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

1.1 Product identifier

Trade name: Etonogestrel Formulation (Nexplanon)
Product code: NEXPLANON

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)
Reproductive toxicity, Category 1A
Long-term (chronic) aquatic hazard, Category 1

H360F: May damage fertility.
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:

H360F May damage fertility.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
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.

Storage:
P405 Store locked up.

Hazardous components which must be listed on the label:
(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one</td>
<td>54048-10-1</td>
<td>258-936-2</td>
<td></td>
<td></td>
<td>Repr. 1A; H360F Aquatic Chronic 1; H410</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 10,000</td>
<td></td>
</tr>
</tbody>
</table>

Substances with a workplace exposure limit :
Barium sulfate | 7727-43-7 | 231-784-4 | | | | >= 10 - < 20 |

For explanation of abbreviations see section 16.
SECTION 4: First aid measures

4.1 Description of first aid measures

General advice: In the case of accident or if you feel unwell, seek medical 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 damage fertility. 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: None known.
SAFETY DATA SHEET
generated according to Regulation (EC) No. 1907/2006

Etonogestrel Formulation (Nexplanon)

Version 2.5
Revision Date: 09.04.2021
SDS Number: 16628-00020
Date of last issue: 10.10.2020
Date of first issue: 29.09.2014

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting:
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Metal oxides
- Sulphur oxides
- Carbon oxides

5.3 Advice for firefighters
Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions
Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- 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.
SEF 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 breathe vapours.
- 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.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage:
- Do not store with the following product types:
  - 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>(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinopregn-4-en-20-yn-3-one</td>
<td>54048-10-1</td>
<td>TWA</td>
<td>0.05 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.5 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Barium sulfate</td>
<td>7727-43-7</td>
<td>OELV - 8 hrs (TWA) (Respirable dust)</td>
<td>5 mg/m³</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.

<table>
<thead>
<tr>
<th>Exposure parameters</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA</td>
<td>0.5 mg/m³ (Barium)</td>
</tr>
</tbody>
</table>

2006/15/EC

Further information: Indicative

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barium sulfate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>13000 mg/kg bw/day</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barium sulfate</td>
<td>Fresh water</td>
<td>0.115 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>62.2 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>600.4 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>207.7 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems are required.
Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

**Personal protective equipment**

**Eye protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Hand protection**

<table>
<thead>
<tr>
<th>Material</th>
<th>Chemical-resistant gloves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Consider double gloving.</td>
</tr>
</tbody>
</table>

**Skin and body protection**

Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Respiratory protection**

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143

| Filter type      | Particulates type (P) |

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Solid form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</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>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</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>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Decomposition temperature
Decomposition temperature: No data available
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: No data available
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.
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:

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:
Acute oral toxicity:
- LD50 (Rat): > 2,000 mg/kg
- LD50 (Mouse): > 2,000 mg/kg

Barium sulfate:
Acute oral toxicity:
- LD50 (Rat): > 5,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:
Species: Mouse
Result: No skin irritation

Species: Guinea pig
Result: No skin irritation

Barium sulfate:
Species: reconstructed human epidermis (RhE)
Method: OECD Test Guideline 439
Remarks: Based on data from similar materials
Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.
Components:

Barium sulfate:

Species: Rabbit
Method: OECD Test Guideline 405
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:

Barium sulfate:

Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorr-4-en-20-yn-3-one:

Genotoxicity in vitro: Test Type: reverse mutation assay
Test system: Salmonella typhimurium
Result: negative

Test Type: in vitro assay
Test system: Chinese hamster ovary cells
Result: negative

Genotoxicity in vivo: Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Germ cell mutagenicity- Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Barium sulfate:

Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.

Components:
(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

Species: Rat
Application Route: Oral
Activity duration: 2 yr
Result: negative

Species: Rat
Application Route: Subcutaneous
Activity duration: 2 yr
Result: negative

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

Barium sulfate:

Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative
Remarks: Based on data from similar materials

Reproductive toxicity
May damage fertility.

