

# SAFETY DATA SHEET



## Trenbolone / Estradiol Formulation

Version  
16.0

Revision Date:  
10.11.2025

SDS Number:  
28269-00035

Date of last issue: 03.11.2025  
Date of first issue: 05.11.2014

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### SECTION 1. IDENTIFICATION

Product identifier : Trenbolone / Estradiol Formulation

Other means of identification : COOPERS REVALOR 400 GROWTH PROMOTANT FOR GRASS FED HEIFERS AND STEERS (48945)  
COOPERS REVALOR FLEX GROWTH PROMOTANT FOR NON BREEDING CATTLE (58656)  
COOPERS REVALOR S STEER GROWTH PROMOTANT AND FINISHING IMPLANTS (46111)  
COOPERS REVALOR-H GROWTH PROMOTANT AND FINISHING IMPLANTS (47248)  
Coopers Revalor XR Growth Promotant and Finishing Implants (90903)

#### Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 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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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification of the substance or mixture in accordance with ABNT NBR 14725 Standard

Carcinogenicity : Category 1A

Reproductive toxicity : Category 1A

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

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

Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic : Category 1

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hazard

### GHS label elements in accordance with ABNT NBR 14725 Standard

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:**

P201 Obtain special 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:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P391 Collect spillage.

**Storage:**

P405 Store locked up.

### 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.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name  | CAS-No.    | Classification  | Concentration (% w/w) |
|--|------------|---|-----------------------|
| 17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate | 10161-34-9 | Carc., 2<br>Repr., 2<br>STOT RE,<br>(Oral)(Endocrine system, Blood) , 1<br>Aquatic Chronic, 1 | = 70 -< 90            |

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|                    |          |   |             |
|--------------------|----------|---|-------------|
| Estradiol          | 50-28-2  | Acute Tox. (Oral), 5<br>Carc., 1A<br>Repr., 1A<br>STOT RE, (Liver, Bone, Blood, Endocrine system) , 1<br>Aquatic Acute, 2<br>Aquatic Chronic, 1 | >= 10 -< 20 |
| Magnesium stearate | 557-04-0 |   | >= 5 -< 10  |

## SECTION 4. FIRST AID MEASURES

### Description of necessary first-aid measures

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).

### Indication of any immediate medical attention and special treatment needed

Notes to physician : Treat symptomatically and supportively.

## SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing : None known.

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### media

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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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## SECTION 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.

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## SECTION 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.

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|                             |  |
|-----------------------------|--|
| Local/Total ventilation     | : If sufficient ventilation is unavailable, use with local exhaust ventilation.  |
| Advice on safe handling     | : Do not get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures            | : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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.   |
| Conditions for safe storage | : Keep in properly labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations.  |
| Materials to avoid          | : Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases   |

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

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

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|  |  |                                     |                     |       |
|--|--|-------------------------------------|---------------------|-------|
|  |  | (Inhalable particulate matter)      |                     |       |
|  |  | TWA (Respirable particulate matter) | 3 mg/m <sup>3</sup> | ACGIH |

**Engineering measures**

- : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.
- 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.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Skin and body protection | : Work uniform or laboratory coat.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially   |

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contaminated clothing.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

|  |   |   |
|--|---|---|
| Physical state                                   | : | powder  |
| Color  | : | yellow  |
| Odor   | : | No data available   |
| Odor 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   |
| Vapor pressure                                   | : | No data available   |
| Relative vapor density                           | : | No data available   |
| Relative density                                 | : | No data available   |
| Density  | : | No data available   |
| Solubility(ies)                                  |   |   |
| Water solubility                                 | : | No data available   |
| Partition coefficient: n-octanol/water           | : | No data available   |
| Autoignition temperature                         | : | No data available   |
| Decomposition temperature                        | : | No data available   |
| Viscosity  |   |   |
| Viscosity, kinematic                             | : | No data available   |
| Explosive properties                             | : | Not explosive   |

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Oxidizing properties : The substance or mixture is not classified as oxidizing.  
Molecular weight : No data available  
Particle characteristics  
Particle size : No data available

