# 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.

The estradiol may aggravate pre-existing estrogen-dependent neoplasias including malignancies of the female reproductive organs and breast, and thromboembolic diseases.

**Indication of immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically.

**General information** 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 (CO2). 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.<br><br>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/m3 | (30 minutes) |
| | TWA (12hrs) | 0.025 ug/m3 | |
| | TWA (8hrs) | 0.04 ug/m3 | |

| | |
|---|---|
| **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.<br><br>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.<br><br>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.<br><br>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)<br>Based on available data, the classification criteria are not met. |
| **Serious eye damage/eye irritation** | Rabbit: Slight irritation. (Estradiol)<br>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)<br>Based on available data, the classification criteria are not met. |
| **Carcinogenicity** | May cause cancer. IARC Group 1 (sufficient evidence of carcinogenicity in humans).<br>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<br>Hazard(s) identification: Hazard statement<br>Composition/information on ingredients: Component information<br>GHS: Classification |