

# SAFETY DATA SHEET



## Estradiol (with Peanut Oil) Formulation

Version  
7.0

Revision Date:  
14.04.2025

SDS Number:  
4150781-00015

Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

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

#### 1.1 Product identifier

Trade name : Estradiol (with Peanut Oil) Formulation

#### 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  
20 Spartan Road  
1619 Spartan, South Africa

Telephone : +27119239300

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)

Eye irritation, Category 2

H319: Causes serious eye irritation.

Skin sensitisation, Category 1

H317: May cause an allergic skin reaction.

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, Category 1

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

#### 2.2 Label elements

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

Hazard pictograms :



# SAFETY DATA SHEET



## Estradiol (with Peanut Oil) Formulation

Version 7.0 Revision Date: 14.04.2025 SDS Number: 4150781-00015 Date of last issue: 04.12.2024 Date of first issue: 15.04.2019

Signal word	:	Danger
Hazard statements	:	H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. 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	:	<b>Prevention:</b> P201 Obtain special instructions before use. 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. P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. P391 Collect spillage.

Hazardous components which must be listed on the label:

Benzyl alcohol  
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.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317	>= 10 - < 20
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;	>= 0,25 - < 0,3

## Estradiol (with Peanut Oil) Formulation

Version  
7.0Revision Date:  
14.04.2025SDS Number:  
4150781-00015Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

		H410 M-Factor (Chronic aquatic toxicity): 1.000	
2,6-Di-tert-butyl-p-cresol	128-37-0 204-881-4	Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	>= 0,1 - < 0,25

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 advice 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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.

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 an allergic skin reaction.  
Causes serious eye irritation.  
May cause cancer.

# SAFETY DATA SHEET



## Estradiol (with Peanut Oil) Formulation

Version  
7.0

Revision Date:  
14.04.2025

SDS Number:  
4150781-00015

Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

May damage fertility. May damage the unborn child.  
Causes damage to organs through prolonged or repeated  
exposure.

### 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.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon 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.

---

## 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.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages

**Estradiol (with Peanut Oil) Formulation**Version  
7.0Revision Date:  
14.04.2025SDS Number:  
4150781-00015Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

cannot be contained.

**6.3 Methods and material for containment and cleaning up**

Methods for cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. 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.

**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 : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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 mist or vapours.  
Do not swallow.  
Do not get in 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.  
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. Contaminated work clothing should not be allowed out of the workplace.  
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.

**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.

# SAFETY DATA SHEET



## Estradiol (with Peanut Oil) Formulation

Version  
7.0

Revision Date:  
14.04.2025

SDS Number:  
4150781-00015

Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

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

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
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

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5,4 mg/m3
	Consumers	Inhalation	Acute systemic effects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	20 mg/kg bw/day
2,6-Di-tert-butyl-p-cresol	Workers	Inhalation	Long-term systemic effects	3,5 mg/m3
	Workers	Dermal	Long-term systemic effects	0,5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,86 mg/m3

## Estradiol (with Peanut Oil) Formulation

Version  
7.0Revision Date:  
14.04.2025SDS Number:  
4150781-00015Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

	Consumers	Dermal	Long-term systemic effects	0,25 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,25 mg/kg bw/day

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0,1 mg/l
	Intermittent use/release	2,3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5,27 mg/kg
	Marine sediment	0,527 mg/kg
	Soil	0,456 mg/kg
2,6-Di-tert-butyl-p-cresol	Fresh water	0,199 µg/l
	Intermittent use/release	0,02 µg/l
	Marine water	0,02 µg/l
	Sewage treatment plant	0,17 mg/l
	Fresh water sediment	0,0996 mg/kg dry weight (d.w.)
	Marine sediment	0,00996 mg/kg dry weight (d.w.)
	Soil	0,04769 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	8,33 mg/kg food

## 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, 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

# SAFETY DATA SHEET



## Estradiol (with Peanut Oil) Formulation

Version 7.0 Revision Date: 14.04.2025 SDS Number: 4150781-00015 Date of last issue: 04.12.2024 Date of first issue: 15.04.2019

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.
Filter type	:	Combined particulates and organic vapour type (A-P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	:	Aqueous solution
Colour	:	yellow
Odour	:	No data available
Odour 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	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	0,920 g/cm <sup>3</sup>
Solubility(ies)		
Water solubility	:	insoluble
Partition coefficient: n-octanol/water	:	Not applicable

**Estradiol (with Peanut Oil) Formulation**

Version 7.0	Revision Date: 14.04.2025	SDS Number: 4150781-00015	Date of last issue: 04.12.2024 Date of first issue: 15.04.2019
----------------	------------------------------	------------------------------	---

---

Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

**9.2 Other information**

Molecular weight	:	No data available
Particle size	:	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 : Can react with strong oxidizing agents.

