

SAFETY DATA SHEETS

This SDS packet was issued with item:

078394244

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

078394186

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).

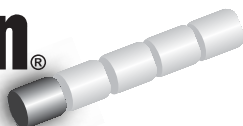
078394251 078707642 078799221 078799247

COMPONENT[®]
BRAND IMPLANTS



E-C WITH Tylan[®]

CALF IMPLANTS



progesterone USP 100 mg and estradiol benzoate 10 mg with 29 mg tylosin tartrate as a local antibacterial

20 dose CARTRIDGE BELT^{*}

For use with a COMPONENT Implanter
For Use In Animals Only

Each CARTRIDGE BELT holds 20 doses of COMPONENT[®] E-C with Tylan Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 100 mg progesterone USP and 10 mg estradiol benzoate plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. COMPONENT[®] E-C Implants are indicated for increased rate of weight gain in suckling beef calves up to approximately 400 lbs of body weight.

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 and follow them carefully at all times, avoiding shortcuts. Skin infection can be avoided by properly preparing implant site and implanter. One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

DO NOT USE IN BULL CALVES INTENDED FOR REPRODUCTION OR IN CALVES LESS THAN 45 DAYS OLD.

WARNING

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**

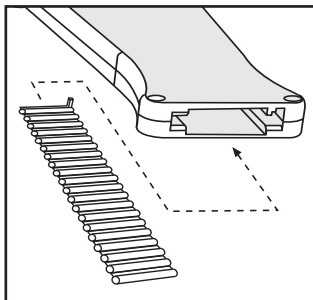
CAUTION:

Bulling, rectal and vaginal prolapse, udder development, ventral edema and elevated tailheads may be reported in calves administered progesterone and estradiol benzoate.

IMPLANTING INSTRUCTIONS:

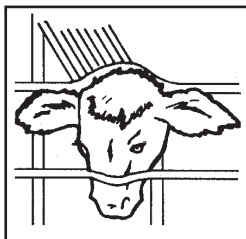
Loading the Implanter

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.



Prepare the Implant Site

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton or brush 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 as 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 and 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

Follow the directions contained in the implanter packaging to ensure the pellets are properly deposited. Proper procedure should prevent breakage or crushing of pellets. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate weight gain. Broken or crushed pellets may interfere with rates of gain and may lead to undesirable side effects such as noted in the CAUTION.

Clean the Needle

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

Storage Conditions

Store at controlled room temperature 15° to 30°C (59° to 86°F)

Avoid excessive heat and humidity.

NADA 110-315, Approved by FDA

Manufactured by a non-sterilizing process.

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

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

COMPONENT E-C 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 E-S Implant, S Implant, and E-C Implant with Tylan
Other means of identification	
Item Code	AH0328, AH0507
Synonyms	Component E-S Implant with Tylan * Component S Implant with Tylan * Component E-C Implant with Tylan
Recommended use	Veterinary Pharmaceutical
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	
Company Name	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
Phone:	1-877-Elanco1 (1-877-352-6261)
Email:	lilly_msds@lilly.com
Emergency Telephone 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	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.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H350	May cause cancer.
H360	May damage fertility or the unborn child.
H362	May cause harm to breast-fed children.
Precautionary statement	
Prevention	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing dust.
P263	Avoid contact during pregnancy/while nursing.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.

P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P285 In case of inadequate ventilation wear respiratory protection.

Response

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P337 + P313 If eye irritation persists: Get medical advice/attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P363 Wash contaminated clothing before reuse.

Storage

P405 Store locked up.

Disposal

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

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Progesterone		57-83-0	59.1 - 65.7
Tylosin Tartrate	Tylosin, (2R,3R)-2,3-dihydroxybutanedioate (salt) LSN 029510	1405-54-5	9.53 - 17.4
Estradiol Benzoate		50-50-0	5.91 - 6.57
Other components below reportable levels			10 - < 20

Composition comments This product consists of 4 or 8 Progesterone and Estradiol Benzoate pellets packaged with a single Tylosin Tartrate (Tylan) pellet as an implant, with 20 implants encased in a single plastic cartridge belt that poses no exposure list 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. Pregnant or breastfeeding women must not handle this product. Wear appropriate personal protective equipment. Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Lilly Exposure Guideline (LEG): 12 hour TWA <100 ug/m3 (Tylosin Tartrate) Lilly Exposure Guideline (LEG): 12 hour TWA 1.0 ug/m3 (Progesterone) Lilly Exposure Guideline (LEG): 8 hour TWA 2.0 ug/m3 (Progesterone) Lilly Exposure Guideline (LEG): 12 hour TWA 0.025 ug/m3 (Estradiol) Lilly Exposure Guideline (LEG): 8 hour TWA 0.04 ug/m3 (Estradiol) Lilly Exposure Guideline (LEG) : Lilly Exposure Guideline (LEG): 30 min Excursion Limit 0.075 ug/m3 (Estradiol)
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. If material is handled in a fume hood or ventilated enclosure, consider using redundant respiratory protection.
Thermal hazards	Not available.

