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

Desogestrel / Ethinyl Estradiol Formulation

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

1.1 Product identifier
Trade name: Desogestrel / 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
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone: 44 1 670 59 30 00
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: H350: May cause cancer.
Reproductive toxicity, Category 1B: H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1: H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1: H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

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

Signal word: Danger

Hazard statements: 
H350: May cause cancer.
H360FD: May damage fertility. May damage the unborn child.
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Date of first issue: 06.10.2014

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.
P260 Do not breathe dust.
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:
Desogestrel
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>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>Desogestrel</td>
<td>54024-22-5</td>
<td>258-929-4</td>
<td></td>
<td></td>
<td>Repr. 1B; H360Fd STOT RE 1; H372 Aquatic Chronic 1; H410</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 10,000</td>
<td></td>
</tr>
<tr>
<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 RE 1; H372 Aquatic Chronic 1; H410</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic</td>
<td></td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of first aid measures

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

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

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

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

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

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

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.
SECTION 5: Firefighting measures

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)

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:
7.3 Specific end use(s)
Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA (inhalable dust)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m⁻³ 8-hour TWA of inhalable dust or 4 mg.m⁻³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with. Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.

<table>
<thead>
<tr>
<th></th>
<th>TWA (Respirable dust)</th>
<th>4 mg/m³</th>
<th>GB EH40</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desogestrel</td>
<td>54024-22-5</td>
<td>TWA</td>
<td>0.04 µg/m³ (OEB 5) Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.4 µg/100 cm²</td>
</tr>
<tr>
<td>Ethinylestradiol</td>
<td>57-63-6</td>
<td>TWA</td>
<td>0.01 µg/m³ (OEB 5) Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.1 µg/100 cm²</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
</table>
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<table>
<thead>
<tr>
<th>Stearic acid</th>
<th>Workers</th>
<th>Inhalation</th>
<th>Long-term systemic effects</th>
<th>17.63 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>10 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>4.348 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>5 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>2.5 mg/kg bw/day</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 face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

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

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : powder
Colour : White to light yellow
Odour : No data available
Odour Threshold : No data available
**Desogestrel / Ethinyl Estradiol Formulation**

### pH
- No data available

### Melting point/freezing point
- No data available

### Initial boiling point and boiling range
- No data available

### 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
- No data available

#### Lower explosion limit / Lower flammability limit
- No data available

### Vapour pressure
- Not applicable

### Relative vapour density
- Not applicable

### Relative density
- No data available

### Density
- 1 g/cm³

### Solubility(ies)
- Water solubility: No data available
- 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.

#### Flammability (liquids)
- No data available

#### Particle size
- No data available

---

**SECTION 10: Stability and reactivity**

### 10.1 Reactivity
Not classified as a reactivity hazard.
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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:

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

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:**

Desogestrel:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Rat
Application Route: Intraperitoneal
Result: negative

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
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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:

Desogestrel:
Species: Rat
Application Route: Oral
Exposure time: 104 weeks
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 81 weeks
Result: negative

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:

Desogestrel:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rabbit, female
Fertility: LOAEL Parent: 2 mg/kg body weight
Result: Effects on fertility

Test Type: Fertility/early embryonic development
Species: Rat, female
Fertility: NOAEL Parent: 0.5 mg/kg body weight  
Result: No effects on fertility

Effects on foetal development  
: Test Type: Embryo-foetal development  
Species: Rabbit, female  
Application Route: Oral  
Developmental Toxicity: NOAEL F1: 1 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects

Test Type: Embryo-foetal development  
Species: Rat, female  
Application Route: Oral  
Embryo-foetal toxicity: LOAEC Parent: 0.125 mg/kg body weight  
Result: No teratogenic effects

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

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:  
Desogestrel:  
Target Organs  
: Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate
Assessment: Causes damage to organs through prolonged or repeated exposure.

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

**Repeated dose toxicity**

**Components:**

**Desogestrel:**
- **Species:** Rat, female
- **LOAEL:** 0.00625 mg/kg
- **Application Route:** Oral
- **Exposure time:** 26 Weeks
- **Target Organs:** Pituitary gland, Uterus (including cervix), Ovary, Mammary gland

- **Species:** Rat
  - **LOAEL:** 0.005 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 52 Weeks
  - **Target Organs:** Pituitary gland, Uterus (including cervix), Ovary, Mammary gland

- **Species:** Dog
  - **LOAEL:** 0.005 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 52 Weeks
  - **Target Organs:** Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate

**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
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**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**:

**Desogestrel**:
- **Ingestion**
  - Symptoms: Headache, changes in libido, Dizziness, Nausea, Vomiting, Diarrhoea, water retention, sodium retention, Gastrointestinal discomfort, mental depression, amenorrhea, insomnia, impaired glucose tolerance, pulmonary embolism
  - Target Organs: Uterus (including cervix)
  - Target Organs: Mammary gland

**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**:

**Desogestrel**:  
- **Toxicity to fish**
  - \( LC_{50} \) (Oncorhynchus mykiss (rainbow trout)): 4 mg/l
  - Exposure time: 96 h
  - Method: FDA 4.11
  - Remarks: Based on data from similar materials
  - \( LC_{50} \) (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
  - Based on data from similar materials

  **Toxicity to daphnia and other aquatic invertebrates**
  - \( EC_{50} \) (Daphnia magna (Water flea)): > 3.9 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: No toxicity at the limit of solubility
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Toxicity to microorganisms: EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

NOEC: 70.8 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity): NOEC: 0.059 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210
Remarks: Based on data from similar materials

NOEC: 0.0000027 mg/l
Exposure time: 183 d
Species: Oryzias latipes (Japanese medaka)
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 1.2 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Remarks: Based on data from similar materials

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

Ethinylestradiol:

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

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

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

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

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

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

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

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

M-Factor (Chronic aquatic toxicity)  
100,000

12.2 Persistence and degradability

Components:

Desogestrel:
Stability in water  
Hydrolysis: < 10 % (5 d)  
Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

Components:

Desogestrel:
Bioaccumulation  
Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): 128  
Remarks: Based on data from similar materials

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:

Desogestrel:
Distribution among environmental compartments  
log Koc: 2.84
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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
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, Desogestrel)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol, Desogestrel)
RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol, Desogestrel)
IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol, Desogestrel)
IATA: Environmentally hazardous substance, solid, n.o.s. (Ethinylestradiol, Desogestrel)

14.3 Transport hazard class(es)
Desogestrel / Ethinyl Estradiol Formulation

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9 (ENVIRONM.)

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9 (ENVIRONM.)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9 (ENVIRONM.)

IMDG
Packing group : III
Labels : 9 (ENVIRONM.)
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
Desogestrel / Ethinyl Estradiol Formulation

IMDG
  Marine pollutant : yes

IATA (Passenger)
  Environmentally hazardous : yes

IATA (Cargo)
  Environmentally hazardous : yes

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

14.7 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 - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

<table>
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<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
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Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined
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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.
H360Fd : May damage fertility. Suspected of damaging the unborn child.
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
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; 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 Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No
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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. 1B: 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.

GB / EN