

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Synovex Plus</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Synovex with Trenbolone Acetate Growth and Finishing Implants for Steers and Heifers * Synovex * Trenbolone Acetate and 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 (USA)</b>	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
<b>Rocky Mountain Poison &amp; Drug Safety</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-888-963-8471
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300  International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (CA)</b>	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
<b>Emergency telephone number</b>	International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	productsupport@zoetis.com
<b>Product Support</b>	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

**Supplier** Not available.

## 2. Hazard identification

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

### Label elements



<b>Signal word</b>	Danger
<b>Hazard statement</b>	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. Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	IF exposed or concerned: Get medical advice/attention.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	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** None known.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Polyethylene Glycol 8000 NF		25322-68-3	<20
Magnesium Stearate		557-04-0	<10
Estradiol Benzoate		50-50-0	28 mg per implant
Trenbolone Acetate		10161-34-9	200 mg per implant

### 4. 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** Remove contact lenses, if present and easy to do. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

**Ingestion** If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center. Rinse mouth. Get medical advice/attention if you feel unwell. Never give anything by mouth to an unconscious person.

**Most important symptoms/effects, acute and delayed** 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. 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).

**Indication of immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

**General information** 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.

### 5. Fire-fighting measures

**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 firefighters** 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.

**Specific methods** Use standard firefighting procedures and consider the hazards of other involved materials.

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

### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. 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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained.

**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 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. Keep containers tightly closed in a dry, cool and well-ventilated place. @ 20 - 25C / 68 - 77F. Keep away from heat and sources of ignition. 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.

**8. Exposure controls/personal protection****Occupational exposure limits****Zoetis****Components****Type****Value**

Estradiol Benzoate (CAS 50-50-0)

TWA

0.2 µg/m<sup>3</sup>

**US. ACGIH Threshold Limit Values****Components****Type****Value****Form**

Magnesium Stearate (CAS 557-04-0)

TWA

3 mg/m<sup>3</sup>

Respirable fraction.

10 mg/m<sup>3</sup>

Inhalable fraction.

**Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)****Components****Type****Value**

Magnesium Stearate (CAS 557-04-0)

TWA

10 mg/m<sup>3</sup>

**Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)****Components****Type****Value****Form**

Magnesium Stearate (CAS 557-04-0)

TWA

3 mg/m<sup>3</sup>

Respirable.

10 mg/m<sup>3</sup>

Inhalable

**Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)****Components****Type****Value****Form**

Magnesium Stearate (CAS 557-04-0)

TWA

3 mg/m<sup>3</sup>

Respirable fraction.

10 mg/m<sup>3</sup>

Inhalable fraction.

**Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)**

Components	Type	Value	Form
Magnesium Stearate (CAS 557-04-0)	TWA	3 mg/m3	Respirable fraction.

**Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)**

Components	Type	Value
Magnesium Stearate (CAS 557-04-0)	15 minute	20 mg/m3
	8 hour	10 mg/m3

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	OEL Additional Information: Skin - May be absorbed through the skin and cause systemic effects.
<b>Control banding approach</b>	Trenbolone acetate - Zoetis OEB 5 (control exposure to <1ug/m3)
<b>Appropriate engineering controls</b>	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 ventilation normally adequate.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves. Impervious gloves.
<b>Other</b>	Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. 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. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. Respirator must be worn if exposed to dust. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.
<b>Thermal hazards</b>	Not applicable.
<b>General hygiene considerations</b>	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>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 information</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. Excessive heat. high humidity. Avoid conditions which create dust. Heat, flames and sparks.
<b>Incompatible materials</b>	Strong oxidising agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Prolonged inhalation may be harmful.
<b>Skin contact</b>	Prolonged skin contact may cause temporary irritation.
Trenbolone Acetate	Species: Rabbit Severity: Non-irritating
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
Trenbolone Acetate	Species: Rabbit Severity: Minimal

**Ingestion** May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

**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. Dusts may irritate the respiratory tract, skin and eyes. May cause reproductive effects. 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

Components	Species	Test Results
Estradiol Benzoate (CAS 50-50-0)		
<u>Acute</u>		
<b>Oral</b>		
LD50	Rat	5000 mg/kg