**10.4 Conditions to avoid**

Conditions to avoid : None known.

**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 toxicological effects**

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

**Estradiol (with Peanut Oil) Formulation**Version  
7.0Revision Date:  
14.04.2025SDS Number:  
4150781-00015Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

Method: Calculation method

**Components:****Benzyl alcohol:**

Acute oral toxicity	:	LD50 (Rat): 1.200 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5,4 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: The substance or mixture has no acute inhalation toxicity

**Estradiol:**

Acute oral toxicity	:	LD50 (Rat): > 2.000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): > 300 mg/kg Application Route: Subcutaneous

**2,6-Di-tert-butyl-p-cresol:**

Acute oral toxicity	:	LD50 (Rat): > 6.000 mg/kg Method: OECD Test Guideline 401
Acute dermal toxicity	:	LD50 (Rat): > 2.000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Benzyl alcohol:**

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

**2,6-Di-tert-butyl-p-cresol:**

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:****Benzyl alcohol:**

Species	:	Rabbit
---------	---	--------

**Estradiol (with Peanut Oil) Formulation**

Version 7.0 Revision Date: 14.04.2025 SDS Number: 4150781-00015 Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

---

**Method** : OECD Test Guideline 405  
**Result** : Irritation to eyes, reversing within 21 days

**Estradiol:**

**Result** : No eye irritation

**2,6-Di-tert-butyl-p-cresol:**

**Species** : Rabbit  
**Method** : OECD Test Guideline 405  
**Result** : No eye irritation  
**Remarks** : Based on data from similar materials

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Benzyl alcohol:**

**Test Type** : Human repeat insult patch test (HRIPT)  
**Exposure routes** : Skin contact  
**Species** : Humans  
**Result** : positive  
  
**Assessment** : Probability or evidence of low to moderate skin sensitisation rate in humans

**Estradiol:**

**Exposure routes** : Skin contact  
**Species** : Guinea pig  
**Assessment** : Does not cause skin sensitisation.  
**Result** : negative

**2,6-Di-tert-butyl-p-cresol:**

**Test Type** : Human repeat insult patch test (HRIPT)  
**Exposure routes** : Skin contact  
**Species** : Humans  
**Result** : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Benzyl alcohol:**

**Genotoxicity in vitro** : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

## Estradiol (with Peanut Oil) Formulation

Version 7.0	Revision Date: 14.04.2025	SDS Number: 4150781-00015	Date of last issue: 04.12.2024 Date of first issue: 15.04.2019
----------------	------------------------------	------------------------------	---

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

### Estradiol:

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Test system: mammalian cells  
Result: positive

Test Type: Chromosome aberration test in vitro  
Test system: mammalian cells  
Result: positive

Test Type: Chromosomal aberration  
Test system: mammalian cells  
Result: positive

Genotoxicity in vivo : Test Type: Chromosomal aberration  
Species: Rat  
Cell type: Bone marrow  
Result: negative

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

### 2,6-Di-tert-butyl-p-cresol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

### Carcinogenicity

May cause cancer.

### Components:

#### Benzyl alcohol:

Species : Mouse

## Estradiol (with Peanut Oil) Formulation

Version 7.0 Revision Date: 14.04.2025 SDS Number: 4150781-00015 Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

Application Route	:	Ingestion
Exposure time	:	103 weeks
Method	:	OECD Test Guideline 451
Result	:	negative

### Estradiol:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	24 Months
LOAEL	:	100 µg/kg
Result	:	positive
Target Organs	:	female reproductive organs

Species	:	Rat
Application Route	:	Subcutaneous
Exposure time	:	13 weeks
LOAEL	:	20 mg/kg body weight
Result	:	positive
Target Organs	:	Endocrine system

Carcinogenicity - Assessment	:	Positive evidence from human epidemiological studies
------------------------------	---	--

### 2,6-Di-tert-butyl-p-cresol:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	22 Months
Result	:	negative

### Reproductive toxicity

May damage fertility. May damage the unborn child.

