

# SAFETY DATA SHEET



Revision date: 29-Jan-2014

Version: 2.1

Page 1 of 8

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

### Product Identifier

**Material Name:** Synovex C

**Trade Name:** Synovex  
**Synonyms:** Progesterone/Estradiol Benzoate  
**Chemical Family:** Mixture

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

**Intended Use:** Veterinary product

### 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:** VMIPRecords@zoetis.com

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

## 2. HAZARDS IDENTIFICATION

**Appearance:** Pellets

### Classification of the Substance or Mixture

#### GHS - Classification

Reproductive Toxicity: Category 1A  
Carcinogenicity: Category 1B

#### EU Classification:

EU Indication of danger: T - Toxic

EU Symbol: T

EU Risk Phrases:

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

## SAFETY DATA SHEET

Material Name: Synovex C  
Revision date: 29-Jan-2014

Page 2 of 8  
Version: 2.1

**Precautionary Statements:** P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
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**  
**Australian Hazard Classification (NOHSC):**

No data available  
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	%
Progesterone	57-83-0	200-350-6	Repr.Cat.2;R60-61 Carc.Cat.2;R45	Carc. 1B (H350) Repr. 1B (H360)	74.1
Estradiol Benzoate	50-50-0	200-043-7	Carc.Cat.1;R45 Repr.Cat.1;R60 Repr.Cat.1;R61	Repr. 1A (H360) Carc.1B (H350)	7.4

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Inert Ingredients	Not applicable	Not Listed	Not Listed	Not Listed	18.5

**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.

## SAFETY DATA SHEET

Material Name: Synovex C  
Revision date: 29-Jan-2014

Page 3 of 8  
Version: 2.1

**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:** No data available

**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

Use with adequate ventilation. Avoid breathing dust, vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

**Specific end use(s):** No data available

## SAFETY DATA SHEET

Material Name: Synovex C  
Revision date: 29-Jan-2014

Page 4 of 8  
Version: 2.1

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Progesterone

Zoetis OEL TWA 8-hr 30 µg/m<sup>3</sup>, Skin

#### Estradiol Benzoate

Zoetis OEL TWA 8-hr 0.2 µg/m<sup>3</sup>, 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 aerosols. 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:

Wear impervious gloves if skin contact is possible.

##### Eyes:

Safety glasses or goggles

##### Skin:

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

##### 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:

Solid Pellets

#### Color:

Yellow

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### 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

#### Progesterone

Predicted 7.4 Log D 4.04

#### 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

## SAFETY DATA SHEET

Material Name: Synovex C  
Revision date: 29-Jan-2014

Page 5 of 8  
Version: 2.1

### 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:** Keep away from heat and other sources of ignition, including electrostatic discharge. 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

**General Information:** Toxicological properties of the formulation have not been investigated. The following information is available for the individual ingredients.

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

##### Progesterone

Rat Oral LD 50 >5000 mg/kg  
Rat Sub-tenon injection (eye) LD 50 327mg/kg

##### Estradiol Benzoate

Rat Oral LD50 5000 mg/kg

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

##### Progesterone

2 Year(s) Rabbit Intramuscular 13 mg/kg LOEL Female reproductive system  
74 Week(s) Dog Subcutaneous 0.08-22.5 mg/day (increased dose) LOEL Female reproductive system

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

##### Progesterone

Reproductive & Fertility Rabbit No route specified Dose not specified Embryotoxicity  
Embryo / Fetal Development Rat No route specified Dose not specified Not Teratogenic  
Embryo / Fetal Development Monkey No route specified Dose not specified Not Teratogenic

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

##### Progesterone

Bacterial Mutagenicity (Ames) Negative  
*In Vivo* Dominant Lethal Assay Mouse Negative  
*In Vivo* Chromosome Aberration Rat Negative  
*In Vitro* Chromosome Aberration Human Negative  
*In Vitro* Cell Transformation Assay Rat Positive

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

## SAFETY DATA SHEET

Material Name: Synovex C  
Revision date: 29-Jan-2014

Page 6 of 8  
Version: 2.1

### 11. TOXICOLOGICAL INFORMATION

#### Progesterone

2 Year(s) Rabbit Intramuscular 13 mg/kg NOEL Not carcinogenic  
18 Month(s) Mouse Subcutaneous 0.059 mg/day LOEL Malignant tumors, Female reproductive system, Mammary gland  
40 Week(s) Rat Subcutaneous 200 mg/kg/day LOEL Malignant tumors, Liver  
19 Week(s) Female Mouse Subcutaneous 25 mg/kg (5 days/week) LOEL Tumors, Mammary gland

**Carcinogen Status:** See below

#### Progesterone

**IARC:** Group 2B (Possibly Carcinogenic to Humans)  
**NTP:** Reasonably Anticipated To Be A Human Carcinogen  
**OSHA:** Listed

#### Estradiol Benzoate

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

### 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

#### Progesterone

Predicted 7.4 Log D 4.04

**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.

## SAFETY DATA SHEET

Material Name: Synovex C  
Revision date: 29-Jan-2014

Page 7 of 8  
Version: 2.1

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



**Progesterone**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen initial date 1/1/88
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 4
for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	200-350-6

**Estradiol Benzoate**

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

**Inert Ingredients**

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**

H350 - May cause cancer  
H360 - May damage fertility or the unborn child

## SAFETY DATA SHEET

**Material Name: Synovex C**  
**Revision date: 29-Jan-2014**

**Page 8 of 8**  
**Version: 2.1**

---

Carcinogenic: Category 1  
Carcinogenic: Category 2  
Toxic to reproduction: Category 1  
Toxic to Reproduction: Category 2

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. Updated Section 9 - Physical and Chemical Properties. Updated Section 15 - Regulatory Information. Updated Section 8 - Exposure Controls / Personal Protection.

**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**