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## SECTION 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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## SECTION 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

#### 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

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|                       |   |   |
|-----------------------|---|---|
|                       |   | Method: OECD Test Guideline 423<br>Assessment: The substance or mixture has no acute oral toxicity<br>Remarks: Based on data from similar materials |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2.000 mg/kg<br>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 sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Estradiol:**

|                    |   |                                    |
|--------------------|---|------------------------------------|
| Routes of exposure | : | Skin contact                       |
| Species            | : | Guinea pig                         |
| Assessment         | : | Does not cause skin sensitization. |
| Result             | : | negative                           |

**Magnesium stearate:**

|                    |   |                         |
|--------------------|---|-------------------------|
| Test Type          | : | Maximization Test       |
| Routes of exposure | : | Skin contact            |
| Species            | : | Guinea pig              |
| Method             | : | OECD Test Guideline 406 |
| Result             | : | negative                |

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||| 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

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

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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                                       |
| 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 |
|----------------------|---|---------------------------------|

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Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 0,18 mg/kg body weight  
Result: Postimplantation loss.

Effects on fetal development : Test Type: Embryo-fetal 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.

Effects on fetal development : Test Type: Embryo-fetal 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-fetal development  
Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 0,2 mg/kg body weight

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|                                    |   |  |
|------------------------------------|---|--|
|                                    |   | Symptoms: Early Resorptions / resorption rate., Reduced number of viable fetuses., Reduced body weight<br>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.   |
| <b>Magnesium stearate:</b>         |   |  |
| Effects on fertility               | : | Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 422<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on fetal development       | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>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.

### Components:

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

|                    |   |   |
|--------------------|---|---|
| Routes of exposure | : | 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    |

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|-------------------|---|--|
| 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:

|                   |   |   |
|-------------------|---|---|
| Species           | : | Rat   |
| LOAEL             | : | >= 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:

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|                   |   |
|-------------------|---|
| Ingestion         | : Symptoms: male reproductive effects, gynecomastia, changes in libido  |
| <b>Estradiol:</b> |   |
| Inhalation        | : Symptoms: tingling, Nose bleeding   |
| Skin contact      | : Symptoms: Skin irritation, Redness, pruritis  |
| Ingestion         | : Symptoms: Headache, Gastrointestinal disturbance, Dizziness, Vomiting, Diarrhea, water retention, liver function change, changes in libido, breast tenderness, menstrual irregularities |

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

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

|                                     |   |
|-------------------------------------|---|
| Toxicity to fish (Chronic toxicity) | : NOEC (Pimephales promelas (fathead minnow)): 0,000035 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 229<br>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<br>Exposure time: 96 h  |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): 2,7 mg/l<br>Exposure time: 48 h   |
| Toxicity to algae/aquatic plants                                       | : NOEC (Pseudokirchneriella subcapitata (green algae)): 1,7 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC50 (Pseudokirchneriella subcapitata (green algae)): > 1,7 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC (Oryzias latipes (Japanese medaka)): 0,000003 mg/l<br>Exposure time: 160 d<br>Method: OECD Test Guideline 210   |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Daphnia magna (Water flea)): 0,2 mg/l<br>Exposure time: 21 d   |
| M-Factor (Chronic aquatic toxicity)                                    | : 1.000  |
| Toxicity to microorganisms   | : EC50: > 100 mg/l<br>Exposure time: 3 h   |

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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

**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  
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

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II

### 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

### Other adverse effects

No data available

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## SECTION 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.

---

## SECTION 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

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Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes  
Remarks : Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids.

### 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  
Remarks : Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids.

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### ANTT

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  
Hazard Identification Number : 90

### 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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## SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

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|         |   |                |
|---------|---|----------------|
| AICS    | : | not determined |
| CA. DSL | : | not determined |
| IECSC   | : | not determined |

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### SECTION 16. OTHER INFORMATION

|               |   |            |
|---------------|---|------------|
| Revision Date | : | 10.11.2025 |
| Date format   | : | dd.mm.yyyy |

#### Further information

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

#### 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 Standardization; 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 Organization for Standardization; KECL - 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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 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, Authorization 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

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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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