

# SAFETY DATA SHEET



Revision date: 15-Oct-2013

Version: 3.0

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

### Product Identifier

**Material Name:** Trenbolone Acetate and Estradiol Benzoate Implant

**Trade Name:** Synovex Choice; Synovex Plus  
**Chemical Family:** Steroid

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

**Intended Use:** Veterinary product used for anabolic therapy

### 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

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

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

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

## 2. HAZARDS IDENTIFICATION

**Appearance:** Implant

### Classification of the Substance or Mixture

#### GHS - Classification

Reproductive Toxicity: Category 1A  
Carcinogenicity: Category 1B

#### EU Classification:

EU Indication of danger: Carcinogenic: Category 1  
Toxic to reproduction: Category 1

EU Symbol: T  
EU Risk Phrases:

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

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H360FD - May damage fertility. May damage the unborn child.  
H350 - May cause cancer

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**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

#### Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system. 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).

#### Known Clinical Effects:

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.

### Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

### 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Trenbolone Acetate	10161-34-9	233-432-5	Repr. 1;R60-61	Repr. 1A (H360FD)	100 or 200 mg/implant
Estradiol Benzoate	50-50-0	200-043-7	Carc.Cat.1;R45 Repr.Cat.1;R60 Repr.Cat.1;R61	Repr. 1A (H360FD) Carc.1B (H350)	14 or 28 mg/implant

### 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

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### 4. 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 CO<sub>2</sub>, 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

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### 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

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### 7. HANDLING AND STORAGE

Restrict access to work area. Minimize dust generation and accumulation. Avoid breathing dust, vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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 as directed by product packaging.  
**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

##### Estradiol Benzoate

Zoetis OEL TWA 8-hr

0.2 µg/m<sup>3</sup>, Skin

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 <1ug/m<sup>3</sup>)

#### Analytical Method:

An analytical method may be available for the compound(s) listed above

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits 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).

##### Hands:

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

##### Eyes:

Wear safety glasses or goggles if eye contact is possible.

##### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

##### 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 OEB, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB range. Respiratory protection should be worn to supplement engineering controls when handling this compound.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State:

Pellets

#### Color:

No data available.

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

#### Water Solubility:

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

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

Polymerization: Will not occur

### 10. STABILITY AND REACTIVITY

Reactivity: No data available  
Chemical Stability: Stable under normal conditions of use.  
Possibility of Hazardous Reactions  
Oxidizing Properties: No data available  
Conditions to Avoid: Fine particles (such as mists) may fuel fires/explosions.  
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers  
Hazardous Decomposition Products: No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**General Information:** The information included in this section describes the potential hazards of various forms of the active ingredients. The toxicities of the two materials can be expected to be similar.

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

##### Trenbolone

Rat Sub-tenon injection (eye) LC 50 > 25 mg/kg

##### Estradiol Benzoate

Rat Oral LD50 5000 mg/kg

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

##### Trenbolone

Eye Irritation Rabbit Minimal  
Skin Irritation Rabbit No effect

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### 11. TOXICOLOGICAL INFORMATION

#### Trenbolone Acetate

Eye Irritation Rabbit Minimal  
Skin Irritation Rabbit Non-irritating

#### Estradiol

90 Day(s) Rat Oral 0.003 mg/kg/day NOEL Blood, Female reproductive system, Male reproductive system, Endocrine system, Liver

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

##### Trenbolone

Reproductive & Fertility Rat Oral 0.5 mg/kg NOEL Fertility  
Reproductive & Fertility Monkey Oral 2 ug/kg NOEL Fertility

##### Estradiol

Reproductive & Fertility-Females Rat Oral 0.003 mg/kg/day LOAEL Reproductive toxicity  
Embryo / Fetal Development Rat Intramuscular 30 mg/kg/day LOAEL Fetotoxicity

##### Trenbolone Acetate

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

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Estradiol

Sister Chromatid Exchange Human Lymphocytes Positive  
Micronucleus Human Positive  
Chromosome Aberration Human Negative  
*In Vivo* Direct DNA Damage Hamster Positive  
*In Vivo* Micronucleus Rodent Bone Marrow Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Estradiol

2 Year(s) Female Mouse Oral 0.1 mg/kg LOEL Tumors, Mammary gland, Female reproductive system

#### Carcinogen Status:

See below

##### Estradiol

IARC: Group 1 (Carcinogenic to Humans)  
NTP: Listed  
OSHA: Listed

##### Estradiol Benzoate

IARC: Group 1 (Carcinogenic to Humans)  
OSHA: Listed

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### 12. ECOLOGICAL INFORMATION

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

**Toxicity:** No data available

**Estradiol**  
Fish LC50 96 Hours 2 mg/L

**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



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### 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

### 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.1B; 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 Material 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**