



**MATERIAL SAFETY DATA SHEET
COMPUDOSE 100, 200 and 400**

AH0351, AH0323, AH0343

Revision 3.5, 22 November 06

STATEMENT OF HAZARDOUS NATURE:

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

The following Statement of Hazardous Nature refers to the contents of the implant which contain oestradiol:

"Hazardous according to criteria of Worksafe Australia"

Toxic; Reproductive Category 1. R60 May impair fertility. R61 May cause harm to the unborn child.

Toxic; Carcinogen Category 1. R45 May cause cancer.

Company Name and Address:

Elanco Animal Health

A Division of Eli Lilly Australia Pty Ltd

A.B.N. 39 000 233 992

112 Wharf Road, West Ryde, N.S.W. 2114, Australia

Contact Numbers:

Tel: (02) 9878 7777

Fax: (02) 9878 7720

Emergency Telephone Numbers:

Elanco Animal Health:

1800 226 324 (Toll free)

OR

Poisons Information Centre:

131126 (Australia-wide)

24 hour emergency contact number, CHEMWATCH **1800 039 008** (spills and accidents)

Section 1 - Identification

Product Names: ElancoAH0351 Oestradiol Compudose 100

ElancoAH0323 Oestradiol Compudose 200

ElancoAH0343 Oestradiol Compudose 400

Other Names: Oestradiol 17b

Manufacturer's Product Codes: AH0351 (Compudose 100)
 AH0323 (Compudose 200)
 AH0343 (Compudose 400)

UN Number: None allocated

Dangerous Goods Class/Subsidiary Risk: None allocated

Hazchem Code: None allocated

Poisons Schedule Number: S5

Pack Size and Container Type:

Compudose 100: Cylindrical multidose cartridges containing 20 implants. Sale cartons contain 5 cartridges, a total of 100 implants.

Compudose 200 and 400: Box of 10 cartridges each containing 10 implants.

Use:

Major Recommended Uses: Growth promotant implants for steers, spayed heifers and vealer heifers. For increased rate of weight gain in pastured steers including suckling steers and in spayed heifers and vealer heifers. For improved feed efficiency and increased rate of weight gain in lot fed steers and spayed heifers.

Major Recommended Method(s) of Application: Subcutaneous ear implantation

Section 2 - Composition / Information on Ingredients

Ingredient	CAS	Concentration %
Oestradiol	50-28-2 4 - 8	
Sodium Bicarbonate	144-55-8 0 - 0.25	
Silicone Rubber	63394-02-5 92 - 96	

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

Exposure Guidelines: Oestradiol - LEG 0.01 micrograms/m³ TWA for 12 hours.

Section 3 - Hazards Identification

Appearance: White cylindrical silicone rubber implant

Physical State: Solid

Odor: Odorless

Emergency Overview

Primary Physical and Health Hazards: Not hazardous if intact. Skin Permeable. Carcinogen. Highly Potent. Reproductive and Hormonal Effects.

Caution Statement: The intact silicon rubber implant is not considered to be a health hazard. Compudose contains oestradiol which may enter the body through the skin, causes cancer, and is highly potent. Effects of exposure to the contents of Compudose may include fetal changes, decreased fertility, reproductive tissue changes, menstrual disorders, and changes in hormone levels.

Routes of Entry: Inhalation and skin absorption.

Potential Signs and Symptoms of Occupational Exposure: The physical nature and packaging of Compudose implants make exposure to significant quantities of the active ingredient, oestradiol, highly unlikely. There have been no reports of ill effects from handling of this device. Although no significant Elanco occupational exposures to oestradiol have been reported, increased breast size and other feminizing effects have been produced in males occupationally exposed to oestrogens. Breast enlargement and menstrual disorders have been reported in oestrogen-exposed women. Even intermittent absorption of small amounts of oestrogen 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 oestrogen production. Other effects of exposure may include headache, nausea, vomiting, abnormal blood clotting, and increased incidence of cancer. Oestradiol is highly potent based on hormonal effects.

Medical Conditions Aggravated by Exposure: Oestradiol may aggravate pre-existing oestrogen-dependent neoplasias including malignancies of the female reproductive organs and breast, thromboembolic diseases, impaired liver or kidney function, and pregnancy.

Carcinogenicity: Oestradiol - IARC Group 1 (sufficient evidence of carcinogenicity in humans). NTP - Reasonably Anticipated Human Carcinogen. Not listed by ACGIH or OSHA.

Remaining ingredients - No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA.

Section 4 - First Aid Measures

SPECIFIC FIRST AID INSTRUCTIONS AS PER AUSTRALIAN REGISTERED LABEL¹
If poisoning occurs, contact a doctor or Poisons Information Centre. Phone 13 1126.

