

Desogestrel Formulation

Version 5.7 Revision Date: 16.10.2020 SDS Number: 21983-00019 Date of last issue: 23.03.2020
Date of first issue: 15.10.2014

Section 1: Identification

Product name : Desogestrel Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Section 2: Hazard identification**GHS Classification**

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate)

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.

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.
P281 Use personal protective equipment as required.

Response:

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

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|------------------|------------|-----------------------|
| Titanium dioxide | 13463-67-7 | < 1 |
| Desogestrel | 54024-22-5 | >= 0.01 -< 0.3 |

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 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.

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).

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Notes to physician : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

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

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : 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 (NO_x)

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.

Hazchem Code : 2Z

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 certain local or national requirements.

Section 7: Handling and storage

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- 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.
- 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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|------------------|------------|----------------------------------|--|----------|
| Titanium dioxide | 13463-67-7 | WES-TWA | 10 mg/m ³ | NZ OEL |
| | | TWA | 10 mg/m ³ (Titanium dioxide) | ACGIH |
| Desogestrel | 54024-22-5 | TWA | 0.04 µg/m ³ (OEB 5) | Internal |
| | | Wipe limit | 0.4 µg/100 cm ² | Internal |

- Engineering measures : Use closed processing systems or containment technologies

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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 | : | 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 | : | 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. |

Section 9: Physical and chemical properties

| | | |
|---|---|-------------------|
| Appearance | : | powder |
| Colour | : | white |
| 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 |

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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

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

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.

Particle size : 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.

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Components:**Titanium dioxide:**

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

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:**Titanium dioxide:**

| | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| Genotoxicity in vivo | : | Test Type: In vivo micronucleus test Species: Mouse Result: negative |

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 |

Carcinogenicity

Not classified based on available information.

Components:**Titanium dioxide:**

| | | |
|------------------------------|---|---|
| Species | : | Rat |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 2 Years |
| Method | : | OECD Test Guideline 453 |
| Result | : | positive |
| Remarks | : | The mechanism or mode of action may not be relevant in humans. |
| Carcinogenicity - Assessment | : | Limited evidence of carcinogenicity in inhalation studies with animals. |

Desogestrel:

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| Application Route | : | Oral |
| Exposure time | : | 104 weeks |

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Result : negative

Species : Mouse
 Application Route : Oral
 Exposure time : 81 weeks
 Result : negative

Reproductive toxicity

May damage fertility. Suspected of damaging 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.

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.

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Repeated dose toxicity**Components:****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 : 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

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

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Section 12: Ecological information**Ecotoxicity****Components:****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
- Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h

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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:****Desogestrel:**

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

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

Mobility in soil**Components:****Desogestrel:**

Distribution among environmental compartments : log Koc: 2.84

Other adverse effects

No data available

Section 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.

Section 14: Transport information**International Regulations****UNRTDG**

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

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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

IMDG-Code

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

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**NZS 5433**

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

Class : 9
Packing group : III
Labels : 9
Hazchem Code : 2Z

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

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

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HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

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

Section 16: Other information

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AllC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Develop-

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ment; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

NZ / EN