

## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Trenbolone / Estradiol Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Carcinogenicity : Category 1A

Reproductive toxicity : Category 1A

Specific target organ toxicity - : Category 1 (Liver, Bone, Blood, Endocrine system)  
repeated exposure

Specific target organ toxicity - : Category 1 (Endocrine system, Blood)  
repeated exposure (Oral)



Short-term (acute) aquatic : Category 3  
hazard

Long-term (chronic) aquatic : Category 1  
hazard

##### GHS label elements

## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

- Hazard pictograms :  
- Signal word : Danger
- Hazard statements : H350 May cause cancer.  
H360FD May damage fertility. May damage the unborn child.  
H372 Causes damage to organs (Liver, Bone, Blood, Endocrine system) through prolonged or repeated exposure.  
H372 Causes damage to organs (Endocrine system, Blood) through prolonged or repeated exposure if swallowed.  
H402 Harmful to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.
- Precautionary statements : **Prevention:**  
P203 Obtain, read and follow all safety instructions before use.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:**  
P318 IF exposed or concerned, get medical advice.  
P391 Collect spillage.
- Storage:**  
P405 Store locked up.
- Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate	10161-34-9	>= 58.8686 - <= 74.07
Estradiol	50-28-2	>= 6.9027 - <= 12.5
Magnesium stearate	557-04-0	>= 1.4717 - <= 1.85

## 4. FIRST AID MEASURES

## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

---

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May cause cancer.  
May damage fertility. May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.  
Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.
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### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Metal oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.

## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

Materials to avoid : Store in accordance with the particular national regulations.  
: Do not store with the following product types:  
Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate	10161-34-9	TWA	0.2 $\mu\text{g}/\text{m}^3$ (OEB 5)	Internal
		Wipe limit	2 $\mu\text{g}/100 \text{ cm}^2$	Internal
Estradiol	50-28-2	TWA	0.05 $\mu\text{g}/\text{m}^3$ (OEB 5)	Internal
	Further information: Skin			
		Wipe limit	0.5 $\mu\text{g}/100 \text{ cm}^2$	Internal
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH

**Engineering measures** : Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
No open handling permitted.  
Totally enclosed processes and materials transport systems are required.  
Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

#### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

---

- potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection** : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.
- Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
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### 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance** : powder
- Colour** : yellow
- Odour** : No data available
- Odour Threshold** : No data available
- pH** : No data available
- Melting point/freezing point** : No data available
- Initial boiling point and boiling range** : No data available
- Flash point** : Not applicable
- Evaporation rate** : No data available
- Flammability (solid, gas)** : May form explosive dust-air mixture during processing, handling or other means.
- Flammability (liquids)** : No data available
- Upper explosion limit / Upper flammability limit** : No data available
- Lower explosion limit / Lower flammability limit** : No data available
- Vapour pressure** : No data available
- Relative vapour density** : No data available

## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

---

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle size : No data available

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### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### **Acute toxicity**

Not classified based on available information.

#### **Product:**

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

---

### Components:

#### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
LD50 (Mouse): 2,700 mg/kg

#### **Estradiol:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Acute toxicity (other routes of administration) : LD50 (Rat): > 300 mg/kg  
Application Route: Subcutaneous

#### **Magnesium stearate:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Assessment: The substance or mixture has no acute oral toxicity  
Remarks: Based on data from similar materials  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Remarks: Based on data from similar materials

### **Skin corrosion/irritation**

Not classified based on available information.

### Components:

#### **Magnesium stearate:**

Species : Rabbit  
Result : No skin irritation  
Remarks : Based on data from similar materials

### **Serious eye damage/eye irritation**

Not classified based on available information.

### Components:

#### **Estradiol:**

Result : No eye irritation

#### **Magnesium stearate:**

Species : Rabbit  
Result : No eye irritation  
Remarks : Based on data from similar materials

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.



# SAFETY DATA SHEET

according to the Globally Harmonized System



## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

---

### Respiratory sensitisation

Not classified based on available information.

