

SAFETY DATA SHEETS

This SDS packet was issued with item:

078705238

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078705220

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078705212 078705246

COMPONENT[®]
BRAND IMPLANTS

VetLife[®]

TE-IS WITH Tylan[®]

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

trenbolone acetate 80 mg and
estradiol USP 16 mg with
29 mg tylosin tartrate as a local antibacterial



20-dose Cartridge Belt*

For use with the COMPONENT One Gun^{®**}

For Use In Animals Only

Each CARTRIDGE BELT holds 20 doses of COMPONENT[®] TE-IS with Tylan Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 80 mg of trenbolone acetate and 16 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. COMPONENT[®] TE-IS Implants are recommended for use in steers fed in confinement for slaughter for INCREASED RATE OF WEIGHT GAIN AND IMPROVED FEED EFFICIENCY.

INDICATIONS FOR USE: This product contains trenbolone acetate and estradiol for increased rate of weight gain and improved feed efficiency in a slow-release delivery system. Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

DOSAGE: Administer 1 implant per animal according to the following instructions.

GENERAL INSTRUCTIONS: Study the instructions which should be followed carefully at all times, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and implanter. During fly season use fly repellent on implant site. One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 5 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. **DO NOT** attempt to salvage implantation site for animal feed or human food.

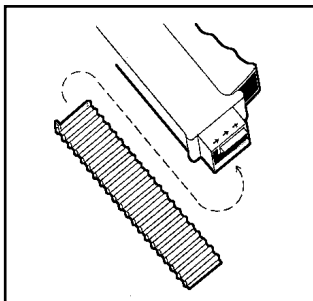
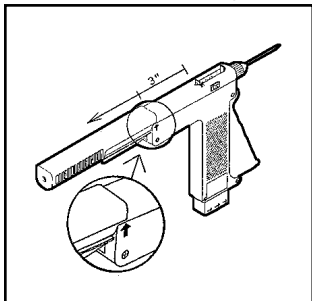
A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) —
FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE —
KEEP OUT OF REACH OF CHILDREN**

IMPLANTING INSTRUCTIONS:

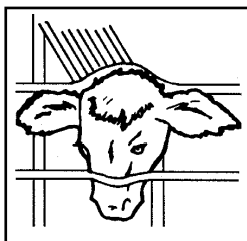
Loading the Implanter

Load the implanter following the instructions supplied with each implanter.



Restrain the Animal

Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint. When implanting horned cattle, better control is obtained with additional use of nose tongs.



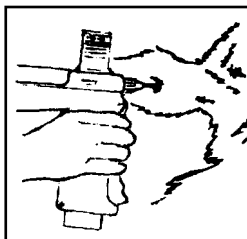
Prepare the Implant Site

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.



Where to Implant

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a point toward the tip of the ear at least a needle length away from the intended deposition site. Avoid injuring the large arteries, veins and cartilage of the ear.



Insert the Needle

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.

Implant the Pellets

After inserting the needle fully in the correct implant position squeeze the trigger fully. As the needle is withdrawn from the ear, the controlled-pressure plunger action properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain.

Clean the Needle

Clean the implanter needle with alcohol or a properly diluted germicidal solution prior to implanting the next animal.

Storage Conditions

Store in a refrigerator (2°-8°C; 36°-46°F) and protect from sunlight. Use before the expiration date printed on the foil pouch.

ANADA 200-221, Approved by FDA

Manufactured by a non-sterilizing process.

*U.S. Patent No. 4,531,938

**U.S. Patent Nos. 4,762,515 and 5,522,797 – Ivy Animal Health, Inc.

COMPONENT TE-IS with Tylan is covered by U.S. Patent No. 5,874,098

COMPONENT and COMPONENT One Gun are registered trademarks of Ivy Animal Health, Inc.

Tylan is a registered trademark of Eli Lilly and Company.

Manufactured for **VetLife** by Ivy Laboratories.

Overland Park, KS 66214, USA

VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

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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)
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	Serious eye damage/eye irritation	Category 2B
	Sensitization, respiratory	Category 1
	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	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.

Skin contact Immediately flush skin with plenty of water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes.

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 immediately.

Ingestion Call a physician or poison control center immediately. 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.

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

Indication of immediate medical attention and special treatment needed 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.

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 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. 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	Type	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	

Elanco OEL

Components	Type	Value
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	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.
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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.
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. 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	<p>The intact implant is not considered hazardous under normal handling procedures.</p> <p>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.</p> <p>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.</p>

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

pH No data available.

