

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

SECTION 1. IDENTIFICATION

Product name : Trenbolone / Estradiol LA 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

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Carcinogenicity : Category 1A

Reproductive toxicity : Category 1A

Specific target organ toxicity - : Category 1 (Liver, Bone, Blood, Endocrine system)
repeated exposure

Specific target organ toxicity - : Category 1 (Endocrine system, Blood)
repeated exposure (Oral)

Short-term (acute) aquatic : Category 3
hazard

Long-term (chronic) aquatic : Category 1
hazard

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H350 May cause cancer.

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

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

Chemical name	CAS-No.	Concentration (% w/w)
17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate	10161-34-9	≥ 50 -< 70
Estradiol	50-28-2	≥ 5 -< 10
Magnesium stearate	557-04-0	≥ 1 -< 5

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.

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

- | | |
|---|---|
| In case of skin contact | : Get medical attention.
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 (CO ₂)
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

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:

Trenbolone / Estradiol LA Formulation

Version 10.1 Revision Date: 14.04.2025 SDS Number: 26085-00024 Date of last issue: 03.12.2024
 Date of first issue: 28.10.2014

Strong oxidizing agents
 Self-reactive substances and mixtures
 Organic peroxides
 Explosives
 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate	10161-34-9	TWA	0.2 μ g/m ³ (OEB 5)	Internal
		Wipe limit	2 μ g/100 cm ²	Internal
Estradiol	50-28-2	TWA	0.05 μ g/m ³ (OEB 5)	Internal
	Further information: Skin			
		Wipe limit	0.5 μ g/100 cm ²	Internal
Magnesium stearate	557-04-0	CMP	10 mg/m ³	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			
		TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH

Engineering measures

: The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable. Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. No open handling permitted. Totally enclosed processes and materials transport systems are required.

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

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 : Consider double gloving.
- Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.
- 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.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : powder
- Color : No data available
- Odor : No data available
- Odor Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : Not applicable

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

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.
Molecular weight	:	No data available
Particle characteristics		
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.

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

Incompatible materials	:	Avoid dust formation.
Hazardous decomposition products	:	Oxidizing agents
	:	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:**17 β -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

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

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:**17 β -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
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	:	Test Type: Micronucleus test Test system: Chinese hamster fibroblasts Result: negative
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Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Result: negative
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Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

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

Species : Mouse, male and female

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

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

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

Species: Rat
Application Route: Ingestion
Fertility: LOAEL: 0,5 mg/kg body weight
Result: Effects on fertility.

Test Type: One-generation reproduction toxicity study
Species: Rat
Duration of Single Treatment: 90 d
Fertility: LOAEL: 0,69 mg/kg body weight
Result: Effects on fertility.

Test Type: Two-generation study
Species: Mouse
Application Route: Oral
Fertility: LOAEL: 0,1 mg/kg body weight
Result: Effects on fertility.

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

Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Subcutaneous
Teratogenicity: LOAEL: 2,5 µg/kg body weight
Symptoms: Reduced body weight
Result: positive, Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 0,2 mg/kg body weight
Symptoms: Early Resorptions / resorption rate., Reduced number of viable fetuses., Reduced body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Reproductive toxicity - Assessment : May damage fertility. May damage the unborn child.

Magnesium stearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

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:**17 β -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:****17 β -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

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

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

Ingestion	: Symptoms: male reproductive effects, gynecomastia, changes in libido
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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:****17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Toxicity to fish (Chronic tox-	: NOEC (Pimephales promelas (fathead minnow)): 0,000035
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Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

icity)	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 (<i>Oryzias latipes</i> (Japanese medaka)): 3,9 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (<i>Daphnia magna</i> (Water flea)): 2,7 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: NOEC (<i>Pseudokirchneriella subcapitata</i> (green algae)): 1,7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 EC50 (<i>Pseudokirchneriella subcapitata</i> (green algae)): > 1,7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	: NOEC (<i>Oryzias latipes</i> (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 (<i>Daphnia magna</i> (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 (<i>Leuciscus idus</i> (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 (<i>Daphnia magna</i> (Water flea)): > 1 mg/l Exposure time: 47 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

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:****17 β -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

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

Mobility in soil**Components:****Estradiol:**

Distribution among environmental compartments : log K_{oc}: 3,81

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	: Do not dispose of waste into sewer. 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, 17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate)
Class	: 9
Packing group	: III
Labels	: 9
Environmentally hazardous	: yes

IATA-DGR

UN/ID No.	: UN 3077
Proper shipping name	: Environmentally hazardous substance, solid, n.o.s. (Estradiol, 17 β -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, 17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate)
Class	: 9
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F

Trenbolone / Estradiol LA Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.12.2024
10.1	14.04.2025	26085-00024	Date of first issue: 28.10.2014

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

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

AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025
Date format : dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
AR OEL / CMP : TLV (Threshold Limit Value)

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 Sys-

Trenbolone / Estradiol LA Formulation

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tem; 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; TECI - Thailand Existing Chemicals Inventory; 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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