### Components:

#### Estradiol:

Exposure routes : Skin contact  
Species : Guinea pig  
Assessment : Does not cause skin sensitisation.  
Result : negative

#### Magnesium stearate:

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### 17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Test system: Salmonella typhimurium  
Result: negative

Test Type: Micronucleus test  
Test system: Chinese hamster fibroblasts  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Result: negative

Test Type: Micronucleus test  
Species: Rat  
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

#### Estradiol:

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Test system: mammalian cells  
Result: positive

Test Type: Chromosome aberration test in vitro  
Test system: mammalian cells  
Result: positive

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

---

Test Type: Chromosomal aberration  
Test system: mammalian cells  
Result: positive

Genotoxicity in vivo : Test Type: Chromosomal aberration  
Species: Rat  
Cell type: Bone marrow  
Result: negative

Test Type: Chromosomal aberration  
Species: Mouse  
Cell type: Bone marrow  
Result: negative

### **Magnesium stearate:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

### **Carcinogenicity**

May cause cancer.

### **Components:**

#### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Species : Mouse, male and female  
Application Route : Oral  
Result : positive  
Target Organs : Liver

Species : Rat, male and female  
Application Route : Oral  
Result : positive  
Target Organs : Pancreas

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

### **Estradiol:**

Species : Mouse  
Application Route : Ingestion  
Exposure time : 24 Months  
LOAEL : 100  $\mu$ g/kg

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

---

Result : positive  
Target Organs : female reproductive organs

Species : Rat  
Application Route : Subcutaneous  
Exposure time : 13 weeks  
LOAEL : 20 mg/kg body weight  
Result : positive  
Target Organs : Endocrine system

Carcinogenicity - Assessment : Positive evidence from human epidemiological studies

### Reproductive toxicity

May damage fertility. May damage the unborn child.

### Components:

#### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Effects on fertility : Test Type: Two-generation study  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 0.18 mg/kg body weight  
Result: Postimplantation loss.

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: oral (feed)  
Developmental Toxicity: LOAEL: 20 mg/kg body weight  
Result: Malformations were observed.

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

#### **Estradiol:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Fertility: LOAEL: 0.5 mg/kg body weight  
Result: Effects on fertility

Test Type: One-generation reproduction toxicity study  
Species: Rat  
Duration of Single Treatment: 90 d  
Fertility: LOAEL: 0.69 mg/kg body weight  
Result: Effects on fertility

Test Type: Two-generation study  
Species: Mouse  
Application Route: Oral  
Fertility: LOAEL: 0.1 mg/kg body weight  
Result: Effects on fertility

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

---

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse, female  
Application Route: Subcutaneous  
Teratogenicity: LOAEL: 4 mg/kg body weight  
Symptoms: Malformations were observed.  
Result: positive, Teratogenic effects

Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Subcutaneous  
Teratogenicity: LOAEL: 2.5 µg/kg body weight  
Symptoms: Reduced body weight  
Result: positive, Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 0.2 mg/kg body weight  
Symptoms: Early Resorptions / resorption rate, Reduced number of viable fetuses, Reduced body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Reproductive toxicity - Assessment : May damage fertility. May damage the unborn child.

### **Magnesium stearate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

### **STOT - single exposure**

Not classified based on available information.

### **STOT - repeated exposure**

Causes damage to organs (Liver, Bone, Blood, Endocrine system) through prolonged or repeated exposure.

Causes damage to organs (Endocrine system, Blood) through prolonged or repeated exposure if swallowed.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

---

### Components:

#### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Exposure routes : Ingestion  
Target Organs : Endocrine system, Blood  
Assessment : Causes damage to organs through prolonged or repeated exposure.