ADDITIONAL INFORMATION PROVIDED BY MANUFACTURER:

¹ Handbook of First Aid Instructions and Safety Directions for Agricultural and Veterinary Chemicals (including Pesticides). Therapeutic Goods Administration

Eyes: The physical nature of Compudose implants and their packaging make injury to the eye, except by accidental mechanical means, extremely unlikely. If by remote circumstances the eyes are exposed and irritation develops, flush eyes with water and contact a physician.

Skin: Oestradiol, the active ingredient in Compudose implants, is well absorbed through the skin. The physical nature of Compudose implants and their packaging eliminate exposure if proper handling instructions are followed. 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.

Inhalation: Compudose implants present negligible human hazard through inhalation because of their 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.

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 oestradiol may be absorbed before excretion. If an adverse reaction should occur, contact a physician.

Section 5 - Fire Fighting Measures

Flash Point: No applicable information found.

UEL: No applicable information found.

LEL: No applicable information found.

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: None known.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

Spills: 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. Large spills due to traffic accidents, etc., should be reported immediately to Elanco Animal Health for assistance. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

Section 7 - Handling and Storage

Storage: Store below 30°C (Room Temperature).

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting:

Respiratory Protection: Use an approved HEPA-filtered or supplied-air respirator.

Eye Protection: Chemical goggles and/or face shield.

Ventilation: Extensive local exhaust or enclosed process equipment.

Other Protective Equipment: 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.

Other Handling Precautions:

CAUTION! Oestradiol 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. 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.

Section 9 - Physical and Chemical Properties

Boiling Point: Not applicable.

Melting Point: Not applicable.

Specific Gravity: Not applicable.

pH: Not applicable.

Evaporation Rate: No applicable information found.

Water Solubility: Insoluble.

Vapor Density: No applicable information found.

Vapor Pressure: No applicable information found.

Section 10 - Stability and Reactivity

Stability: Stable at normal temperatures and pressures.

Incompatibility: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

Hazardous Decomposition: May emit toxic fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Animal Toxicity Data Single Exposure

Toxicity data for Compudose 400 and oestradiol, the active ingredient, are reported as indicated.

Oral: Oestradiol - Rat, 500 mg/kg, no deaths.

Skin: Compudose 400 - Rabbit, 5 implants taped to skin, no deaths or toxicity.
Oestradiol - Rabbit, 100 mg/kg, no deaths or toxicity.

Inhalation: No applicable information found.

Skin Contact: Oestradiol - Rabbit, nonirritant.

Eye Contact: Oestradiol - Rabbit, slight irritant.

Animal Toxicity Data Repeat Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

Target Organ Effects: Oestradiol – Mammary, pituitary, uterine, cervical, vaginal, testicular, and lymphoid tissue changes reported in a number of chronic and subchronic subcutaneous injection studies. Effects reported with doses as low as 2.5 micrograms.

Reproduction: Oestradiol - Reproductive tissue changes, decreased fertility, menstrual irregularities, foetal changes and developmental changes in offspring.

Sensitization: No applicable information found.

Mutagenicity: Oestradiol – Negative in bacterial cells. Induced micronuclei but not chromosomal aberrations, aneuploidy, or sister chromatid exchanges in in-vitro human cell assays. It 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.

Section 12 - Ecological Information

No environmental data for the mixture or formulation. The environmental data for ingredient(s) or related material(s) are presented.

Ecotoxicity data: No applicable information found.

Environmental fate: Oestradiol

10-day abiotic degradation in drinking water (measured): 39%

Environmental Summary: Oestradiol - Material is almost insoluble in water and is not expected to leach significantly from soil into groundwater. Oestrogens, as a class of

compounds, are relatively persistent in the environment. However, they are naturally occurring organic molecules and so some degradation is expected.

Section 13 - Disposal Considerations

Disposal: Unused implants may not be disposed of in any way but are to be retained by the purchaser/user. Dispose of discarded needles and empty cartridges by wrapping with paper and putting in garbage.

Section 14 - Transport Information

No special transport requirements necessary.

Section 15 - Other Information

Sections revised: Header and Footer: Removed automatic print date from header. Pagination changed to page number only. Added CHEMWATCH contact details.. Section 15: Deleted contact point details.

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.

GLOSSARY

ACGIH = American Conference of Governmental Industrial Hygienists

AIHA = American Industrial Hygiene Association

BEI = Biological Exposure Index

CAS Number = Chemical Abstract Service Registry Number

CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)

CHEMTREC = Chemical Transportation Emergency Center

DOT = Department of Transportation

EC = European Community

EINECS = European Inventory of Existing Chemical Substances

ELINCS = European List of New Chemical Substances

EPA = Environmental Protection Agency

HEPA = High Efficiency Particulate Air (Filter)

IARC = International Agency for Research on Cancer

ICAO/IATA = International Civil Aviation Organization/International Air Transport Association

IEG = Lilly Interim Exposure Guideline

IMO = International Maritime Organization
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline
STEL = Short Term Exposure Limit
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations
WEEL = Workplace Environmental Exposure Level (AIHA)