### Components:

#### Benzyl alcohol:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative

#### 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
----------------------	---	--

## Estradiol (with Peanut Oil) Formulation

Version  
7.0Revision Date:  
14.04.2025SDS Number:  
4150781-00015Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

	<p>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</p> <p>Test Type: Two-generation study Species: Mouse Application Route: Oral Fertility: LOAEL: 0,1 mg/kg body weight Result: Effects on fertility</p> <p>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</p> <p>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.</p> <p>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</p> <p>Reproductive toxicity - Assessment : May damage fertility. May damage the unborn child.</p>
<b>2,6-Di-tert-butyl-p-cresol:</b>	
Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

### STOT - single exposure

|| Not classified based on available information.

### STOT - repeated exposure

|| Causes damage to organs through prolonged or repeated exposure.

**Estradiol (with Peanut Oil) Formulation**Version  
7.0Revision Date:  
14.04.2025SDS Number:  
4150781-00015Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019**Components:****Estradiol:**Target Organs  
Assessment

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

**2,6-Di-tert-butyl-p-cresol:**

Assessment

- : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

**Repeated dose toxicity****Components:****Benzyl alcohol:**Species  
NOAEL  
Application Route  
Exposure time  
Method

- : Rat
- : 1,072 mg/l
- : inhalation (dust/mist/fume)
- : 28 Days
- : OECD Test Guideline 412

**Estradiol:**Species  
LOAEL  
Application Route  
Exposure time  
Target Organs

- : Rat
- : >= 0,17 mg/kg
- : Ingestion
- : 90 d
- : Mammary gland, Ovary, Uterus (including cervix), Liver, Bone, Endocrine system, Blood, Testis

**2,6-Di-tert-butyl-p-cresol:**Species  
NOAEL  
Application Route  
Exposure time

- : Rat
- : 25 mg/kg
- : Ingestion
- : 22 Months

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Estradiol:**Inhalation  
Skin contact  
Ingestion

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

**Estradiol (with Peanut Oil) Formulation**Version  
7.0Revision Date:  
14.04.2025SDS Number:  
4150781-00015Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019**SECTION 12: Ecological information****12.1 Toxicity****Components:****Benzyl alcohol:**

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 51 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

**Estradiol:**

Toxicity to fish	: LC50 (Oryzias latipes (Japanese medaka)): 3,9 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 2,7 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: NOEC (Pseudokirchneriella subcapitata (green algae)): 1,7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	EC50 (Pseudokirchneriella subcapitata (green algae)): > 1,7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to 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

## Estradiol (with Peanut Oil) Formulation

Version  
7.0Revision Date:  
14.04.2025SDS Number:  
4150781-00015Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

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

### 2,6-Di-tert-butyl-p-cresol:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 0,57 mg/l  
 Exposure time: 96 h  
 Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,48 mg/l  
 Exposure time: 48 h  
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0,24 mg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,24 mg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to microorganisms : EC50 : > 10.000 mg/l  
 Exposure time: 3 h  
 Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 0,053 mg/l  
 Exposure time: 30 d  
 Species: Oryzias latipes (Japanese medaka)  
 Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,316 mg/l  
 Exposure time: 21 d  
 Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity) : 1

**Estradiol (with Peanut Oil) Formulation**

Version 7.0      Revision Date: 14.04.2025      SDS Number: 4150781-00015      Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

---

**12.2 Persistence and degradability****Components:****Benzyl alcohol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 - 96 %  
Exposure time: 14 d

**Estradiol:**

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

**2,6-Di-tert-butyl-p-cresol:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 4,5 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C

**12.3 Bioaccumulative potential****Components:****Benzyl alcohol:**

Partition coefficient: n-octanol/water : log Pow: 1,05

**Estradiol:**

Partition coefficient: n-octanol/water : log Pow: 4,01

**2,6-Di-tert-butyl-p-cresol:**

Bioaccumulation : Species: Cyprinus carpio (Carp)  
Bioconcentration factor (BCF): 330 - 1.800

Partition coefficient: n-octanol/water : log Pow: 5,1

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

Distribution among environmental compartments : log Koc: 3,81

**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.

**Estradiol (with Peanut Oil) Formulation**

Version 7.0 Revision Date: 14.04.2025 SDS Number: 4150781-00015 Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

---

**12.6 Other adverse effects****Product:**

Endocrine disrupting potential : 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.

