

SAFETY DATA SHEET



Revision date: 29-Jan-2014

Version: 2.1

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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: VMIPSrecords@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

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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.

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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 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 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

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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/m³, Skin

Estradiol Benzoate

Zoetis OEL TWA 8-hr 0.2 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 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

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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))

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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.

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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

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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