

SAFETY DATA SHEETS

This SDS packet was issued with item:

078705196

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 078799288



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	
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.
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
Other components below reportable levels			25.8

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.

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)		
Acute		
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

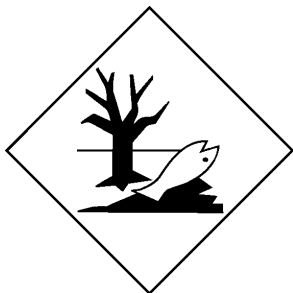
UN number UN3077
UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Estradiol, Trenbolone Acetate)
Transport hazard class(es)
Class 9
Subsidiary risk -
Label(s) 9
Packing group III
Environmental hazards Yes
ERG Code 9L
Special precautions for user Not available.
Other information
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**

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

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: 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

Table with 3 columns: Country(s) or region, Inventory name, On inventory (yes/no)*. Rows include Canada (Domestic/Non-Domestic Substances List) and United States & Puerto Rico (Toxic Substances Control Act Inventory).

*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
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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