

## Section 1 - Identification of the Substance/Mixture and Supplier

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<b>Product Identifier:</b>	<b>Synovex® H Heifer Growth and Finishing Implants</b>
<b>APVMA Approval No:</b>	49955
<b>Other names:</b>	None
<b>Chemical family:</b>	Testosterone Propionate/Oestradiol Benzoate blend in an implant pellet
<b>Recommended Use:</b>	For improved weight gain in heifers during the growth or finishing phases
<b>Restrictions on use</b>	For veterinary use only
<b>Emergency Phone:</b>	<b>1800 814 883 (all hours)</b>

## Section 2 - Hazards Identification

**Appearance:** White solid

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 4

Reproductive Toxicity: Category 1A

Carcinogenicity: Category 1B

### Label Elements

**Signal Word:**

**Danger**

**Hazard Statements:**

H302 - Harmful if swallowed

H350 - May cause cancer

H360FD - May damage fertility. May damage the unborn child.

**Precautionary Statements:**

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P264 - Wash hands thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P308 + P313 - IF exposed or concerned: Get medical attention/advice

P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell

P330 - Rinse mouth

P405 - Store locked up

P501 - Dispose of contents/container in accordance with all local and national regulations



### Other Hazards

**Long Term:**

Repeat-dose studies in animals have shown a potential to cause adverse effects on liver. Occupational studies have shown that males working with estrogen-like compounds have shown clinical signs of hyperestrogenism including enlarged

## SAFETY DATA SHEET

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).

**Known Clinical Effects:**

Clinical use has caused effects on reproductive system, including prolonged erection (priapism), breast development in males (gynecomastia), loss of libido decreased sperm count, impairment of male fertility, development of male characteristics (masculinization), development of male characteristics in the female fetus, menstrual irregularities, changes in cervical erosion and secretion, impairment of female fertility. Clinical use of this drug has caused prostate cancer, liver cancer and kidney cancer.

**Note:**

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

**Section 3 - Composition/Information on Ingredients**

**Hazardous**

<b>Ingredients</b>	<b>CAS No</b>	<b>Conc,%</b>	<b>GHS Classification</b>
Estradiol Benzoate	50-50-0	1-10	Repr. 1A (H360FD) Carc.1B (H350)
Testosterone propionate	57-85-2	70-80	Repr. 1A (H360FD) Carc.1B (H350) Acute Tox. 4 (H302)
Non-hazardous Ingredients	Proprietary	10-20	Not Listed
Povidone	9003-39-8	<0.1	Not Listed

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non-hazardous ingredients are also possible.

**Section 4 - First Aid Measures**

**Description of First Aid Measures**

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**SAFETY DATA SHEET**

**Symptoms and Effects of Exposure:**

For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:**

None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:**

None

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## Section 5 - Fire Fighting Measures

**Extinguishing Media:**

Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:**

Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:**

Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters**

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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## Section 6 - Accidental Release Measures

**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Environmental Precautions**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and Material for Containment and Cleaning Up**

**Measures for Cleaning / Collecting:**

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:**

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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## Section 7 - Handling and Storage

**Precautions for Safe Handling**

Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:**

Store as directed by product packaging.

**Specific end use(s):**

No data available

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### SAFETY DATA SHEET

## Section 8 - Exposure Controls and Personal Protection

### Control Parameters

**Estradiol Benzoate**  
Zoetis OEL TWA 8-hr 0.2 µg/m<sup>3</sup> Skin

**Testosterone propionate**  
Zoetis OEL TWA 8-hr 4µg/m<sup>3</sup> Skin

### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

## Section 9 - Physical and Chemical Properties:

<b>Physical State:</b>	Solid	<b>Color:</b>	White
<b>Odor:</b>	No data available	<b>Odor Threshold:</b>	No data available
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Solvent Solubility:** No data available