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) No test data available.

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

Partition coefficient (n-octanol/water) No data available.

Auto-ignition temperature No data available.

Decomposition temperature No data available.

Viscosity No data available.

Other information

Density No data available.

Explosive properties Not explosive..

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 reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials. None known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition 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)		
Oral		
LD50	Rat	5000 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		
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.	
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 1910.1001-1052)

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

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

Specific target organ toxicity - repeated exposure

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

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)			
<i>Chronic</i>			
Other	NOEC	Pseudokirchnerella subcapitata	>= 0.523 mg/l, 72 h
Aquatic			
<i>Acute</i>			
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
<i>Chronic</i>			
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
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)
<i>Acute</i>			
	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)
<i>Chronic</i>			
	LC50	Earthworms (Eisenia fetida)	> 102.6 mg/kg, 14 days
		Quail (Bobwhite quail)	> 2000 mg/kg, 14 days
Aquatic			
<i>Acute</i>			
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)

LILLY AQUATIC EXPOSURE GUIDELINES:**Tylosin Tartrate**

Acute LAEG (at the edge of the acute mixing zone):

220 µg/l

Chronic LAEG (at the edge of the chronic mixing zone):

99 µg/l

Drinking water LAEG (at the point where surface water is taken for drinking water):

36 µg/l

Estradiol

Drinking water LAEG (at the point where surface water is taken for drinking water): 0.0002 µg/l

Chronic LAEG (at the edge of the chronic mixing zone): 0.0009 µg/l

Acute LAEG (at the edge of the acute mixing zone): 0.009 µg/l

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)

Other adverse effects Not available.

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

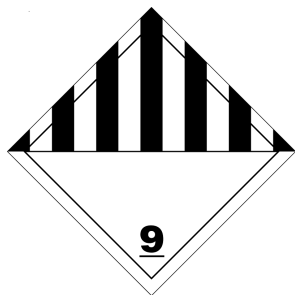
IMDG

UN number UN3077
UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Trenbolone Acetate, Estradiol)
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.

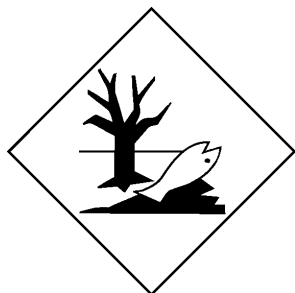
Transport in bulk according to Not applicable.

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.
CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

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)

Classified hazard categories

Serious eye damage or eye irritation
Respiratory or skin sensitization
Carcinogenicity
Reproductive toxicity

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

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

California Proposition 65



WARNING: WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

California Proposition 65 - CRT: Listed date/Carcinogenic substance

Estradiol (CAS 50-28-2)

Listed: January 1, 1988

California Proposition 65 - CRT: Listed date/Developmental toxin

Estradiol (CAS 50-28-2)

Listed: April 1, 1990

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 03-17-2015

Revision date 03-26-2019

Version # 04

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 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



SAFETY DATA SHEET

1. Identification

Product identifier	Component TE-IH, TE-H, or TE-200 Implant
Other means of identification	
Item Code	AH0806, AH0841, AH0368
Synonyms	Component TE-IH Implant * Component TE-H Implant * Component TE-200 Implant
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)
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	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

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.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Response

P308 + P313	IF exposed or concerned: Get medical advice/attention.
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Storage

P405	Store locked up.
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Disposal

P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
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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	64.5
Estradiol		50-28-2	6.5
Other components below reportable levels			29

Composition comments This product consists of 2 to 7 pellets per implant, with 20 implants packaged in a single polypropylene belt that poses no exposure risk unless the belt is damaged.

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. Get medical attention immediately.

Skin contact Immediately flush skin with plenty of water. Get medical attention immediately. Remove contaminated clothing and shoes.

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 Call a physician or poison control center immediately. 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.

Most important symptoms/effects, acute and delayed May cause cancer. May cause reproductive effects.

Indication of immediate medical attention and special treatment needed 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.

General information IF exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). 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. See Section 8 of the SDS for Personal Protective Equipment. Avoid inhalation of dust and contact with skin and eyes.

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. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping. Be aware of potential for dust explosion when using electrical equipment.

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

Environmental precautions Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling NOT INTENDED FOR HUMAN USE. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use only with adequate ventilation. Avoid contact with eyes, skin, and clothing. Should be handled in closed systems, if possible. Wash hands thoroughly after handling. Observe good industrial hygiene practices.

