according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade 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 Im-

plants (90903)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-

stance/Mixture

: Veterinary product

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

#### **SECTION 2: Hazards identification**

## 2.1 Classification of the substance or mixture

## Classification (REGULATION (EC) No 1272/2008)

Carcinogenicity, Category 1A H350: May cause cancer.

Reproductive toxicity, Category 1A H360FD: May damage fertility. May damage the

unborn child.

Specific target organ toxicity - repeated

exposure, Category 1

H372: Causes damage to organs through pro-

longed or repeated exposure.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

#### 2.2 Label elements

## Labelling (REGULATION (EC) No 1272/2008)

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 through prolonged or

repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

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.

#### Hazardous components which must be listed on the label:

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

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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.

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# **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
17β-hydroxyestra-4,9,11-trien-3- one 17-acetate	10161-34-9 233-432-5	Carc. 2; H351 Repr. 2; H361fd STOT RE 1; H372 (Endocrine system, Blood) Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 1,000	>= 58.8686 - <= 74.07
Estradiol	50-28-2 200-023-8	Carc. 1A; H350 Repr. 1A; H360FD STOT RE 1; H372 (Liver, Bone, Blood, Endocrine system) Aquatic Chronic 1; H410	>= 6.9027 - <= 12.5
		M-Factor (Chronic aquatic toxicity): 1,000	
		specific concentration limit Carc. 1A; H350 >= 0.01 % Repr. 1A; H360FD >= 0.01 % STOT RE 1; H372 >= 0.01 %	

For explanation of abbreviations see section 16.

## **SECTION 4: First aid measures**

# 4.1 Description of first aid measures

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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).

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.

#### 4.2 Most important symptoms and effects, both acute and delayed

Risks : 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.

#### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## **SECTION 5: Firefighting measures**

# 5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

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.

#### **SECTION 6: Accidental release measures**

## 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

## 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## **SECTION 7: Handling and storage**

# 7.1 Precautions for safe handling

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 as-

sessment

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.

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 contami-

nated 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.

## 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

 Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## **SECTION 8: Exposure controls/personal protection**

## 8.1 Control parameters

## **Occupational Exposure Limits**

dusts non-specific 4 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable

dust)

Basis: IE OEL

10 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable

dust)

Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	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 <sup>2</sup>	Internal	
Estradiol	50-28-2	TWA	0.05 μg/m3 (OEB 5)	Internal	
	Further information: Skin				
		Wipe limit	0.5 μg/100 cm <sup>2</sup>	Internal	
Magnesium stea- rate	557-04-0	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL	

## 8.2 Exposure controls

## **Engineering measures**

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

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

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Remarks : Consider double gloving.

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143

Filter type : Particulates type (P)

## **SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

Physical state : powder

Colour : yellow

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling 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

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

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Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

# **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

Not classified as a reactivity hazard.

## 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## **SECTION 11: Toxicological information**

## 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation exposure Skin contact Ingestion

Ingestion
Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

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

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

LD50 (Mouse): 2,700 mg/kg

**Estradiol:** 

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

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

administration) 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 sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

**Estradiol:** 

Exposure routes : Skin contact Species : Guinea pig

Assessment : Does not cause skin sensitisation.

Result : negative

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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- As-

sessment

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

## Carcinogenicity

May cause cancer.

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#### **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-

ment

Positive evidence from human epidemiological studies

## Reproductive toxicity

May damage fertility. May damage the unborn child.

#### Components:

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

Effects on fertility : Test Type: Two-generation study

Species: Rat

**Application Route: Oral** 

Fertility: LOAEL: 0.18 mg/kg body weight

Result: Postimplantation loss.

Effects on foetal develop-

ment

Test Type: Embryo-foetal 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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adverse effects on development, based on animal experi-

ments.

**Estradiol:** 

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Fertility: LOAEL: 0.5 mg/kg body weight

Result: Effects on fertility

Test Type: One-generation reproduction toxicity study

Species: Rat

Duration of Single Treatment: 90 d Fertility: LOAEL: 0.69 mg/kg body weight

Result: Effects on fertility

Test Type: Two-generation study

Species: Mouse Application Route: Oral

Fertility: LOAEL: 0.1 mg/kg body weight

Result: Effects on fertility

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse, female

Application Route: Subcutaneous

Teratogenicity: LOAEL: 4 mg/kg body weight Symptoms: Malformations were observed. Result: positive, Teratogenic effects

Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Subcutaneous

Teratogenicity: LOAEL: 2.5 µg/kg body weight

Symptoms: Reduced body weight

Result: positive, Embryotoxic effects and adverse effects on

the offspring were detected.

