1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Desogestrel / Ethinyl Estradiol Formulation

Supplier’s company name, address and phone number
Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33nd floor
           Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
E-mail address : EHSSTEWARD@organon.com
Emergency telephone number : 215-631-6999

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Carcinogenicity : Category 1A
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate, Liver, Blood)
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 (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate, Liver, Blood) 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.
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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;=20 - &lt;30</td>
<td>8-98</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>&gt;=1 - &lt;10</td>
<td>2-608</td>
</tr>
<tr>
<td>Desogestrel</td>
<td>54024-22-5</td>
<td>&gt;=0.1 - &lt;0.25</td>
<td></td>
</tr>
<tr>
<td>Ethinylestradiol</td>
<td>57-63-6</td>
<td>&gt;=0.025 - &lt;0.1</td>
<td></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.
In case of eye contact: Thoroughly clean shoes before reuse. 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: 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)

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

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
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.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact:
- Oxidizing agents

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.

Storage
Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

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

<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>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Desogestrel</td>
<td>54024-22-5</td>
<td>TWA</td>
<td>0.04 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.4 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Ethinylestradiol</td>
<td>57-63-6</td>
<td>TWA</td>
<td>0.01 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.1 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

Hand protection:
Material: Chemical-resistant gloves
Remarks: Consider double gloving.
Eye protection:
If the work environment or activity involves dusty conditions,
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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>White to light yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
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</tr>
<tr>
<td>Lower explosion limit and upper explosion limit / flammability limit</td>
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</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not applicable</td>
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<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
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<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
octanol/water

Vapour pressure : Not applicable

Density and/or relative density
Relative density : No data available

Density : 1 g/cm3

Relative vapour density : Not applicable

Explosive properties : Not explosive

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

Particle characteristics
Particle size : No data available

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

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

Starch:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Stearic acid:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Acute inhalation toxicity: LC50 (Rat): > 2 mg/l
   Exposure time: 1 h
   Test atmosphere: vapour
   Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
   Assessment: The substance or mixture has no acute dermal toxicity

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:

Stearic acid:
Species: Rabbit
Method: Patch Test 24 Hrs.
Result: No skin irritation

Ethinylestradiol:
Remarks: No data available

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

Components:

Starch:
Species: Rabbit
Result: No eye irritation

Stearic acid:
Species: Rabbit
Result: No eye irritation
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:
Starch:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Stearic acid:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

Ethinylestradiol:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

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

Stearic acid:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials
Desogestrel:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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

Species: Mouse
Application Route: Oral
Exposure time: 81 weeks
Result: negative
Ethinyloestradiol:
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:
Stearic acid:
Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

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

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

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 (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate, Liver, Blood) 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:**

**Starch:**
- **Species:** Rat
- **NOAEL:** >= 2,000 mg/kg
- **Application Route:** Skin contact
- **Exposure time:** 28 Days
- **Method:** OECD Test Guideline 410

**Stearic acid:**
- **Species:** Rat
- **NOAEL:** 1,000 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 42 Days
- **Method:** OECD Test Guideline 422
- **Remarks:** Based on data from similar materials

**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
Exposure time: 95 d

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, amenorhea, 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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Stearic acid:
Toxicity to fish: LL50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
Exposure time: 48 h
Method: DIN 38412

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 10 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants

NOELR (Pseudokirchneriella subcapitata (green algae)): > 10 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOELR (Daphnia magna (Water flea)): > 0.5 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to microorganisms

EC10 (Pseudomonas putida): 883 mg/l
Exposure time: 18 h

Desogestrel:

Toxicity to fish

LC50 (Oncorhynchus mykiss (rainbow trout)): 4 mg/l
Exposure time: 96 h
Method: FDA 4.11
Remarks: Based on data from similar materials

LC50 (Lepomis macrochirus (Bluegill sunfish)): 1.3 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility
Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates

EC50 (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
Based on data from similar materials

Toxicity to fish (Chronic toxicity)

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

NOEC (Oryzias latipes (Japanese medaka)): 0.0000027 mg/l
Exposure time: 183 d
Remarks: Based on data from similar materials
### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- **NOEC** (Daphnia magna (Water flea)): 1.2 mg/l
- Exposure time: 21 d
- Remarks: Based on data from similar materials

### M-Factor (Chronic aquatic toxicity)
- **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

### 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 fish (Chronic toxicity)
- **NOEC** (Pimephales promelas (fathead minnow)): 0.01 µg/l
- Exposure time: 35 d
- Method: OECD Test Guideline 210
  - **NOEC** (Zebrafish): 0.00031 µg/l
  - Exposure time: 339 d

#### 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)
- **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:**

**Stearic acid:**
Biodegradability : Result: Readily biodegradable.
Biodegradation: 71 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

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

Bioaccumulative potential

**Components:**

**Stearic acid:**
Partition coefficient: n-octanol/water : log Pow: 8.23

**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

Mobility in soil

**Components:**

**Desogestrel:**
Distribution among environmental compartments : log Koc: 2.84

**Ethinylestradiol:**
Distribution among environmental compartments : log Koc: 3.86

Hazardous to the ozone layer
Not applicable
Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposition 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, Desogestrel)
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, Desogestrel)
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, Desogestrel)
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.

National Regulations
Refer to section 15 for specific national regulation.
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

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable
Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance (Category Z)
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
SAFETY DATA SHEET

Desogestrel / Ethinyl Estradiol Formulation

Version 6.1  Revision Date: 2020/10/16  SDS Number: 19066-00018  Date of last issue: 2020/03/23  Date of first issue: 2014/10/06

ACGIH / TWA : 8-hour, time-weighted average

AllC - Australian Inventory of Industrial Chemicals; 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 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; 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 - Transport 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.

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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