SAFETY DATA SHEET

Trenbolone / Estradiol LA Formulation

SECTION 1. IDENTIFICATION

Product name : Trenbolone / Estradiol LA Formulation

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 : EHSDATASEWARD@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:
**SAFETY DATA SHEET**

**Trenbolone / Estradiol LA Formulation**

**Version** 7.0  
**Revision Date:** 04/04/2023  
**SDS Number:** 26122-00020  
**Date of last issue:** 10/01/2022  
**Date of first issue:** 10/28/2014

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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.

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

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17β-hydroxyestra-4,9,11-trien-3-one 17-acetate</td>
<td>10161-34-9</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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**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.  
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:
- Contact with dust can cause mechanical irritation or drying of the skin.
- Dust contact with the eyes can lead to mechanical irritation.
- May cause cancer.
- May damage fertility. May damage the unborn child.
- Causes damage to organs through prolonged or repeated exposure.

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>Inert or nuisance dust</th>
<th>50 Million particles per cubic foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value type (Form of exposure): TWA (total dust)</td>
<td></td>
</tr>
<tr>
<td>Basis: OSHA Z-3</td>
<td></td>
</tr>
</tbody>
</table>

| 15 mg/m³ |
| Value type (Form of exposure): TWA (total dust) |
Basis: OSHA Z-3

5 mg/m³
Value type (Form of exposure): TWA (respirable fraction)
Basis: OSHA Z-3

15 Million particles per cubic foot
Value type (Form of exposure): TWA (respirable fraction)
Basis: OSHA Z-3

Dust, nuisance dust and particulates
10 mg/m³
Value type (Form of exposure): PEL (Total dust)
Basis: CAL PEL

5 mg/m³
Value type (Form of exposure): PEL (respirable dust fraction)
Basis: CAL PEL

<table>
<thead>
<tr>
<th>Components</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-triene-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></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>2 µg/100 cm²</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></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.5 µg/100 cm²</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>

Engineering measures: Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment: 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
Hand protection

Material: Chemical-resistant gloves

Remarks: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection

Wear the following personal protective equipment:

Safety goggles

Skin and body protection

Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.

Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Color: No data available

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: No data available
### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Heat, flames and sparks. Avoid dust formation.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### 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**
- LD50 (Rat): > 5,000 mg/kg
- LD50 (Mouse): 2,700 mg/kg

**Components:**

**17β-hydroxyestr-4,9,11-trien-3-one 17-acetate:**
- Acute oral toxicity: LD50 (Rat): > 5,000 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 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-hydroxyestr-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
  - 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-hydroxyestr-4,9,11-trien-3-one 17-acetate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse, male and female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, male and female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Pancreas</td>
</tr>
</tbody>
</table>
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
  (Estrogens, Steroidal)

Reproductive toxicity
May damage fertility. May damage the unborn child.

**Components:**

**17β-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 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.
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  
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 fetal development: Test Type: Embryo-fetal development
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:

<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Endocrine system, Blood</td>
</tr>
<tr>
<td>Assessment</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

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>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.004 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.08 mg/kg</td>
</tr>
<tr>
<td>Exposure time</td>
<td>14 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Testis, Ovary, Liver, Uterus (including cervix)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.04 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>3.6 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>23 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey, female</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.01 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.04 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>122 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>female reproductive organs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey, male</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.002 mg/kg</td>
</tr>
</tbody>
</table>
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Trenbolone / Estradiol LA Formulation

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:

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:
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>NOEC (Pimephales promelas (fathead minnow)): 0.000035 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
<td>Method: OECD Test Guideline 229</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>Estradiol:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Oryzias latipes (Japanese medaka)): 3.9 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and</td>
<td>EC50 (Daphnia magna (Water flea)): 2.7 mg/l</td>
<td></td>
</tr>
<tr>
<td>other aquatic invertebrates</td>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 1.7 mg/l</td>
<td></td>
</tr>
<tr>
<td>plants</td>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1.7 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Magnesium stearate:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td>Method: DIN 38412</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and</td>
<td>EL50 (Daphnia magna (Water flea)): &gt; 1 mg/l</td>
<td></td>
</tr>
<tr>
<td>other aquatic invertebrates</td>
<td>Exposure time: 47 h</td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic</td>
<td>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1</td>
<td></td>
</tr>
</tbody>
</table>
plants

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

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
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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
- 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

IATA-DGR
- UN/ID No.: 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: 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, 17β-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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

49 CFR
- UN/ID/NA 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: 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
17β-hydroxyestra-4,9,11-trien-3-one 17-acetate 10161-34-9
D-Glucose, 4-O-β-D-galactopyranosyl-, monohydrate 64044-51-5
Estradiol 50-28-2

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
Estradiol 50-28-2
California Permissible Exposure Limits for Chemical Contaminants

MAGNESIUM STEARATE

557-04-0

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

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

Further information

NFPA 704:

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<tr>
<th>Category</th>
<th>Rating</th>
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<tbody>
<tr>
<td>Health</td>
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<tr>
<td>Flammability</td>
<td>1</td>
</tr>
<tr>
<td>Instability</td>
<td>0</td>
</tr>
<tr>
<td>Special hazard</td>
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</table>

HMIS® IV:

<table>
<thead>
<tr>
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<th>Rating</th>
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<tbody>
<tr>
<td>HEALTH</td>
<td>* 3</td>
</tr>
<tr>
<td>FLAMMABILITY</td>
<td>3</td>
</tr>
<tr>
<td>PHYSICAL HAZARD</td>
<td>0</td>
</tr>
</tbody>
</table>

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

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; 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 Sys-
SAFETY DATA SHEET

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Version  7.0  Revision Date: 04/04/2023

Date of last issue: 10/01/2022
[-] Date of first issue: 10/28/2014

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 04/04/2023

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

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