



SAFETY DATA SHEET

1. Identification

Product identifier	Compudose
Other means of identification	
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
Item Code	AH0320, AH0323, AH0327, AH0340, AH0343, AH0347, AH0351, AH0370, AH0373, AH0918, AH0919, QA330A, SI6480, UC5190, UC5199

Recommended use of the chemical and restrictions on use

Recommended use	Veterinary Pharmaceutical
Restrictions on use	Not available.

Details of manufacturer or importer

Manufacturer

Company name	Elanco Animal Health A Division of Eli Lilly Australia Pty Ltd
Address	A.B.N. 39 000 233 992 112 Wharf Road, West Ryde, N.S.W. 2114, Australia
Telephone	(02) 9878 7777
Fax	(02) 9878 7720
e-mail	lilly_msds@lilly.com
Emergency phone number	Elanco Animal Health: 1800 226 324 (Toll free) OR Poisons Information Centre: 131126 (Australia-wide)
24 hr emergency contact number	CHEMWATCH 1800 039 008 (spills and accidents)
24 hr emergency contact number (Local)	CHEMWATCH +61 2 9186 1132 (spills and accidents)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Carcinogenicity	Category 1A
	Reproductive toxicity	Category 1A
	Reproductive toxicity	Effects on or via lactation
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 2
	Hazardous to the aquatic environment, long-term hazard	Category 2

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard Environment

Signal word

Danger

Hazard Statement(s)

May cause cancer. May damage fertility or the unborn child. May cause harm to breast-fed children. Toxic to aquatic life with long lasting effects.

Precautionary Statement(s)

Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust or mist. Avoid contact during pregnancy/while nursing. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Use personal protective equipment as required.
Response	IF exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards which do not result in classification	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Estradiol	50-28-2	4 - 8

Composition comments

The full text for all R- and H-phrases is displayed in section 16.

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

Description of necessary 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 accidenta 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.
Personal protection for first-aid responders	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.

Symptoms caused by exposure

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.

Medical attention and special treatment

Provide general supportive measures and treat symptomatically.

5. Fire-fighting measures

Extinguishing media

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 fire fighters

Wear self-contained breathing apparatus and protective clothing.

Fire fighting equipment/instructions

Use water spray to cool unopened containers.

Hazchem Code

2Z

General fire hazards

No unusual fire or explosion hazards noted.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

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.

For emergency responders

Use personal protection recommended in Section 8 of the SDS.

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.

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 CHEMWATCH and Elanco Animal Health for assistance.

Other issues relating to spills and releases

Clean up in accordance with all applicable regulations.

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 and personal protection

Control parameters Follow standard monitoring procedures.

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	

Occupational exposure limits No exposure limits noted for ingredient(s).

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines No exposure standards allocated.

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, for example personal protective equipment (PPE)

Eye/face protection Wear safety glasses with side shields (or goggles). (AS/NZS 1337)

Skin protection

Hand protection Wear appropriate chemical resistant gloves. (AS 2161)

Other Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Respiratory protection Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. Select appropriate respirator for physical characteristics of material. (AS/NZS 1715)

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures 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.

Colour Light yellow.

Odour Odourless.

Odour 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.

Vapour pressure	No data available.
Vapour 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 physical and chemical parameters

Density No data available.

Explosive properties No data available.

Oxidising 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 polymerisation does not occur.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Strong oxidising agents.

Hazardous decomposition products May emit toxic fumes when heated to decomposition.

11. Toxicological information

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/irritation	Rabbit: Slight irritation. (Estradiol) Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	
Respiratory sensitisation	Due to lack of data the classification is not possible.
Skin sensitisation	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.

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	Due to 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 (CAS 50-28-2)		
Aquatic		
Fish	LC50	Medaka, high-eyes (Oryzias latipes)
		Rainbow trout, donaldson trout (Oncorhynchus mykiss)
		460 µg/l, 72 h
		> 0.5 mg/l, 48 h

* 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. 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 for this product.
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 methods Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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.

ADG

UN number 3077
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 Not available.
Hazchem Code 2Z
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.
Not classified as dangerous goods when transported by road or rail in packaging or receptacles not exceeding 500 kg (L) according to ADG 7 SP AU01.

RID

UN number 3077
UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Estradiol)
Transport hazard class(es)
Class 9
Subsidiary risk -
Label(s) 9
Packing group III
Environmental hazards Yes
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IATA

UN number 3077
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 3077

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

Transport hazard class(es)

Class 9

Subsidiary risk -

Packing group III

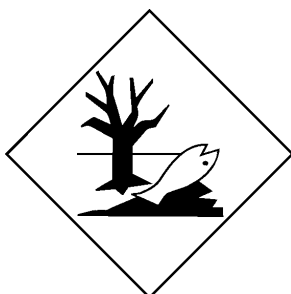
Environmental hazards

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.

ADG; IATA; IMDG; RID**Marine pollutant****15. Regulatory information****Safety, health and environmental regulations****National regulations**

APVMA approval number 46230, 36799, 36789
Poison Schedule 5

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Estradiol (CAS 50-28-2)

oestradiol

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Estradiol (CAS 50-28-2)

applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. Pregnant women should not work with the product, if there is the least risk of exposure.

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	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

Issue date 13-March-2015

Revision date 15-September-2015

Key abbreviations or acronyms used
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 MERCHANTABILITY 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
Hazard(s) identification: GHS Hazard Statements
Composition/information on ingredients: Component information
Disposal considerations: Residual waste
Disposal considerations: Contaminated packaging
GHS: Classification