SAFETY DATA SHEET

1. Identification

Product identifier: Synovex S

Other means of identification:

Synonyms: SYNOVEX® S * Synovex® S Steer Growth and Finishing Implants * Progesterone and 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)

2. Hazard(s) identification

Classification of the hazardous chemical:

Physical hazards: Not classified.
Health hazards: Carcinogenicity Category 1A
Reproductive toxicity Category 1A
Environmental hazards: Not classified.

Label elements, including precautionary statements:

Hazard symbol(s):

Health hazard

Signal word: Danger

Hazard statement(s): 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. Use personal protective equipment as required.

Response: 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.

Other hazards which do not result in classification: None known.

Supplemental information: None.

3. Composition/information on ingredients

Mixture
<table>
<thead>
<tr>
<th>Identity of chemical ingredients</th>
<th>CAS number and other unique identifiers</th>
<th>Concentration of ingredients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estradiol Benzoate</td>
<td>50-50-0</td>
<td>20 mg per implant</td>
</tr>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>200 mg per implant</td>
</tr>
</tbody>
</table>

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. 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**
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**
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.

**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**
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Apply extinguishing media carefully to avoid creating airborne dust.

**Suitable extinguishing media**
Do not use water jet as an extinguisher, as this will spread the fire.

**Unsuitable extinguishing media**
Combustible. Avoid generating airborne dust. During fire, gases hazardous to health may be formed.

**Specific hazards arising from the chemical**
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**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. Local authorities should be advised if significant spillages cannot be contained.

**For emergency responders**
Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Keep unnecessary personnel away. Ventilate the contaminated area. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Do not breathe dust. Avoid contact with eyes, skin, and clothing. 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 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 - 25°C / 68 - 77°F. Keep away from heat and sources of ignition. Protect from light. Protect from sunlight. 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. Keep out of the reach of children.

**8. Exposure controls and personal protection**

**Control parameters**

Follow standard monitoring procedures.

**Occupational exposure limits**

<table>
<thead>
<tr>
<th>Zoetis Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estradiol Benzoate (CAS 50-50-0)</td>
<td>TWA</td>
<td>0.2 µg/m³</td>
</tr>
<tr>
<td>Progesterone (CAS 57-83-0)</td>
<td>TWA</td>
<td>30 µg/m³</td>
</tr>
</tbody>
</table>

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Exposure guidelines**

Ensure adequate ventilation, especially in confined areas. Engineering controls should be used as the primary means to control exposures. 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.

**Appropriate engineering controls**

Ensure adequate ventilation, especially in confined areas. Engineering controls should be used as the primary means to control exposures. 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, for example personal protective equipment (PPE)**

**Eye/face protection**

If contact is likely, safety glasses with side shields are recommended.

**Skin protection**

Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**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 the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

**Thermal hazards**

Not applicable.
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

**Appearance**
- Pellets.

**Physical state**
- Solid.

**Form**
- Solid.

**Colour**
- Yellow.

**Odour**
- Not available.

**Odour threshold**
- Not available.

**pH**
- Not available.

**Melting point/freezing point**
- Not available.

**Initial boiling point and boiling range**
- Not available.

**Flash point**
- Not available.

**Evaporation rate**
- Not available.

**Flammability (solid, gas)**
- Not available.

**Upper/lower flammability or explosive limits**
- Flammability limit - lower (%)
- Not available.

- Flammability limit - upper (%)
- Not available.

- Explosive limit - lower (%)
- Not available.

- Explosive limit – upper (%)
- Not available.