Components	Species	Test Results
Magnesium Stearate (CAS 557-04-0)		
<b>Acute</b>		
<b>Inhalation</b>		
LC50	Rat	> 2000 mg/m3
<b>Oral</b>		
LD50	Rat	> 2000 mg/kg
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
<b>Corrosivity</b>		
Trenbolone Acetate	Species: Rabbit	Severity: Non-irritating
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation.	
<b>Eye contact</b>		
Trenbolone Acetate	Species: Rabbit	Severity: Minimal
<b>Respiratory or skin sensitisation</b>		
<b>Canada - Alberta OELs: Irritant</b>		
Magnesium Stearate (CAS 557-04-0)	Irritant	
<b>Respiratory sensitisation</b>	Not a respiratory sensitiser.	
<b>Skin sensitisation</b>	This product is not expected to cause skin sensitisation.	
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Carcinogenicity</b>	May cause cancer.	
<b>ACGIH Carcinogens</b>		
Magnesium Stearate (CAS 557-04-0)	A4 Not classifiable as a human carcinogen.	
<b>Canada - Manitoba OELs: carcinogenicity</b>		
Magnesium Stearate (CAS 557-04-0)	Not classifiable as a human carcinogen.	
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>		
Estradiol Benzoate (CAS 50-50-0)	Known To Be Human Carcinogen.	
<b>Reproductive toxicity</b>	May damage fertility or the unborn child. This material causes changes in reproductive hormone levels resulting in inhibition of ovulation. Clinical use of this drug has resulted in the development of male characteristics in females.	
<b>Reproductivity</b>		
Trenbolone Acetate	2 ug/kg Reproductive & Fertility, Fertility Result: NOEL Species: Pig Organ: No route specified	
<b>Specific target organ toxicity - single exposure</b>	Not classified.	
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.	
<b>Aspiration hazard</b>	Not an aspiration hazard.	
<b>Chronic effects</b>	Prolonged inhalation may be harmful.	
<b>12. Ecological information</b>		
<b>Ecotoxicity</b>	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.	

Components	Species	Test Results
Polyethylene Glycol 8000 NF (CAS 25322-68-3)		
<b>Aquatic</b>		
<i>Acute</i>		
Fish	LC50 Atlantic salmon ( <i>Salmo salar</i> )	> 1000 mg/l, 96 hours
<b>Persistence and degradability</b>	No data is available on the degradability of this product.	
<b>Bioaccumulative potential</b>	No data available.	
<b>Mobility in soil</b>	No data available.	
<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.	

### 13. Disposal considerations

<b>Disposal instructions</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. 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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	None known.
<b>Waste from residues / unused products</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.

### 14. Transport information

<b>TDG</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.

### 15. Regulatory information

<b>Canadian regulations</b>	
<b>Controlled Drugs and Substances Act</b>	
Estradiol Benzoate (CAS 50-50-0)	23
<b>Export Control List (CEPA 1999, Schedule 3)</b>	
Not listed.	
<b>Greenhouse Gases</b>	
Not listed.	
<b>Precursor Control Regulations</b>	
Not regulated.	
<b>International regulations</b>	
<b>Stockholm Convention</b>	
Not applicable.	
<b>Rotterdam Convention</b>	
Not applicable.	
<b>Kyoto Protocol</b>	
Not applicable.	
<b>Montreal Protocol</b>	
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	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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** 03-October-2016**Revision date** 28-July-2022**Version No.** 03

**List of abbreviations**

LC50: Lethal Concentration 50%.  
 LD50: Lethal Dose 50%.  
 NOEL: No observed effect level.  
 TWA: Time Weighted Average.

**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  
 Identification: Recommended restrictions  
 Composition / Information on Ingredients: Disclosure Overrides  
 Composition/information on ingredients: Component information  
 First-aid measures: Eye contact  
 First-aid measures: Most important symptoms/effects, acute and delayed  
 Fire-fighting measures: General fire hazards  
 Accidental release measures: Methods and materials for containment and cleaning up  
 Handling and storage: Conditions for safe storage, including any incompatibilities  
 Toxicological information: Symptoms related to the physical, chemical and toxicological characteristics  
 Other information: List of abbreviations