SECTION 1. IDENTIFICATION

Product name: Desogestrel / Ethinyl Estradiol Formulation

Manufacturer or supplier's details
Company name of supplier: Organon & Co.
Address: 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
Emergency telephone: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
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)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air. 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.

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.
P280 Wear protective gloves, protective clothing, eye protection...
and face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

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

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

| Substance / Mixture   | Components
|-----------------------|-------------
|                      | Chemical name | CAS-No.     | Concentration (% w/w) |
| Mixture              | Starch        | 9005-25-8  | >= 20 - < 30           |
|                      | Stearic acid  | 57-11-4    | >= 5 - < 10            |
|                      | Desogestrel   | 54024-22-5 | >= 0.1 - < 1           |
|                      | Ethinylestradiol | 57-63-6 | >= 0.01 - < 0.1        |

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

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

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

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

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

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

Most important symptoms and effects, both acute and delayed
May cause cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin.
SECTION 5. FIRE-FIGHTING MEASURES

Protection of first-aiders: Dust contact with the eyes can lead to mechanical irritation. 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.

**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 fire-fighters:** In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 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...
SECTION 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 labeled 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 Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSOAL PROTECTION

Ingredients 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>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>TWA (Inhalable particulate)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
Desogestrel / Ethinyl Estradiol Formulation

TWA (Respirable particulate matter) | 3 mg/m³ | ACGIH

Desogestrel 54024-22-5 TWA 0.04 µg/m³ (OEB 5) Internal
Wipe limit 0.4 µg/100 cm² Internal

Ethinylestradiol 57-63-6 TWA 0.01 µg/m³ (OEB 5) Internal
Wipe limit 0.1 µg/100 cm² Internal

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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

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

Eye protection

Remarks: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection

Remarks: 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
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: powder
- **Color**: White to light yellow
- **Odor**: No data available
- **Odor Threshold**: No data available
- **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.
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapor pressure**: Not applicable
- **Relative vapor density**: Not applicable
- **Relative density**: No data available
- **Density**: 1 g/cm³
- **Solubility(ies)**
  - **Water solubility**: No data available
SECTION 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.

SECTION 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: vapor
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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Starch:
- Test Type: Maximization Test
- Routes of exposure: Skin contact
- Species: Guinea pig
- Result: negative

Stearic acid:
- Test Type: Maximization Test
- Routes of exposure: 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:
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

IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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 fetal 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 fetal development: Test Type: Embryo-fetal development
<table>
<thead>
<tr>
<th>Species: Rabbit, female</th>
<th>Application Route: Oral</th>
<th>Developmental Toxicity: NOAEL F1: 1 mg/kg body weight</th>
<th>Result: Embryotoxic effects and adverse effects on the offspring were detected. No teratogenic effects.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Embryo-fetal development</td>
<td>Species: Rat, female</td>
<td>Application Route: Oral</td>
<td>Embryo-fetal toxicity: LOAEC Parent: 0.125 mg/kg body weight</td>
</tr>
</tbody>
</table>

**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 fetal 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 (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
Species: Rabbit
LOAEL: 0.015 mg/kg
Application Route: Oral
Exposure time: 20 Weeks
Target Organs: Liver

Species: Dog
NOAEL: 0.04 mg/kg
LOAEL: 0.2 mg/kg
Application Route: Oral
Exposure time: 95 d
Target Organs: Blood

Species: Rat, male and female
NOAEL: 0.0015 mg/kg
LOAEL: 0.005 mg/kg
Application Route: Oral
Exposure time: 2 y
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, Diarrhea, water retention, sodium retention, Gastro-intestinal 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, Diarrhea, Headache, Dizziness, mood swings, Edema, liver function change, water retention, hair loss, gynecomastia, effects on menstruation

SECTION 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.

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

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

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

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

**Ethinylestradiol:**
Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 264
Method: OECD Test Guideline 305

**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
3. 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.

SECTION 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.

Domestic regulation

49 CFR
UN/ID/NA number: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Ethinylestradiol, Desogestrel)
Class: 9
Packing group: III
SAFETY DATA SHEET
Desogestrel / Ethinyl Estradiol Formulation

Version 8.4 Revision Date: 10/16/2020 SDS Number: 19077-00018 Date of last issue: 03/23/2020 Date of first issue: 10/06/2014

Labels: CLASS 9
ERG Code: 171
Marine pollutant: yes (Ethinylestradiol, Desogestrel)
Remarks: Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Combustible dust
Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations
Pennsylvania Right To Know
Lactose  63-42-3
Starch  9005-25-8
Stearic acid  57-11-4
Ethinylestradiol  57-63-6

California Prop. 65
WARNING: This product can expose you to chemicals including Ethinylestradiol, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
Polyvinyl pyrrolidone  9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
Starch  9005-25-8

The ingredients of this product are reported in the following inventories:
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:  

Health 0  
Flammability 1  
Special hazard 0  
Instability 0

HMIS® IV:

HEALTH * 3  
FLAMMABILITY 3  
PHYSICAL HAZARD 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NIOSH REL : USA. NIOSH Recommended Exposure Limits  
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants  
ACGIH / TWA : 8-hour, time-weighted average  
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek  
OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Organiza-

Revision Date: **10/16/2020**

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.

US / Z8