

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Synovex H</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	SYNOVEX® H * Synovex® H Heifer Growth and Finishing Implants * Testosterone Propionate-Estradiol Benzoate Implant
<b>Recommended use of the chemical and restrictions on use</b>	
<b>Recommended use</b>	Veterinary product ( Hormone )
<b>Restrictions on use</b>	Not for human use
<b>Details of manufacturer or importer</b>	
<b>Company Name (AU)</b>	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
<b>Tel</b>	1800 814 883
<b>Fax</b>	(02) 8876 0444
<b>Email</b>	productsupport.au@zoetis.com
<b>Emergency Phone</b>	1800 814 883 (all hours)
<b>Police and Fire Brigade</b>	Dial 000
<b>If ineffective</b>	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

## 2. Hazard(s) identification

### Classification of the hazardous chemical

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Carcinogenicity	Category 1A
	Reproductive toxicity	Category 1A
<b>Environmental hazards</b>	Not classified.	

### Label elements, including precautionary statements

#### Hazard symbol(s)



Health hazard      Exclamation mark

<b>Signal word</b>	Danger
<b>Hazard statement(s)</b>	Harmful if swallowed. May cause cancer. May damage fertility or the unborn child.

#### Precautionary statement(s)

<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Use personal protective equipment as required.
<b>Response</b>	IF exposed or concerned: Get medical advice/attention. IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell. Rinse mouth.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.

**Other hazards which do not result in classification**      None known.

**Supplemental information** Occupational studies have shown that males working with estrogen-like compounds have shown clinical signs of hyperestrogenism including enlarged breasts and milk secretion. Loss of libido, breast tenderness, and changes in sex hormone levels have also occurred. Occupational exposure in females has resulted in menstrual irregularities (breakthrough bleeding, menstrual flow changes, spotting and amenorrhea).

### 3. Composition/information on ingredients

#### Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Estradiol Benzoate	50-50-0	20 mg per implant
Testosterone propionate	57-85-2	200 mg per implant

### 4. First-aid measures

#### Description of necessary first aid measures

**Inhalation** Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

**Skin contact** Wash off with soap and water. Get medical attention if symptoms occur. Wash contaminated clothing before reuse.

**Eye contact** Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

**Ingestion** Rinse mouth. Call a physician or poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to an unconscious person.

**Personal protection for first-aid responders** IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. 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** Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Dusts may irritate the respiratory tract, skin and eyes. May cause reproductive effects.

**Medical attention and special treatment** Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

### 5. Fire-fighting measures

#### Extinguishing media

**Suitable extinguishing media** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>). Apply extinguishing media carefully to avoid creating airborne dust.

**Unsuitable extinguishing media** Do not use water jet as an extinguisher, as this will spread the fire.

**Specific hazards arising from the chemical** Combustible. Avoid generating airborne dust. During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for fire fighters** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Fire fighting equipment/instructions** In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers. During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Hazchem code** None.

**General fire hazards** May form combustible dust concentrations in air. Fine particles (such as mists) may fuel fires/explosions.

**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. Local authorities should be advised if significant spillages cannot be contained.

**For emergency responders** Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Keep unnecessary personnel away. Ventilate the contaminated area. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

**Environmental precautions** Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

**Methods and materials for containment and cleaning up** Ensure adequate ventilation. Avoid the generation of dusts during clean-up. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Collect spill with an inert, non-combustible absorbent material and transfer to labeled container for disposal. Clean contaminated surface thoroughly. Prevent release to the environment.

Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

## 7. Handling and storage

**Precautions for safe handling** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not use in areas without adequate ventilation. Avoid dust formation. Combustible dust clouds may be created where operations produce fine material (dust). Should be handled in closed systems, if possible. Do not breathe dust. Do not taste or swallow. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment.

**Conditions for safe storage, including any incompatibilities** Store locked up. Protect from moisture. Keep containers tightly closed in a dry, cool and well-ventilated place. @ 20 - 25C / 68 - 77F. Keep away from heat and sources of ignition. Protect from light. Protect from sunlight. Avoid dust formation. Keep away from food, drink and animal feeding stuffs. Store away from incompatible materials (see Section 10 of the SDS). Use care in handling/storage. Keep out of the reach of children.

## 8. Exposure controls and personal protection

**Control parameters** Follow standard monitoring procedures.

### Occupational exposure limits

#### Zoetis

#### Components

	Type	Value
Estradiol Benzoate (CAS 50-50-0)	TWA	0.2 µg/m <sup>3</sup>
Testosterone propionate (CAS 57-85-2)	TWA	4 µg/m <sup>3</sup>

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

**Exposure guidelines** OEL Additional Information: Skin - May be absorbed through the skin and cause systemic effects.

**Appropriate engineering controls** Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General room ventilation is adequate unless the process generates dust, mist or aerosols.

### Individual protection measures, for example personal protective equipment (PPE)

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended.

