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 : MSD
Innishannon
County Cork - Ireland

Telephone : 353 214329300
Telefax : 908-735-1496
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Carcinogenicity, Category 1A H350: May cause cancer.
Reproductive toxicity, Category 1A H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1 H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, 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.

Date of last issue: 03.05.2019
Date of first issue: 30.09.2014
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
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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
</table>
| Estradiol  | 50-28-2 | 200-023-8 |          | Carc. 1A; H350  
Repr. 1A; H360FD 
STOT RE 1; H372  
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 |

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 skin contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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4.2 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 and personal protective equipment recommendations.

6.2 Environmental precautions
Environmental precautions
Discharge into the environment must be avoided. 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 deter
mine 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.
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.
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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Date of last issue: 03.05.2019 Date of first issue: 30.09.2014

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<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>Cellulose</td>
<td>9004-34-6</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Further information</td>
<td>Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
<td>TWA</td>
<td>0.05 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information</td>
<td>Skin</td>
<td></td>
<td></td>
<td></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>Further information</td>
<td>Wipe limit</td>
<td>0.5 µg/100 cm²</td>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>OELV - 8 hrs (TWA) (Respirable dust)</td>
<td>0.8 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Further information</td>
<td>Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Talc</td>
<td></td>
<td>OELV - 8 hrs (TWA) (inhalable dust)</td>
<td>10 mg/m³</td>
<td>IE OEL</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 I.S. 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.

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1 g/cm3</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-</td>
<td>No data available</td>
</tr>
</tbody>
</table>
octanol/water
Auto-ignition temperature : No data available
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

**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

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:** 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
- **LOAEL:** 10 mg/kg body weight
- **Result:** negative

- **Species:** Mouse
- **Application Route:** oral (feed)
- **LOAEL:** 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
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Test Type: Two-generation study  
Species: Mouse  
Application Route: Oral  
Fertility: LOAEL: 0.1 mg/kg body weight  
Result: Effects on fertility

Effects on foetal development:  

Test Type: Embryo-foetal development  
Species: Mouse, female  
Application Route: Subcutaneous  
Teratogenicity: LOAEL: 4 mg/kg body weight  
Symptoms: Malformations were observed.  
Result: positive, Teratogenic effects

Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Subcutaneous  
Teratogenicity: LOAEL: 2.5 µg/kg body weight  
Symptoms: Reduced body weight  
Result: positive, Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 0.2 mg/kg body weight  
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.

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, pruritus
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 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

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
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 %
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:
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Date of first issue: 30.09.2014

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
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product:
Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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-dione 17-acetate)

IATA: 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

**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

**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 (EC) No 850/2004 on persistent organic pollutants** : Not applicable

**Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals** : Not applicable

**REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)** : Not applicable


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

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations.
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according to Regulation (EC) No. 1907/2006

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regulations, where applicable.

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
Carc.: Carcinogenicity
Repr.: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; 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
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Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Category</th>
<th>Code</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carc. 1A</td>
<td>H350</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Repr. 1A</td>
<td>H360FD</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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

IE / EN