according to the Hazardous Products Regulations



Trenbolone / Estradiol Formulation

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SECTION 1. IDENTIFICATION

Product name : Trenbolone / Estradiol Formulation

Other means of identification : COOPERS REVALOR 400 GROWTH PROMOTANT FOR

GRASS FED HEIFERS AND STEERS (48945)

COOPERS REVALOR FLEX GROWTH PROMOTANT FOR

NON BREEDING CATTLE (58656)

COOPERS REVALOR S STEER GROWTH PROMOTANT

AND FINISHING IMPLANTS (46111)

COOPERS REVALOR-H GROWTH PROMOTANT AND

FINISHING IMPLANTS (47248)

Coopers Revalor XR Growth Promotant and Finishing

Implants (90903)

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 37 McCarville Street

Charlottetown, PE C1E 2A7

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Carcinogenicity : Category 1A

Reproductive toxicity : Category 1A

Specific target organ toxicity :

- repeated exposure

Category 1 (Liver, Bone, Blood, Endocrine system)

Specific target organ toxicity:

- repeated exposure (Oral)

Category 1 (Endocrine system, Blood)

GHS label elements

Hazard pictograms

Signal Word : Danger

Hazard Statements : H350 May cause cancer.

H360FD May damage fertility. May damage the unborn child. H372 Causes damage to organs (Liver, Bone, Blood, Endocrine

system) through prolonged or repeated exposure.

according to the Hazardous Products Regulations



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H372 Causes damage to organs (Endocrine system, Blood) through prolonged or repeated exposure if swallowed.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe dust.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves, protective clothing, eye protection

and face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

Other hazards

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | Common Name/Synonym | CAS-No. | Concentration (% w/w) |
|--------------------|---|------------|-----------------------|
| | No data availa- ble | 10161-34-9 | >= 60 - < 80 * |
| Estradiol | No data availa- ble | 50-28-2 | >= 10 - < 30 * |
| Magnesium stearate | Octadecanoic acid, magnesi- um salt (2:1) | 557-04-0 | >= 5 - < 10 * |

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

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

according to the Hazardous Products Regulations



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Get medical attention.

In case of contact, immediately flush skin with soap and plenty In case of skin contact

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.

May cause cancer.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

Protection of first-aiders

delaved

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. 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 prod-

ucts

Carbon oxides

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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

according to the Hazardous Products Regulations



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Personal precautions, protec- :

tive equipment and emer-

gency 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.

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

ventilation.

Do not get on skin or clothing. Advice on safe handling

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.

according to the Hazardous Products Regulations



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Materials to avoid : Do not store with the following product types:

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 | |
|--|---------------------------|--|--|-----------|--|
| 17β-hydroxyestra-4,9,11-trien- 3-one 17-acetate | 10161-34-9 | TWA | 0.2 μg/m3 (OEB 5) | Internal | |
| | | Wipe limit | 2 μg/100 cm ² | Internal | |
| Estradiol | 50-28-2 | TWA | 0.05 µg/m3 (OEB 5) | Internal | |
| | Further information: Skin | | | | |
| | | Wipe limit | 0.5 µg/100 cm ² | Internal | |
| Magnesium stearate | 557-04-0 | TWA | 10 mg/m ³ | CA AB OEL | |
| | | TWA (Inhal- able) | 10 mg/m³ | CA BC OEL | |
| | | TWA (Respirable) | 3 mg/m³ | CA BC OEL | |
| | | TWAEV (in- halable dust) | 10 mg/m³ | CA QC OEL | |
| | | TWAEV (respirable aerosol frac- tion) | 3 mg/m³ | CA QC OEL | |
| | | TWA (Inhalable particulate matter) | 10 mg/m ³ | ACGIH | |
| | | TWA (Respirable particulate matter) | 3 mg/m³ | 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

according to the Hazardous Products Regulations



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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.

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 Hand protection

Particulates type

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 : yellow

according to the Hazardous Products Regulations



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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.

Molecular weight : No data available

Particle characteristics

according to the Hazardous Products Regulations



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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 reac-

tions

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.
Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

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

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

LD50 (Mouse): 2,700 mg/kg

Estradiol:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Acute toxicity (other routes of : LD50 (Rat): > 300 mg/kg

administration) 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 tox-

icity

Remarks: Based on data from similar materials

according to the Hazardous Products Regulations



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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

according to the Hazardous Products Regulations



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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 syn-

thesis 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

according to the Hazardous Products Regulations



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Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

May cause cancer.

