

# 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</b>	Veterinary product ( Hormone )
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name (US)</b>	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
<b>Rocky Mountain Poison and Drug Center</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-800-366-5288
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300  International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (EU)</b>	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
<b>Emergency telephone number</b>	International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	VMIPSrecords@zoetis.com

## 2. Hazard(s) identification

<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.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger
<b>Hazard statement</b>	Harmful if swallowed. May cause cancer. May damage fertility or the unborn child.
<b>Precautionary statement</b>	
<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. Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	If exposed or concerned: Get medical advice/attention. If swallowed: Call a poison center/doctor 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.

<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	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

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Estradiol Benzoate		50-50-0	20 mg per implant
Testosterone propionate		57-85-2	200 mg per implant

**Composition comments** In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

### 4. First-aid measures

<b>Inhalation</b>	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.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if symptoms occur. Wash contaminated clothing before reuse.
<b>Eye contact</b>	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.
<b>Ingestion</b>	Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to an unconscious person.
<b>Most important symptoms/effects, acute and delayed</b>	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.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
<b>General information</b>	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.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ). Apply extinguishing media carefully to avoid creating airborne dust.
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	Combustible. Avoid generating airborne dust. During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	May form combustible dust concentrations in air. Fine particles (such as mists) may fuel fires/explosions.

### 6. Accidental release measures

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

**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.

**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 feedings. 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/personal protection**

**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**

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

**Control banding approach**

Not available.

**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, such as personal protective equipment**

**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 vapor cartridge, full facepiece, dust and mist filter.

**Thermal hazards**

Not applicable.

**General hygiene considerations**

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>Color</b>	Not available.
<b>Odor</b>	Not applicable.
<b>Odor 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>Vapor pressure</b>	Not available.
<b>Vapor 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 information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

**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 oxidizing 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 likely 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.
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**Skin contact** Prolonged skin contact may cause temporary irritation.  
**Eye contact** Direct contact with eyes may cause temporary irritation.  
**Ingestion** Harmful if swallowed.

**Symptoms related to the physical, chemical and toxicological characteristics** 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).

**Information on toxicological effects**

**Acute toxicity** Harmful if swallowed.

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

Components	Species	Test Results
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Estradiol Benzoate (CAS 50-50-0)

**Acute**

**Oral**

LD50 Rat 5000 mg/kg

Testosterone propionate (CAS 57-85-2)

**Acute**

**Oral**

LD50 Mouse 1350 mg/kg  
Rat 1000 mg/kg

**Chronic**

**Subcutaneous**

LOEL Rat 80 - 100 mg (Carc study, Results: Tumors, Male reproductive system)

**Subacute**

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

**Respiratory or skin sensitization**

**Respiratory sensitization** Not a respiratory sensitizer.

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

**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.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Estradiol Benzoate (CAS 50-50-0) Known To Be Human Carcinogen.

**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.

**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 instructions** 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. 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.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** None known.

**Waste from residues / unused products** 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**

**DOT**  
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

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**Classified hazard categories** Acute toxicity (any route of exposure)  
Carcinogenicity  
Reproductive toxicity

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations**

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations**

**California Proposition 65**



**WARNING:** This product can expose you to chemicals including Testosterone propionate, which are known to the State of California to cause birth defects or other reproductive harm.

**California Proposition 65 - CRT: Listed date/Developmental toxin**

Estradiol Benzoate (CAS 50-50-0) Listed: April 1, 1990

**California Proposition 65 - CRT: Listed date/Female reproductive toxin**

Estradiol Benzoate (CAS 50-50-0) Listed: April 1, 1990

Testosterone propionate (CAS 57-85-2) Listed: April 1, 1990

**California Proposition 65 - CRT: Listed date/Male reproductive toxin**

Estradiol Benzoate (CAS 50-50-0) Listed: April 1, 1990

Testosterone propionate (CAS 57-85-2) Listed: April 1, 1990

**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

Country(s) or region	Inventory name	On inventory (yes/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, including date of preparation or last revision

**Issue date** 05-26-2017

**Revision date** 09-05-2019

**Version #** 02

**List of abbreviations** 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** Identification: Recommended restrictions  
Regulatory information: California Proposition 65  
Regulatory information: US state regulations