#### **Estradiol:**

Target Organs : Liver, Bone, Blood, Endocrine system  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### **Repeated dose toxicity**

### Components:

#### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Species : Pig  
NOAEL : 0.004 mg/kg  
LOAEL : 0.08 mg/kg  
Exposure time : 14 Weeks  
Target Organs : Testis, Ovary, Liver, Uterus (including cervix)

Species : Rat  
NOAEL : 0.04 mg/kg  
LOAEL : 3.6 mg/kg  
Application Route : Oral  
Exposure time : 23 Weeks  
Target Organs : Blood

Species : Monkey, female  
NOAEL : 0.01 mg/kg  
LOAEL : 0.04 mg/kg  
Application Route : Oral  
Exposure time : 122 Days  
Target Organs : female reproductive organs

Species : Monkey, male  
NOAEL : 0.002 mg/kg  
LOAEL : 0.04 mg/kg  
Application Route : Oral  
Exposure time : 30 Days  
Target Organs : male reproductive organs

Species : Rat  
NOAEL : 0.05 mg/kg  
LOAEL : 0.1 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : male reproductive organs, Ovary, Uterus (including cervix)

#### **Estradiol:**

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

Species : Rat  
LOAEL :  $\geq 0.17$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 d  
Target Organs : Mammary gland, Ovary, Uterus (including cervix), Liver, Bone, Endocrine system, Blood, Testis

### Magnesium stearate:

Species : Rat  
NOAEL :  $> 100$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Ingestion : Symptoms: male reproductive effects, gynecomastia, changes in libido

#### **Estradiol:**

Inhalation : Symptoms: tingling, Nose bleeding  
Skin contact : Symptoms: Skin irritation, Redness, pruritis  
Ingestion : Symptoms: Headache, Gastrointestinal disturbance, Dizziness, Vomiting, Diarrhoea, water retention, liver function change, changes in libido, breast tenderness, menstrual irregularities

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Toxicity to fish (Chronic toxicity) : NOEC: 0.000035 mg/l  
Exposure time: 21 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 229  
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 1,000

#### **Estradiol:**

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): 3.9 mg/l  
Exposure time: 96 h

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Trenbolone / Estradiol Formulation

Version 8.2      Revision Date: 02.11.2023      SDS Number: 28284-00025      Date of last issue: 30.09.2023  
Date of first issue: 05.11.2014

- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.7 mg/l  
Exposure time: 48 h
- Toxicity to algae/aquatic plants : NOEC ( Pseudokirchneriella subcapitata (green algae)): 1.7 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- EC50 ( Pseudokirchneriella subcapitata (green algae)): > 1.7 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- Toxicity to microorganisms : EC50: > 100 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209
- NOEC: 100 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209
- Toxicity to fish (Chronic toxicity) : NOEC: 0.000003 mg/l  
Exposure time: 160 d  
Species: Oryzias latipes (Japanese medaka)  
Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.2 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)
- M-Factor (Chronic aquatic toxicity) : 1,000

### Magnesium stearate:

- Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Method: DIN 38412  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l  
Exposure time: 47 h  
Test substance: Water Accommodated Fraction  
Method: Directive 67/548/EEC, Annex V, C.2.  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility
- Toxicity to algae/aquatic plants : EL50 ( Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.2	02.11.2023	28284-00025	Date of first issue: 05.11.2014

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No toxicity at the limit of solubility

NOELR ( Pseudokirchneriella subcapitata (green algae)): > 1 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l  
Exposure time: 16 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

### Persistence and degradability

#### Components:

##### **Estradiol:**

Biodegradability : Result: rapidly degradable  
Biodegradation: 84 %  
Exposure time: 24 hrs

##### **Magnesium stearate:**

Biodegradability : Result: Not biodegradable  
Remarks: Based on data from similar materials

### Bioaccumulative potential

#### Components:

##### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Partition coefficient: n-octanol/water : log Pow: 3.77

##### **Estradiol:**

Partition coefficient: n-octanol/water : log Pow: 4.01

##### **Magnesium stearate:**

Partition coefficient: n-octanol/water : log Pow: > 4

### Mobility in soil

#### Components:

##### **Estradiol:**

Distribution among environmental compartments : log Koc: 3.81



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### Other adverse effects

No data available

## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Estradiol, 17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate)  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

#### IATA-DGR

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Estradiol, 17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

#### IMDG-Code

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Estradiol, 17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

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### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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## 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

#### The components of this product are reported in the following inventories:

AICS : not determined  
DSL : not determined  
IECSC : not determined

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## 16. OTHER INFORMATION

Revision Date : 02.11.2023

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect

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Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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