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

1.1 Product identifier
Trade name: Etonogestrel / Ethinyl 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, 33rd floor
07302 Jersey City, New Jersey, U.S.A
Telephone: 551-430-6000
E-mail address of person responsible for the SDS: EHSSTEWARD@organon.com

1.4 Emergency telephone number
215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Carcinogenicity, Category 1A: H350: May cause cancer.
Reproductive toxicity, Category 1A: H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1: H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1: H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms:
Signal word: Danger

Hazard statements:
H350: May cause cancer.
H360FD: May damage fertility. May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H410  Very toxic to aquatic life with long lasting effects.

Precautionary statements  :

**Prevention:**
- P201  Obtain special instructions before use.
- P264  Wash skin thoroughly after handling.
- 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:**
(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one
Ethinylestradiol

**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>(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>Repr. 1A; H360F Aquatic Chronic 1; H410</td>
<td>&gt;= 0.3 - &lt; 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 10,000</td>
<td></td>
</tr>
</tbody>
</table>
### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

**General advice**: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

**Protection of first-aiders**: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

**If inhaled**: If inhaled, remove to fresh air. Get medical attention.

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

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

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

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

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: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice (see section 7) and personal 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, fume, gas, mist, vapours or spray. 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. 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

<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-dinorpregn-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>Ethinyl estradiol</td>
<td>57-63-6</td>
<td>TWA</td>
<td>0.01 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.1 µg/100 cm²</td>
<td>Internal</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**
- Material: Chemical-resistant gloves
- Remarks: Consider double gloving.

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

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

- **Physical state**: solid
- **Colour**: white
- **Odour**: odourless
- **Odour Threshold**: No data available
- **Melting point/freezing point**: Not applicable
- **Initial boiling point and boiling range**: Not applicable
- **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**: Not applicable
- **Lower explosion limit / Lower flammability limit**: Not applicable
- **Flash point**: Not applicable
- **Auto-ignition temperature**: No data available
<table>
<thead>
<tr>
<th>Decomposition temperature</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>insoluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</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>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td></td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**9.2 Other information**

- **Explosives**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
- **Evaporation rate**: Not applicable
- **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-dinopregn-4-en-20-yn-3-one:

Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
LD50 (Mouse): > 2,000 mg/kg

Ethinylestradiol:
Acute oral toxicity: LD50 (Rat): 1,200 mg/kg
LD50 (Mouse): 1,737 mg/kg

Acute inhalation toxicity: Remarks: No data available

Acute dermal toxicity: Remarks: No data available

Skin corrosion/irritation
Not classified based on available information.

Components:

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

Species: Mouse
Result: No skin irritation

Species: Guinea pig
Result: No skin irritation

Ethinylestradiol:
Remarks: No data available

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

**Ethinylestradiol:**

Remarks: No data available

### Respiratory or skin sensitisation

#### Skin sensitisation
Not classified based on available information.

#### Respiratory sensitisation
Not classified based on available information.

## Components:

**Ethinylestradiol:**

Remarks: No data available

### Germ cell mutagenicity
Not classified based on available information.

## Components:

**(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-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.

**Ethinylestradiol:**

### Genotoxicity in vitro
- Test Type: Bacterial reverse mutation assay (AMES)
  - Test system: Salmonella typhimurium
  - Result: negative
- Test Type: Bacterial reverse mutation assay (AMES)
  - Test system: Escherichia coli
  - Result: negative
- Test Type: Chromosome aberration test in vitro
  - Test system: Human lymphocytes
  - Result: equivocal
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Etonogestrel / Ethinyl Estradiol Formulation

Genotoxicity in vivo
Test Type: Chromosomal aberration
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: positive

Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

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

Carcinogenicity
May cause cancer.