**Vapour pressure**
- Not available.

**Vapour density**
- Not available.

**Relative density**
- Not available.

**Solubility(ies)**
- Solubility (water)
  - Insoluble

**Partition coefficient (n-octanol/water)**
- Not available.

**Auto-ignition temperature**
- 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**

**Incompatible materials**
- Strong oxidising agents.

**Hazardous decomposition products**
- Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.
11. Toxicological information

Information on possible routes of exposure

**Inhalation**
Prolonged inhalation may be harmful.

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

**Eye contact**
Direct contact with eyes may cause temporary irritation.

**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. 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**
May be absorbed through the skin and cause systemic effects.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estradiol Benzoate (CAS 50-50-0)</td>
<td>Oral LD50</td>
<td>Rat 5000 mg/kg</td>
</tr>
<tr>
<td>Progesterone (CAS 57-83-0)</td>
<td>Oral LD50</td>
<td>Rat &gt; 5000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Other LD50</td>
<td>Rat 327 mg/kg [Sub-tenon injection (eye)]</td>
</tr>
<tr>
<td></td>
<td>Chronic Intramuscular</td>
<td>Rabbit 13 mg/kg, 2 years (Target organ: Female reproductive system)</td>
</tr>
<tr>
<td></td>
<td>Chronic Subcutaneous</td>
<td>Rabbit 13 mg/kg, 2 years (Not carcinogenic)</td>
</tr>
<tr>
<td></td>
<td>Chronic Intramuscular</td>
<td>Dog 0.08 - 22.5 mg/day, 74 weeks (Target organ: Female reproductive system)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mouse 0.059 mg/day, 18 months [Effects: Malignant tumors; Target(s): Female reproductive system, Mammary gland]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mouse (F) 25 mg/kg, 19 weeks [Effects: Tumors; Target: Mammary gland]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rat 200 mg/kg/day, 40 weeks [Effects: Malignant tumors; Target: Liver]</td>
</tr>
</tbody>
</table>

**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**
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.

**Mutagenicity**

<table>
<thead>
<tr>
<th>Species</th>
<th>Bacterial Mutagenicity (Ames)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progesterone</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>
### Mutagenicity

**Progesterone**

- **In Vitro Cell Transformation Assay**
  - Result: positive
  - Species: Rat
- **In Vitro Chromosome Aberration**
  - Result: negative
  - Species: Human
- **In Vivo Chromosome Aberration**
  - Result: negative
  - Species: Rat
- **In Vivo Dominant Lethal Assay**
  - Result: negative
  - Species: Mouse

### Carcinogenicity

- May cause cancer.

- **IARC Monographs. Overall Evaluation of Carcinogenicity**
  - Progesterone (CAS 57-83-0) 2A Probably carcinogenic to humans.

### Reproductive toxicity

- May damage fertility or the unborn child.

#### Developmental effects

- **Progesterone**
  - Embryo / Fetal Development, Not Teratogenic
  - Species: Monkey
  - Organ: No route specified
  - Embryo / Fetal Development, Not Teratogenic
  - Species: Rat
  - Organ: No route specified

#### Reproductivity

- **Progesterone**
  - Reproductive & Fertility, Embryotoxicity
  - Species: Rabbit
  - 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.

#### Persistence and degradability

- No data is available on the degradability of this product.

#### Bioaccumulative potential

- No data available.

#### Partition coefficient

- **n-octanol / water (log Kow)**
  - Progesterone: 4.04, (Log D @ pH 7.4, predicted)

#### 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 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
This Safety Data Sheet was prepared in accordance with the Australia Model Code of Practice for the preparation of safety data sheets for hazardous chemicals.

APVMA Registration No: 49956

Poison Schedule (Product) – Schedule 5

This SDS replaces version: Issued October 2016

Australia Medicines & Poisons Appendix A
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D
Estradiol Benzoate (CAS 50-50-0)
Progesterone (CAS 57-83-0)

Australia Medicines & Poisons Appendix E
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G
Progesterone (CAS 57-83-0)

Australia Medicines & Poisons Appendix H
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K
Poisons schedule number not allocated.
Australia Medicines & Poisons Schedule 10
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4
Progesterone (CAS 57-83-0)

Australia Medicines & Poisons Schedule 5
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9
Poisons schedule number not allocated.

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

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

Material name: Synovex S  
905
<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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**
04-September-2019

**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
Composition / Information on Ingredients: Disclosure Overrides