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

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

1.4 Emergency telephone number
    1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
    Carcinogenicity, Category 1A
    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.
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

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-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>54048-10-1 258-936-2</td>
<td>Repr. 1A; H360F Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 10,000</td>
<td>&gt;= 0.3 - &lt; 1</td>
</tr>
<tr>
<td>Ethinylestradiol</td>
<td>57-63-6 200-342-2</td>
<td>Acute Tox. 4; H302 Carc. 1A; H350 Repr. 1B; H360FD STOT RE 1; H372 Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity):</td>
<td>&gt;= 0.1 - &lt; 0.25</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
5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products: Carbon oxides

5.3 Advice 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

- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

6.2 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

- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-
mine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

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

Advice on safe handling:
Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
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)
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Version 4.2  Revision Date: 09/13/2019  SDS Number: 16784-00016  Date of last issue: 24.04.2019

Date of first issue: 29.09.2014

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yne-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>Ethinylestradiol</td>
<td>57-63-6</td>
<td>TWA</td>
<td>0.01 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Wipe limit 0.5 µg/100 cm² Internal

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

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 rec-
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
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.
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)
Water solubility : insoluble
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.
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-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: 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-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

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.

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
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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

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

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

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

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

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
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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:
12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number
ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name
ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol, (17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol, (17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-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,
## Etonogestrel / Ethinyl Estradiol Formulation

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

### 14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>Class</th>
<th>Code</th>
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<tbody>
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<td>ADN</td>
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</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>Class</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>III</td>
</tr>
<tr>
<td>ADR</td>
<td>III</td>
</tr>
<tr>
<td>RID</td>
<td>III</td>
</tr>
<tr>
<td>IMDG</td>
<td>III</td>
</tr>
</tbody>
</table>

ADN  
- Packing group: III  
- Classification Code: M7  
- Hazard Identification Number: 90  
- Labels: 9

ADR  
- Packing group: III  
- Classification Code: M7  
- Hazard Identification Number: 90  
- Labels: 9  
- Tunnel restriction code: (-)

RID  
- Packing group: III  
- Classification Code: M7  
- Hazard Identification Number: 90  
- Labels: 9

IMDG  
- Packing group: III  
- Labels: 9  
- EmS Code: F-A, S-F

IATA (Cargo)  
- Packing instruction (cargo aircraft): 956  
- Packing instruction (LQ): Y956  
- Packing group: III  
- Labels: Miscellaneous

IATA (Passenger)  
- Packing instruction (passenger aircraft): 956  
- Packing instruction (LQ): Y956  
- Packing group: III  
- Labels: Miscellaneous
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Date of first issue: 29.09.2014

14.5 Environmental hazards

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
<th>Hazard</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>Environmentally hazardous</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>ADR</td>
<td>Environmentally hazardous</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>RID</td>
<td>Environmentally hazardous</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>IMDG</td>
<td>Marine pollutant</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>IATA (Passenger)</td>
<td>Environmentally hazardous</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>IATA (Cargo)</td>
<td>Environmentally hazardous</td>
<td>yes</td>
<td></td>
</tr>
</tbody>
</table>

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
- REACH - List of substances subject to authorisation (Annex XIV): Not applicable
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
- Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable
- Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
- REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

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

Other regulations:

- Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
- Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations.
The components of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

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

Etonogestrel / Ethinyl Estradiol Formulation

Version 4.2  Revision Date: 09/13/2019  SDS Number: 16784-00016  Date of last issue: 24.04.2019

Date of first issue: 29.09.2014

Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture: Carc. 1A H350 Calculation method
Repr. 1A H360FD Calculation method
STOT RE 1 H372 Calculation method
Aquatic Chronic 1 H410 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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