



SAFETY DATA SHEET

1. Identification

Product identifier	Component E-S Implant, Component S Implant, or Component E-C Implant
Other means of identification	
Item Code	AH0330, AH0830, AH0333, AH0833
Synonyms	Component E-S Implant * Component S Implant * Component E-C 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.
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	Not available.
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	73.96
Estradiol Benzoate		50-50-0	7.4
Polyethylene Glycol		25322-68-3	16.1
Magnesium Stearate		557-04-0	2.2
Other components below reportable levels			0.34

Composition comments This product consists of implants encased in a single plastic cartridge belt that poses no exposure risk unless the belt is damaged.

4. First-aid measures

Inhalation	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 immediately.
Ingestion	Call a physician or poison control center immediately. Never give anything by mouth to a victim who is unconscious or is having convulsions. If conscious, give the victim plenty of water to drink.
Most important symptoms/effects, acute and delayed	May cause cancer. May cause reproductive effects.

Intact implants are not considered hazardous under normal handling procedures. Caution should be used to avoid contact with the contents which contain progesterone and estradiol.

Chronic over-exposure to progesterone may cause adverse effects including: breakthrough bleeding, spotting, changes in cervical erosion and secretions, edema, weight gain or loss, cholestatic jaundice, discoloration of the skin and mental depression. Breast tenderness or excessive flow of milk has occasionally occurred. Adverse central nervous system effects including nervousness, insomnia, fatigue, and dizziness have also occasionally occurred. Rarely headache, elevated body temperature, nausea, or jaundice have been reported. Thromboembolic disorders including thrombophlebitis and pulmonary embolism have been reported. As the potential of teratogenic effects exists, pregnant women should avoid exposure to progesterone, especially during the first four months of pregnancy. Masculinization of the female fetus has reportedly occurred when progestin was used during pregnancy. Clitoral hypertrophy and fusion of the labia have been reported in female newborns. Hypospadias has occurred in male newborns.

Increased breast size in boys and pseudoprecocious puberty in girls have been observed in children born to women occupationally exposed to estrogen. In men, overexposure may lead to gynecomastia (breast tenderness, breast nodules or enlarged breasts). In women, overexposure may cause menstrual irregularities (breakthrough bleeding, change in menstrual flow, spotting, amenorrhea) and breast changes (tenderness, enlargement, and secretion). Other effects of exposure to estradiol may include headache, nausea, vomiting, abnormal blood clotting, and increased incidence of cancer. An accelerated skeletal maturation, strong pigmentation of the sexual organs and a feminizing syndrome in boys has also been noted in children of parents who work in estrogen production.

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.

5. Fire-fighting measures

Suitable extinguishing media	Dry chemical. Carbon dioxide (CO2).
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. 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. 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. 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. 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 away from incompatible materials (see Section 10 of the SDS).

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

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
Polyethylene Glycol (CAS 25322-68-3)	TWA	10 mg/m3	Particulate.

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Lilly Exposure Guideline (LEG): 12 hour TWA ug/m3 (Testosterone) 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): 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	Yellow

Odor None known.

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 None known.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products

Hazardous decomposition products formed under fire conditions.

11. Toxicological information**Information on toxicological effects****Acute toxicity** This information is not available.

Components	Species	Test Results
Magnesium Stearate (CAS 557-04-0)		
Acute		
Inhalation		
LC50	Rat	> 2000 mg/m3, 1 hours
Polyethylene Glycol (CAS 25322-68-3)		
Acute		
Oral		
LD50	Rat	30200 mg/kg

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

Skin corrosion/irritation This information is not available.**Serious eye damage/eye irritation** This information is not available.**Respiratory or skin sensitization****Respiratory sensitization** This information is not available.**Skin sensitization** This information is not available.**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. 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)

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** This information is not available.**Specific target organ toxicity - repeated exposure** This information is 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 Benzoate (CAS 50-50-0)		
Aquatic		
Fish	LC50 Medaka, high-eyes (Oryzias latipes)	460 µg/l, 72 h (Estradiol)

Components	Species	Test Results
	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	> 0.5 mg/l, 48 h (Estradiol)
Polyethylene Glycol (CAS 25322-68-3)		
Aquatic		
<i>Acute</i>		
Crustacea	LC50 Water flea (Daphnia magna)	1000 mg/l, 48 hours
Fish	LC50 Guppy (Poecilia reticulata)	> 100 mg/l, 96 hours

* 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

Mobility in soil No data available.

Other adverse effects Not available.

Ecotoxicological Properties

Drinking Water

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

Chronic Exposure of Aquatic Organisms

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

Acute Exposure of Aquatic Organisms

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

13. Disposal considerations

Disposal instructions Do not allow this material to drain into sewers/water supplies. 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 Benzoate)
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. (Estradiol Benzoate)
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	



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

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)	Yes
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 09-11-2015

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
Physical & Chemical Properties: Multiple Properties
Ecological Information: Ecotoxicity
GHS: Classification