

# SAFETY DATA SHEET

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



## Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.10.2025
12.0	03.11.2025	28283-00036	Date of first issue: 05.11.2014

### 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 Implants (90903)

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Drynam Road  
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

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 prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Cat-	H410: Very toxic to aquatic life with long lasting

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effects.

### 2.2 Label elements

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

Hazard pictograms	:																	
Signal word	:	Danger																
Hazard statements	:	<table><tr><td>H350</td><td>May cause cancer.</td></tr><tr><td>H360FD</td><td>May damage fertility. May damage the unborn child.</td></tr><tr><td>H372</td><td>Causes damage to organs through prolonged or repeated exposure.</td></tr><tr><td>H410</td><td>Very toxic to aquatic life with long lasting effects.</td></tr></table>	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.								
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	:	<table><tr><td colspan="2"><b>Prevention:</b></td></tr><tr><td>P201</td><td>Obtain special instructions before use.</td></tr><tr><td>P260</td><td>Do not breathe dust.</td></tr><tr><td>P273</td><td>Avoid release to the environment.</td></tr><tr><td>P280</td><td>Wear protective gloves/ protective clothing/ eye protection/ face protection.</td></tr><tr><td colspan="2"><b>Response:</b></td></tr><tr><td>P308 + P313</td><td>IF exposed or concerned: Get medical advice/ attention.</td></tr><tr><td>P391</td><td>Collect spillage.</td></tr></table>	<b>Prevention:</b>		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.	<b>Response:</b>		P308 + P313	IF exposed or concerned: Get medical advice/ attention.	P391	Collect spillage.
<b>Prevention:</b>																		
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.																	
<b>Response:</b>																		
P308 + P313	IF exposed or concerned: Get medical advice/ attention.																	
P391	Collect spillage.																	

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

17 $\beta$ -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)
17 $\beta$ -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	$\geq 70 - < 90$
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  M-Factor (Chronic aquatic toxicity): 1,000  specific concentration limit Carc. 1A; H350 $\geq 0.01$ % Repr. 1A; H360FD $\geq 0.01$ % STOT RE 1; H372 $\geq 0.01$ %	$\geq 10 - < 20$

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-

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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 (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

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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 products : 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 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.

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## 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 protective 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 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.

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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.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>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 contaminated clothing before re-use.<br>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:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases |

### 7.3 Specific end use(s)

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

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### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

dusts non-specific

4 mg/m<sup>3</sup>

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

Basis: IE OEL

10 mg/m<sup>3</sup>

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
17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate	10161-34-9	TWA	0.2 $\mu$ g/m <sup>3</sup> (OEB 5)	Internal
		Wipe limit	2 $\mu$ g/100 cm <sup>2</sup>	Internal
Estradiol	50-28-2	TWA	0.05 $\mu$ g/m <sup>3</sup> (OEB 5)	Internal
	Further information: Skin			
		Wipe limit	0.5 $\mu$ g/100 cm <sup>2</sup>	Internal
Magnesium stearate	557-04-0	OELV - 8 hrs (TWA)	10 mg/m <sup>3</sup>	IE OEL

#### 8.2 Exposure controls

##### 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.

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,

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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

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, disposable 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 exposure assessment demonstrates exposures outside the recommended 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 : solid

Form : 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, 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



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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
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, handling or other means. Can react with strong oxidizing agents.
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### 10.4 Conditions to avoid

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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.

## SECTION 11: Toxicological information

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

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

#### Acute toxicity

Not classified based on available information.

#### Components:

##### 17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
LD50 (Mouse): 2,700 mg/kg

##### Estradiol:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Acute toxicity (other routes of administration) : LD50 (Rat): > 300 mg/kg  
Application Route: Subcutaneous

#### Skin corrosion/irritation

Not classified based on available information.

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Estradiol:

Result : No eye irritation

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

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### 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

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### 17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Test system: Salmonella typhimurium Result: negative
	Test Type: Micronucleus test Test system: Chinese hamster fibroblasts Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Result: negative
	Test Type: Micronucleus test Species: Rat Result: negative
Germ cell mutagenicity- Assessment	: Weight of evidence does not support classification as a germ cell mutagen.

#### Estradiol:

Genotoxicity in vitro	: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Test system: mammalian cells Result: positive
	Test Type: Chromosome aberration test in vitro Test system: mammalian cells Result: positive
	Test Type: Chromosomal aberration Test system: mammalian cells Result: positive
Genotoxicity in vivo	: Test Type: Chromosomal aberration Species: Rat

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Cell type: Bone marrow  
Result: negative

Test Type: Chromosomal aberration  
Species: Mouse  
Cell type: Bone marrow  
Result: negative

### Carcinogenicity

May cause cancer.

### Components:

#### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Species	: Mouse, male and female
Application Route	: Oral
Result	: positive
Target Organs	: Liver

Species	: Rat, male and female
Application Route	: Oral
Result	: positive
Target Organs	: Pancreas

Carcinogenicity - Assessment	: Limited evidence of carcinogenicity in animal studies
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#### **Estradiol:**

Species	: Mouse
Application Route	: Ingestion
Exposure time	: 24 Months
LOAEL	: 100 $\mu$ g/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
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### Reproductive toxicity

May damage fertility. May damage the unborn child.

