SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Nomegestrol / Estradiol Formulation

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 Substance/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
   Reproductive toxicity, Category 1A
   Specific target organ toxicity - repeated exposure, Category 1
   Long-term (chronic) aquatic hazard, Category 1

   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.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : 
   Signal word : Danger
   Hazard statements : H350 May cause cancer.
                      H360FD May damage fertility. May damage the unborn child.
                      H372 Causes damage to organs through prolonged or repeated exposure.
H410  Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:
P201  Obtain special instructions before use.
P260  Do not breathe dust.
P273  Avoid release to the environment.
P280  Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313  IF exposed or concerned: Get medical advice/ attention.
P391  Collect spillage.

Hazardous components which must be listed on the label:

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.

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
<td>200-023-8</td>
<td></td>
<td>Carc. 1A; H350 Repr. 1A; H360FD STOT RE 1; H372 (Liver, Bone, Blood, Endocrine system) Aquatic Chronic 1; H410</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
</tbody>
</table>
### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

<table>
<thead>
<tr>
<th>General advice</th>
<th>Protection of first-aiders</th>
<th>If inhaled</th>
<th>In case of skin contact</th>
<th>In case of eye contact</th>
<th>If swallowed</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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).</td>
<td>If inhaled, remove to fresh air. Get medical attention.</td>
<td>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.</td>
<td>If in eyes, rinse well with water. Get medical attention if irritation develops and persists.</td>
<td>If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>M-Factor (Chronic aquatic toxicity):</th>
<th>M-Factor (Chronic aquatic toxicity):</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.000</td>
<td>10</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
4.2 Most important symptoms and effects, both acute and delayed

**Risks:**
- May cause cancer.
- May damage fertility. May damage the unborn child.
- Causes damage to organs through prolonged or repeated exposure.
- Contact with dust can cause mechanical irritation or drying of the skin.
- Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

**Treatment:**
- Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

**Unsuitable extinguishing media:**
- None known.

5.2 Special hazards arising from the substance or mixture

**Specific hazards during firefighting:**
- 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 pro-
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.

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...
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

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
<td>TWA</td>
<td>0.05 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.5 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate</td>
<td>58652-20-3</td>
<td>TWA</td>
<td>0.2 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>TWA (respirable dust)</td>
<td>2 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>6 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
</tbody>
</table>

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
  Equipment should conform to NS EN 166

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 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. Equipment should conform to NS EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: powder
Colour: white
Odour: odourless
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

Flash point: No data available

Auto-ignition temperature: No data available
Decomposition temperature : No data available
Decomposition temperature:

pH : No data available

Viscosity:
Viscosity, dynamic : No data available
Viscosity, kinematic : No data available

Solubility(ies):
Water solubility : No data available
Partition coefficient: n-octanol/water:
Vapour pressure : No data available
Relative density : No data available
Density : 1 g/cm³
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.

10.4 Conditions to avoid:
Conditions to avoid:
Heat, flames and sparks. Avoid dust formation.
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Version 3.6
Revision Date: 09.04.2021
SDS Number: 17232-00017
Date of last issue: 16.10.2020
Date of first issue: 30.09.2014

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:

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)
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
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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
- LOAEL: 100 µg/kg
- Result: positive
- Target Organs: female reproductive organs

Species:
- 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
- Result: negative
- Species: Mouse
- Application Route: oral (feed)
- 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

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

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

Effects on foetal development:
- 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.

Effects on foetal development:
- 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
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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.

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.

11.2 Information on other hazards

Endocrine disrupting properties

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

**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 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
  - Method: OECD Test Guideline 209
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
</table>

### 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

### 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 %
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 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 or ID number

<p>| | | |</p>
<table>
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</tr>
</thead>
<tbody>
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<td>UN 3077</td>
</tr>
<tr>
<td>ADR</td>
<td>:</td>
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<tr>
<td>IATA</td>
<td>:</td>
<td>UN 3077</td>
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</tbody>
</table>

14.2 UN proper shipping name

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>:</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)</td>
</tr>
<tr>
<td>ADR</td>
<td>:</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)</td>
</tr>
<tr>
<td>RID</td>
<td>:</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)</td>
</tr>
<tr>
<td>IMDG</td>
<td>:</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)</td>
</tr>
<tr>
<td>IATA</td>
<td>:</td>
<td>Environmentally hazardous substance, solid, n.o.s. (Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>ADN</td>
<td>: 9</td>
</tr>
<tr>
<td>ADR</td>
<td>: 9</td>
</tr>
<tr>
<td>RID</td>
<td>: 9</td>
</tr>
<tr>
<td>IMDG</td>
<td>: 9</td>
</tr>
<tr>
<td>IATA</td>
<td>: 9</td>
</tr>
</tbody>
</table>

14.4 Packing group

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>Packing group : III</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

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

**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.
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, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and of the Council concerning the export and import of dangerous chemicals : Not applicable

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

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

Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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.
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Version 3.6  Revision Date: 09.04.2021  SDS Number: 17232-00017  Date of last issue: 16.10.2020
Date of first issue: 30.09.2014

Full text of H-Statements

<table>
<thead>
<tr>
<th>H</th>
<th>Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>H350</td>
<td>May cause cancer.</td>
</tr>
<tr>
<td>H360F</td>
<td>May damage fertility.</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>
</tbody>
</table>

Full text of other abbreviations

- Aquatic Chronic: Long-term (chronic) aquatic hazard
- Carc.: Carcinogenicity
- Repr.: Reproductive toxicity
- STOT RE: Specific target organ toxicity - repeated exposure
- FOR-2011-12-06-1358: Norway. Occupational Exposure limits
- FOR-2011-12-06-1358 / TWA: Long term exposure 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; 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; 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

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Version 3.6  Revision Date: 09.04.2021  SDS Number: 17232-00017  Date of last issue: 16.10.2020

Date of first issue: 30.09.2014

Classification of the mixture:  
- Carc. 1A: H350  Calculation method
- Repr. 1A: H360FD  Calculation method
- STOT RE 1: H372  Calculation method
- Aquatic Chronic 1: H410  Calculation method

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

NO / EN