

# SAFETY DATA SHEET



## Section 1 - Identification

**Product identifier** Synovex H

### Other means of identification

**Synonyms** SYNOVEX® H \* Synovex® H Heifer Growth and Finishing Implants \* Testosterone Propionate-Estradiol Benzoate Implant

### Recommended use of the chemical and restrictions on use

**Recommended use** Veterinary product ( Hormone )

**Restrictions on use** Not for human use

### Details of manufacturer or importer

**Company Name (AU)** Zoetis Australia Pty Ltd  
ABN 94 156 476 425  
Level 6, 5 Rider Boulevard  
Rhodes NSW 2138 AUSTRALIA

**Tel** 1800 814 883

**Fax** (02) 8876 0444

**Email** productsupport.au@zoetis.com

**Emergency Phone** 1800 814 883 (all hours)

**Police and Fire Brigade** Dial 000

**If ineffective** Dial Poisons Information Centre (13 1126 from anywhere in Australia)

## Section 2 - Hazard(s) identification

### Classification of the hazardous chemical

**Physical hazards** Not classified.

<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Carcinogenicity	Category 1A
	Reproductive toxicity	Category 1A

**Environmental hazards** Not classified.

### Label elements, including precautionary statements

**Hazard symbol(s)**



Health  
hazard

Exclamation  
mark

**Signal word** Danger

**Hazard statement(s)** Harmful if swallowed. May cause cancer. May damage fertility or the unborn child.

### Precautionary statement(s)

**Prevention** 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. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell. Rinse mouth. 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.

### 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).

Other hazards which do not result in classification      None known.

## Section 3 - Composition and 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

## Section 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. For breathing difficulties, oxygen may be necessary. Call a physician if symptoms develop or persist.
Skin contact	Take off immediately all contaminated clothing. Wash off with soap and water. 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	Take off contaminated clothing and shoes immediately. 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. For personal protection, see section 8 of the SDS. You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.
Symptoms caused by exposure	Dusts may irritate the respiratory tract, skin and eyes. Exposure may cause temporary irritation, redness, or discomfort. May cause reproductive effects.
Medical attention and special treatment	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

## Section 5 - Firefighting measures

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. 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.
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.

## Section 6 - Accidental release measures

### Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Ensure adequate ventilation.
For emergency responders	Keep unnecessary personnel away. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Do not breathe dust. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. Use personal protection recommended in Section 8 of the SDS.

<b>Environmental precautions</b>	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.
<b>Methods and materials for containment and cleaning up</b>	<p>ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Avoid the generation of dusts during clean-up. Ensure adequate ventilation. Prevent release to the environment. Prevent product from entering drains.</p> <p>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.</p> <p>Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination.</p> <p>Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.</p>

## Section 7 - Handling and storage

<b>Precautions for safe handling</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Combustible dust clouds may be created where operations produce fine material (dust). Avoid dust formation. Do not breathe dust. Do not taste or swallow. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Should be handled in closed systems, if possible. Do not use in areas without adequate ventilation. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. Avoid accidental injection.
<b>Conditions for safe storage, including any incompatibilities</b>	Protect from moisture. Store locked up. Keep away from heat and sources of ignition. Protect from sunlight. Keep containers tightly closed in a dry, cool and well-ventilated place. Avoid dust formation. Keep away from food, drink and animal feeding stuffs. Storage Temperature: 20 - 25C / 68 - 77F. Protect from light. Store away from incompatible materials (see Section 10 of the SDS).

## Section 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/m³
Testosterone propionate (CAS 57-85-2)	TWA	4 µg/m³
Biological limit values	No biological exposure limits noted for the ingredient(s).	
Exposure guidelines	No exposure standards allocated. OEL Additional Information: Skin - May be absorbed through the skin and cause systemic effects.	
Appropriate engineering controls	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. Ensure adequate ventilation, especially in confined areas. 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	Respirator must be worn if exposed to dust. 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.	

## Section 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>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>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Explosive limit - lower ( %)</b>	Not available.
<b>Explosive limit – upper (%)</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.

## Section 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>	Sunlight. Avoid conditions which create dust. Exposure to light. Heat, flames and sparks. Contact with incompatible materials. high humidity.
<b>Incompatible materials</b>	Alkali metals. Peroxides.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## Section 11 - Toxicological information

### Information on possible routes of exposure

<b>Inhalation</b>	Prolonged inhalation may be harmful. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<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 sensitiser.

**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

**Developmental effects**  
Testosterone propionate

1.25 mg/kg/day Embryo / Fetal Development, teratogenic  
Result: LOEL  
Species: Monkey  
Organ: Subcutaneous

<b>Specific target organ toxicity - single exposure</b>	Not classified.
<b>Specific target organ toxicity - repeated exposure</b>	Due to partial or complete lack of data the classification is not possible. Liver. This product may affect through prolonged or repeated exposure.
<b>Aspiration hazard</b>	Not an aspiration hazard.
<b>Chronic effects</b>	Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

## Section 12 - Ecological information

<b>Ecotoxicity</b>	Avoid release to the environment. 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.
<b>Persistence and degradability</b>	No data available for this product.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available for this product.
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## Section 13 - Disposal considerations

<b>Disposal methods</b>	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 or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations. 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.
<b>Residual waste</b>	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.
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## Section 14 - Transport information

<b>ADG</b>	Not regulated as dangerous goods.
<b>RID</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.

## Section 15 - Regulatory information

<b>Safety, health and environmental regulations</b>	
<b>National regulations</b>	This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals.  APVMA No. 49955  Poison Schedule (Product): Schedule 6  <b>Australia Medicines &amp; Poisons Appendix D</b> Estradiol Benzoate (CAS 50-50-0)

Testosterone propionate (CAS 57-85-2)

**High Volume Industrial Chemicals (HVIC)**

Not listed.

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

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 Carcinogenic Substances**

Not regulated.

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

Not listed.

**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 Industrial Chemicals (AICIS)	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).

**Section 16 - Any other relevant information**

**Issue date** 05-September-2019

**Revision date** 29-July-2024

**Key abbreviations or acronyms used** AICIS: Australian Inventory of Industrial Chemicals.  
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** This document has undergone significant changes and should be reviewed in its entirety.