### Components:

#### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Effects on fertility	: Test Type: Two-generation study
	Species: Rat
	Application Route: Oral

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	Fertility: LOAEL: 0.18 mg/kg body weight Result: Postimplantation loss.
Effects on foetal development	: 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 - Assessment	: Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

### Estradiol:

Effects on fertility	: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Fertility: LOAEL: 0.5 mg/kg body weight Result: Effects on fertility  Test Type: One-generation reproduction toxicity study Species: Rat Duration of Single Treatment: 90 d Fertility: LOAEL: 0.69 mg/kg body weight Result: Effects on fertility  Test Type: Two-generation study Species: Mouse Application Route: Oral Fertility: LOAEL: 0.1 mg/kg body weight Result: Effects on fertility
Effects on foetal development	: Test Type: Embryo-foetal development Species: Mouse, female Application Route: Subcutaneous Teratogenicity: LOAEL: 4 mg/kg body weight Symptoms: Malformations were observed. Result: positive, Teratogenic effects  Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Subcutaneous Teratogenicity: LOAEL: 2.5 µg/kg body weight Symptoms: Reduced body weight Result: positive, Embryotoxic effects and adverse effects on the offspring were detected.  Test Type: Embryo-foetal development Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.2 mg/kg body weight

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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 off-spring were detected only at high maternally toxic doses

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

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

### Components:

#### 17 $\beta$ -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:

#### 17 $\beta$ -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
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NOAEL	: 0.002 mg/kg
LOAEL	: 0.04 mg/kg
Application Route	: Oral
Exposure time	: 30 Days
Target Organs	: male reproductive organs

Species	: Rat
NOAEL	: 0.05 mg/kg
LOAEL	: 0.1 mg/kg
Application Route	: Oral
Exposure time	: 3 Months
Target Organs	: male reproductive organs, Ovary, Uterus (including cervix)

### **Estradiol:**

Species	: Rat
LOAEL	: $\geq 0.17$ 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**

Not classified based on available information.

### **Product:**

Assessment	: 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.
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### **Experience with human exposure**

#### **Components:**

##### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Ingestion	: Symptoms: male reproductive effects, gynaecomastia, changes in libido
-----------	---

##### **Estradiol:**

Inhalation	: Symptoms: tingling, Nose bleeding
Skin contact	: Symptoms: Skin irritation, Redness, pruritis
Ingestion	: Symptoms: Headache, Gastrointestinal disturbance, Dizziness, Vomiting, Diarrhoea, water retention, liver function change, changes in libido, breast tenderness, menstrual irregularities

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### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Components:

##### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Toxicity to fish (Chronic toxicity)	: NOEC: 0.000035 mg/l Exposure time: 21 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 229 Remarks: Based on data from similar materials
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M-Factor (Chronic aquatic toxicity)	: 1,000
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##### **Estradiol:**

Toxicity to fish	: LC50 (Oryzias latipes (Japanese medaka)): 3.9 mg/l Exposure time: 96 h
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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
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	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 1.7 mg/l 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 toxicity)	: 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 (Chronic toxicity)	: NOEC: 0.2 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)
--	--

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

### 12.2 Persistence and degradability

#### Components:

##### **Estradiol:**

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

### 12.3 Bioaccumulative potential

#### Components:

##### **17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

||Partition coefficient: n- : log Pow: 3.77  
octanol/water

##### **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 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.

### 12.7 Other adverse effects

No data available

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### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

- |                        |   |  |
|------------------------|---|--|
| Product                | : | Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.  |

### 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.<br>(Estradiol, 17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate) |
| ADR  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(Estradiol, 17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate) |
| RID  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(Estradiol, 17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate) |
| IMDG | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(Estradiol, 17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate) |
| IATA | : | Environmentally hazardous substance, solid, n.o.s.<br>(Estradiol, 17 $\beta$ -hydroxyestra-4,9,11-trien-3-one 17-acetate) |

#### 14.3 Transport hazard class(es)

- |     | Class | Subsidiary risks |
|-----|-------|------------------|
| ADN | :     | 9                |
| ADR | :     | 9                |
| RID | :     | 9                |

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**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  
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

Remarks : Above applies only to containers over 119 gallons (450 liters)  
in case of liquids, or 882 lbs. (400 kg) in case of solids.

#### IATA (Cargo)

Packing instruction (cargo aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

Remarks : Above applies only to containers over 119 gallons (450 liters)  
in case of liquids, or 882 lbs. (400 kg) in case of solids.

#### IATA (Passenger)

Packing instruction (passenger aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

Remarks : Above applies only to containers over 119 gallons (450 liters)  
in case of liquids, or 882 lbs. (400 kg) in case of solids.

### 14.5 Environmental hazards

#### ADN

Environmentally hazardous : yes

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### 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.

## 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.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable  
Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable  
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable  
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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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.

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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### 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

CA. DSL : not determined

IECSC : not determined

## 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.
H350	: May cause cancer.
H360FD	: May damage fertility. May damage the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure.

### Full text of other abbreviations

Aquatic Chronic	: Long-term (chronic) aquatic hazard
Carc.	: Carcinogenicity
Repr.	: Reproductive toxicity

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STOT RE	:	Specific target organ toxicity - repeated exposure
IE OEL	:	Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2
Carc.	:	Carcinogenicity
Repr.	:	Reproductive toxicity
STOT RE	:	Specific target organ toxicity - repeated exposure
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; AIIIC - 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 Harmonised 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 Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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 Chemicals; OECD - Organisation 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 Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Carc. 1A	H350
Repr. 1A	H360FD
STOT RE 1	H372

### Classification procedure:

Calculation method
Calculation method
Calculation method

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Aquatic Chronic 1

H410

Calculation method

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IE / EN