to fresh air. Oxygen or artificial respiration if needed. Get medical attention immediately. 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 cancer. May cause reproductive effects.

symptoms/effects, acute and delayed Indication of immediate

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

medical attention and special treatment needed

function, and pregnancy.

General information

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

Water. Carbon dioxide (CO2). Dry chemical.

Unsuitable extinguishing media

None known.

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.

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 eves. 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	
Biological limit values	No biological exposure limits noted for the	ingredient(s).	
Exposure 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		

In

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Chemical resistant gloves.

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

Material name: Component TE-G, TE-IS, and TE-S Implants with Tylan 4375 Version #: 02 Revision date: 09-21-2015 Issue date: 03-17-2015

Select appropriate respirator for physical characteristics of material. Select respirator with Respiratory protection

appropriate protection factor. If material is handled in a fume hood or ventilated enclosure,

consider using redundant respiratory protection.

Not available. Thermal hazards

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

Solid. Physical state

Form Solid. Cylindrical pellets packaged as an implant.

Blue (Tylosin Tartrate) Color

Light yellow (Component TE-S)

Odor Odorless

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

range

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

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

Solubility(ies)

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

No data available. Partition coefficient

(n-octanol/water)

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

Other information

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

Oxidizing properties No oxidizing properties. No data available. Potential for dust

explosion

10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

Chemical stability

Possibility of hazardous reactions

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

Conditions to avoid

Contact with incompatible materials. None known.

Incompatible materials Hazardous decomposition

Strong oxidizing agents.

products

Hazardous decomposition products formed under fire conditions.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
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 140	5-54-5)	
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Inhalation		
LC50	Rat	> 600 mg/m3, 1 h
Oral		
LD50	Rat	> 6200 mg/kg

^{*} Estimates for product may be based on additional component data not shown.

Due to partial or complete lack of data the classification is not possible. Skin corrosion/irritation

Serious eye damage/eye

irritation

Causes eye irritation. (Tylosin Tartrate) (cleared within 7 days)

Respiratory or skin sensitization

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)

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)

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

Material name: Component TE-G, TE-IS, and TE-S Implants with Tylan 4375 Version #: 02 Revision date: 09-21-2015 Issue date: 03-17-2015

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 listed

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

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

Aspiration hazard

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	2)		
Aquatic			
Fish	LC50	Medaka, high-eyes (Oryzias latipes)	460 μg/l, 72 h
		Rainbow trout,donaldson trout (Oncorhynchus mykiss)	> 0.5 mg/l, 48 h
Trenbolone Acetate (Ca	AS 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 1	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
		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)

^{*} Estimates for product may be based on additional component data not shown.

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)

Estradiol 4.01 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)

> > **Test Results**

Not available. Other adverse effects

Ecotoxicological Properties

Drinking Water Components

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) 220 µg/l, (Lilly Aquatic Exposure Guildeline) Tylosin Tartrate

13. Disposal considerations

Disposal instructions 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

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

Transport hazard class(es)

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

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

Other information

Passenger and cargo

aircraft

Allowed.

Cargo aircraft only Allowed.

IMDG

UN3077 **UN** number

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

Tartrate)

Transport hazard class(es)

9 Class 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

Not applicable.

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.

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 listed.

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

(SDWA)

Not regulated.

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 Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Estradiol (CAS 50-28-2)

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

Not listed

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

Estradiol (CAS 50-28-2)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

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
 09-21-2015

Version # 02
Lilly Lab Code Health: 2

Lilly Lab Code

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

Material name: Component TE-G, TE-IS, and TE-S Implants with Tylan 4375 Version #: 02 Revision date: 09-21-2015 Issue date: 03-17-2015

^{*}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).

Revision Information

Product and Company Identification: Alternate Trade Names

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

Composition/information on ingredients: Component information Exposure controls/personal protection: Exposure guidelines GHS: Classification