

Nomegestrol / Estradiol Formulation

Version 3.6 Revision Date: 09.04.2021 SDS Number: 17239-00017 Date of last issue: 16.10.2020
Date of first issue: 30.09.2014

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

1.1 Product identifier

Trade name : Nomegestrol / Estradiol Formulation

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

Use of the Sub-stance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.
30 Hudson Street, 33nd floor
07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

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, Category 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.

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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:

Estradiol
 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate

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.

Dust contact with the eyes can lead to mechanical irritation.

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

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

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
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	>= 2,5 - < 10
17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate	58652-20-3 261-379-8	Repr. 1A; H360F Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 10	>= 1 - < 2,5

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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 : 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.
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SECTION 5: Firefighting measures**5.1 Extinguishing media**

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)

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Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixtureSpecific 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
Nitrogen oxides (NOx)**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.
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.

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

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
Organic peroxides
Explosives
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**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	TWA OEL-RL (Respirable dust)	5 mg/m ³	ZA OEL
Further information: Recommended Limit				
		TWA OEL-RL (inhalable dust)	10 mg/m ³	ZA OEL
Further information: Recommended Limit				
		STEL OEL-RL (Dust)	20 mg/m ³	ZA OEL
Further information: Recommended Limit				
Estradiol	50-28-2	TWA	0.05 µg/m ³ (OEB 5)	Internal
Further information: Skin				
		Wipe limit	0.5 µg/100 cm ²	Internal
17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate	58652-20-3	TWA	0,2 µg/m ³	Internal
		Wipe limit	2 µg/100 cm ²	Internal
Talc	14807-96-6	TWA OEL-RL (Respirable dust)	1 mg/m ³	ZA OEL
Further information: Recommended Limit				
		TWA OEL-RL (inhalable dust)	10 mg/m ³	ZA OEL
Further information: Recommended Limit				

8.2 Exposure controls**Engineering measures**

Minimize workplace exposure concentrations.

Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment

Eye protection : Wear the following personal protective equipment:
Safety goggles

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special

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applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: powder
Colour	: white
Odour	: odourless
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)	: May form explosive dust-air mixture during processing, handling or other means.
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	: 1 g/cm ³
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available

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Decomposition temperature : No data available

Viscosity

 Viscosity, dynamic : 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

Flammability (liquids) : No data available

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 : May form explosive dust-air mixture during processing, handling 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.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

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Acute toxicity

Not classified based on available information.

Components:**Estradiol:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

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

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

LD50 (Mouse): > 2.000 mg/kg

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

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

Germ cell mutagenicity

Not classified based on available information.

Components:**Estradiol:**

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

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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

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Genotoxicity in vitro

: Test Type: Ames test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo

: Test Type: In vivo micronucleus test

Species: Rat

Application Route: Oral

Result: negative

Test Type: In vivo micronucleus test

Species: Mouse

Application Route: Oral

Result: negative

Carcinogenicity

May cause cancer.

Components:

Estradiol:

Species

: Mouse

Application Route

: Ingestion

Exposure time

: 24 Months

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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

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Species : Rat
 Application Route : oral (feed)
 Activity duration : 52 Weeks
 : 10 mg/kg body weight
 Result : negative

Species : Mouse
 Application Route : oral (feed)
 : 20 mg/kg body weight
 Result : positive
 Target Organs : Mammary gland, Pituitary gland

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:**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- : Test Type: Embryo-foetal development

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ment

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

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Effects on foetal development : Test Type: Development
 Species: Rat
 Application Route: Oral
 Result: negative

Test Type: Embryo-foetal development
 Species: Rabbit
 Application Route: Oral
 Result: negative, No teratogenic effects

Reproductive toxicity - Assessment : Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:**Estradiol:**

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

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Repeated dose toxicity

Components:

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

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Species	:	Mouse
NOAEL	:	20 mg/kg
Application Route	:	Oral
Exposure time	:	52 Weeks

Species	:	Rat
NOAEL	:	20 mg/kg
Application Route	:	Oral
Exposure time	:	52 Weeks

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

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

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Ingestion	:	Symptoms: acne, amenorhea, Headache, Dizziness, Nausea, breast tenderness, changes in libido, insomnia, musculoskeletal pain, mood swings, muscle pain, muscle twitching
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SECTION 12: Ecological information

12.1 Toxicity

Components:

Estradiol:

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): 3,9 mg/l Exposure time: 96 h
Toxicity to daphnia and other	:	EC50 (Daphnia magna (Water flea)): 2,7 mg/l

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- aquatic invertebrates 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
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
- 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:**
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 3,07 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0,69 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- Toxicity to microorganisms : EC50 (Natural microorganism): > 2,8 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
- NOEC (Natural microorganism): 2,8 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

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Toxicity to fish (Chronic toxicity) : NOEC: 0,0013 mg/l
Exposure time: 27 d
Species: Zebrafish

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 3,65 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity) : 10

12.2 Persistence and degradability

Components:

Estradiol:

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

12.3 Bioaccumulative potential

Components:

Estradiol:

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

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Bioaccumulation : Species: Zebrafish
Bioconcentration factor (BCF): 44

Partition coefficient: n-octanol/water : log Pow: 3,7

12.4 Mobility in soil

Components:

Estradiol:

Distribution among environmental compartments : log Koc: 3,81

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:

Distribution among environmental compartments : log Koc: 3,35
Method: OECD Test Guideline 106

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

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0.1% or higher.

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.

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 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-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-

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IATA : dione 17-acetate)
: Environmentally hazardous substance, solid, n.o.s.
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-
dione 17-acetate)

14.3 Transport hazard class(es)

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

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

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 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

H350 : May cause cancer.

H360F : May damage fertility.

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.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard

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Carc.	:	Carcinogenicity
Repr.	:	Reproductive toxicity
STOT RE	:	Specific target organ toxicity - repeated exposure
ZA OEL	:	South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL	:	Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL	:	Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European 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 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 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; 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:

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

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

SAFETY DATA SHEET



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

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