SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Etonogestrel / Ethinyl Estradiol Formulation

Version        Revision Date:         SDS Number:         Date of last issue: 2018/10/15
4.10           09/13/2019              16777-00015        Date of first issue: 2014/09/29

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Etonogestrel / Ethinyl Estradiol Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 199 Wenhai North Road
          HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone : 908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance : solid
Colour : white
Odour : odourless

May cause cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

GHS Classification
Carcinogenicity : Category 1A
Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
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.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
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.

**Disposal:**
P501 Dispose of contents/ container to an approved waste disposal plant.

**Physical and chemical hazards**
Not classified based on available information.

**Health hazards**
May cause cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

**Environmental hazards**
Very toxic to aquatic life with long lasting effects.

**Other hazards which do not result in classification**
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</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>&gt;= 0.3 -&lt; 1</td>
</tr>
<tr>
<td>Ethinylestradiol</td>
<td>57-63-6</td>
<td>&gt;= 0.1 -&lt; 0.25</td>
</tr>
</tbody>
</table>

4. 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.

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.

Most important symptoms and effects, both acute and delayed: 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.

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).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

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.

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

6. ACCIDENTAL RELEASE MEASURES
Etonogestrel / Ethinyl Estradiol Formulation

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

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.

Methods and materials for containment and 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.

7. HANDLING AND STORAGE

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.

Avoidance of contact:
- Oxidizing agents

Storage
Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
Materials to avoid: Do not store with the following product types: Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</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>Ethinylestradiol</td>
<td>57-63-6</td>
<td>TWA</td>
<td>0.01 µg/m3 (OEB 5)</td>
<td>Internal</td>
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<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.1 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

### 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

#### 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
  - Eye/face 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.

#### 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.

### Hand protection

- Material: Chemical-resistant gloves
Remarks : Consider double gloving.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid
Colour : white
Odour : odourless
Odour Threshold : No data available
pH : Not applicable
Melting point/freezing point : Not applicable
Initial boiling point and boiling range : Not applicable
Flash point : Not applicable
Evaporation rate : 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
Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : 1 g/cm³
Solubility(ies) :
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks.
Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes: 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-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-dinopregn-4-en-20-yn-3-one:

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

- **Test Type:** in vitro assay
- **Test system:** Chinese hamster ovary cells
- **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-dinopregn-4-en-20-yn-3-one:**
  - **Species:** Rat
  - **Application Route:** Oral
  - **Activity duration:** 2 yr
  - 0.5 mg/kg body weight
  - **Result:** negative
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Species: Rat
Application Route: Subcutaneous
Activity duration: 2 yr
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-dinopregn-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
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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-dinopregn-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

12. ECOLOGICAL INFORMATION

Ecotoxicity

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
## Etonogestrel / Ethinyl Estradiol Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
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</tr>
</thead>
</table>

**Method:** OECD Test Guideline 203

**Remarks:** No toxicity at the limit of solubility

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>EC50 (Daphnia magna (Water flea)):</th>
<th>Exposure time</th>
<th>Exposure time: 48 h</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>NOEC (Daphnia magna (Water flea)):</th>
<th>Exposure time</th>
<th>Exposure time: 32 d</th>
</tr>
</thead>
</table>

**Method:** OECD Test Guideline 210

**NOEC (Oryzias latipes (Japanese medaka)):** 0.0000027 mg/l

**Exposure time:** 183 d

**Method:** OECD Test Guideline 229

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>NOEC (Daphnia magna (Water flea)):</th>
<th>Exposure time</th>
<th>Exposure time: 21 d</th>
</tr>
</thead>
</table>

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

**Toxicity to microorganisms**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>NOEC: 70.8 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>EC50: &gt; 1,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**Ethinylestradiol:**

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>NOEC (Daphnia magna (Water flea)):</th>
<th>Exposure time</th>
<th>Exposure time: 1.2 mg/l</th>
</tr>
</thead>
</table>

**Toxicity to microorganisms:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>NOEC: 70.8 mg/l</th>
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<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**Toxicity to fish (Chronic toxicity):**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>NOEC (Pimephales promelas (fathead minnow)):</th>
<th>Exposure time</th>
<th>Exposure time: 0.01 µg/l</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>NOEC (Zebrafish):</th>
<th>Exposure time</th>
<th>Exposure time: 339 d</th>
</tr>
</thead>
</table>

**Toxicity to algae/aquatic plants:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)):</th>
<th>Exposure time</th>
<th>Exposure time: 6.7 mg/l</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)):</th>
<th>Exposure time</th>
<th>Exposure time: 6.7 mg/l</th>
</tr>
</thead>
</table>

**Exposure time:** 72 h

**Method:** OECD Test Guideline 201

**Toxicity to fish:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>NOEC (Pimephales promelas (fathead minnow)):</th>
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<th>Exposure time: 0.01 µg/l</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>NOEC (Zebrafish):</th>
<th>Exposure time</th>
<th>Exposure time: 339 d</th>
</tr>
</thead>
</table>

**Method:** OECD Test Guideline 210

**Toxicity to fish:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
<th>NOEC (Pimephales promelas (fathead minnow)):</th>
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<th>Exposure time: 0.01 µg/l</th>
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**Method:** OECD Test Guideline 210

**Toxicity to fish:**

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<th>NOEC (Zebrafish):</th>
<th>Exposure time</th>
<th>Exposure time: 339 d</th>
</tr>
</thead>
</table>

**Method:** OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.75 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

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

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

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

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

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
mental compartments

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ethinylestradiol, (17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s.
(Ethinylestradiol, (17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ethinylestradiol, (17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)
Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.
SAFETY DATA SHEET
generated according to GB/T 16483 and GB/T 17519

Etonogestrel / Ethinyl Estradiol Formulation

Version 4.10
Revision Date: 09/13/2019
SDS Number: 16777-00015
Date of last issue: 2018/10/15
Date of first issue: 2014/09/29

National Regulations

GB 6944/12268
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ethinylestradiol, (17a)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinopregn-4-en-20-yn-3-one)
Class : 9
Packing group : III
Labels : 9

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.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information
Date format : yyyy/mm/dd

Full text of other abbreviations
AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

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.