**Water Solubility:** Insoluble

**pH:** No data available

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available

**Partition Coefficient: (Method, pH, Endpoint, Value)**  
No data available

**Decomposition Temperature (°C):** No data available

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

### Flammability:

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

## SAFETY DATA SHEET

## Section 10 - Stability and Reactivity

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	None
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	No data available

## Section 11 - Toxicological Information

### Information on Toxicological Effects

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Testosterone propionate

Rat	Oral	LD 50	1000 mg/kg
Mouse	Oral	LD 50	1350mg/kg

##### Estradiol Benzoate

Rat	Oral	LD50	5000 mg/kg
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#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Testosterone propionate

5 Day(s)	Mouse	Oral	1000 mg/kg/day	NOAEL	None identified
28 Day(s)	Monkey	Subcutaneous	2.7 mg/kg/day	LOAEL	Endocrine system

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### Testosterone propionate

Embryo / Fetal Development	Monkey	Subcutaneous	1.25 mg/kg/day	LOEL	Teratogenic
Embryo / Fetal Development	Rat	Subcutaneous	0.4 mg/kg	NOEL	Teratogenic

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Testosterone propionate

Not specified	Rat	Subcutaneous	80-100 mg	LOEL	Tumors, Male reproductive system
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#### Carcinogen Status:

See below

##### Testosterone propionate

<b>IARC:</b>	Group 2A (Probably Carcinogenic to Humans)
<b>OSHA:</b>	Listed

##### Estradiol Benzoate

<b>IARC:</b>	Group 1 (Carcinogenic to Humans)
<b>OSHA:</b>	Listed

##### Povidone

<b>IARC:</b>	Group 3 (Not Classifiable)
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## SAFETY DATA SHEET

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## Section 12 - Ecological Information

<b>Environmental Overview:</b>	Environmental properties have not been investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

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## Section 13 - Disposal Considerations

**Disposal:** DO NOT dispose of unused implants in any way other than surrender to an approved retailer/wholesaler. Dispose of empty cartridges by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated 'sharps' container.

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## Section 14 - Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under IATA, ADG or IMDG regulations.

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## Section 15 - Regulatory Information

### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

<b>Estradiol Benzoate</b>	
<b>Australia (AICS):</b>	Present
<b>Povidone</b>	
<b>Australia (AICS):</b>	Present
<b>Testosterone propionate</b>	
<b>Australia (AICS):</b>	Present
<b>Poison Schedule:</b>	S6

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## Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

### Acronyms:

<b>ADG Code</b>	Australian Code for the Transport of Dangerous Goods by Road and Rail (7 <sup>th</sup> edition)
<b>AICS</b>	Australian Inventory of Chemical Substances
<b>SWA</b>	Safe Work Australia, formerly ASCC and NOHSC
<b>CAS number</b>	Chemical Abstracts Service Registry Number
<b>Hazchem Code</b>	Emergency action code of numbers and letters that provide information to emergency services especially firefighters

### SAFETY DATA SHEET

IARC	International Agency for Research on Cancer
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

**This version issued: 23 Nov 2018** and is valid til 01 Oct 2021.

**Supersedes:** Revision issued 01 Oct 2016.

**Revision History:**

Date of Revision	Reason
October 2015	Update Zoetis company name and address
01 Oct 2016	Update to GHS
23 Nov 2018	Minor Update: Section 9 Physical State

Contact Points:

Zoetis	1800 814 883
Police and Fire Brigade:	Dial 000

**If ineffective:**

**Dial Poisons Information Centre  
(13 11 26 from anywhere in Australia)**

**THIS SDS SUMMARISES OUR CURRENT AND BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION ABOUT THE PRODUCT DETAILED IN THIS SDS, AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE FOR THE RECOMMENDED USE. EACH USER OF THE PRODUCT MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THEIR OWN WORKPLACE. IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT ZOETIS.**

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (December 2011)

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**End of Safety Data Sheet**

**SAFETY DATA SHEET**