General hygiene considerations

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

In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Under normal use and handling conditions, wear goggles to protect eyes and wear impermeable gloves and protective equipment to avoid direct contact with skin. Wash thoroughly with soap and water after handling.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Powder. Cylindrical pellets packaged as an implant.
Color	Blue (Tylosin Tartrate)

Light yellow (Progesterone and Estradiol Benzoate)

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) No data available.

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
Tylosin Tartrate (CAS 1405-54-5)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Inhalation		
LC50	Rat	> 600 mg/m3, 1 h
Oral		
LD50	Rat	> 6200 mg/kg

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

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)

Progesterone did not induce dominant lethal mutations in mice or chromosomal aberrations in rats treated in vivo. It did not induce chromosomal aberrations or sister chromatid exchanges in cultured human cells, nor chromosomal aberrations or DNA strand breaks in rodent cells.

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 Benzoate)

IARC 2B (sufficient evidence of carcinogenicity in animals). Progestogen-only contraceptives and progestins are possibly carcinogenic to humans (Group 2) (Progesterone)

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

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Estradiol Benzoate (CAS 50-50-0)

Known To Be Human Carcinogen.

Progesterone (CAS 57-83-0)

Reasonably Anticipated to be a 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 Toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Estradiol Benzoate (CAS 50-50-0)			
Aquatic			
Fish	LC50	Medaka, high-eyes (Oryzias latipes)	460 µg/l, 72 h (Estradiol)
		Rainbow trout,donaldson trout (Oncorhynchus mykiss)	> 0.5 mg/l, 48 h (Estradiol)
Tylosin Tartrate (CAS 1405-54-5)			
	EC50	Oats (Seedling)	140 mg/kg (Growth, as free base)
		Soybean (Seedling)	53 mg/kg (Growth, as free base)
		Tomato (Seedling)	43 mg/kg (Growth, as free base)
Acute			
	LC50	Duck (Mallard duck)	> 5000 mg/kg, 5 days (dietary, as free base)
		Quail (Bobwhite quail)	> 5000 mg/kg, 5 days (dietary, as free base)
Other	EC50	Pseudokirchnerella subcapitata	0.22 mg/l (average specific growth rate) (as free base)
Chronic			
	LC50	Earthworms (Eisenia fetida)	> 102.6 mg/kg, 14 days
		Quail (Bobwhite quail)	> 2000 mg/kg, 14 days
Aquatic			
Acute			
Crustacea	EC50	Daphnia magna	> 300 mg/l (as free base)
Fish	LC50	Bluegill (Lepomis macrochirus)	> 300 mg/l (as free base)
		Rainbow Trout	> 300 mg/l (as free base)

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

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

Bioaccumulative potential The product contains potentially bioaccumulating substances.

Partition coefficient n-octanol / water (log Kow)

Estradiol Benzoate	4.01
Progesterone	3.87
Tylosin Tartrate	17, (pH 7)
	17, (pH 9)
	5, (pH 5)

Mobility in soil Soil degradation half-life (100 ppm): 62 days (tylosin factor A); 37 days (tylosin factor D)
Soil degradation half-life (1 mg/kg; 4 soils): 50.3 to 105 days
Leaching in soil column: none

Adsorption

Soil/sediment sorption - log Koc

Tylosin Tartrate	1652 Silt Loom (pH 5.7)
	200 Sandy Loom (pH 4.6)
	2233 Sandy Loom (pH 7.6)

Other adverse effects Not available.

Ecotoxicological Properties

Drinking Water

Components	Test Results
Estradiol Benzoate	0.00022 µg/l, (Lilly Aquatic Exposure Guideline)
Tylosin Tartrate	36 µg/l, (Lilly Aquatic Exposure Guideline)

Chronic Exposure of Aquatic Organisms

Components

Estradiol Benzoate
Tylosin Tartrate

Test Results

0.0009 µg/l, (Lilly Aquatic Exposure Guideline)
99 µg/l, (Lilly Aquatic Exposure Guideline)

Acute Exposure of Aquatic Organisms

Components

Estradiol Benzoate
Tylosin Tartrate

Test Results

0.009 µg/l, (Lilly Aquatic Exposure Guideline)
220 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.

