Safer use of: Estradiol Benzoate and Trenbolone Acetate Extended Release Implant

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Estradiol Benzoate and Trenbolone Acetate Extended Release Implant
Trade Name: Synovex®
Synonyms: Synovex® ONE-Feedlot; Synovex® ONE-Grass; sustained-release Synovex® Plus
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Pellets

Classification of the Substance or Mixture

Reproductive Toxicity: Category 1A
Carcinogenicity: Category 1A

EU Classification:
EU Indication of danger: T - Toxic
EU Symbol: T
EU Risk Phrases:
R61 - May cause harm to the unborn child.
R45 - May cause cancer.
R60 - May impair fertility.

Label Elements

Signal Word: Danger
Hazard Statements:
H360 - May damage fertility or the unborn child
H350 - May cause cancer

ZT00521
Precautionary Statements:
- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
Short Term:
May cause mild eye irritation. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy. May have the potential to produce effects on the developing fetus.

Australian Hazard Classification (NOHSC):

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

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trenbolone Acetate</td>
<td>10161-34-9</td>
<td>233-432-5</td>
<td>Repr. 1;R60-61</td>
<td>Repr. 1A (H360FD)</td>
<td>25 mg/pellet</td>
</tr>
<tr>
<td>Estradiol Benzoate</td>
<td>50-50-0</td>
<td>200-043-7</td>
<td>Carc.Cat.1;R45</td>
<td>Carc.1A (H350)</td>
<td>3.5 mg/pellet</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>&lt;2</td>
</tr>
<tr>
<td>Dibutyl sebacate</td>
<td>109-43-3</td>
<td>203-672-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>&lt;2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene Glycol 8000 NF</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>&lt;15</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>&lt;3</td>
</tr>
<tr>
<td>Pellet coating</td>
<td>Mixture</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>&lt;15</td>
</tr>
</tbody>
</table>

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

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16.
4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:**  
Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:**  
Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:**  
Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:**  
Remove to fresh air and keep patient at rest. Seek medical attention immediately.

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

**Symptoms and Effects of Exposure:**  
For information on potential signs and symptoms of exposure, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:**  
None known

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

**Notes to Physician:**  
None

5. FIRE-FIGHTING MEASURES

**Extinguishing Media:**  
Extinguish fires with CO2, extinguishing powder, foam, or water.

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

**Hazardous Combustion Products:**  
Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:**  
Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters**

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

6. ACCIDENTAL RELEASE MEASURES

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

Ensure adequate ventilation. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Avoid dust formation.

**Environmental Precautions**

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

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

**Measures for Cleaning / Collecting:**  
Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Additional Consideration for Large Spills:**  
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
7. HANDLING AND STORAGE

Precautions for Safe Handling
When handling, use appropriate personal protective equipment (see Section 8). Use adequate ventilation. Avoid breathing dust, vapor or mist. Avoid contact with eyes, skin and clothing. Wash hands and any exposed skin after removal of PPE. Avoid open handling. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames. Keep container tightly closed when not in use.

Specific end use(s): Veterinary product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

Estradiol Benzoate
Zoetis OEL TWA 8-hr 0.2 µg/m³, Skin

Magnesium stearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Dibutyl sebacate
Latvia OEL - TWA 10 mg/m³
Lithuania OEL - TWA 10 mg/m³

Polyethylene Glycol 8000 NF
Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³
Switzerland OEL -TWAs 1000 ppm

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Trenbolone Acetate
Zoetis OEB OEB 5 (control exposure to <1µg/m³)

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| Hands: | Wear impervious gloves as minimum protection. |
| Eyes: | Wear safety goggles as minimum protection. |
| Skin: | Wear impervious protective clothing when handling this compound. |
| Respiratory protection: | If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| Physical State: | Pellets |
| Odor: | Not applicable |
| Molecular Formula: | Mixture |
| Color: | No data available |
| Odor Threshold: | No data available |
| Molecular Weight: | Mixture |

| Solvent Solubility: | No data available |
| Water Solubility: | No data available |
| pH: | No data available |
| Melting/Freezing Point (°C): | No data available |
| Boiling Point (°C): | No data available |
| Partition Coefficient: (Method, pH, Endpoint, Value): | No data available |
| Decomposition Temperature (°C): | No data available |
| Evaporation Rate (Gram/s): | No data available |
| Vapor Pressure (kPa): | No data available |
| Vapor Density (g/ml): | No data available |
| Relative Density: | No data available |
| Viscosity: | No data available |

| Flammability: | Autoignition Temperature (Solid) (°C): No data available |
| | Flammability (Solids): No data available |
| | Flash Point (Liquid) (°C): No data available |
| | Upper Explosive Limits (Liquid) (% by Vol.): No data available |
| | Lower Explosive Limits (Liquid) (% by Vol.): No data available |

10. STABILITY AND REACTIVITY

| Reactivity: | No data available |
| Chemical Stability: | Stable under normal conditions of use. |
| Possibility of Hazardous Reactions | No data available |
| Oxidizing Properties: | Fine particles (such as dust and mists) may fuel fires/explosions. |
| Conditions to Avoid: | As a precautionary measure, keep away from strong oxidizers |
| Incompatible Materials: | Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors. |
| Hazardous Decomposition Products: | No data available |
11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. Routes of exposure: skin contact

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

Estradiol Benzoate
Rat Oral LD50 5000 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Irritation / Sensitization: (Study Type, Species, Severity)

Trenbolone Acetate
Eye Irritation Rabbit Minimal
Skin Irritation Rabbit Non-irritating

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

Trenbolone Acetate
Reproductive & Fertility Pig No route specified 2 ug/kg NOEL Fertility

Carcinogen Status: See below

Estradiol Benzoate
IARC: Group 1 (Carcinogenic to Humans)

Povidone
IARC: Group 3 (Not Classifiable)
12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.

14. TRANSPORT INFORMATION

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

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.
15. REGULATORY INFORMATION

Trenbolone Acetate
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **EU EINECS/ELINCS List**: 233-432-5

Estradiol Benzoate
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: 200-043-7

Magnesium stearate
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: 209-150-3

Dibutyl sebacate
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: 203-672-5

Polyethylene Glycol 8000 NF
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **Standard for the Uniform Scheduling for Drugs and Poisons**: Schedule 3
- **EU EINECS/ELINCS List**: Not Listed

Povidone
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: Not Listed

Pellet coating
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **EU EINECS/ELINCS List**: Not Listed
16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage the unborn child.
Carcinogenicity-Cat.1A; H350 - May cause cancer

Toxic to reproduction: Category 1
Carcinogenic: Category 1

R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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.

End of Safety Data Sheet