



SAFETY DATA SHEET

1. Identification

Product identifier	Compudose
Other means of identification	
Item Code	AH0320, AH0323, AH0327, AH0340, AH0343, AH0347, AH0351, AH0370, AH0373, AH0918, AH0919, QA330A, SI6480, UC5190, UC5199
Synonyms	Estra-1,3,5(10)-triene-3,17-diol (17beta)- * Shur-Gain * 033636 Formulation * Controlled Release Implant * Estradiol Implants * Compudose 100 * Encore * Compudose 400 * Compudose 200
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.
P260	Do not breathe dust or mist.
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	%
Estradiol		50-28-2	4 - 8

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

Implant may be dusted with sodium bicarbonate or tetracycline. Intact implants are not considered hazardous under normal handling procedures.

4. First-aid measures

Inhalation	This product presents negligible human hazard through inhalation because of its physical nature and packaging. Because of the size of the implant it may cause mechanical obstruction of the airway if accidentally inhaled by a small child. If this should occur, immediately contact a physician.
Skin contact	Estradiol, the active ingredient in Compudose implants, is well absorbed through the skin, as is tetracycline, the local antibacterial agent. The physical nature of Compudose implants and their packaging eliminate exposure if proper handling instructions are followed. However, certain Compudose implants are coated with approximately 1.5 mg of tetracycline. In allergic or sensitive individuals, a skin or systemic reaction may develop if the packaging is broken and the dose is handled. Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.
Eye contact	The physical nature of this product and its packaging make injury to the eye, except by accidental mechanical means, extremely unlikely. If by remote circumstances the eyes are exposed and irritation develops, contact a physician.
Ingestion	Because of the physical nature of Compudose implants, it is difficult to conceive of their presenting an acute oral hazard. If a dose is accidentally swallowed, it is estimated that 2 mg of estradiol may be absorbed before excretion. If an adverse reaction should occur, contact a physician.
Most important symptoms/effects, acute and delayed	May cause cancer. May cause reproductive effects.
	The physical nature and packaging of Compudose implants make exposure to significant quantities of the active ingredient, estradiol, highly unlikely. There have been no reports of ill effects from the handling of this device. Although no significant Elanco occupational exposures to estradiol have been reported, increased breast size and other feminizing effects have been produced in males occupationally exposed to estrogens. Breast enlargement and menstrual disorders have been reported in estrogen-exposed women. Even intermittent absorption of small amounts of estrogen through the skin may result in accumulation of relatively high systemic levels. Increased breast size in boys and pseudoprecocious puberty in girls have been observed in children born to occupationally exposed women. An accelerated skeletal maturation, strong pigmentation of the sexual organs and a feminizing syndrome in boys has also been noted in children whose parents work in estrogen production. Other effects of exposure may include headache, nausea, vomiting, abnormal blood clotting, and increased incidence of cancer. The estradiol is highly potent based on hormonal 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, and thromboembolic diseases.
General information	Provide general supportive measures and treat symptomatically.
	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). 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 (CO ₂). Dry chemical.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	Fire or excessive heat may produce hazardous decomposition products. Dust may form explosive mixture with air.
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. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. Avoid contact with skin, eyes and clothing. Wear suitable protective clothing, gloves and eye/face protection.
Methods and materials for containment and cleaning up	If the silicon rubber implant remains intact, scoop or scrape up material into containers for disposal. If the silicon rubber implant is broken and the contents are released, contain dry material by lightly misting with water, followed by sweeping up or vacuuming. Vacuuming may disperse dust if appropriate dust collection filter is not part of the vacuum. 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 Spillages: Prevent further migration into the environment. 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	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. Avoid release to the environment.
Conditions for safe storage, including any incompatibilities	Store in a cool, dry place with adequate ventilation. Keep away from incompatible materials, open flames, and high temperatures. Do not store in open or unlabelled containers. Store locked up.

8. Exposure controls/personal protection

Occupational exposure limits

Lilly (LEG)

Components

	Type	Value	Form
Estradiol (CAS 50-28-2)	Excursion Limit	0.075 ug/m ³	(30 minutes)
	TWA (12hrs)	0.025 ug/m ³	
	TWA (8hrs)	0.04 ug/m ³	

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	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	Wear appropriate 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.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

CAUTION! Highly Potent. Use good industrial hygiene practices in handling this material.

Estradiol is a potent drug. Avoid skin contact and inhalation. Overexposure can cause tender enlargement of the breasts and breast nodule formation in both males and females, loss of sex drive in males, and menstrual disorders in females. It has been identified as a confirmed animal carcinogen and a suspect reproductive hazard.

The physical nature and packaging of this product makes exposure to significant quantities of the active ingredient highly unlikely. 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.

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.

9. Physical and chemical properties

Appearance Cylindrical silicone rubber implant.

Physical state Solid.

Form Solid.

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 No data available.

Oxidizing properties No data available.

Percent volatile No data available.

VOC (Weight %) 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	May emit toxic fumes when heated to decomposition.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Product	Species	Test Results
---------	---------	--------------

Compudose

Acute

Dermal

Rabbit

5 Implants taped to skin, no deaths or toxicity (Compudose 400)

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.

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

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. Did not induce chromosomal aberrations in bone marrow cells of mice treated in-vivo. (Estradiol) 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 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. Reproductive tissue changes, decreased fertility, menstrual irregularities, fetal changes, and developmental changes in offspring. (Estradiol)
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Not classified.
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

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

Persistence and degradability 10-day abiotic degradation in drinking water (measured): 39% (Estradiol)

Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol / water (log Kow)

Estradiol 4.01

Mobility in soil No data available.

Other adverse effects Not available.

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 Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations. Confirm disposal procedures with environmental engineer and local 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)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards Yes
ERG Code 9L
Special precautions for user Not available.
Other information
Passenger and cargo aircraft Allowed.
Cargo aircraft only Allowed.

IMDG

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

Transport hazard class(es)

Class 9

Subsidiary risk -

Packing group III

Environmental hazards

Marine pollutant Yes

EmS F-A, S-F

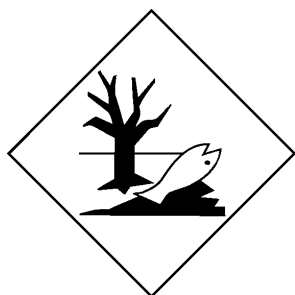
Special precautions for user Not available.

Transport in bulk according to 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.

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

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
OXYTETRACYCLINE HYDROCHLORIDE (CAS 2058-46-0) Listed: October 1, 1991

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	Yes
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 03-13-2015

Revision date 09-15-2015

Version # 02

Lilly Lab Code Health: 1
Fire: 1
Reactivity: 0
Special 1: C
Special 2: P
Special 3: R

List of abbreviations

LEG: Lilly Exposure Guideline

TWA: Time Weighted Average

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
Hazard(s) identification: Hazard statement
Composition/information on ingredients: Component information
GHS: Classification