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

1.1 Product identifier
   Trade name: Desogestrel / Ethinyl Estradiol Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company: MSD
   117 16th Road
   07033 Halfway house, Midrand, South Africa
   Telephone: +27 11 655 3000
   Telefax: 908-735-1496
   E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Carcinogenicity, Category 1A
   Reproductive toxicity, Category 1B
   Specific target organ toxicity - repeated exposure, Category 1
   Long-term (chronic) aquatic hazard, Category 1
   H350: May cause cancer.
   H360FD: May damage fertility. May damage the unborn child.
   H372: Causes damage to organs through prolonged or repeated exposure.
   H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms: 
   Signal word: Danger
   Hazard statements: 
   H350: May cause cancer.
   H360FD: May damage fertility. May damage the unborn child.
   H372: Causes damage to organs through prolonged or repeated exposure.
peated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

Hazardous components which must be listed on the label:
Desogestrel
Ethinylestradiol

2.3 Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
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</thead>
<tbody>
<tr>
<td>Desogestrel</td>
<td>54024-22-5</td>
<td>258-929-4</td>
<td></td>
<td>Repr. 1B; H360Fd STOT RE 1; H372 (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate) Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 10.000</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
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<tr>
<td>Ethinylestradiol</td>
<td>57-63-6</td>
<td>200-342-2</td>
<td></td>
<td>Acute Tox. 4; H302 Carc. 1A; H350 Repr. 1B; H360FD STOT RE 1; H372 (Liver, Blood) Aquatic Chronic 1;</td>
<td>&gt;= 0,025 - &lt; 0,1</td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of first aid measures

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

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

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

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

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

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

4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

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

4.3 Indication of any immediate medical attention and special treatment needed

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

5.1 Extinguishing media

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

Unsuitable extinguishing media:
None known.

5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products:
- Carbon oxides
- Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

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

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

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

Advice on safe handling: Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. 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.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

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

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
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</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA OEL-RL (Respirable dust)</td>
<td>5 mg/m³</td>
<td>ZA OEL</td>
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<tr>
<td></td>
<td></td>
<td>TWA OEL-RL (inhalable dust)</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
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</table>

Further information: Recommended Limit

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<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
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<tbody>
<tr>
<td>Desogestrel</td>
<td>54024-22-5</td>
<td>TWA</td>
<td>0.04 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
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<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.4 µg/100 cm²</td>
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<td>Ethynylestradiol</td>
<td>57-63-6</td>
<td>TWA</td>
<td>0.01 µg/m³ (OEB 5)</td>
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<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.1 µg/100 cm²</td>
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</tbody>
</table>

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

<table>
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<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
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<td>Stearic acid</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>17,63 mg/m3</td>
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<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>10 mg/kg bw/day</td>
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<tr>
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<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>4,348 mg/m3</td>
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<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>5 mg/kg bw/day</td>
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<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>2.5 mg/kg bw/day</td>
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</tbody>
</table>

8.2 Exposure controls

Engineering measures

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems are required.

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.
Personal protective equipment

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

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: powder

Colour: White to light yellow

Odour: No data available

Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: Not applicable

Evaporation rate: Not applicable

Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: Not applicable

Relative vapour density: Not applicable
Desogestrel / Ethinyl Estradiol Formulation

Relative density : No data available
Density : 1 g/cm³

Solubility(ies)
  Water solubility : No data available
  Partition coefficient: n-octanol/water : Not applicable
  Auto-ignition temperature : No data available
  Decomposition temperature : No data available

Viscosity
  Viscosity, kinematic : Not applicable

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

9.2 Other information
  Flammability (liquids) : No data available
  Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
  Not classified as a reactivity hazard.

10.2 Chemical stability
  Stable under normal conditions.

10.3 Possibility of hazardous reactions
  Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
  Can react with strong oxidizing agents.

