



**MATERIAL SAFETY DATA SHEET
COMPUDOSE-G**

AH0359

Revision 1.3, 22 November 2006

STATEMENT OF HAZARDOUS NATURE:

The intact Compudose-G 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 and trenbolone acetate:

"Hazardous according to criteria of Worksafe Australia"

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

Harmful; Carcinogen Category 3. R40 Possible risks of irreversible effects.

Harmful; Mutagen Category 3. R40 Possible risks of irreversible effects.

Company Name and Address:

Elanco Animal Health
A Division of Eli Lilly Australia Pty Ltd
A.B.N. 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 Name: Elanco^{AH0359} Compudose-G Growth and Finishing Implants for Steers and Heifers

Other Names: cattle implant; implant

Manufacturer's Product Code: AH0359

UN Number: Not applicable

Dangerous Goods Class/Subsidiary Risk: Not applicable

Hazchem Code: Not applicable

Poisons Schedule Number: S5

Pack Size and Container Type: Box of 100 implants (5 foil pouch envelopes x 20 implants)

Use:

Major Recommended Uses: For improved growth promotion in pasture fed steers and heifers.

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

Section 2 - Composition / Information on Ingredients

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration %</u>
Trenbolone acetate	10161-34-9	61.9
Oestradiol	50-28-2	12.4
Cholesterol	57-88-5	19.8
Magnesium Stearate	557-04-0	3.0
Povidone	9003-39-8	2.5
Ethylcellulose	9004-57-3	0.5

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

Exposure Guidelines: Oestradiol - PEL and TLV not established. LEG 0.01 micrograms/m³ TWA for 12 hours.

Magnesium stearate - (Stearates) TLV 10 mg/m³ TWA.

Section 3 - Hazards Identification

Appearance: Yellow cylindrical pellets, 3 packaged as implant in a 20-dose polyethylene cartridge belt. Contains a detectable marker (stainless steel).

Physical State: Solid

Emergency Overview

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

Caution Statement: The intact implant is not considered to be a health hazard. Compudose-G contains trenbolone acetate and oestradiol which may enter the body through the skin, causes cancer, and is highly potent. Effects of exposure to contents of Compudose-G Implant may include foetal 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: Intact implants are not considered hazardous under normal handling procedures. Caution should be used to avoid contact with the contents which contain trenbolone acetate and oestradiol. Although no significant Elanco occupational exposures have been reported to oestradiol or trenbolone acetate, prominent increased breast size and other feminising 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. Other effects of exposure to oestradiol 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 whose parents work in estrogen production. 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 to humans). NTP – Known Human Carcinogen. Not listed by ACGIH or OSHA.

Cholesterol - IARC Group 3 (inadequate evidence of human carcinogenicity). Not listed by NTP, ACGIH or OSHA.

Magnesium stearate - ACGIH A4 (not classifiable as a human carcinogen). Not listed by IARC, NTP or OSHA.

Polyvinylpyrrolidone - IARC Group 3 (not classifiable as to human carcinogenicity). Not listed by NTP, ACGIH or OSHA.

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

Section 4 - First Aid Measures

Eyes: Flush eyes with plenty of water. Get medical attention.

Skin: 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: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a doctor immediately.

Ingestion: Do not induce vomiting. Call a physician or Poisons Information Centre. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a doctor.

SPECIFIC FIRST AID INSTRUCTIONS AS PER AUSTRALIAN REQUIREMENTS¹: If poisoning occurs, contact a doctor or Poisons Information Centre. Phone 13 1126.

Section 5 - Fire Fighting Measures

Flash Point: Not applicable.

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 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 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. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Large spills due to traffic accidents, etc., should be reported immediately to Elanco Animal Health for assistance.

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

Prevent spilled material from spreading onto adjacent land or into streams, ponds, or lakes.

Section 7 - Handling and Storage

Storage: Store between 2°C and 8°C (Refrigerate. Do not freeze).

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

The intact implant is not considered hazardous under normal handling procedures. The following are 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: 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

Appearance: Yellow cylindrical pellets, packaged as an implant

Odour: Odourless

Boiling Point: Not applicable.

Melting Point: No applicable information found.

Specific Gravity: No applicable information found.

pH: No applicable information found.

Evaporation Rate: No applicable information found.

Water Solubility: Insoluble.

Vapor Density: No applicable information found.

Vapor Pressure: No applicable information found.

Solvent solubility: Alcohol, acetone.

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

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

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

Cholesterol – Rabbit, 6000 mg/kg, no deaths (subchronic study)

Skin: 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.

Cholesterol – Decreased offspring survival, decreased foetal weight, and cleft palate observed at high oral doses or with subcutaneous injections.

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.

Cholesterol – negative in Ames assay. Negative in Syrian hamster embryo cell, Chinese hamster ovary cell, mouse lymphoma and unscheduled DNA synthesis assays.

Section 12 - Ecological Information

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

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.

Cholesterol – Material can be considered to be bioaccumulative, but is expected to readily degrade in the environment. Cholesterol is insoluble in water and is not expected to leach from soil into groundwater.

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 empty cartridges by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labeled "sharps" container.

Section 14 - Transport Information

No special transport requirements necessary.

Section 15 - Other Information

Sections revised: Header and Footer: Added Page number to header.

Contact details added Chemwatch for emergency spills contact. Removed reason for revision from page 1.

Section 15: Removed Contact point

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)