#### Skin protection

##### Hand protection

Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

##### Other

Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

#### Respiratory protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respirator must be worn if exposed to dust. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

**Thermal hazards** Not applicable.

**Hygiene measures** Observe any medical surveillance requirements. Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

<b>Appearance</b>	Pellets.
<b>Physical state</b>	Solid.
<b>Form</b>	Solid.
<b>Colour</b>	Not available.
<b>Odour</b>	Not applicable.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other physical and chemical parameters</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidising properties</b>	Not oxidising.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Heat, flames and sparks. Exposure to light. Excessive heat. high humidity. Sunlight. Avoid conditions which create dust.
<b>Incompatible materials</b>	Strong oxidising agents.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on possible routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Prolonged inhalation may be harmful.
<b>Skin contact</b>	Prolonged skin contact may cause temporary irritation.
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	Harmful if swallowed.

**Symptoms related to exposure** Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Occupational studies have shown that males working with estrogen-like compounds have shown clinical signs of hyperestrogenism including enlarged breasts and milk secretion. Loss of libido, breast tenderness, and changes in sex hormone levels have also occurred. Occupational exposure in females has resulted in menstrual irregularities (breakthrough bleeding, menstrual flow changes, spotting and amenorrhea).

**Acute toxicity** Harmful if swallowed.

Product	Species	Test Results
Synovex H		
<u>Acute</u>		
Oral		
LD50		1330 mg/kg (Calculated ATE)

Components	Species	Test Results
Estradiol Benzoate (CAS 50-50-0)		
<u>Acute</u>		
Oral		
LD50	Rat	5000 mg/kg
Testosterone propionate (CAS 57-85-2)		
<u>Acute</u>		
Oral		
LD50	Mouse	1350 mg/kg
	Rat	1000 mg/kg
<u>Chronic</u>		
Subcutaneous		
LOEL	Rat	80 - 100 mg (Carc study, Results: Tumors, Male reproductive system)
<u>Subacute</u>		
Oral		
NOAEL	Mouse	1000 mg/kg/day, 5 days (No target organs identified)
Subcutaneous		
LOAEL	Monkey	2.7 mg/kg/day, 28 days (Target organs: Endocrine system)

**Skin corrosion/irritation** Prolonged skin contact may cause temporary irritation.

**Serious eye damage/irritation** Direct contact with eyes may cause temporary irritation.

### Respiratory or skin sensitisation

**Respiratory sensitisation** Not a respiratory sensitizer.

**Skin sensitisation** This product is not expected to cause skin sensitisation.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Carcinogenicity** May cause cancer. Clinical use of this drug has caused prostate cancer, liver cancer, kidney cancer.

### IARC Monographs. Overall Evaluation of Carcinogenicity

Testosterone propionate (CAS 57-85-2) 2A Probably carcinogenic to humans.

**Reproductive toxicity** May damage fertility or the unborn child. Clinical use has caused effects on reproductive system, including prolonged erection (priapism), breast development in males (gynecomastia), decreased sperm count, impairment of male fertility, development of male characteristics (masculinization), and impairment of female fertility and changes in cervical erosion and secretion.

**Developmental effects**

Testosterone propionate

0.4 mg/kg Embryo / Fetal Development, teratogenic

Result: NOEL

Species: Rat

Organ: Subcutaneous

1.25 mg/kg/day Embryo / Fetal Development, teratogenic

Result: LOEL

Species: Monkey

Organ: Subcutaneous

**Specific target organ toxicity - single exposure** Not classified.

**Specific target organ toxicity - repeated exposure** Due to partial or complete lack of data the classification is not possible. This product may affect Liver. through prolonged or repeated exposure.

**Aspiration hazard** Not an aspiration hazard.

**Chronic effects** Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

## 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available for this product.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

**Disposal methods** Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways and ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.

**Residual waste** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

**ADG**

Not regulated as dangerous goods.

**RID**

Not regulated as dangerous goods.

**IATA**

Not regulated as dangerous goods.

**IMDG**

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

## 15. Regulatory information

### Safety, health and environmental regulations

#### National regulations

This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA No. 49955

Poison Schedule (Product): Schedule 6

This SDS replaces version: Issued November 2018

#### **Australia Medicines & Poisons Appendix A**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix B**

Poisons schedule number not allocated.

#### **Australia Medicines & Poisons Appendix D**

Estradiol Benzoate (CAS 50-50-0)

Testosterone propionate (CAS 57-85-2)

#### **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**

Poisons schedule number not allocated.

#### **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 10**

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**

Poisons schedule number not allocated.

#### **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**

**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)	No
Canada	Domestic Substances List (DSL)	No
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	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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** 05-September-2019

**Key abbreviations or acronyms used** ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).

**Disclaimer** Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.

**Revision information** Product and Company Identification: Synonyms  
Composition / Information on Ingredients: Ingredients  
Toxicological Information: Toxicological Data