Components:
(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

Effects on fertility: Test Type: Fertility
Species: Rat, female
Application Route: Oral
Fertility: LOAEL: 0.012 mg/kg body weight
Result: Effects on fertility

Test Type: Fertility
Species: Rabbit, female
Application Route: Oral
Dose: 0.05 milligram per kilogram
Result: Effects on fertility
Effects on foetal development: Species: Rat, female
Duration of Single Treatment: 14 d
General Toxicity Maternal: NOAEL: 1.8 mg/kg body weight
Result: No teratogenic effects

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

**Barium sulfate:**

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

**Effects on foetal development**
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Ingestion
- Method: OECD Test Guideline 414
- Result: negative
- Remarks: Based on data from similar materials

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
Not classified based on available information.

**Components:**

**Barium sulfate:**
Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

**Repeated dose toxicity**

**Components:**

**(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**
- Species: Rat
- LOAEL: 0.5 mg/kg
- Application Route: Oral
- Exposure time: 1 yr
- Target Organs: Reproductive organs, Endocrine system

- Species: Dog
- LOAEL: 0.625 mg/kg
- Application Route: Oral
- Exposure time: 26 Weeks
- Target Organs: Reproductive organs, Endocrine system
Barium sulfate:
Species: Rat
NOAEL: 61.1 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

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 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.

Experience with human exposure

Components:
(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:
Inhalation: Symptoms: Headache, Dizziness, Abdominal pain, Nausea, Skin disorders, effects on menstruation, vaginitis, breast tenderness, mood swings, male reproductive effects, Sweating

SECTION 12: Ecological information

12.1 Toxicity

Components:
(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 4.0 mg/l
Exposure time: 96 h
Method: FDA 4.11

LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1.3 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 3.9 mg/l
Exposure time: 48 h
Method: FDA 4.08
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms: NOEC: 70.8 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

EC50 : > 1,000 mg/l  
Exposure time: 3 h
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 0.059 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

NOEC: 0.0000027 mg/l  
Exposure time: 183 d  
Species: Oryzias latipes (Japanese medaka)  
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1.2 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity) : 10,000

**Barium sulfate:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10 - 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50 : > 600 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials

NOEC : > 600 mg/l  
Exposure time: 3 h
12.2 Persistence and degradability

**Components:**

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

- **Stability in water:** Hydrolysis: < 10 % (5 d)
  - Method: FDA 3.09

12.3 Bioaccumulative potential

**Components:**

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

- **Bioaccumulation:** Species: Lepomis macrochirus (Bluegill sunfish)
  - Bioconcentration factor (BCF): 128
  - Method: OECD Test Guideline 305

- **Partition coefficient: n-octanol/water:** log Pow: 3.5

**Barium sulfate:**

- **Bioaccumulation:** Species: Lepomis macrochirus (Bluegill sunfish)
  - Bioconcentration factor (BCF): < 500

- **Partition coefficient: n-octanol/water:** log Pow: -1.03
  - Remarks: Calculation

12.4 Mobility in soil

**Components:**

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

- **Distribution among environmental compartments:** log Koc: 2.84
  - Method: FDA 3.08

12.5 Results of PBT and vPvB assessment

**Product:**

- **Assessment:** This substance/mixture contains no components considered
12.6 Endocrine disrupting properties

**Product:**

**Assessment:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>UN 3077</td>
</tr>
<tr>
<td>ADR</td>
<td>UN 3077</td>
</tr>
<tr>
<td>RID</td>
<td>UN 3077</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 3077</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 3077</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (17α)-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)</td>
</tr>
<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)</td>
</tr>
<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,</td>
</tr>
</tbody>
</table>
N.O.S. ((17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. ((17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)

IATA : Environmentally hazardous substance, solid, n.o.s. ((17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)

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 (passen- : 956
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 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

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Specific Requirements</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)</td>
<td>: Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).</td>
<td>: Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>REACH - List of substances subject to authorisation (Annex XIV)</td>
<td>: Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulation (EC) No 1005/2009 on substances that deplete the ozone layer</td>
<td>: Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulation (EU) 2019/1021 on persistent organic pollutants (recast)</td>
<td>: Not applicable</td>
<td></td>
<td></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, 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
H360F : May damage fertility.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Aquatic Chronic : Long-term (chronic) aquatic hazard
Repr. : Reproductive toxicity
2006/15/EC : Europe. Indicative occupational exposure limit values
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
2006/15/EC / TWA : Limit Value - eight hours
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; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:
Repr. 1A          H360F
Aquatic Chronic 1 H410

Classification procedure: 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.

IE / EN