SAFETY DATA SHEET

Etonogestrel / Ethinyl Estradiol Formulation

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 : MSD
   117 16th Road
   07033 Halfway house, Midrand, South Africa
   Telephone : +27 11 655 3000
   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
   Reproductive toxicity, Category 1A
   Specific target organ toxicity - repeated exposure, Category 1
   Long-term (chronic) aquatic hazard, Category 1
   H350: May cause cancer.
   H360FD: May damage fertility. May damage the unborn child.
   H372: Causes damage to organs through prolonged or repeated exposure.
   H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : ☢️ ☢️
   Signal word : Danger
   Hazard statements : H350 May cause cancer.
   H360FD May damage fertility. May damage the unborn child.
   H372 Causes damage to organs through prolonged or re-
peated 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
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>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></td>
<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 Chronic1; H410</td>
<td>&gt;= 0,3 - &lt; 1</td>
</tr>
<tr>
<td></td>
<td>Ethinylestradiol</td>
<td>57-63-6</td>
<td>200-342-2</td>
<td></td>
<td></td>
<td>Acute Tox.4; H302 Carc.1A; H350 Repr.1B; H360FD STOT RE1; H372 Aquatic Chronic1; H410</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
</tr>
</tbody>
</table>

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

4.1 Description of first aid measures

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

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

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

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

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

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

4.2 Most important symptoms and effects, both acute and delayed

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

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

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

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.
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 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 determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.
SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. 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
**SAFETY DATA SHEET**

**Etonogestrel / Ethinyl Estradiol Formulation**

<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>
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<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.5 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Ethinylestradiol</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.

Filter type: Particulates type (P)

**SECTION 9: Physical and chemical properties**

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

Appearance: solid

Colour: white

Odour: odourless

Odour Threshold: No data available
SAFETY DATA SHEET

Etonogestrel / Ethinyl Estradiol Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Initial boiling point and boiling</td>
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</tr>
<tr>
<td>range</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
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</tr>
<tr>
<td>Evaporation rate</td>
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<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
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<tr>
<td>Upper explosion limit / Upper</td>
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<tr>
<td>flammability limit</td>
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<tr>
<td>Lower explosion limit / Lower</td>
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<tr>
<td>flammability limit</td>
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</tr>
<tr>
<td>Vapour pressure</td>
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<tr>
<td>Relative vapour density</td>
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<tr>
<td>Relative density</td>
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<tr>
<td>Density</td>
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<td>Solubility(ies)</td>
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<tr>
<td>Water solubility</td>
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<td>Partition coefficient: n-octanol/water</td>
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<td>Auto-ignition temperature</td>
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<tr>
<td>Decomposition temperature</td>
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<tr>
<td>Viscosity</td>
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<tr>
<td>Viscosity, kinematic</td>
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<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
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9.2 Other information

<table>
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<tr>
<th>Property</th>
<th>Value</th>
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</thead>
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<tr>
<td>Flammability (liquids)</td>
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<tr>
<td>Molecular weight</td>
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</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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:

(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

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-dinorpregn-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

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-dinorpregn-4-en-20-yne-3-one:

Species: Rat
Application Route: Oral
Activity duration: 2 yr
Exposure time: 0,5 mg/kg body weight
Result: negative

Species: Rat
Application Route: Subcutaneous
Activity duration: 2 yr
Exposure time: 0,02 mg/kg body weight
Result: negative

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

*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.

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

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-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 tox-: NOEC: 0.059 mg/l
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | NOEC: 1,2 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea) |
<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>10.000</td>
</tr>
<tr>
<td><strong>Ethinylestradiol:</strong></td>
<td></td>
</tr>
</tbody>
</table>
| 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 |
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

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

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

14.2 UN proper shipping name

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<th>Code</th>
<th>Name</th>
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<tr>
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<td>(Ethinylestradiol, (17α)-13-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.</td>
</tr>
<tr>
<td></td>
<td>(Ethinylestradiol, (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, N.O.S.</td>
</tr>
<tr>
<td></td>
<td>(Ethinylestradiol, (17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)</td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.</td>
</tr>
<tr>
<td></td>
<td>(Ethinylestradiol, (17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)</td>
</tr>
<tr>
<td>IATA</td>
<td>Environmentally hazardous substance, solid, n.o.s.</td>
</tr>
<tr>
<td></td>
<td>(Ethinylestradiol, (17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>Code</th>
<th>Code</th>
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</thead>
<tbody>
<tr>
<td>ADN</td>
<td>9</td>
</tr>
<tr>
<td>ADR</td>
<td>9</td>
</tr>
<tr>
<td>RID</td>
<td>9</td>
</tr>
<tr>
<td>IMDG</td>
<td>9</td>
</tr>
<tr>
<td>IATA</td>
<td>9</td>
</tr>
</tbody>
</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>Code</th>
<th>Group</th>
<th>Code</th>
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</thead>
<tbody>
<tr>
<td>ADN</td>
<td>III</td>
<td>M7</td>
</tr>
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</table>
SAFETY DATA SHEET

Etonogestrel / Ethinyl Estradiol Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.2</td>
<td>09/13/2019</td>
<td>16800-00016</td>
<td>24.04.2019</td>
</tr>
</tbody>
</table>

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.
SAFETY DATA SHEET

Etonogestrel / Ethinyl Estradiol Formulation

Version 4.2
Revision Date: 09/13/2019
SDS Number: 16800-00016
Date of last issue: 24.04.2019
Date of first issue: 29.09.2014

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
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; 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 Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:
- Carc. 1A: H350
- Repr. 1A: H360FD
- STOT RE 1: H372
- 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.

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