Test Type: Embryo-foetal development

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: 0.2 mg/kg body weight Symptoms: Early Resorptions / resorption rate, Reduced

number of viable fetuses, Reduced body weight

Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Reproductive toxicity - As-

sessment

May damage fertility. May damage the unborn child.

#### STOT - single exposure

Not classified based on available information.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

## **Components:**

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

Exposure routes : Ingestion

Target Organs : Endocrine system, Blood

Assessment : Causes damage to organs through prolonged or repeated

exposure.

**Estradiol:** 

Target Organs : Liver, Bone, Blood, Endocrine system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

#### Repeated dose toxicity

#### **Components:**

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

Species : Pig

NOAEL : 0.004 mg/kg LOAEL : 0.08 mg/kg Exposure time : 14 Weeks

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

Species : Rat

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

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

Target Organs : female reproductive organs

Species : Monkey, male NOAEL : 0.002 mg/kg LOAEL : 0.04 mg/kg Application Route : Oral

Exposure time : 30 Days

Target Organs : male reproductive organs

Species : Rat

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

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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.

#### 11.2 Information on other hazards

## **Endocrine disrupting properties**

**Product:** 

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### **Experience with human exposure**

## **Components:**

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

Ingestion : Symptoms: male reproductive effects, gynecomastia, changes

in libido

**Estradiol:** 

Inhalation : Symptoms: tingling, Nose bleeding

Skin contact : Symptoms: Skin irritation, Redness, pruritis

Ingestion : Symptoms: Headache, Gastrointestinal disturbance, Dizzi-

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

ularities

## **SECTION 12: Ecological information**

## 12.1 Toxicity

#### **Components:**

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

Toxicity to fish (Chronic tox- : NOEC: 0.000035 mg/l

icity) Exposure time: 21 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 229

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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

Exposure time: 72 h

Method: OECD Test Guideline 201

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

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.000003 mg/l

Exposure time: 160 d

Species: Oryzias latipes (Japanese medaka)

Method: OECD Test Guideline 210

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.2 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic

toxicity)

1.000

## 12.2 Persistence and degradability

## **Components:**

**Estradiol:** 

Biodegradability Result: rapidly degradable

> Biodegradation: 84 % Exposure time: 24 hrs

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## 12.3 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-

: log Pow: 4.01

octanol/water

# 12.4 Mobility in soil

## **Components:**

#### **Estradiol:**

Distribution among environ-

: log Koc: 3.81

mental compartments

#### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

## 12.6 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

## 12.7 Other adverse effects

No data available

#### **SECTION 13: Disposal considerations**

## 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## **SECTION 14: Transport information**

#### 14.1 UN number or ID number

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Estradiol,  $17\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

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

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

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

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Estradiol,  $17\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate)

**IATA** : Environmentally hazardous substance, solid, n.o.s.

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

## 14.3 Transport hazard class(es)

Class Subsidiary risks

 ADN
 : 9

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

## 14.4 Packing group

**ADN** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Labels : 9
Tunnel restriction code : (-)

**RID** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**IMDG** 

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 956

ger aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

**ADR** 

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not.

Not applicable

Not applicable

Not applicable

Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone

layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

**HAZARDS** 

#### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

#### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

#### **Full text of H-Statements**

H350 : May cause cancer.

H351 : Suspected of causing cancer.

H360FD : May damage fertility. May damage the unborn child.

H361fd : Suspected of damaging fertility. Suspected of damaging the

unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure.

H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

H410 : Very toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard

Carc. : Carcinogenicity
Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

Sources of key data used to compile the 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/

## Classification of the mixture: Classification procedure:

Carc. 1A H350 Calculation method
Repr. 1A H360FD Calculation method
STOT RE 1 H372 Calculation method
Aquatic Chronic 1 H410 Calculation method

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.

IE / EN