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

Product Identifier

Material Name: Testosterone Propionate-Estradiol Benzoate Implant
Trade Name: Synovex H
Chemical Family: Steroid

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

Intended Use: Veterinary formulation
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
Contact E-Mail: VMIPSrecords@zoetis.com

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

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

2. HAZARDS IDENTIFICATION

Appearance: White liquid

Classification of the Substance or Mixture

GHS - Classification
Acute Oral Toxicity: Category 4
Reproductive Toxicity: Category 1A
Carcinogenicity: Category 1B

EU Classification:
EU Indication of danger: Toxic to reproduction: Category 1
Carcinogenic: Category 2

EU Symbol: T

EU Risk Phrases:
R22 - Harmful if swallowed.
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Label Elements

Signal Word: Danger
Hazard Statements:
H302 - Harmful if swallowed
H350 - May cause cancer
H360FD - May damage fertility. May damage the unborn child.
Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P264 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
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 liver. 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:
Clinical use has caused effects on reproductive system, including prolonged erection (priapism), breast development in males (gynecomastia), loss of libido decreased sperm count, impairment of male fertility, development of male characteristics (masculinization), development of male characteristics in the female fetus, menstrual irregularities, changes in cervical erosion and secretion, impairment of female fertility. Clinical use of this drug has caused prostate cancer, liver cancer and kidney cancer.

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>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Estradiol Benzoate</td>
<td>50-50-0</td>
<td>200-043-7</td>
<td>Carc. Cat.1;R45</td>
<td>Repr. 1A (H360FD)</td>
<td>1-10</td>
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<td></td>
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<td>Repr. Cat.1;R60</td>
<td>Carc.1B (H350)</td>
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<td></td>
<td></td>
<td>Repr. Cat.1;R61</td>
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<td></td>
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<tr>
<td>Testosterone propionate</td>
<td>57-85-2</td>
<td>200-351-1</td>
<td>Carc. Cat.2;R45</td>
<td>Repr. 1A (H360FD)</td>
<td>70-80</td>
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<td>Repr. Cat.1;R60</td>
<td>Carc.1B (H350)</td>
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<tr>
<td></td>
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<td></td>
<td>Repr. Cat.1;R61</td>
<td>Acute Tox. 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xn;R22</td>
<td>(H302)</td>
<td></td>
</tr>
</tbody>
</table>
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

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 spill with absorbent material. 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
Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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/m³, Skin

**Testosterone propionate**
- Zoetis OEL TWA 8-hr: 4 µg/m³, Skin

#### 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, disposable gloves (double suggested) 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 disposable 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.
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: No data available.
Molecular Formula: Mixture
Color: White
Odor Threshold: No data available.
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: Insoluble
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
- Oxidizing Properties: None
- Conditions to Avoid: Fine particles (such as dust and 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

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

**Testosterone propionate**
- Rat Oral LD50 1000 mg/kg
- Mouse Oral LD50 1350mg/kg

**Estradiol Benzoate**
- Rat Oral LD50 5000 mg/kg
11. TOXICOLOGICAL INFORMATION

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Testosterone propionate
5 Day(s) Mouse Oral 1000 mg/kg/day NOAEL None identified
28 Day(s) Monkey Subcutaneous 2.7 mg/kg/day LOAEL Endocrine system

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

Testosterone propionate
Embryo / Fetal Development Monkey Subcutaneous 1.25 mg/kg/day LOEL Teratogenic
Embryo / Fetal Development Rat Subcutaneous 0.4 mg/kg NOEL Teratogenic

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

Testosterone propionate
Not specified Rat Subcutaneous 80-100 mg LOEL Tumors, Male reproductive system

Carcinogen Status: See below

Testosterone propionate
IARC: Group 2A (Probably Carcinogenic to Humans)
OSHA: Listed

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

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

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

Non-hazardous Ingredients
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- 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
15. REGULATORY INFORMATION

**EU EINECS/ELINCS List**
- Not Listed

**Testosterone propionate**
- 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: 200-351-1

16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Carcinogenicity-Cat.1B; H350 - May cause cancer
Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage 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.
Updated Section 3 - Composition / Information on Ingredients.
Updated Section 4 - First Aid Measures.
Updated Section 5 - Fire Fighting Measures.
Updated Section 6 - Accidental Release Measures.
Updated Section 7 - Handling and Storage.
Updated Section 8 - Exposure Controls / Personal Protection.
Updated Section 9 - Physical and Chemical Properties.
Updated Section 10 - Stability and Reactivity.
Updated Section 11 - Toxicology Information.
Updated Section 12 - Ecological Information.
Updated Section 13 - Disposal Considerations.
Updated Section 14 - Transport Information.
Updated Section 15 - Regulatory Information.

**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