1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Desogestrel / Ethinyl Estradiol Formulation

Manufacturer or supplier’s details
Company: Organon & Co.
Address: JL Raya Pandaan KM. 48
         Pandaan, Jawa Timur - Indonesia
Telephone: 551-430-6000
Emergency telephone number: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

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

2. HAZARDS IDENTIFICATION

GHS Classification
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.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>&lt; 10</td>
</tr>
<tr>
<td></td>
<td>Desogestrel</td>
<td>54024-22-5</td>
<td>&gt;= 0.025 - &lt; 0.25</td>
</tr>
<tr>
<td></td>
<td>Ethinylestradiol</td>
<td>57-63-6</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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

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

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

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

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
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 surfac-
es, 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

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.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>TWA (Inhal-)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
### Desogestrel / Ethinyl Estradiol Formulation

<table>
<thead>
<tr>
<th>Engineering measures</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal protective equipment</td>
<td></td>
</tr>
<tr>
<td>Respiratory protection</td>
<td>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</td>
</tr>
<tr>
<td>Filter type</td>
<td>Particulates type</td>
</tr>
<tr>
<td>Hand protection</td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td>Chemical-resistant gloves</td>
</tr>
<tr>
<td>Remarks</td>
<td>Consider double gloving.</td>
</tr>
<tr>
<td>Eye protection</td>
<td>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.</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>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.</td>
</tr>
<tr>
<td>Hygiene measures</td>
<td>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</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</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>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</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>
<td>No data available</td>
</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>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
</tbody>
</table>
Viscosity, kinematic: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
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:** 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
  - 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:

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: 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.

**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:**
**Desogestrel / Ethinyl Estradiol Formulation**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, female</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.00625 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>26 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Pituitary gland, Uterus (including cervix), Ovary, Mammary gland</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.005 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>52 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Pituitary gland, Uterus (including cervix), Ovary, Mammary gland</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.005 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>52 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.25 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.015 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>20 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.04 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>95 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, male and female</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.0015 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>Oral</td>
</tr>
</tbody>
</table>
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

**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):
- 10,000

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
  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): 100,000

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

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

Persistence and degradability

Components:

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
SAFETY DATA SHEET
Desogestrel / Ethinyl Estradiol Formulation

Version 4.8  Revision Date: 2021/04/09  SDS Number: 19060-00019  Date of last issue: 2020/10/16
Date of first issue: 2014/10/06

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

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ethinylestradiol, 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.

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

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use: Not applicable
Prohibited substances: Not applicable
SAFETY DATA SHEET

Desogestrel / Ethinyl Estradiol Formulation

Version 4.8
Revision Date: 2021/04/09
SDS Number: 19060-00019
Date of last issue: 2020/10/16
Date of first issue: 2014/10/06

Restricted substances: Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable

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)
ID OEL: Indonesia. Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
ID OEL / NAB: Long term exposure limit

AIIIC - 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 Chemicals in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Develop-
<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.8</td>
<td>2021/04/09</td>
<td>19060-00019</td>
<td>2020/10/16</td>
<td>2014/10/06</td>
</tr>
</tbody>
</table>

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.

ID / EN