10.4 Conditions to avoid
  Conditions to avoid : Heat, flames and sparks.
  Avoid dust formation.

10.5 Incompatible materials
  Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
  No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
  Information on likely routes of : Inhalation
exposure
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:
Desogestrel:
Acute oral toxicity: LD50 (Rat, male and female): > 2.000 mg/kg
LD50 (Mouse, male and female): > 2.000 mg/kg

Ethinylestradiol:
Acute oral toxicity: LD50 (Rat): 1.200 mg/kg
LD50 (Mouse): 1.737 mg/kg
Acute inhalation toxicity: Remarks: No data available
Acute dermal toxicity: Remarks: No data available

Skin corrosion/irritation
Not classified based on available information.

Components:
Ethinylestradiol:
Remarks: No data available

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

Components:
Ethinylestradiol:
Remarks: No data available

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Ethinylestradiol:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.
Components:

Desogestrel:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Genotoxicity in vivo: Test Type: Micronucleus test
Species: Rat
Application Route: Intraperitoneal
Result: negative

Ethinylestradiol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Test system: Salmonella typhi 
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:

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

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

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

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

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

Ethinylestradiol:
Effects on fertility:
Species: Hamster
Fertility: LOAEL: 6.3 mg/kg body weight
Result: Effects on fertility
Effects on foetal development:

- Test Type: Four-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: > 0.006 mg/kg body weight
  - Result: Specific developmental abnormalities

- Test Type: Two-generation reproduction toxicity study
  - Species: Rat, male and female
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 0.005 mg/kg body weight
  - Result: Specific developmental abnormalities

Reproductive toxicity - Assessment:

- Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.
- Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure:
Not classified based on available information.

STOT - repeated exposure:
Causes damage to organs through prolonged or repeated exposure.

Components:

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

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

Repeated dose toxicity:

Components:

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

- Species: Rat
- LOAEL: 0.005 mg/kg
- Application Route: Oral
- Exposure time: 52 Weeks
- Target Organs: Pituitary gland, Uterus (including cervix), Ovary, Mammary gland
Species: Dog
LOAEL: 0,005 mg/kg
Application Route: Oral
Exposure time: 52 Weeks
Target Organs: Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate

Ethinylestradiol:
Species: Rat
NOAEL: 0,25 mg/kg
LOAEL: 0,5 mg/kg
Application Route: Oral
Exposure time: 2 Weeks
Target Organs: Liver

Species: Rabbit
LOAEL: 0,015 mg/kg
Application Route: Oral
Exposure time: 20 Weeks
Target Organs: Liver

Species: Dog
NOAEL: 0,04 mg/kg
LOAEL: 0,2 mg/kg
Application Route: Oral
Exposure time: 95 d
Target Organs: Blood

Species: Rat, male and female
NOAEL: 0,0015 mg/kg
LOAEL: 0,005 mg/kg
Application Route: Oral
Exposure time: 2 yr
Target Organs: Reproductive organs, Mammary gland, Liver, Uterus (including cervix)

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

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

**Ethinylestradiol:**
Ingestion: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea, Headache, Dizziness, mood swings, Oedema, liver function
change, water retention, hair loss, gynecomastia, effects on menstruation

SECTION 12: Ecological information

12.1 Toxicity

Components:

Desogestrel:
Toxicity to fish: 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 microorganisms: EC50: > 1.000 mg/l
   Exposure time: 3 h
   Test Type: Respiration inhibition
   Method: OECD Test Guideline 209
   Remarks: Based on data from similar materials

   NOEC: 70,8 mg/l
   Exposure time: 3 h
   Test Type: Respiration inhibition
   Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity): NOEC: 0,059 mg/l
   Exposure time: 32 d
   Species: Pimephales promelas (fathead minnow)
   Method: OECD Test Guideline 210
   Remarks: Based on data from similar materials

   NOEC: 0,0000027 mg/l
   Exposure time: 183 d
   Species: Oryzias latipes (Japanese medaka)
   Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 1,2 mg/l
   Exposure time: 21 d
   Species: Daphnia magna (Water flea)
   Remarks: Based on data from similar materials

