SAFETY DATA SHEET
Desogestrel Formulation

Version 7.0  Revision Date: 2020/03/23  SDS Number: 21976-00018  Date of last issue: 2019/09/13  Date of first issue: 2014/10/15

1. PRODUCT AND COMPANY IDENTIFICATION

   Chemical product name : Desogestrel Formulation

   Supplier’s company name, address and phone number
   Company name of supplier : MSD
   Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
   Telephone : 048-588-8411
   E-mail address : EHSDATASTEWARD@msd.com
   Emergency telephone number : 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

   GHS classification of chemical product
   Reproductive toxicity : Category 1B
   Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate)
   Long-term (chronic) aquatic hazard : Category 1

   GHS label elements
   Hazard pictograms :
   Signal word : Danger
   Hazard statements : H360Fd May damage fertility. Suspected of damaging the unborn child.
   H372 Causes damage to organs (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate) 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
Important symptoms and outlines of the emergency assumed:
- 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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
</tr>
<tr>
<td></td>
<td>Titanium dioxide</td>
</tr>
<tr>
<td></td>
<td>Desogestrel</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.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
May damage fertility. Suspected of damaging 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 and personal protective equipment recommendations.

Environmental precautions:
Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

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

### 7. HANDLING AND STORAGE

**Handling**

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

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

Advice on safe handling:
Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact:
Oxidizing agents

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

**Storage**

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

Materials to avoid:
Do not store with the following product types:
Strong oxidizing agents
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>Titanium dioxide</td>
<td>13463-67-7</td>
<td>OEL-M (Respirable dust)</td>
<td>1 mg/m³ (Titanium)</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Class 2 Dust</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-M (Total dust)</td>
<td>4 mg/m³ (Titanium)</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Class 2 Dust</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desogestrel</td>
<td>54024-22-5</td>
<td>TWA</td>
<td>0.04 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.4 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Engineering measures: Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. No open handling permitted. Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

Personal protective equipment

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

Filter type: Particulates type

Hand protection:

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection:

Material: Wear safety glasses with side shields or goggles.

Remarks: 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:

Material: Work uniform or laboratory coat.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

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

**Propylene glycol:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity: LC50 (Rabbit): > 159 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  - Assessment: The substance or mixture has no acute dermal toxicity

**Titanium dioxide:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Desogestrel Formulation

**Acute inhalation toxicity**
- LC50 (Rat): > 6.82 mg/l
- Exposure time: 4 h
- Test atmosphere: dust/mist
- Assessment: The substance or mixture has no acute inhalation toxicity

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

**Skin corrosion/irritation**
- Not classified based on available information.

**Components:**

**Propylene glycol:**
- **Species:** Rabbit
- **Method:** OECD Test Guideline 404
- **Result:** No skin irritation

**Titanium dioxide:**
- **Species:** Rabbit
- **Result:** No skin irritation

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

**Components:**

**Propylene glycol:**
- **Species:** Rabbit
- **Result:** No eye irritation
- **Method:** OECD Test Guideline 405

**Titanium dioxide:**
- **Species:** Rabbit
- **Result:** No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
- Not classified based on available information.

**Respiratory sensitisation**
- Not classified based on available information.

**Components:**

**Propylene glycol:**
- **Test Type:** Maximisation Test
- **Exposure routes:** Skin contact
### Species Data

**Titanium dioxide:**
- **Test Type:** Local lymph node assay (LLNA)
- **Exposure routes:** Skin contact
- **Species:** Mouse
- **Result:** negative

**Germ cell mutagenicity**
Not classified based on available information.

### Components

**Propylene glycol:**
- **Genotoxicity in vitro:** Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

**Titanium dioxide:**
- **Genotoxicity in vitro:** Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

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

**Carcinogenicity**
Not classified based on available information.

### Propylene glycol:
- **Species:** Rat
- **Application Route:** Ingestion
- **Exposure time:** 2 Years
- **Result:** negative
### Titanium dioxide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application Route</strong></td>
<td>Inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>2 Years</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>OECD Test Guideline 453</td>
</tr>
<tr>
<td><strong>Result</strong></td>
<td>Positive</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

### Carcinogenicity - Assessment:

- Limited evidence of carcinogenicity in inhalation studies with animals.

