

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Synovex Plus</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Synovex * Trenbolone Acetate and 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>	australia.animalhealth@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>	Carcinogenicity	Category 1A
	Reproductive toxicity	Category 1A
<b>Environmental hazards</b>	Not classified.	

### Label elements, including precautionary statements

#### Hazard symbol(s)



Health hazard

<b>Signal word</b>	Danger
<b>Hazard statement(s)</b>	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. Use personal protective equipment as required.
<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.

**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 (%)
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

#### Description of necessary 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>	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.

**Personal protection for first-aid responders** 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.

**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. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

**For emergency responders** Wear appropriate protective equipment and clothing during clean-up. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Ventilate the contaminated area. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Do not breathe dust. 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 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 and personal protection****Control parameters**

Follow standard monitoring procedures.

**Occupational exposure limits****Zoetis****Components**

Estradiol Benzoate (CAS 50-50-0)

**Type**

TWA

**Value**

0.2 µg/m<sup>3</sup>

**Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)****Components**

Magnesium stearate (CAS 557-04-0)

**Type**

TWA

**Value**

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

**Form**

Inhalable dust.

**Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)****Components**

Magnesium stearate (CAS 557-04-0)

**Type**

TWA

**Value**

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

**Form**

Inspirable dust.

**US. ACGIH Threshold Limit Values****Components**

Magnesium stearate (CAS 557-04-0)

**Type**

TWA

**Value**

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

**Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)****Components**

Polyethylene Glycol 8000 NF (CAS 25322-68-3)

**Type**

TWA

**Value**

1000 mg/m<sup>3</sup>

**Form**

Inhalable fraction.

**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**

Trenbolone acetate - Zoetis OEB 5 (control exposure to <1ug/m<sup>3</sup>)

<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, for example personal protective equipment (PPE)</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>Hygiene measures</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>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.

**Decomposition temperature** Not available.

**Viscosity** Not available.

**Other physical and chemical parameters**

**Explosive properties** Not explosive.

**Oxidising properties** Not oxidising.

**10. Stability and reactivity**

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

**Possibility of hazardous reactions** No dangerous reaction known under conditions of normal use.

**Conditions to avoid** Contact with incompatible materials. Excessive heat. high humidity. Avoid conditions which create dust. Heat, flames and sparks.

**Incompatible materials** Strong oxidising agents.

**Hazardous decomposition products** No hazardous decomposition products are known.

**11. Toxicological information**

**Information on possible routes of exposure**

**Inhalation** Prolonged inhalation may be harmful.

**Skin contact** Prolonged skin contact may cause temporary irritation.  
Trenbolone Acetate Species: Rabbit  
Severity: Non-irritating

**Eye contact** 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 exposure** Direct contact with eyes 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**

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

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

**Corrosivity**  
Trenbolone Acetate Species: Rabbit  
Severity: Non-irritating

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

**Eye contact**  
Trenbolone Acetate

Species: Rabbit  
Severity: Minimal

### 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.

#### ACGIH Carcinogens

Magnesium stearate (CAS 557-04-0)

A4 Not classifiable as a human carcinogen.

**Reproductive toxicity** 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.

#### Reproductivity

Trenbolone Acetate

2 ug/kg Reproductive & Fertility, Fertility  
Result: NOEL  
Species: Pig  
Organ: No route specified

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

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

**Aspiration hazard** Not an aspiration hazard.

**Chronic effects** Prolonged inhalation may be harmful.

## 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.

### Components

### Species

### Test results

Polyethylene Glycol 8000 NF (CAS 25322-68-3)

#### Aquatic

Fish

LC50

Atlantic salmon (*Salmo salar*)

> 1000 mg/l, 96 hours

**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 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.

### 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. unregistered

Poison Schedule (Product) – Schedule 5

#### Australia Medicines & Poisons Appendix D

ANABOLIC STEROIDAL AGENTS, INCLUDING THOSE SEPARATELY SPECIFIED IN SCHEDULE 4 (CAS 50-50-0)

#### Australia Medicines & Poisons Schedule 2

MACROGOLS (CAS 25322-68-3)

#### Australia Medicines & Poisons Schedule 3

MACROGOLS (CAS 25322-68-3)

#### High Volume Industrial Chemicals (HVIC)

Not listed.

#### Importation of Ozone Deleting 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

Australia

#### Inventory name

Australian Inventory of Chemical Substances (AICS)

#### On inventory (yes/no)\*

No

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
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
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

<b>Issue date</b>	03-October-2016
<b>Revision date</b>	16-March-2017
<b>Disclaimer</b>	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.
<b>Revision information</b>	Composition / Information on Ingredients: Disclosure Overrides Composition/information on ingredients: Composition comments Disposal considerations: Disposal methods Disposal considerations: Contaminated packaging Transport Information: Material Transportation Information Regulatory information: National regulations