SAFETY DATA SHEET

Trenbolone / Estradiol Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Trenbolone / Estradiol Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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)
Short-term (acute) aquatic hazard : Category 3
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. H402 Harmful to aquatic life. 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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17β-hydroxyestra-4,9,11-trien-3-one 17-acetate</td>
<td>10161-34-9</td>
<td>&gt;= 50 -&lt; 70</td>
</tr>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
<td>&gt;= 10 -&lt; 20</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. Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

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 certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures:
- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- 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.

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>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

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

Eye protection:
- Wear the following personal protective equipment:
  - Safety goggles

Skin and body protection:
- Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
- Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
Appearance : powder
Color : yellow
Odor : No data available
Odor Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : No data available
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : No data available
Relative vapor density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
 Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
SAFETY DATA SHEET

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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: > 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

Skin corrosion/irritation:
Not classified based on available information.

Serious eye damage/eye irritation:
Not classified based on available information.
Components:

**Estradiol:**

Result: No eye irritation

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

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

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
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.

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
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Version: 7.4  Revision Date: 23.03.2020  SDS Number: 28261-00015  Date of last issue: 13.09.2019  Date of first issue: 05.11.2014

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

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  

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  

**Persistence and degradability**  

**Components:**  

**Estradiol:**  
Biodegradability: Result: rapidly degradable  
Biodegradation: 84 %  
Exposure time: 24 hrs
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

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.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

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

IATA-DGR
UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Estradiol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)
Class : 9
Packing group : III
Labels : Miscellaneous,
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes
IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Estradiol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)

Class : 9
Subsidiary risk : ENVIRONM.
Packing group : III
Labels : 9 (ENVIRONM.)
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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents Registry : Not applicable
Control of precursors and essential chemicals for the preparation of drugs : Not applicable

International Regulations
The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
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.

AR / Z8