Waste codes

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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. (Tylosin Tartrate)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	Yes
ERG Code	9L
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

IMDG

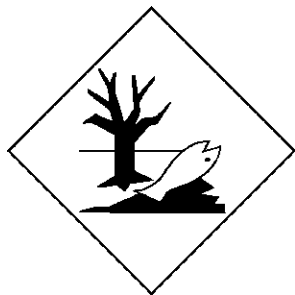
UN number	UN3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tylosin Tartrate)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

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

Not applicable.

IATA; IMDG





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 - Yes
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

Progesterone (CAS 57-83-0)

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

Progesterone (CAS 57-83-0)

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

Progesterone (CAS 57-83-0)

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

Progesterone (CAS 57-83-0)

Listed: January 1, 1988

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

Estradiol Benzoate (CAS 50-50-0) Listed: April 1, 1990

US - California Proposition 65 - CRT: Listed date/Female reproductive toxin

Estradiol Benzoate (CAS 50-50-0) Listed: April 1, 1990

Progesterone (CAS 57-83-0) Listed: April 1, 1990

US - California Proposition 65 - CRT: Listed date/Male reproductive toxin

Estradiol Benzoate (CAS 50-50-0) Listed: April 1, 1990

Progesterone (CAS 57-83-0) 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** 09-11-2015**Version #** 02**Lilly Lab Code** Health: 2
Fire: 1
Reactivity: 0
Special 1: C
Special 2: R
Special 3: P
Special 4: A**Disclaimer** As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health
0011+1-877-352-6261
0011+1-800-428-4441**Revision Information** Product and Company Identification: Alternate Trade Names
GHS: Classification



SAFETY DATA SHEET

1. Identification

Product identifier	Component E-S Implant, S Implant, and E-C Implant with Tylan
Other means of identification	
Item Code	AH0328, AH0507
Synonyms	Component E-S Implant with Tylan * Component S Implant with Tylan * Component E-C Implant with Tylan
Recommended use	Veterinary Pharmaceutical
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	
Company Name	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
Phone:	1-877-Elanco1 (1-877-352-6261)
Email:	lilly_msds@lilly.com
Emergency Telephone 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)

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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	%
Progesterone		57-83-0	59.1 - 65.7
Tylosin Tartrate	Tylosin, (2R,3R)-2,3-dihydroxybutanedioate (salt) LSN 029510	1405-54-5	9.53 - 17.4
Estradiol Benzoate		50-50-0	5.91 - 6.57
Other components below reportable levels			10 - < 20

Composition comments This product consists of 4 or 8 Progesterone and Estradiol Benzoate pellets packaged with a single Tylosin Tartrate (Tylan) pellet as an implant, with 20 implants encased in a single plastic cartridge belt that poses no exposure list 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.
Environmental precautions	Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance. Avoid discharge into drains, water courses or onto the ground. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

7. Handling and storage

Precautions for safe handling	NOT INTENDED FOR HUMAN USE. Do not handle until all safety precautions have been read and understood. Pregnant or breastfeeding women must not handle this product. Wear appropriate personal protective equipment. Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Lilly Exposure Guideline (LEG): 12 hour TWA <100 ug/m3 (Tylosin Tartrate) Lilly Exposure Guideline (LEG): 12 hour TWA 1.0 ug/m3 (Progesterone) Lilly Exposure Guideline (LEG): 8 hour TWA 2.0 ug/m3 (Progesterone) Lilly Exposure Guideline (LEG): 12 hour TWA 0.025 ug/m3 (Estradiol) Lilly Exposure Guideline (LEG): 8 hour TWA 0.04 ug/m3 (Estradiol) Lilly Exposure Guideline (LEG) : Lilly Exposure Guideline (LEG): 30 min Excursion Limit 0.075 ug/m3 (Estradiol)
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. If material is handled in a fume hood or ventilated enclosure, consider using redundant respiratory protection.
Thermal hazards	Not available.

General hygiene considerations

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

In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Under normal use and handling conditions, wear goggles to protect eyes and wear impermeable gloves and protective equipment to avoid direct contact with skin. Wash thoroughly with soap and water after handling.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Powder. Cylindrical pellets packaged as an implant.
Color	Blue (Tylosin Tartrate)

Light yellow (Progesterone and Estradiol Benzoate)

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) No data available.

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
Tylosin Tartrate (CAS 1405-54-5)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Inhalation		
LC50	Rat	> 600 mg/m3, 1 h
Oral		
LD50	Rat	> 6200 mg/kg

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

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)

Progesterone did not induce dominant lethal mutations in mice or chromosomal aberrations in rats treated in vivo. It did not induce chromosomal aberrations or sister chromatid exchanges in cultured human cells, nor chromosomal aberrations or DNA strand breaks in rodent cells.

