

Desogestrel / Ethinyl Estradiol Formulation

Version 2.5 Revision Date: 09.04.2021 SDS Number: 19078-00019 Date of last issue: 16.10.2020
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

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 : 551-430-6000

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

1.4 Emergency telephone number

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.
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.

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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 |
| Ethinylestradiol | 57-63-6 200-342-2 | Acute Tox. 4; H302 Carc. 1A; H350 Repr. 1B; H360FD STOT RE 1; H372 (Liver, Blood) | >= 0,025 - < 0,1 |

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|--|--|--|--|
| | | Aquatic Chronic 1; H410 | |
| | | 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.

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 (CO₂)
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_x)

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).

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Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

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

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

- | | | |
|-------------------------|---|--|
| Technical measures | : | Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types: |

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Strong oxidizing agents
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

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

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|--|------------|-------------------------------|--------------------------------|----------|
| Starch | 9005-25-8 | TWA OEL-RL (Respirable dust) | 5 mg/m ³ | ZA OEL |
| Further information: Recommended Limit | | | | |
| | | TWA OEL-RL (inhalable dust) | 10 mg/m ³ | ZA OEL |
| Further information: Recommended Limit | | | | |
| Desogestrel | 54024-22-5 | TWA | 0.04 µg/m ³ (OEB 5) | Internal |
| | | Wipe limit | 0.4 µg/100 cm ² | Internal |
| Ethinylestradiol | 57-63-6 | TWA | 0.01 µg/m ³ (OEB 5) | Internal |
| | | Wipe limit | 0.1 µg/100 cm ² | 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 ³ |
| | Workers | Skin contact | Long-term systemic effects | 10 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 4,348 mg/m ³ |
| | 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.

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Personal protective equipment

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

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

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

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

9.2 Other information

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

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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

10.4 Conditions to avoid

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

10.5 Incompatible materials

| | | |
|--------------------|---|------------------|
| Materials to avoid | : | Oxidizing agents |
|--------------------|---|------------------|

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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

Information on likely routes of : Inhalation

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exposure

Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:**Desogestrel:**

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

Ethinylestradiol:

Acute oral toxicity : LD50 (Rat): 1.200 mg/kg
LD50 (Mouse): 1.737 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Not classified based on available information.

Components:**Ethinylestradiol:**

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Ethinylestradiol:**

Remarks : No data available

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Ethinylestradiol:**

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

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

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

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Ethinylestradiol:

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

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

Carcinogenicity - Assessment : Positive evidence from human epidemiological studies

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:**Desogestrel:**

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

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

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

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

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

Ethinylestradiol:

Effects on fertility : Species: Hamster
 Fertility: LOAEL: 6,3 mg/kg body weight
 Result: Effects on fertility

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Effects on foetal development : Test Type: Four-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: > 0,006 mg/kg body weight
Result: Specific developmental abnormalities

Test Type: Two-generation reproduction toxicity study
Species: Rat, male and female
Application Route: Oral
Developmental Toxicity: LOAEL: 0,005 mg/kg body weight
Result: Specific developmental abnormalities

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:**Desogestrel:**

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

Ethinylestradiol:

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

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

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

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

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

Ethinylestradiol:

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

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

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

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

Aspiration toxicity

Not classified based on available information.

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

Ingestion : Symptoms: Headache, changes in libido, Dizziness, Nausea, Vomiting, Diarrhoea, water retention, sodium retention, Gastrointestinal discomfort, mental depression, amenorhea, 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

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change, water retention, hair loss, gynecomastia, effects on menstruation

SECTION 12: Ecological information**12.1 Toxicity****Components:****Desogestrel:**

- | | | |
|--|---|--|
| Toxicity to fish | : | <p>LC50 (Oncorhynchus mykiss (rainbow trout)): 4 mg/l Exposure time: 96 h Method: FDA 4.11 Remarks: Based on data from similar materials</p> <p>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</p> |
| Toxicity to daphnia and other aquatic invertebrates | : | <p>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</p> |
| Toxicity to microorganisms | : | <p>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</p> <p>NOEC : 70,8 mg/l Exposure time: 3 h Test Type: Respiration inhibition Remarks: Based on data from similar materials</p> |
| Toxicity to fish (Chronic toxicity) | : | <p>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</p> <p>NOEC: 0,0000027 mg/l Exposure time: 183 d Species: Oryzias latipes (Japanese medaka) Remarks: Based on data from similar materials</p> |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | <p>NOEC: 1,2 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Remarks: Based on data from similar materials</p> |
| M-Factor (Chronic aquatic | : | 10.000 |

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toxicity)

Ethinylestradiol:

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

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

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

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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.

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.

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Contaminated packaging : Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
 : 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)

ADN : 9
 ADR : 9
 RID : 9
 IMDG : 9
 IATA : 9

14.4 Packing group

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

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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

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.

SECTION 16: Other information

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

Full text of H-Statements

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

Full text of other abbreviations

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

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

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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; 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 |

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

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