

SAFETY DATA SHEETS

This SDS packet was issued with item:

078408684

N/A

SAFETY DATA SHEET



1. Identification

Product identifier Synovex Plus

Other means of identification

Synonyms Synovex * Trenbolone Acetate and Estradiol Benzoate Impant

Recommended use Veterinary product (Hormone)

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (US) 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 (EU) Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

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

Contact E-Mail VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Carcinogenicity Category 1A
Reproductive toxicity Category 1A

Environmental hazards Not classified.

OSHA defined 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.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information

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).

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Polyethylene Glycol 8000 NF		25322-68-3	<20
Magnesium stearate		557-04-0	<10
Estradiol Benzoate		50-50-0	28 mg per implant
Trenbolone Acetate		10161-34-9	200 mg per implant

Composition comments In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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 If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. Rinse mouth. Get medical advice/attention if you feel unwell. 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. 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. Keep people away from and upwind of spill/leak. 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. 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 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. Keep containers tightly closed in a dry, cool and well-ventilated place. @ 20 - 25C / 68 - 77F. Keep away from heat and sources of ignition. Avoid dust formation. Keep away from food, drink and animal feedingstuffs. Store away from incompatible materials (see Section 10 of the SDS). Use care in handling/storage.

8. Exposure controls/personal protection

Occupational exposure limits

Zoetis

Components

Type

Value

Estradiol Benzoate (CAS 50-50-0)

TWA

0.2 µg/m³

US. ACGIH Threshold Limit Values

Components

Type

Value

Magnesium stearate (CAS 557-04-0)

TWA

10 mg/m3

US. Workplace Environmental Exposure Level (WEEL) Guides

Components

Type

Value

Form

Polyethylene Glycol 8000 NF (CAS 25322-68-3)

TWA

10 mg/m3

Particulate.

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

Trenbolone acetate - Zoetis OEB 5 (control exposure to <1ug/m3)

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas. 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 ventilation normally adequate.

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.

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. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. Respirator must be worn if exposed to dust. Chemical respirator with organic vapor 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.
Color	Not available.
Odor	Not applicable.
Odor 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.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
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.
Oxidizing properties	Not oxidizing.

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. Excessive heat. high humidity. Avoid conditions which create dust. Heat, flames and sparks.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Prolonged inhalation may be harmful.
Skin contact	Prolonged skin contact may cause temporary irritation.
Trenbolone Acetate	Species: Rabbit Severity: Non-irritating
Eye contact	Direct contact with eyes may cause temporary irritation.
Trenbolone Acetate	Species: Rabbit Severity: Minimal

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

Components	Species	Test Results
Estradiol Benzoate (CAS 50-50-0)		

Acute

Oral

LD50	Rat	5000 mg/kg
------	-----	------------

Magnesium stearate (CAS 557-04-0)

Acute

Inhalation

LC50	Rat	> 2000 mg/m3
------	-----	--------------

Oral

LD50	Rat	> 2000 mg/kg
------	-----	--------------

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Trenbolone Acetate	Species: Rabbit Severity: Non-irritating
--------------------	---------------------------------------------

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye Contact

Trenbolone Acetate	Species: Rabbit Severity: Minimal
--------------------	--------------------------------------

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity May cause cancer.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Estradiol Benzoate (CAS 50-50-0)

Known To Be Human Carcinogen.

Reproductive toxicity

May damage fertility or the unborn child. This material causes changes in reproductive hormone levels resulting in inhibition of ovulation. Clinical use of this drug has resulted in the development of male characteristics in females.

Reproductivity

Trenbolone Acetate

2 ug/kg Reproductive & Fertility, Fertility
Result: NOEL
Species: Pig
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.

Components

Species

Test Results

Polyethylene Glycol 8000 NF (CAS 25322-68-3)

Aquatic

Fish

LC50

Atlantic salmon (*Salmo salar*)

> 1000 mg/l, 96 hours

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available.

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

DOT

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

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Developmental toxin

Estradiol Benzoate (CAS 50-50-0) Listed: April 1, 1990

US - California Proposition 65 - CRT: Listed date/Female reproductive toxin

Estradiol Benzoate (CAS 50-50-0) Listed: April 1, 1990

US - California Proposition 65 - CRT: Listed date/Male reproductive toxin

Estradiol Benzoate (CAS 50-50-0) Listed: April 1, 1990

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	Yes

Country(s) or region	Inventory name	On inventory (yes/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, including date of preparation or last revision

Issue date	01-05-2015
Revision date	05-26-2017
Version #	04
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	Composition / Information on Ingredients: Disclosure Overrides Composition/information on ingredients: Composition comments Disposal considerations: Disposal instructions Disposal considerations: Contaminated packaging Transport Information: Material Transportation Information