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 Benzoate)

IARC 2B (sufficient evidence of carcinogenicity in animals). Progestogen-only contraceptives and progestins are possibly carcinogenic to humans (Group 2) (Progesterone)

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

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Estradiol Benzoate (CAS 50-50-0)

Known To Be Human Carcinogen.

Progesterone (CAS 57-83-0)

Reasonably Anticipated to be a 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 Toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Estradiol Benzoate (CAS 50-50-0)			
Aquatic			
Fish	LC50	Medaka, high-eyes (Oryzias latipes)	460 µg/l, 72 h (Estradiol)
		Rainbow trout,donaldson trout (Oncorhynchus mykiss)	> 0.5 mg/l, 48 h (Estradiol)
Tylosin Tartrate (CAS 1405-54-5)			
Acute	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)
	LC50	Duck (Mallard duck)	> 5000 mg/kg, 5 days (dietary, as free base)
		Quail (Bobwhite quail)	> 5000 mg/kg, 5 days (dietary, as free base)
Other	EC50	Pseudokirchnerella subcapitata	0.22 mg/l (average specific growth rate) (as free base)
Chronic			
	LC50	Earthworms (Eisenia fetida)	> 102.6 mg/kg, 14 days
		Quail (Bobwhite quail)	> 2000 mg/kg, 14 days
Aquatic			
Acute			
Crustacea	EC50	Daphnia magna	> 300 mg/l (as free base)
Fish	LC50	Bluegill (Lepomis macrochirus)	> 300 mg/l (as free base)
		Rainbow Trout	> 300 mg/l (as free base)

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

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

Bioaccumulative potential The product contains potentially bioaccumulating substances.

Partition coefficient n-octanol / water (log Kow)

Estradiol Benzoate	4.01
Progesterone	3.87
Tylosin Tartrate	17, (pH 7)
	17, (pH 9)
	5, (pH 5)

Mobility in soil Soil degradation half-life (100 ppm): 62 days (tylosin factor A); 37 days (tylosin factor D)
Soil degradation half-life (1 mg/kg; 4 soils): 50.3 to 105 days
Leaching in soil column: none

Adsorption

Soil/sediment sorption - log Koc

Tylosin Tartrate	1652 Silt Loom (pH 5.7)
	200 Sandy Loom (pH 4.6)
	2233 Sandy Loom (pH 7.6)

Other adverse effects Not available.

Ecotoxicological Properties

Drinking Water

Components	Test Results
Estradiol Benzoate	0.00022 µg/l, (Lilly Aquatic Exposure Guideline)
Tylosin Tartrate	36 µg/l, (Lilly Aquatic Exposure Guideline)

Chronic Exposure of Aquatic Organisms

Components

Estradiol Benzoate
Tylosin Tartrate

Test Results

0.0009 µg/l, (Lilly Aquatic Exposure Guideline)
99 µg/l, (Lilly Aquatic Exposure Guideline)

Acute Exposure of Aquatic Organisms

Components

Estradiol Benzoate
Tylosin Tartrate

Test Results

0.009 µg/l, (Lilly Aquatic Exposure Guideline)
220 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.

Waste codes

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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. (Tylosin Tartrate)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards Yes
ERG Code 9L
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.
Other information
Passenger and cargo aircraft Allowed.
Cargo aircraft only Allowed.

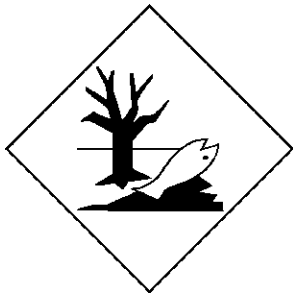
IMDG

UN number UN3077
UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tylosin Tartrate)
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 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





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 - Yes
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

Progesterone (CAS 57-83-0)

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

Progesterone (CAS 57-83-0)

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

Progesterone (CAS 57-83-0)

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

Progesterone (CAS 57-83-0)

Listed: January 1, 1988

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

Estradiol Benzoate (CAS 50-50-0) Listed: April 1, 1990

US - California Proposition 65 - CRT: Listed date/Female reproductive toxin

Estradiol Benzoate (CAS 50-50-0) Listed: April 1, 1990

Progesterone (CAS 57-83-0) Listed: April 1, 1990

US - California Proposition 65 - CRT: Listed date/Male reproductive toxin

Estradiol Benzoate (CAS 50-50-0) Listed: April 1, 1990

Progesterone (CAS 57-83-0) 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** 09-11-2015**Version #** 02**Lilly Lab Code** Health: 2
Fire: 1
Reactivity: 0
Special 1: C
Special 2: R
Special 3: P
Special 4: A

Disclaimer As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health
0011+1-877-352-6261
0011+1-800-428-4441**Revision Information** Product and Company Identification: Alternate Trade Names
GHS: Classification