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

8. Exposure controls/personal protection

Occupational exposure limits

Lilly (LEG)

Components

	Type	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	

Elanco OEL

Components

	Type	Value
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).

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.

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

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

Light yellow

Odor

Odorless

Odor threshold

No data available.

pH

No data available.

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)	No test data available.
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)	Insoluble
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Viscosity	No data available.
Other information	
Density	No data available.
Explosive properties	Not explosive.
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 reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.

11. Toxicological information

Information on toxicological effects

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

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)		
Oral		
LD50	Rat	5000 mg/kg
Skin corrosion/irritation	Rabbit: No irritation. (Estradiol) Based on available data, the classification criteria are not met.	

Serious eye damage/eye irritation	Rabbit: Slight irritation. (Estradiol) Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	
Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.
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) Based on available data, the classification criteria are not met.
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.
IARC Monographs. Overall Evaluation of Carcinogenicity	
Estradiol (CAS 50-28-2)	1 Carcinogenic to humans.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)	
Not regulated.	
US. National Toxicology Program (NTP) Report on Carcinogens	
Estradiol (CAS 50-28-2)	Known To Be Human Carcinogen.
Reproductive toxicity	May damage fertility or the unborn child. May cause harm to breastfed babies. Reproductive tissue changes, decreased fertility, menstrual irregularities, fetal changes, and developmental changes in offspring. (Estradiol and Trenbolone Acetate)
Specific target organ toxicity - single exposure	Reproductive organs. See also the Reproductive Effects section. (Estradiol) Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	Reproductive organs. See also the Reproductive Effects section. (Estradiol) Based on available data, the classification criteria are not met.
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)			
<i>Chronic</i>			
Other	NOEC	Pseudokirchnerella subcapitata	>= 0.523 mg/l, 72 h
Aquatic			
<i>Acute</i>			
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
<i>Chronic</i>			
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

LILLY AQUATIC EXPOSURE GUIDELINES:

Estradiol

Drinking water LAEG (at the point where surface water is taken for drinking water):	0.0002 µg/l
Chronic LAEG (at the edge of the chronic mixing zone):	0.0009 µg/l
Acute LAEG (at the edge of the acute mixing zone):	0.009 µg/l

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available on bioaccumulation.

Partition coefficient n-octanol / water (log Kow)

Estradiol

4.01

Mobility in soil

No data available.

Other adverse effects

Not available.

13. Disposal considerations**Disposal instructions**

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**

UN3077

UN proper shipping name

Environmentally hazardous substance, solid, n.o.s. (Estradiol, Trenbolone Acetate)

Transport hazard class(es)**Class**

9

Subsidiary risk

-

Label(s)

9

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**

UN3077

UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Estradiol, Trenbolone Acetate)

Transport hazard class(es)**Class**

9

Subsidiary risk

-

Label(s)

9

Packing group

III

Environmental hazards**Marine pollutant**

Yes

EmS

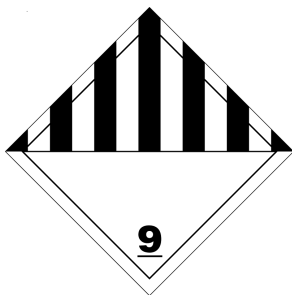
F-A, S-F

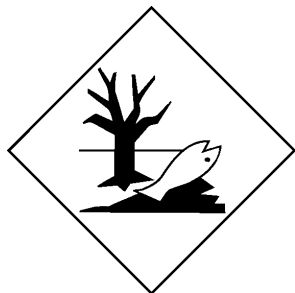
Special precautions for user

Not available.

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

Not applicable.

IATA; IMDG



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.

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)

Classified hazard categories

Carcinogenicity
Reproductive toxicity

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

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

California Proposition 65



WARNING: WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

California Proposition 65 - CRT: Listed date/Carcinogenic substance

Estradiol (CAS 50-28-2)

Listed: January 1, 1988

California Proposition 65 - CRT: Listed date/Developmental toxin

Estradiol (CAS 50-28-2)

Listed: April 1, 1990

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 03-16-2015

Revision date 03-26-2019

Version # 04

List of abbreviations LEG: Lilly Exposure Guideline.
TWA: Time Weighted Average Value.
LD: Lethal Dose.
LD50: Lethal Dose 50%.
IARC: International Agency for Research on Cancer.
NTP: National Toxicology Program.
OSHA: Occupational Safety & Health Administration.
NOEC: No observed effect concentration.
EC50: Effective Concentration 50%.
LC50: Lethal Concentration 50%.

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 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:

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