1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Trenbolone / Estradiol LA Formulation

Manufacturer or supplier's details

Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

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)
Long-term (chronic) aquatic hazard: Category 1

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.
H410 Very toxic to aquatic life with long lasting effects.
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.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

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;= 60 -&lt;= 100</td>
</tr>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
<td>&gt;= 2.5 -&lt; 10</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

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.
## 5. FIREFIGHTING 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 firefighters
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

## 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
- Sweep up or vacuum up spillage and collect in suitable con-
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 labelled 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>
</tbody>
</table>
SAFETY DATA SHEET

Trenbolone / Estradiol LA Formulation

Wipe limit | 2 µg/100 cm² | Internal
---|---|---
Estradiol 50-28-2 | TWA | 0.05 µg/m³ (OEB 5)

Further information: Skin

Wipe limit | 0.5 µg/100 cm² | Internal
---|---|---
Magnesium stearate 557-04-0 | NAB | 10 mg/m³

Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals

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: Chemical-resistant gloves

Remarks:
Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and 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.

## 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>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour 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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour 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</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
</tbody>
</table>
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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

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 sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Estradiol:
Exposure routes : Skin contact
Species : Guinea pig
Assessment : Does not cause skin sensitisation.
Result : negative

Magnesium stearate:
Test Type : Maximisation Test
Exposure routes : 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

**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

### 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
SAFETY DATA SHEET

Trenbolone / Estradiol LA Formulation

Version 5.8
Revision Date: 2021/04/09
SDS Number: 26105-00017
Date of last issue: 2020/10/16
Date of first issue: 2014/10/28

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 foetal development: Test Type: Embryo-foetal development
Reproductive toxicity - Assessment

Species: Rat
Application Route: oral (feed)
Developmental Toxicity: LOAEL: 20 mg/kg body weight
Result: Malformations were observed.

Reproductive toxicity - Assessment

: Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

Estradiol:

Effects on fertility

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

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

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

Effects on foetal development

: Test Type: Embryo-foetal 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-foetal 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 foetal development: Test Type: Embryo-foetal 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:
Exposure routes: 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
**SAFETY DATA SHEET**

**Trenbolone / Estradiol LA Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.8</td>
<td>2021/04/09</td>
<td>26105-00017</td>
<td>2020/10/16</td>
<td>2014/10/28</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>23 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Blood</td>
</tr>
<tr>
<td>Species</td>
<td>Monkey, female</td>
</tr>
<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>Exposure time</th>
<th>30 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>male 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>
<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>30 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>male reproductive organs</td>
</tr>
</tbody>
</table>

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

**Estradiol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>&gt;= 0.17 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Target Organs</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>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt; 100 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Remarks</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, Dizzi-
SAFETY DATA SHEET

Trenbolone / Estradiol LA Formulation

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

$\text{17\beta-hydroxyestra}-4,9,11\text{-trien-3\text{-one 17-acetate}}$:

- **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

- **M-Factor (Chronic aquatic toxicity)**: 1,000

**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

- **M-Factor (Chronic aquatic toxicity)**: 1,000

- **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

TOXELR (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- log Pow: 3.77
octanol/water

**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

### 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.

### 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.

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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PB/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PB/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use: Not applicable
Prohibited substances: Not applicable
Restricted substances: Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable

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

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ID OEL: Indonesia. Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
ID OEL / NAB: Long term exposure limit

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for 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; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; 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

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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