### Desogestrel:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>104 weeks</td>
</tr>
<tr>
<td><strong>Result</strong></td>
<td>Negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>81 weeks</td>
</tr>
<tr>
<td><strong>Result</strong></td>
<td>Negative</td>
</tr>
</tbody>
</table>

### Reproductive toxicity

May damage fertility. Suspected of damaging the unborn child.

### Components:

#### Propylene glycol:

- **Effects on fertility**
  - Test Type: Three-generation reproduction toxicity study
  - Species: Mouse
  - Application Route: Ingestion
  - Result: Negative

- **Effects on foetal development**
  - Test Type: Embryo-foetal development
  - Species: Mouse
  - Application Route: Ingestion
  - Result: Negative

#### 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.

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) 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.

Repeated dose toxicity

Components:

Propylene glycol:
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

Titanium dioxide:
Species: Rat
NOAEL: 24,000 mg/kg
Application Route: Ingestion
Exposure time: 28 Days

Species: Rat
NOAEL: 10 mg/m3
Application Route: Inhalation (dust/mist/fume)
Exposure time: 2 yr

Desogestrel:
Species: Rat, female
## LOAEL

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

### Species

- **Rat**

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

### Species

- **Dog**

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

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

**Components:**

**Desogestrel:**

**Ingestion**

- Symptoms: Headache, changes in libido, Dizziness, Nausea, Vomiting, Diarrhoea, water retention, sodium retention, Gastrointestinal discomfort, mental depression, amenorhea, insomnia, impaired glucose tolerance, pulmonary embolism

  Target Organs: Uterus (including cervix)

  Target Organs: Mammary gland

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

**Components:**

**Propylene glycol:**

**Toxicity to fish**

- LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
- Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates**

- EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
- Exposure time: 48 h

**Toxicity to algae/aquatic plants**

- ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d

Toxicity to microorganisms:
NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

Titanium dioxide:

Toxicity to fish:
LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:
EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h

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

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
Remarks: Based on data from similar materials

Titanium dioxide:

Toxicity to fish:
LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:
EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h

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

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:
NOEC (Daphnia magna (Water flea)): 1.2 mg/l
aquatic invertebrates (Chronic toxicity)  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
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Propylene glycol:
Biodegradability  : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

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

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

Bioaccumulative potential

Components:

Propylene glycol:
Partition coefficient: n-octanol/water  : log Pow: -1.07

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

Desogestrel:
Bioaccumulation  : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 128
SAFETY DATA SHEET

Desogestrel Formulation

Version 7.0  Revision Date: 2020/03/23  SDS Number: 21976-00018  Date of last issue: 2019/09/13  Date of first issue: 2014/10/15

Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water: log Pow: 3.5

Mobility in soil

Components:

Desogestrel:
Distribution among environmental compartments: log Koc: 2.84

Desogestrel:
Distribution among environmental compartments: log Koc: 2.84

Hazardous to the ozone layer
Not applicable

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. (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. (Desogestrel)
Class: 9
Packing group: III
Labels: Miscellaneous,
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes
SAFETY DATA SHEET

Desogestrel Formulation

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Desogestrel)
Class : 9
Subsidiary risk : ENVIRONM.
Packing group : III
Labels : 9 (ENVIRONM.)
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.

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

15. REGULATORY INFORMATION

Related Regulations

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

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane-1,2-diol</td>
<td>106</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

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

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable
Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium(IV) oxide</td>
<td>191</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Not applicable

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

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

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

Poisonous and Deleterious Substances Control Law
Not applicable

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

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

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

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

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Classified as marine pollutant

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

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable
Waste Disposal and Public Cleansing Law

Industrial waste

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

- AICS: not determined
- DSL: not determined
- IECSC: not determined

16. OTHER INFORMATION

Further information

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

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

Date format: yyyy/mm/dd

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average
- JP OEL JSOH / OEL-M: Occupational Exposure Limit-Mean

Abbreviations:
- AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evalua-
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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