M-Factor (Chronic aquatic): 10.000
toxicity)

**Ethinylestradiol:**

**Toxicity to fish**

: LC50 (Lepomis macrochirus (Bluegill sunfish)): 1,6 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203

**Toxicity to algae/aquatic plants**

: EC50 (Pseudokirchneriella subcapitata (green algae)): > 6,7 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

  NOEC (Pseudokirchneriella subcapitata (green algae)): 6,7 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

**Toxicity to microorganisms**

: EC50 : > 1.000 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

  NOEC : 24,9 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

**Toxicity to fish (Chronic toxicity)**

: NOEC: 0,01 µg/l
  Exposure time: 35 d
  Species: Pimephales promelas (fathead minnow)
  Method: OECD Test Guideline 210

  NOEC: 0,00031 µg/l
  Exposure time: 339 d
  Species: Zebrafish

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

: NOEC: 0,75 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Method: OECD Test Guideline 211

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

: 100.000

### 12.2 Persistence and degradability

**Components:**

**Desogestrel:**

**Stability in water**

: Hydrolysis: < 10 % (5 d)
  Remarks: Based on data from similar materials
12.3 Bioaccumulative potential

**Components:**

**Desogestrel:**
- Bioaccumulation
- Species: Lepomis macrochirus (Bluegill sunfish)
- Bioconcentration factor (BCF): 128
- Remarks: Based on data from similar materials
- Partition coefficient: n-octanol/water: log Pow: 3.5

**Ethinylestradiol:**
- Bioaccumulation
- Species: Lepomis macrochirus (Bluegill sunfish)
- Bioconcentration factor (BCF): 264
- Method: OECD Test Guideline 305
- Partition coefficient: n-octanol/water: log Pow: 4.15

12.4 Mobility in soil

**Components:**

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

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

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product:**
- Dispose of in accordance with local regulations.
- According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
- Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**Contaminated packaging:**
- Empty containers should be taken to an approved waste handling site for recycling or disposal.
- If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

**ADN:**
- UN 3077
# SAFETY DATA SHEET

Desogestrel / Ethinyl Estradiol Formulation

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<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
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14.2 UN proper shipping name

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14.3 Transport hazard class(es)

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14.4 Packing group

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<td>Labels: 9</td>
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Packing group: III
Labels: 9
EmS Code: F-A, S-F

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

IATA (Passenger)
Packing instruction (passenger aircraft): 956
Packing instruction (LQ): Y956
Packing group: III
Labels: Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous: yes

ADR
Environmentally hazardous: yes

RID
Environmentally hazardous: yes

IMDG
Marine pollutant: yes

IATA (Passenger)
Environmentally hazardous: yes

IATA (Cargo)
Environmentally hazardous: yes

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

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined
15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

- **H302** : Harmful if swallowed.
- **H350** : May cause cancer.
- **H360Fd** : May damage fertility. Suspected of damaging the unborn child.
- **H360FD** : May damage fertility. May damage the unborn child.
- **H372** : Causes damage to organs through prolonged or repeated exposure.
- **H410** : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

- **Acute Tox.** : Acute toxicity
- **Aquatic Chronic** : Long-term (chronic) aquatic hazard
- **Carc.** : Carcinogenicity
- **Repr.** : Reproductive toxicity
- **STOT RE** : Specific target organ toxicity - repeated exposure
- **ZA OEL** : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
- **ZA OEL / TWA OEL-RL** : Long term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Re-
SAFETY DATA SHEET

Desogestrel / Ethinyl Estradiol Formulation

Version 2.4
Revision Date: 16.10.2020
SDS Number: 19078-00018
Date of last issue: 23.03.2020
Date of first issue: 06.10.2014

Further information
Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:

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<th>Classification</th>
<th>Value</th>
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</tr>
<tr>
<td>Repr. 1B</td>
<td>H360FD</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure:
Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

ZA / EN