

## Desogestrel / Ethinyl Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.0	06.04.2024	19078-00026	Date of first issue: 06.10.2014

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**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 : PharmaceuticalRecommended 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

Hazard statements : H350 May cause cancer.

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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.

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	54024-22-5 258-929-4	Repr. 1B; H360Fd STOT RE 1; H372 (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate) Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 10.000	>= 0,1 - < 0,25

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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	$\geq 0,025 - < 0,1$
		M-Factor (Chronic aquatic toxicity): 100.000	

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.  
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.

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**4.3 Indication of any immediate medical attention and special treatment needed**

Treatment : Treat symptomatically and supportively.

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**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.

**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 (NO<sub>x</sub>)

**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.

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**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.

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**6.3 Methods and material for containment and cleaning up**

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

**6.4 Reference to other sections**

See sections: 7, 8, 11, 12 and 13.

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**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

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

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

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

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

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**7.2 Conditions for safe storage, including any incompatibilities**

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

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

**7.3 Specific end use(s)**

Specific use(s) : No data available

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Starch	9005-25-8	OEL-RL	10 mg/m <sup>3</sup>	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
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.

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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. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Particulates type (P)

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**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

Appearance	:	powder
Colour	:	White to light yellow
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available

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Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	1 g/cm <sup>3</sup>
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

**9.2 Other information**

Flammability (liquids)	:	No data available
Particle size	:	No data available

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**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.
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**10.4 Conditions to avoid**

Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
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**10.5 Incompatible materials**

Materials to avoid	:	Oxidizing agents
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**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.



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**SECTION 11: Toxicological information****11.1 Information on toxicological effects**

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

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

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**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- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**Carcinogenicity**

May cause cancer.

**Components:****Desogestrel:**

||Species : Rat

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Application Route : Oral  
Exposure time : 104 weeks  
Result : negative

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

**Ethinylestradiol:**

Species : Rat, male and female  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

Species : Monkey, female  
Application Route : Oral  
Exposure time : 10 Years  
Result : negative

Carcinogenicity - Assessment : Positive evidence from human epidemiological studies

**Reproductive toxicity**

May damage fertility. May damage the unborn child.

**Components:****Desogestrel:**

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

Test Type: Fertility/early embryonic development  
Species: Rat, female  
Fertility: NOAEL Parent: 0,5 mg/kg body weight  
Result: No effects on fertility

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

Test Type: Embryo-foetal development  
Species: Rat, female  
Application Route: Oral  
Embryo-foetal toxicity: LOAEC Parent: 0,125 mg/kg body weight  
Result: No teratogenic effects

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

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effects on development, based on animal experiments.

**Ethinylestradiol:**

- |                                    |   |   |
|------------------------------------|---|---|
| Effects on fertility               | : | Species: Hamster<br>Fertility: LOAEL: 6,3 mg/kg body weight<br>Result: Effects on fertility   |
| Effects on foetal development      | : | Test Type: Four-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: > 0,006 mg/kg body weight<br>Result: Specific developmental abnormalities               |
|                                    |   | Test Type: Two-generation reproduction toxicity study<br>Species: Rat, male and female<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 0,005 mg/kg body weight<br>Result: Specific developmental abnormalities |
| Reproductive toxicity - Assessment | : | Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.  |

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Causes damage to organs through prolonged or repeated exposure.

**Components:****Desogestrel:**

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

**Ethinylestradiol:**

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

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

- |                   |   |  |
|-------------------|---|--|
| Species           | : | Rat, female  |
| LOAEL             | : | 0,00625 mg/kg  |
| Application Route | : | Oral   |
| Exposure time     | : | 26 Weeks   |
| Target Organs     | : | Pituitary gland, Uterus (including cervix), Ovary, Mammary gland |

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

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

**Ethinylestradiol:**

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

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

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

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

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Desogestrel:**

Ingestion : Symptoms: Headache, changes in libido, Dizziness, Nausea, Vomiting, Diarrhoea, water retention, sodium retention, Gas-

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trointestinal 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
Toxicity to daphnia and other aquatic invertebrates	:	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 microorganisms	:	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)	:	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
Toxicity to fish (Chronic toxicity)	:	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
Toxicity to fish (Chronic toxicity)	:	NOEC: 0,0000027 mg/l
		Exposure time: 183 d Species: Oryzias latipes (Japanese medaka)

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	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
<b>Ethinylestradiol:</b>	
Toxicity to fish	: LC50 (Lepomis macrochirus (Bluegill sunfish)): 1,6 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 6,7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC (Pseudokirchneriella subcapitata (green algae)): 6,7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	: EC50 : > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209  NOEC : 24,9 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	: NOEC: 0,01 µg/l Exposure time: 35 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210  NOEC: 0,00031 µg/l Exposure time: 339 d Species: Zebrafish
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 0,75 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	: 100.000

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**12.2 Persistence and degradability****Components:****Desogestrel:**

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

**12.3 Bioaccumulative potential****Components:****Desogestrel:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): 128  
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: 3,5

**Ethinylestradiol:**

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

Partition coefficient: n-octanol/water : log Pow: 4,15

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

Distribution among environmental compartments : log Koc: 2,84

**Ethinylestradiol:**

Distribution among environmental compartments : log Koc: 3,86

**12.5 Results of PBT and vPvB assessment****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 Other adverse effects****Product:**

Endocrine disrupting potential : 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.



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**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**

- ADN : UN 3077
- ADR : UN 3077
- RID : UN 3077
- 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 |
|------|-------|------------------|
| ADN  | : 9   |                  |
| ADR  | : 9   |                  |
| RID  | : 9   |                  |
| IMDG | : 9   |                  |

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**IATA** : 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**

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

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**14.6 Special precautions for user**

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

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Remarks : Not applicable for product as supplied.

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**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

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

**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

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**SECTION 16: Other information**

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

**Full text of H-Statements**

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

**Full text of other abbreviations**

Acute Tox.	:	Acute toxicity
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Carc.	:	Carcinogenicity
Repr.	:	Reproductive toxicity
STOT RE	:	Specific target organ toxicity - repeated exposure
ZA OEL	:	South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL-RL	:	Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by

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Road; AIIIC - 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

**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

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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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