SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Trenbolone / Estradiol Formulation

Version: 10.3
Revision Date: 12/07/2023
SDS Number: 28298-00027
Date of last issue: 11/02/2023
Date of first issue: 11/05/2014

SECTION 1. IDENTIFICATION

Product name: 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)

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
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)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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.

Precautionary Statements:
- Prevention:
  - P201 Obtain special instructions before use.
  - P202 Do not handle until all safety precautions have been read and understood.
  - P260 Do not breathe dust.
  - P264 Wash skin thoroughly after handling.
  - P270 Do not eat, drink or smoke when using this product.
  - P280 Wear protective gloves, protective clothing, eye protection and face protection.
- Response:
  - P308 + P313 IF exposed or concerned: Get medical attention.
- Storage:
  - P405 Store locked up.
- Disposal:
  - P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>17β-hydroxyestra-4,9,11-trien-3-one 17-acetate</td>
<td>10161-34-9</td>
</tr>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
</tr>
</tbody>
</table>

SECTION 4. 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.
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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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

**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.

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 labeled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types: Strong oxidizing agents
- Self-reactive substances and mixtures
- Organic peroxides
- Explosives
- Gases
**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

*Ingredients with workplace control parameters*

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>17β-hydroxyestra-4,9,11-trien-3-one 17-acetate</td>
<td>10161-34-9</td>
<td>TWA</td>
<td>0.2 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
<td>TWA</td>
<td>0.05 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

**Further information: Skin**

| | Wipe limit | 0.5 µg/100 cm² | Internal |
| Magnesium stearate | 557-04-0 | | |

*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**: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: powder

**Color**: yellow
# Trenbolone / Estradiol Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic: No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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.

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:
17β-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
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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 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
Remarks: Based on data from similar materials
Germ cell mutagenicity
Not classified based on available information.

Components:

17β-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 :
Species: Mouse
Result: negative

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 :
Species: Rat
Cell type: Bone marrow
Result: negative

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:**

**17β-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 µg/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

**IARC**
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

**NTP**
Known to be human carcinogen
Estradiol 50-28-2
Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:

17β-hydroxysterostrol-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 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
### Reproductive toxicity - Assessment

**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 fetal development**
- Test Type: Embryo-fetal 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.

### Components:

**17β-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:

**17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Pig</th>
<th>NOAEL</th>
<th>0.004 mg/kg</th>
<th>LOAEL</th>
<th>0.08 mg/kg</th>
<th>Exposure time</th>
<th>14 Weeks</th>
<th>Target Organs</th>
<th>Testis, Ovary, Liver, Uterus (including cervix)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
<td>NOAEL</td>
<td>0.04 mg/kg</td>
<td>LOAEL</td>
<td>3.6 mg/kg</td>
<td>Application Route</td>
<td>Oral</td>
<td>Exposure time</td>
<td>23 Weeks</td>
</tr>
<tr>
<td>Species</td>
<td>Monkey, female</td>
<td>NOAEL</td>
<td>0.01 mg/kg</td>
<td>LOAEL</td>
<td>0.04 mg/kg</td>
<td>Application Route</td>
<td>Oral</td>
<td>Exposure time</td>
<td>122 Days</td>
</tr>
<tr>
<td>Species</td>
<td>Monkey, male</td>
<td>NOAEL</td>
<td>0.002 mg/kg</td>
<td>LOAEL</td>
<td>0.04 mg/kg</td>
<td>Application Route</td>
<td>Oral</td>
<td>Exposure time</td>
<td>30 Days</td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
<td>NOAEL</td>
<td>0.05 mg/kg</td>
<td>LOAEL</td>
<td>0.1 mg/kg</td>
<td>Application Route</td>
<td>Oral</td>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
<td>NOAEL</td>
<td>&gt;=0.17 mg/kg</td>
<td>LOAEL</td>
<td>0.1 mg/kg</td>
<td>Application Route</td>
<td>Ingestion</td>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
<td>NOAEL</td>
<td>&gt;100 mg/kg</td>
<td>LOAEL</td>
<td>&gt;100 mg/kg</td>
<td>Application Route</td>
<td>Ingestion</td>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Species</td>
<td>Monkey, female</td>
<td>NOAEL</td>
<td>0.01 mg/kg</td>
<td>LOAEL</td>
<td>0.04 mg/kg</td>
<td>Application Route</td>
<td>Oral</td>
<td>Exposure time</td>
<td>122 Days</td>
</tr>
<tr>
<td>Species</td>
<td>Monkey, male</td>
<td>NOAEL</td>
<td>0.002 mg/kg</td>
<td>LOAEL</td>
<td>0.04 mg/kg</td>
<td>Application Route</td>
<td>Oral</td>
<td>Exposure time</td>
<td>30 Days</td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
<td>NOAEL</td>
<td>0.05 mg/kg</td>
<td>LOAEL</td>
<td>0.1 mg/kg</td>
<td>Application Route</td>
<td>Oral</td>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
<td>NOAEL</td>
<td>&gt;=0.17 mg/kg</td>
<td>LOAEL</td>
<td>0.1 mg/kg</td>
<td>Application Route</td>
<td>Ingestion</td>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
<td>NOAEL</td>
<td>&gt;100 mg/kg</td>
<td>LOAEL</td>
<td>&gt;100 mg/kg</td>
<td>Application Route</td>
<td>Ingestion</td>
<td>Exposure time</td>
<td>90 d</td>
</tr>
</tbody>
</table>

