

SAFETY DATA SHEETS

This SDS packet was issued with item:

078705246

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).

078394269

COMPONENT[®]
BRAND IMPLANTS

VetLife[®]

TE-IH WITH Tylan[®]

**FOR HEIFERS FED IN
CONFINEMENT FOR SLAUGHTER**

trenbolone acetate 80 mg and
estradiol USP 8 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-IH with Tylan Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 80 mg of trenbolone acetate and 8 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. COMPONENT[®] TE-IH Implants are recommended for use in heifers fed in confinement for slaughter for INCREASED RATE OF WEIGHT GAIN.

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

NOTE: Studies have demonstrated that administration of COMPONENT[®] TE-IH can result in decreased marbling scores when compared to non-implanted heifers.

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.

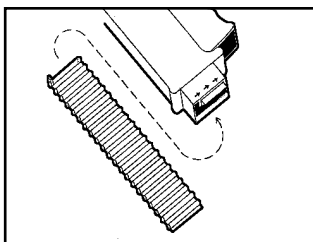
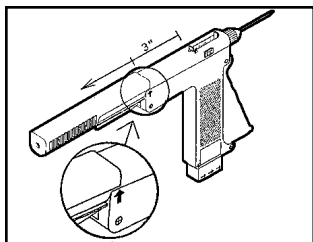
A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**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

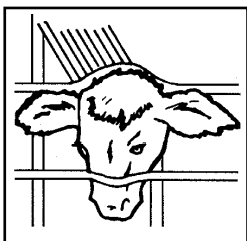
Load the implanter following the instructions supplied with each implanter.



Obtained by Global Safety Management, Inc. (www.globalsafetynet.com)

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.



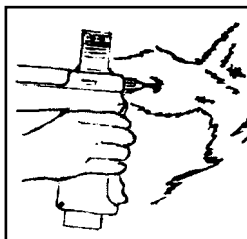
Prepare the Implant Site

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 200-346, 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-IH 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.



SAFETY DATA SHEET

1. Identification

| | |
|---|---|
| Product identifier | Component TE-S, TE-G, TE-IS Implants, or Compudose G (TE-G) |
| Other means of identification | |
| Item Code | AH0367, AH0864, AH0803, AH0359, AH0804 |
| Synonyms | Component TE-S Implant * Component TE-G Implant * Component TE-IS Implant * Compudose G (TE-G) |
| 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 Numbers: | Elanco Product Technical Support / Human or Animal Exposure Reporting: 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 | 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. |
| P263 | Avoid contact during pregnancy/while nursing. |
| P264 | Wash hands thoroughly after handling. |
| P270 | Do not eat, drink or smoke when using this product. |
| P281 | Use personal protective equipment as required. |

Response

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

| | |
|--|---|
| 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 | 61.92 |
| Estradiol | | 50-28-2 | 12.38 |
| Magnesium Stearate | | 557-04-0 | 3 |
| Other components below reportable levels | | | 22.8 |

Composition comments This product consists of 2 to 7 Trenbolone Acetate and Estradiol (TE-S) pellets packaged 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 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. Pregnant or breastfeeding women must not handle this product. 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

US. ACGIH Threshold Limit Values

| Components | Type | Value |
|-----------------------------------|------|----------|
| Magnesium Stearate (CAS 557-04-0) | TWA | 10 mg/m3 |

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 | |
| | TWA (12hrs) | 0.05 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).

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

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

| Components | Species | Test Results |
|-------------------------|---------|------------------------------------|
| Estradiol (CAS 50-28-2) | | |
| <u>Acute</u> | | |
| Dermal | | |
| LD | Rabbit | > 100 mg/kg No deaths or toxicity. |

| Components | Species | Test Results |
|-------------------------------------|---------|------------------------|
| Oral | | |
| LD | Rat | > 500 mg/kg No deaths. |
| Magnesium Stearate (CAS 557-04-0) | | |
| Acute | | |
| Inhalation | | |
| LC50 | Rat | > 2000 mg/m3, 1 hours |
| Trenbolone Acetate (CAS 10161-34-9) | | |
| Acute | | |
| Oral | | |
| LD | Rat | > 5000 mg/kg |
| LD50 | Mouse | 2700 mg/kg |

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

| | |
|--|---|
| Skin corrosion/irritation | Due to partial or complete lack of data the classification is not possible. |
| Serious eye damage/eye irritation | Due to partial or complete lack of data the classification is not possible. |
| Respiratory or skin sensitization | |
| Respiratory sensitization | Due to partial or complete lack of data the classification is not possible. |
| Skin sensitization | Due to partial or complete 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 1910.1001-1050)

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 | Not available. |
| Specific target organ toxicity - repeated exposure | Not available. |
| Aspiration hazard | No aspiration toxicity classification |

12. Ecological information

| | |
|--------------------|--|
| Ecotoxicity | Toxic to aquatic life with long lasting effects. |
|--------------------|--|

| Components | Species | Test Results |
|-------------------------|---------|---|
| Estradiol (CAS 50-28-2) | | |
| 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 |

| Components | | Species | Test Results |
|-------------------------------------|------|---------------|-----------------|
| Trenbolone Acetate (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 |

* 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 No data available on bioaccumulation.

