SAFETY DATA SHEET

Trenbolone / Estradiol LA Formulation

SECTION 1. IDENTIFICATION

Product name: Trenbolone / Estradiol LA Formulation
Other means of identification: No data available

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 Hazardous Products Regulations
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: 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.
May form explosive dust-air mixture during processing, handling or other means.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</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>No data available</td>
<td>10161-34-9</td>
<td>&gt;= 60 - &lt; 80 *</td>
</tr>
<tr>
<td>Estradiol</td>
<td>No data available</td>
<td>50-28-2</td>
<td>&gt;= 5 - &lt; 10 *</td>
</tr>
<tr>
<td>Magnesium stearate Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td></td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

### 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 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.


SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<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>
</table>

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Version: 7.0  
Revision Date: 04/04/2023  
SDS Number: 26094-00021  
Date of last issue: 10/01/2022  
Date of first issue: 10/28/2014

<table>
<thead>
<tr>
<th>Component</th>
<th>TWA</th>
<th>Wipe limit</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>17β-hydroxyestra-4,9,11-trien-3-one 17-acetate</td>
<td>0.2 µg/m³ (OEB 5)</td>
<td>2 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Estradiol</td>
<td>0.05 µg/m³ (OEB 5)</td>
<td></td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>10 mg/m³</td>
<td>0.5 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

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!

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.).

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

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: 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!

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Color</td>
<td>No data available</td>
</tr>
<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>
</tbody>
</table>
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Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : No data available

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: > 2,000 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

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
<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>Skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

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

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test system: Salmonella typhimurium</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: Micronucleus test</td>
</tr>
<tr>
<td></td>
<td>Test system: Chinese hamster fibroblasts</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Micronucleus test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

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

**Estradiol:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test system: mammalian cells</td>
</tr>
<tr>
<td></td>
<td>Result: positive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Chromosome aberration test in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test system: mammalian cells</td>
</tr>
<tr>
<td></td>
<td>Result: positive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Chromosomal aberration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Cell type: Bone marrow</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

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-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

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.

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

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monkey, male</td>
<td>0.002 mg/kg</td>
<td>0.04 mg/kg</td>
<td>Oral</td>
<td>30 Days</td>
<td>male reproductive organs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.05 mg/kg</td>
<td>0.1 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>male reproductive organs, Ovary, Uterus (including cervix)</td>
</tr>
</tbody>
</table>

**Estradiol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt;= 0.17 mg/kg</td>
<td>Ingestion</td>
<td>90 d</td>
<td>Mammary gland, Ovary, Uterus (including cervix), Liver, Bone, Endocrine system, Blood, Testis</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 100 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
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
- **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
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.

- 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
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
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)
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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

Domestic regulation

TDG
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
ERG Code : 171
Marine pollutant : yes (Estradiol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)

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

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined
SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWA / TWAEV : Time-weighted average exposure value


Revision Date : 04/04/2023
Date format : mm/dd/yyyy
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.

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