Components:

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

Species : Mouse, male and female

Application Route : Oral
Result : positive
Target Organs : Liver

Species : Rat, male and female

Application Route : Oral
Result : positive
Target Organs : Pancreas

Carcinogenicity - Assess-

ment

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 - Assess-

: Positive evidence from human epidemiological studies

ment

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

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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 - As-

sessment

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

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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 - As-

sessment

May damage fertility. May damage the unborn child.

Magnesium stearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

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

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Liver, Bone, Blood, Endocrine system) through prolonged or repeated exposure.

Causes damage to organs (Endocrine system, Blood) through prolonged or repeated exposure if swallowed.

Components:

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

Routes of exposure : Ingestion

Target Organs : Endocrine system, Blood

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Estradiol:

Target Organs : Liver, Bone, Blood, Endocrine system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

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

Species : Pig

 NOAEL
 : 0.004 mg/kg

 LOAEL
 : 0.08 mg/kg

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Exposure time 14 Weeks

Target Organs : Testis, Ovary, Liver, Uterus (including cervix)

Species

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

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 : Monkey, female

Target Organs

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

: male reproductive organs

: Rat Species

NOAEL : 0.05 mg/kg LOAEL : 0.1 mg/kg Application Route : Oral

Exposure time : 3 Months

Target Organs : male representations

: male reproductive organs, Ovary, Uterus (including cervix)

Estradiol:

Species

LOAEL
Application Route : Ingestion
Exposure time : 90 d
Target Organs : Mammary : >= 0.17 mg/kg

Mammary gland, Ovary, Uterus (including cervix), Liver, Bone,

Endocrine system, Blood, Testis

Magnesium stearate:

Species : Rat

NOAEL : > 100 mg/kgApplication Route : Ingestion Exposure time : 90 Days

Remarks Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

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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

Symptoms: Skin irritation, Redness, pruritis Skin contact

Symptoms: Headache, Gastrointestinal disturbance, Dizzi-Ingestion

> ness, Vomiting, Diarrhea, water retention, liver function change, changes in libido, breast tenderness, menstrual irreg-

ularities

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

Toxicity to fish (Chronic tox-NOEC (Pimephales promelas (fathead minnow)): 0.000035

Exposure time: 21 d

Method: OECD Test Guideline 229

Remarks: Based on data from similar materials

Estradiol:

icity)

Toxicity to fish LC50 (Oryzias latipes (Japanese medaka)): 3.9 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : 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

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 tox-

icity)

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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.2 mg/l

Exposure time: 21 d

according to the Hazardous Products Regulations



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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 Method: Directive 67/548/EEC, Annex V, C.2. 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

according to the Hazardous Products Regulations



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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: nlog Pow: 3.77

octanol/water

Estradiol:

Partition coefficient: nlog Pow: 4.01

octanol/water

Magnesium stearate:

Partition coefficient: n-: log Pow: > 4

octanol/water

Mobility in soil

Components:

Estradiol:

Distribution among environ- : log Koc: 3.81

mental compartments

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

Class Ш Packing group Labels 9 Environmentally hazardous yes

according to the Hazardous Products Regulations



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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 (passen-

ger aircraft)

956

Environmentally hazardous : yes

Remarks : Above applies only to containers over 119 gallons (450 liters)

in case of liquids, or 882 lbs. (400 kg) in case of solids.

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

Remarks : Above applies only to containers over 119 gallons (450 liters)

in case of liquids, or 882 lbs. (400 kg) in case of solids.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

TDG

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Estradiol, 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate)

Class : 9
Packing group : III
Labels : 9
ERG Code : 171

Marine pollutant : yes(Estradiol, 17β-hydroxyestra-4,9,11-trien-3-one 17-

acetate)

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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

according to the Hazardous Products Regulations



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AICS : not determined

CA. DSL : not determined

IECSC : not determined

Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average CA AB OEL / TWA : 8-hour Occupational exposure limit CA BC OEL / TWA : 8-hour time weighted average

CA QC OEL / TWAEV : Time-weighted average exposure 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 Standardization; 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 Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of

according to the Hazardous Products Regulations



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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

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 Agen-

cy, http://echa.europa.eu/

Revision Date : 11/10/2025 Date format : mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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