

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

---

### 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 Sub-stance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
30 Hudson Street, 33rd floor  
07302 Jersey City, New Jersey, U.S.A

Telephone : +1-551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

+1-215-631-6999

---

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Carcinogenicity, Category 1A	H350: May cause cancer.
Reproductive toxicity, Category 1B	H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1	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

---

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

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.  
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

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Desogestrel	54024-22-5	Repr. 1B; H360Fd	>= 0,1 - < 0,25

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

	258-929-4	STOT RE 1; H372 (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate) Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 10.000  specific concentra- tion limit Repr. 1B; H360Fd >= 0,01 % STOT RE 1; H372 >= 0,01 %	
Ethinylestradiol	57-63-6 200-342-2	Acute Tox. 4; H302 Carc. 1A; H350 Repr. 1B; H360FD STOT RE 1; H372 (Liver, Blood) Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 100.000  specific concentra- tion limit Carc. 1A; H350 >= 0,01 % Repr. 1B; H360FD >= 0,01 % STOT RE 1; H372 >= 0,01 %	>= 0,025 - < 0,1

For explanation of abbreviations see section 16.

### 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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.0	06.04.2024	19071-00026	Date of first issue: 06.10.2014

---

- 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 (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.0	06.04.2024	19071-00026	Date of first issue: 06.10.2014

---

### 5.2 Special hazards arising from the substance or mixture

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 (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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desogestrel / Ethinyl Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.0	06.04.2024	19071-00026	Date of first issue: 06.10.2014

---

### 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.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>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.<br>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:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases |

### 7.3 Specific end use(s)

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

Dust      5 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (respirable dust)  
Basis: FOR-2011-12-06-1358

10 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (total dust)  
Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Desogestrel	54024-22-5	TWA	0.04 µg/m <sup>3</sup> (OEB 5)	Internal
		Wipe limit	0.4 µg/100 cm <sup>2</sup>	Internal
Ethinylestradiol	57-63-6	TWA	0.01 µg/m <sup>3</sup> (OEB 5)	Internal
		Wipe limit	0.1 µg/100 cm <sup>2</sup>	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Stearic acid	Workers	Inhalation	Long-term systemic effects	17,63 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	4,348 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	5 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	2,5 mg/kg bw/day

#### 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/face 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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.0	06.04.2024	19071-00026	Date of first issue: 06.10.2014

---

Hand protection		Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
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. Equipment should conform to NS EN 143
Filter type	:	Particulates type (P)

---

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	White to light yellow
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
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
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

---

Decomposition temperature : No data available

pH : No data available

Viscosity  
Viscosity, kinematic : Not applicable

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-  
octanol/water : Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : 1 g/cm<sup>3</sup>

Relative vapour density : Not applicable

Particle characteristics  
Particle size : No data available

### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : Not applicable

---

## 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.0	06.04.2024	19071-00026	Date of first issue: 06.10.2014

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure : Inhalation  
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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

---

### 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 typhimurium  
Result: negative

|| : Test Type: Bacterial reverse mutation assay (AMES)  
Test system: Escherichia coli  
Result: negative

|| : Test Type: Chromosome aberration test in vitro  
Test system: Human lymphocytes  
Result: equivocal

|| Genotoxicity in vivo : Test Type: Chromosomal aberration  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Oral  
Result: positive

|| : Test Type: Micronucleus test  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Oral  
Result: negative

|| Germ cell mutagenicity- As- : Weight of evidence does not support classification as a germ

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

Assessment      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 off-

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

spring 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

---

|| 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desogestrel / Ethinyl Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.0	06.04.2024	19071-00026	Date of first issue: 06.10.2014

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.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

##### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### 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
------------------	--

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

	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 toxicity)	: 10.000

### 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



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desogestrel / Ethinyl Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.0	06.04.2024	19071-00026	Date of first issue: 06.10.2014

---

### 12.4 Mobility in soil

#### Components:

##### **Desogestrel:**

|| Distribution among environmental compartments : log K<sub>oc</sub>: 2,84

##### **Ethinylestradiol:**

|| Distribution among environmental compartments : log K<sub>oc</sub>: 3,86

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

---

## 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.  
Do not dispose of waste into sewer.

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 or ID number

ADN : UN 3077  
ADR : UN 3077  
RID : UN 3077

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

---

**IMDG** : UN 3077

**IATA** : UN 3077

### 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Ethinylestradiol, Desogestrel)

**ADR** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Ethinylestradiol, Desogestrel)

**RID** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Ethinylestradiol, Desogestrel)

**IMDG** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Ethinylestradiol, Desogestrel)

**IATA** : Environmentally hazardous substance, solid, n.o.s.  
(Ethinylestradiol, Desogestrel)

### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
<b>ADN</b>	: 9	
<b>ADR</b>	: 9	
<b>RID</b>	: 9	
<b>IMDG</b>	: 9	
<b>IATA</b>	: 9	

### 14.4 Packing group

**ADN**  
Packing group : III  
Classification Code : M7  
Hazard Identification Number : 90  
Labels : 9

**ADR**  
Packing group : III  
Classification Code : M7  
Hazard Identification Number : 90  
Labels : 9  
Tunnel restriction code : (-)

**RID**  
Packing group : III  
Classification Code : M7  
Hazard Identification Number : 90  
Labels : 9

**IMDG**

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.0	06.04.2024	19071-00026	Date of first issue: 06.10.2014

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 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:  
Number on list 75  
Substance(s) or mixture(s) are listed here according to their appearance

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014



in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

If you intend to use this product as tattoo ink, please contact your vendor.

- REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable
- REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
- Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
- Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

### 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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Desogestrel / Ethinyl Estradiol Formulation

Version 4.0      Revision Date: 06.04.2024      SDS Number: 19071-00026      Date of last issue: 26.09.2023  
Date of first issue: 06.10.2014

### 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  
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits  
FOR-2011-12-06-1358 / : Long term exposure limit  
TWA

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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 Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Desogestrel / Ethinyl Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.0	06.04.2024	19071-00026	Date of first issue: 06.10.2014

---

### 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/>

### Classification of the mixture:

Carc. 1A	H350
Repr. 1B	H360FD
STOT RE 1	H372
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

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

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.

NO / EN