**Estradiol:**

| Species   | Rat     | NOAEL  | >=0.17 mg/kg | LOAEL  | 0.1 mg/kg  | Application Route | Ingestion| Exposure time | 90 d                                                                 |
| Species   | Rat     | NOAEL  | >100 mg/kg  | LOAEL  | >100 mg/kg | Application Route | Ingestion| Exposure time | 90 d                                                                 |

**Magnesium stearate:**

| Species   | Rat     | NOAEL  | >100 mg/kg  | LOAEL  | >100 mg/kg | Application Route | Ingestion| Exposure time | 90 d                                                                 |
| Species   | Rat     | NOAEL  | >100 mg/kg  | LOAEL  | >100 mg/kg | Application Route | Ingestion| Exposure time | 90 d                                                                 |
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:

17β-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, Diarrhea, water retention, liver function change, changes in libido, breast tenderness, menstrual irregularities

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:
Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.000035 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 229
Remarks: Based on data from similar materials

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

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
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<thead>
<tr>
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<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
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<td>12/07/2023</td>
<td>28298-00027</td>
<td>11/02/2023</td>
<td>11/05/2014</td>
</tr>
</tbody>
</table>

**Toxicity to fish (Chronic toxicity):**
- **NOEC** (Oryzias latipes (Japanese medaka)): 0.000003 mg/l
- Exposure time: 160 d
- Method: OECD Test Guideline 210

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**
- **NOEC** (Daphnia magna (Water flea)): 0.2 mg/l
- Exposure time: 21 d

**Toxicity to microorganisms:**
- **EC50**: > 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
- 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.

**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

**Remarks:** Based on data from similar materials

**NOELR (Pseudokirchneriella subcapitata (green algae)):**
- **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:

17β-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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.
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
## SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

### Trenbolone / Estradiol Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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</tr>
</tbody>
</table>

#### UN number
- UN 3077

#### Proper shipping name
- ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Estradiol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)

#### Class
- 9

#### Packing group
- III

#### Labels
- 9

#### Environmentally hazardous
- yes

### IATA-DGR

<table>
<thead>
<tr>
<th>UN/ID No.</th>
<th>Proper shipping name</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN 3077</td>
<td>Environmentally hazardous substance, solid, n.o.s. (Estradiol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)</td>
</tr>
</tbody>
</table>

#### Class
- 9

#### Packing group
- III

#### Labels
- Miscellaneous

#### Packing instruction (cargo aircraft)
- 956

#### Packing instruction (passenger aircraft)
- 956

#### Environmentally hazardous
- yes

### IMDG-Code

<table>
<thead>
<tr>
<th>UN number</th>
<th>Proper shipping name</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN 3077</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Estradiol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)</td>
</tr>
</tbody>
</table>

#### Class
- 9

#### Packing group
- III

#### Labels
- 9

#### EmS Code
- F-A, S-F

#### Marine pollutant
- yes

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

<table>
<thead>
<tr>
<th>UN/ID/NA number</th>
<th>Proper shipping name</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN 3077</td>
<td>Environmentally hazardous substance, solid, n.o.s. (Estradiol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)</td>
</tr>
</tbody>
</table>

#### Class
- 9

#### Packing group
- III

#### Labels
- CLASS 9

#### ERG Code
- 171

#### Marine pollutant
- yes (Estradiol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)

#### Remarks
- Above applies only to containers over 119 gallons or 450 liters.
- Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.
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.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust
                        Carcinogenicity
                        Reproductive toxicity
                        Specific target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Chemical Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>10161-34-9</td>
<td>17β-hydroxyestra-4,9,11-trien-3-one 17-acetate</td>
</tr>
<tr>
<td>57-88-5</td>
<td>Cholesterol</td>
</tr>
<tr>
<td>50-28-2</td>
<td>Estradiol</td>
</tr>
<tr>
<td>26780-50-7</td>
<td>Polyglactin</td>
</tr>
<tr>
<td>9004-57-3</td>
<td>Cellulose, ethyl ether</td>
</tr>
</tbody>
</table>

California Prop. 65
WARNING: This product can expose you to chemicals including Estradiol, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Chemical Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-28-2</td>
<td>Estradiol</td>
</tr>
</tbody>
</table>

California Permissible Exposure Limits for Chemical Contaminants

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>
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SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

- Flammability
- Health
- Instability

HMIS® IV:

- HEALTH
- FLAMMABILITY
- PHYSICAL HAZARD

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "∗" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- CAL PEL: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
- OSHA Z-3: USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
- ACGIH / TWA: 8-hour, time-weighted average
- CAL PEL / PEL: Permissible exposure limit
- OSHA Z-3 / TWA: 8-hour time weighted average

Additional abbreviations:

- AIIC - Australian Inventory of Industrial Chemicals
- ASTM - American Society for the Testing of Materials
- bw - Body weight
- CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act
- CMR - Carcinogen, Mutagen or Reproductive Toxicant
- DIN - Standard of the German Institute for Standardisation
- DOT - Department of Transportation
- DSL - Domestic Substances List (Canada)
- ECx - Concentration associated with x% response
- EHS - Extremely Hazardous Substance
- 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
- HAZCHEM - Hazardous Chemicals Identification System
- 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
- MSHA - Mine Safety and Health Administration
- n.o.s. - Not Otherwise Specified
- NFPA - National Fire Protection Association
- NO(A)EC - No Observed (Adverse)
SAFETY DATA SHEET
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Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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


Revision Date: 12/07/2023

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.

US / Z8