SAFETY DATA SHEET
Trenbolone / Estradiol LA Formulation

Version 7.4 Revision Date: 23.03.2020 SDS Number: 26113-00015 Date of last issue: 13.09.2019
Date of first issue: 28.10.2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Trenbolone / Estradiol LA Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
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/
face protection.

**Response:**
P308 + P313 IF exposed or concerned: Get medical advice/attention.

**Storage:**
P405 Store locked up.

**Disposal:**
P501 Dispose of contents/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**

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>17β-hydroxyestra-4,9,11-trien-3-one 17-acetate</td>
</tr>
<tr>
<td></td>
<td>Estradiol</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</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.
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.
Protection of first-aiders: Dust contact with the eyes can lead to mechanical irritation. 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 firefighting: 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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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
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. 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. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

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 Organic peroxides Explosives Gases

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>
<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></td>
<td></td>
<td>Wipe limit</td>
<td>2 µg/100 cm²</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>
</tbody>
</table>

Further information: Skin

| | Wipe limit | 0.5 µg/100 cm² | Internal |
Magnesium stearate | 557-04-0 | VLE-PPT | 10 mg/m³ | NOM-010-STPS-2014

| | | TWA (Inhalable particulate matter) | 10 mg/m³ | ACGIH
| | | TWA (Respirable particulate matter) | 3 mg/m³ | ACGIH

**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! 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).

**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
**SECTION 10. STABILITY AND REACTIVITY**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</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>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></td>
</tr>
<tr>
<td>Water solubility</td>
<td>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></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>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>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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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

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  
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-hydroxyestra-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

**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
assessment fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

**Estradiol:**

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

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

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

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

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

- Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Subcutaneous
  - Developmental Toxicity: LOAEL: 0.2 mg/kg body weight
  - 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
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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:
Species: Pig
NOAEL: 0.004 mg/kg
LOAEL: 0.08 mg/kg
Exposure time: 14 Weeks
Target Organs: Testis, Ovary, Liver, Uterus (including cervix)

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

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

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

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

**Estradiol:**
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:
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

Toxicity to microorganisms : EC50: > 100 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 100 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

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

**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
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.
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: 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.: 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: 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Estradiol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)
Class: 9
Subsidiary risk: ENVIRONM.
Packing group: III
Labels: 9 (ENVIRONM.)
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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

NOM-002-SCT
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

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

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: Not applicable

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)
NOM-010-STPS-2014: Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-PPT: Time weighted average limit value

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for
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Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System


Revision Date: 23.03.2020

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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