

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 of the chemical and restrictions on use	
Recommended use	Veterinary product (Hormone)
Restrictions on use	Not for human use
Details of manufacturer or importer	
Company Name (AU)	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
Tel	1800 814 883
Fax	(02) 8876 0444
Email	productsupport.au@zoetis.com
Emergency Phone	1800 814 883 (all hours)
Police and Fire Brigade	Dial 000
If ineffective	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Carcinogenicity	Category 1A
	Reproductive toxicity	Category 1A
Environmental hazards	Not classified.	

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard

Signal word	Danger
Hazard statement(s)	May cause cancer. May damage fertility or the unborn child.

Precautionary statement(s)

Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required.
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 which do not result in classification None known.

Supplemental information None.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Estradiol Benzoate	50-50-0	20 mg per implant
Progesterone	57-83-0	200 mg per implant

4. First-aid measures

Description of necessary 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.
Personal protection for first-aid responders	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.
Symptoms caused by exposure	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.
Medical attention and special treatment	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂). 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 fire fighters	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.
Hazchem code	None.
General fire hazards	May form combustible dust concentrations in air. Fine particles (such as mists) may fuel fires/explosions.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

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

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.

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 and personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

Components

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.

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, for example personal protective equipment (PPE)

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.

Hygiene measures 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 physical and chemical parameters	
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 possible 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 exposure 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).

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/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

Mutagenicity
Progesterone

In Vitro Cell Transformation Assay
Result: positive
Species: Rat

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.

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 methods	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.
Residual waste	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

ADG	Not regulated as dangerous goods.
RID	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

Safety, health and environmental regulations

National regulations	This Safety Data Sheet was prepared in accordance with the Australia Model Code of Practice for the preparation of safety data sheets for hazardous chemicals. APVMA Registration No: 49956 Poison Schedule (Product) – Schedule 5 This SDS replaces version: Issued October 2016
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Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Estradiol Benzoate (CAS 50-50-0)

Progesterone (CAS 57-83-0)

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Progesterone (CAS 57-83-0)

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Progesterone (CAS 57-83-0)

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

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
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

Country(s) or region	Inventory name	On inventory (yes/no)*
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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

Issue date	04-September-2019
Disclaimer	Zoetis Inc. believes that the information contained in this 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. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	Product and Company Identification: Synonyms Composition / Information on Ingredients: Disclosure Overrides