Components:
(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinopregn-4-en-20-yn-3-one:
Species: Rat
Application Route: Oral
Activity duration: 2 yr
Result: 0.5 mg/kg body weight

Species: Rat
Application Route: Subcutaneous
Activity duration: 2 yr
Result: 0.02 mg/kg body weight

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

Ethinylestradiol:
Species: Rat, male and female
Application Route: Oral
Exposure time: 2 Years
Result: negative

Species: Monkey, female
Application Route: Oral
Exposure time: 10 Years
Result: negative

Carcinogenicity - Assessment
Positive evidence from human epidemiological studies

Reproductive toxicity
May damage fertility. May damage the unborn child.
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.

Ethinylestradiol:

Effects on fertility:
- Species: Hamster
  - Fertility: LOAEL: 6.3 mg/kg body weight
  - Result: Effects on fertility

Effects on foetal development:
- Test Type: Four-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: > 0.006 mg/kg body weight
  - Result: Specific developmental abnormalities
- Test Type: Two-generation reproduction toxicity study
  - Species: Rat, male and female
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 0.005 mg/kg body weight
  - Result: Specific developmental abnormalities

Reproductive toxicity - Assessment:
- Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.
  - Clear evidence of adverse effects on development, based on animal experiments.

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

STOT - repeated exposure:
Causes damage to organs through prolonged or repeated exposure.
Components:

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

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

Ethinylestradiol:
Species: Rat
NOAEL: 0.25 mg/kg
LOAEL: 0.5 mg/kg
Application Route: Oral
Exposure time: 2 Weeks
Target Organs: Liver

Species: Rabbit
LOAEL: 0.015 mg/kg
Application Route: Oral
Exposure time: 20 Weeks
Target Organs: Liver

Species: Dog
NOAEL: 0.04 mg/kg
LOAEL: 0.2 mg/kg
Application Route: Oral
Exposure time: 95 d
Target Organs: Blood

Species: Rat, male and female
NOAEL: 0.0015 mg/kg
LOAEL: 0.005 mg/kg
Application Route: Oral
Exposure time: 2 yr
Target Organs: Reproductive organs, Mammary gland, Liver, Uterus (including cervix)
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-
ered 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-dinopregn-4-en-20-yn-3-one:

Inhalation : Symptoms: Headache, Dizziness, Abdominal pain, Nausea,
Skin disorders, effects on menstruation, vaginitis, breast ten-
derness, mood swings, male reproductive effects, Sweating

Ethinylestradiol:

Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea,
Headache, Dizziness, mood swings, Oedema, liver function
change, water retention, hair loss, gynecomastia, effects on
menstruation

SECTION 12: Ecological information

12.1 Toxicity

Components:

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinopregn-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 Guide 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

Ethinylestradiol:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 1.6 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 6.7 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 6.7 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

NOEC : 24.9 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 0.01 µg/l
Exposure time: 35 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

NOEC: 0.00031 µg/l
Exposure time: 339 d  
Species: Zebrafish

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):  
NOEC: 0.75 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity):  
100,000

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

Ethinylestradiol:
Bioaccumulation:  
Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): 264  
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water:  
log Pow: 4.15

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

Ethinylestradiol:
Distribution among environmental compartments:  
log Koc: 3.86

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 Endocrine disrupting properties

Product: 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

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

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

IATA : Environmentally hazardous substance, solid, n.o.s. (Ethinylestradiol, (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 |
Etonogestrel / Ethinyl Estradiol Formulation

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

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

Etonogestrel / Ethinyl Estradiol Formulation

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
H302: Harmful if swallowed.
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

Acute Tox.: Acute toxicity
Aquatic Chronic: Long-term (chronic) aquatic hazard
Carc.: Carcinogenicity
Repr.: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure

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; IECS - Inventory of Existing Chemical Substances in
Etonogestrel / Ethinyl Estradiol Formulation

Version: 4.5
Revision Date: 09.04.2021
SDS Number: 16784-00019
Date of last issue: 16.10.2020
Date of first issue: 29.09.2014

Further information
Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:

<table>
<thead>
<tr>
<th>Carc.</th>
<th>Repr.</th>
<th>STOT RE</th>
<th>Aquatic Chronic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>1A</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Classification procedure:
- Carc. 1A: Calculation method
- Repr. 1A: Calculation method
- STOT RE 1: Calculation method
- Aquatic Chronic 1: 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