Partition coefficient n-octanol / water (log Kow)

Estradiol 4.01

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

Ecotoxicological Properties

Drinking Water

| Components | Test Results |
|------------|--|
| Estradiol | 0.00022 µg/l, (Lilly Aquatic Exposure Guideline) |

Chronic Exposure of Aquatic Organisms

| Components | Test Results |
|------------|---|
| Estradiol | 0.0009 µg/l, (Lilly Aquatic Exposure Guideline) |

Acute Exposure of Aquatic Organisms

| Components | Test Results |
|------------|--|
| Estradiol | 0.009 µg/l, (Lilly Aquatic Exposure Guideline) |

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) |
| Transport hazard class(es) | |
| Class | 9 |
| Subsidiary risk | - |
| Label(s) | 9 |
| 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. |
| Cargo aircraft only | Allowed. |

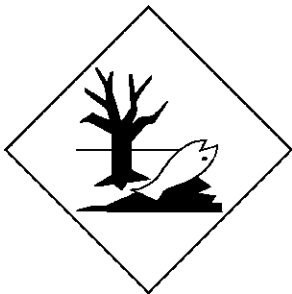
IMDG

| | |
|-----------------------------------|---|
| UN number | UN3077 |
| UN proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (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 | 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

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)

Hazard categories

Immediate Hazard - No
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 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 09-21-2015

Version # 02

Lilly Lab Code Health: 1
Fire: 1
Reactivity: 0
Special 1: C
Special 2: R

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
Exposure controls/personal protection: Exposure guidelines
Transport Information: Material Transportation Information
GHS: Classification



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 | |
| 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 Numbers: | Elanco Product Technical Support / Human or Animal Exposure Reporting: 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 | 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. |
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| P264 | Wash hands thoroughly after handling. |
| P270 | Do not eat, drink or smoke when using this product. |
| P281 | Use personal protective equipment as required. |

Response

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

| | |
|--|---|
| 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 | 64.5 |
| Estradiol | | 50-28-2 | 6.5 |
| Magnesium Stearate | | 557-04-0 | 3 |
| Other components below reportable levels | | | 26 |

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.

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. Pregnant or breastfeeding women must not handle this product. 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****US. ACGIH Threshold Limit Values**

| Components | Type | Value |
|-----------------------------------|------|----------|
| Magnesium Stearate (CAS 557-04-0) | TWA | 10 mg/m3 |

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 | |
| | TWA (12hrs) | 0.05 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).

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

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

| Components | Species | Test Results |
|-------------------------|---------|------------------------------------|
| Estradiol (CAS 50-28-2) | | |
| <u>Acute</u> | | |
| Dermal | | |
| LD | Rabbit | > 100 mg/kg No deaths or toxicity. |

| Components | Species | Test Results |
|-------------------------------------|---------|------------------------|
| Oral | | |
| LD | Rat | > 500 mg/kg No deaths. |
| Magnesium Stearate (CAS 557-04-0) | | |
| Acute | | |
| Inhalation | | |
| LC50 | Rat | > 2000 mg/m3, 1 hours |
| Trenbolone Acetate (CAS 10161-34-9) | | |
| Acute | | |
| Oral | | |
| LD | Rat | > 5000 mg/kg |
| LD50 | Mouse | 2700 mg/kg |

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

| | |
|--|---|
| Skin corrosion/irritation | Due to partial or complete lack of data the classification is not possible. |
| Serious eye damage/eye irritation | Due to partial or complete lack of data the classification is not possible. |
| Respiratory or skin sensitization | |
| Respiratory sensitization | Due to partial or complete lack of data the classification is not possible. |
| Skin sensitization | Due to partial or complete 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 1910.1001-1050)

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 | Not available. |
| Specific target organ toxicity - repeated exposure | Not available. |
| Aspiration hazard | No aspiration toxicity classification |

12. Ecological information

| | |
|--------------------|--|
| Ecotoxicity | Toxic to aquatic life with long lasting effects. |
|--------------------|--|

| Components | Species | Test Results |
|-------------------------|---------|---|
| Estradiol (CAS 50-28-2) | | |
| 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 |

| Components | | Species | Test Results |
|-------------------------------------|------|---------------|-----------------|
| Trenbolone Acetate (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 |

* 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 No data available on bioaccumulation.

Partition coefficient n-octanol / water (log Kow)

Estradiol 4.01

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

Ecotoxicological Properties

Drinking Water

| Components | Test Results |
|------------|--|
| Estradiol | 0.00022 µg/l, (Lilly Aquatic Exposure Guideline) |

Chronic Exposure of Aquatic Organisms

| Components | Test Results |
|------------|---|
| Estradiol | 0.0009 µg/l, (Lilly Aquatic Exposure Guideline) |

Acute Exposure of Aquatic Organisms

| Components | Test Results |
|------------|--|
| Estradiol | 0.009 µg/l, (Lilly Aquatic Exposure Guideline) |

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) |
| Transport hazard class(es) | |
| Class | 9 |
| Subsidiary risk | - |
| Label(s) | 9 |
| 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. |
| Cargo aircraft only | Allowed. |

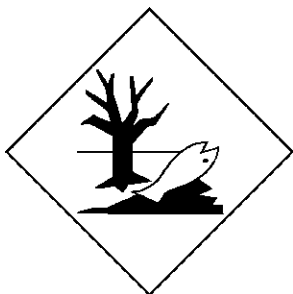
IMDG

| | |
|-----------------------------------|---|
| UN number | UN3077 |
| UN proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (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 | 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

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)

Hazard categories

Immediate Hazard - No
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 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 09-21-2015

Version # 02

Lilly Lab Code Health: 1
Fire: 1
Reactivity: 0
Special 1: C
Special 2: R

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:

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Revision Information Product and Company Identification: Alternate Trade Names
Composition/information on ingredients: Component information
Exposure controls/personal protection: Exposure guidelines
GHS: Classification