SAFETY DATA SHEET

1. Identification

Product identifier **Synovex S**

Other means of identification

Synonyms SYNOVEX® S * Synovex® S Steer Growth and Finishing Implants * Progesterone and Estradiol Benzoate Implant

Recommended use Veterinary product (Hormone)

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (USA) Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)

Rocky Mountain Poison and Drug Center 1-866-531-8896

Product Support/Technical Services 1-800-366-5288

Emergency telephone numbers CHEMTREC (24 hours): 1-800-424-9300
International CHEMTREC (24 hours): +1-703-527-3887

Company Name (CA) Zoetis Canada Inc.
16740 Trans-Canada Highway
Kirkland, Quebec, H9H 4M7

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

Contact E-Mail productsupport@zoetis.com

Product Support 1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at https://www.zoetis.ca/sds/sds.aspx

Supplier Not available.

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Carcinogenicity	Category 1A
Reproductive toxicity	Category 1A

Environmental hazards Not classified.

Label elements

Signal word Danger

Hazard statement May cause cancer. May damage fertility or the unborn child.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.

Response IF exposed or concerned: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Estradiol Benzoate		50-50-0	20 mg per implant
Progesterone		57-83-0	200 mg per implant

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

Skin contact Wash off with soap and water. Get medical attention if symptoms occur. Wash contaminated clothing before reuse.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Call a physician or poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Dusts may irritate the respiratory tract, skin and eyes. May cause reproductive effects.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

General information IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Apply extinguishing media carefully to avoid creating airborne dust.

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical Combustible. Avoid generating airborne dust. During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers. During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards May form combustible dust concentrations in air. Fine particles (such as mists) may fuel fires/explosions.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Ventilate the contaminated area. Wear appropriate protective equipment and clothing during clean-up. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Avoid the generation of dusts during clean-up. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Collect spill with an inert, non-combustible absorbent material and transfer to labeled container for disposal. Clean contaminated surface thoroughly. Prevent release to the environment.

Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not use in areas without adequate ventilation. Avoid dust formation. Combustible dust clouds may be created where operations produce fine material (dust). Should be handled in closed systems, if possible. Do not breathe dust. Do not taste or swallow. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store locked up. Protect from moisture. Keep containers tightly closed in a dry, cool and well-ventilated place. @ 20 - 25C / 68 - 77F. Keep away from heat and sources of ignition. Protect from light. Protect from sunlight. Avoid dust formation. Keep away from food, drink and animal feeding stuffs. Store away from incompatible materials (see Section 10 of the SDS). Use care in handling/storage. Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits

Zoetis

Components	Type	Value
Estradiol Benzoate (CAS 50-50-0)	TWA	0.2 µg/m³
Progesterone (CAS 57-83-0)	TWA	30 µg/m³

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

OEL Additional Information: Skin - May be absorbed through the skin and cause systemic effects.

Control banding approach

Not available.

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas. Engineering controls should be used as the primary means to control exposures. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General room ventilation is adequate unless the process generates dust, mist or aerosols.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

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

Other

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

Respiratory protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respirator must be worn if exposed to dust. 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. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

Thermal hazards

Not applicable.

General hygiene considerations	Observe any medical surveillance requirements. Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	Pellets.
Physical state	Solid.
Form	Solid.
Colour	Yellow.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Insoluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks. Exposure to light. Excessive heat. high humidity. Sunlight. Avoid conditions which create dust.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Prolonged inhalation may be harmful.

Skin contact	Prolonged skin contact may cause temporary irritation.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. 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).

Information on toxicological effects

Acute toxicity May be absorbed through the skin and cause systemic effects.

Components	Species	Test results
Estradiol Benzoate (CAS 50-50-0)		
Acute		
Oral		
LD50	Rat	5000 mg/kg
Progesterone (CAS 57-83-0)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
Other		
LD50	Rat	327 mg/kg [Sub-tenon injection (eye)]
Chronic		
Intramuscular		
LOEL	Rabbit	13 mg/kg, 2 years (Target organ: Female reproductive system)
NOEL	Rabbit	13 mg/kg, 2 years (Not carcinogenic)
Subcutaneous		
LOEL	Dog	0.08 - 22.5 mg/day, 74 weeks (Target organ: Female reproductive system)
	Mouse	0.059 mg/day, 18 months [Effects: Malignant tumors; Target(s): Female reproductive system, Mammary gland]
	Mouse (F)	25 mg/kg, 19 weeks [Effects: Tumors; Target: Mammary gland]
	Rat	200 mg/kg/day, 40 weeks [Effects: Malignant tumors; Target: Liver]

Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitisation

Respiratory sensitisation	Not a respiratory sensitizer.
Skin sensitisation	This product is not expected to cause skin sensitisation.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Progesterone	Bacterial Mutagenicity (Ames) Result: negative In Vitro Cell Transformation Assay Result: positive Species: Rat

Mutagenicity

Progesterone	In Vitro Chromosome Aberration Result: negative Species: Human
	In Vivo Chromosome Aberration Result: negative Species: Rat
	In Vivo Dominant Lethal Assay Result: negative Species: Mouse

Carcinogenicity May cause cancer.

IARC Monographs. Overall Evaluation of Carcinogenicity

Progesterone (CAS 57-83-0)	2A Probably carcinogenic to humans.

US. National Toxicology Program (NTP) Report on Carcinogens

Estradiol Benzoate (CAS 50-50-0)	Known To Be Human Carcinogen.
Progesterone (CAS 57-83-0)	Reasonably Anticipated to be a Human Carcinogen.

Reproductive toxicity May damage fertility or the unborn child.

Developmental effects

Progesterone	Embryo / Fetal Development, Not Teratogenic Species: Monkey Organ: No route specified
	Embryo / Fetal Development, Not Teratogenic Species: Rat Organ: No route specified

Reproductivity

Progesterone	Reproductive & Fertility, Embryotoxicity Species: Rabbit Organ: No route specified

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

Progesterone	4.04, (Log D @ pH 7.4, predicted)

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code None known.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

TDG

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Estradiol Benzoate (CAS 50-50-0)	23
Progesterone (CAS 57-83-0)	23

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

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Revision information Product and Company Identification: Synonyms
Composition / Information on Ingredients: Disclosure Overrides