---

**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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

---

**SECTION 14: Transport information****14.1 UN number**

ADN	: UN 3082
ADR	: UN 3082
RID	: UN 3082
IMDG	: UN 3082
IATA	: UN 3082

**14.2 UN proper shipping name**

ADN	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Estradiol, 2,6-Di-tert-butyl-p-cresol)
ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Estradiol, 2,6-Di-tert-butyl-p-cresol)
RID	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Estradiol, 2,6-Di-tert-butyl-p-cresol)
IMDG	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Estradiol, 2,6-Di-tert-butyl-p-cresol)
IATA	: Environmentally hazardous substance, liquid, n.o.s. (Estradiol, 2,6-Di-tert-butyl-p-cresol)

**14.3 Transport hazard class(es)**

# SAFETY DATA SHEET



## Estradiol (with Peanut Oil) Formulation

Version 7.0 Revision Date: 14.04.2025 SDS Number: 4150781-00015 Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

	Class	Subsidiary risks
<b>ADN</b>	:	9
<b>ADR</b>	:	9
<b>RID</b>	:	9
<b>IMDG</b>	:	9
<b>IATA</b>	:	9

### 14.4 Packing group

<b>ADN</b>		
Packing group	:	III
Classification Code	:	M6
Hazard Identification Number	:	90
Labels	:	9
<b>ADR</b>		
Packing group	:	III
Classification Code	:	M6
Hazard Identification Number	:	90
Labels	:	9
Tunnel restriction code	:	(-)
<b>RID</b>		
Packing group	:	III
Classification Code	:	M6
Hazard Identification Number	:	90
Labels	:	9
<b>IMDG</b>		
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
<b>IATA (Cargo)</b>		
Packing instruction (cargo aircraft)	:	964
Packing instruction (LQ)	:	Y964
Packing group	:	III
Labels	:	Miscellaneous
<b>IATA (Passenger)</b>		
Packing instruction (passenger aircraft)	:	964
Packing instruction (LQ)	:	Y964
Packing group	:	III
Labels	:	Miscellaneous

### 14.5 Environmental hazards

<b>ADN</b>		
Environmentally hazardous	:	yes
<b>ADR</b>		
Environmentally hazardous	:	yes
<b>RID</b>		
Environmentally hazardous	:	yes

# SAFETY DATA SHEET



## Estradiol (with Peanut Oil) Formulation

Version 7.0 Revision Date: 14.04.2025 SDS Number: 4150781-00015 Date of last issue: 04.12.2024 Date of first issue: 15.04.2019

---

### 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 Transport in bulk according to Annex II of Marpol and the IBC Code

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

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

AICS : not determined

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

H302 : Harmful if swallowed.  
H317 : May cause an allergic skin reaction.  
H319 : Causes serious eye irritation.  
H350 : May cause cancer.  
H360FD : May damage fertility. May damage the unborn child.  
H372 : Causes damage to organs through prolonged or repeated exposure.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Aquatic Acute : Short-term (acute) aquatic hazard

# SAFETY DATA SHEET



## Estradiol (with Peanut Oil) Formulation

Version 7.0 Revision Date: 14.04.2025 SDS Number: 4150781-00015 Date of last issue: 04.12.2024 Date of first issue: 15.04.2019

Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Carc.	:	Carcinogenicity
Eye Irrit.	:	Eye irritation
Repr.	:	Reproductive toxicity
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure

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; KECL - 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 - 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; 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

### 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:

Eye Irrit. 2	H319	Calculation method
Skin Sens. 1	H317	Calculation method
Carc. 1A	H350	Calculation method
Repr. 1A	H360FD	Calculation method
STOT RE 1	H372	Calculation method
Aquatic Chronic 1	H410	Calculation method

### Classification procedure:

# SAFETY DATA SHEET



## Estradiol (with Peanut Oil) Formulation

Version  
7.0

Revision Date:  
14.04.2025

SDS Number:  
4150781-00015

Date of last issue: 04.12.2024  
Date of first issue: 15.04.2019

---

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.

ZA / EN