

SAFETY DATA SHEET



Etonogestrel / Ethinyl Estradiol Formulation



Version 7.9 Revision Date: 26.09.2023 SDS Number: 16762-00023 Date of last issue: 20.03.2023
Date of first issue: 29.09.2014

SECTION 1. IDENTIFICATION

Product name : Etonogestrel / Ethinyl Estradiol Formulation

Manufacturer or supplier's details

Company : Organon & Co.

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

Telephone : 1-551-430-6000

Emergency telephone : 1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Carcinogenicity : Category 1A

Reproductive toxicity : Category 1A

Specific target organ toxicity - repeated exposure : Category 1 (Liver, Blood)

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

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 (Liver, Blood) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**

Etonogestrel / Ethinyl Estradiol Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 7.9 | 26.09.2023 | 16762-00023 | Date of first issue: 29.09.2014 |

P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.
 Contact with dust can cause mechanical irritation or drying of the skin.
 May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|------------|-----------------------|
| (17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one | 54048-10-1 | $\geq 0,3$ -< 1 |
| Ethinylestradiol | 57-63-6 | $\geq 0,1$ -< 0,25 |

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
 When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
 Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
 Remove contaminated clothing and shoes.
 Get medical attention.
 Wash clothing before reuse.
 Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.
 Get medical attention if irritation develops and persists.

Etonogestrel / Ethinyl Estradiol Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 7.9 | 26.09.2023 | 16762-00023 | Date of first issue: 29.09.2014 |

| | | |
|---|---|---|
| If swallowed | : | If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : | May 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. |
| Protection of first-aiders | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| Notes to physician | : | Treat symptomatically and supportively. |

SECTION 5. FIRE-FIGHTING MEASURES

| | | |
|--|---|---|
| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. |
| Methods and materials for containment and cleaning up | : | Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are |

Etonogestrel / Ethinyl Estradiol Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 7.9 | 26.09.2023 | 16762-00023 | Date of first issue: 29.09.2014 |

released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

- 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, fume, gas, mist, vapors or spray.
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.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|------------|----------------------------------|--|----------|
| (17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one | 54048-10-1 | TWA | 0.05 $\mu\text{g}/\text{m}^3$ (OEB 5) | Internal |

Etonogestrel / Ethinyl Estradiol Formulation

Version 7.9 Revision Date: 26.09.2023 SDS Number: 16762-00023 Date of last issue: 20.03.2023
 Date of first issue: 29.09.2014

| | | | | |
|------------------|---------|------------|--------------------------------|----------|
| | | Wipe limit | 0.5 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 |

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

Personal protective equipment

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

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

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

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid

SAFETY DATA SHEET



Etonogestrel / Ethinyl Estradiol Formulation



Version 7.9 Revision Date: 26.09.2023 SDS Number: 16762-00023 Date of last issue: 20.03.2023
Date of first issue: 29.09.2014

| | | |
|--|---|---|
| Color | : | white |
| Odor | : | odorless |
| Odor Threshold | : | No data available |
| pH | : | Not applicable |
| Melting point/freezing point | : | Not applicable |
| Initial boiling point and boiling range | : | Not applicable |
| Flash point | : | Not applicable |
| Evaporation rate | : | Not applicable |
| 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 | : | Not applicable |
| Lower explosion limit / Lower flammability limit | : | Not applicable |
| Vapor pressure | : | Not applicable |
| Relative vapor density | : | Not applicable |
| Relative density | : | No data available |
| Density | : | 1 g/cm ³ |
| Solubility(ies) Water solubility | : | insoluble |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Autoignition 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. |
| Molecular weight | : | No data available |

Etonogestrel / Ethinyl Estradiol Formulation

Version 7.9 Revision Date: 26.09.2023 SDS Number: 16762-00023 Date of last issue: 20.03.2023
Date of first issue: 29.09.2014

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.
Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:**(17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
LD50 (Mouse): > 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:**(17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

Species : Mouse
Result : No skin irritation

Species : Guinea pig
Result : No skin irritation

Etonogestrel / Ethinyl Estradiol Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 7.9 | 26.09.2023 | 16762-00023 | Date of first issue: 29.09.2014 |

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 sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Ethinylestradiol:**

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:**(17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**Genotoxicity in vitro : Test Type: reverse mutation assay
Test system: Salmonella typhimurium
Result: negativeTest Type: in vitro test
Test system: Chinese hamster ovary cells
Result: negativeGenotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

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

Ethinylestradiol:Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Test system: Salmonella typhimurium
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Etonogestrel / Ethinyl Estradiol Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 7.9 | 26.09.2023 | 16762-00023 | Date of first issue: 29.09.2014 |

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:**(17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

Species : Rat
Application Route : Oral
Activity duration : 2 y
: 0,5 mg/kg body weight
Result : negative

Species : Rat
Application Route : Subcutaneous
Activity duration : 2 y
: 0,02 mg/kg body weight
Result : negative

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

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

Etonogestrel / Ethinyl Estradiol Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 7.9 | 26.09.2023 | 16762-00023 | Date of first issue: 29.09.2014 |

Carcinogenicity - Assessment : Positive evidence from human epidemiological studies

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:**(17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

Effects on fertility : Test Type: Fertility
Species: Rat, female
Application Route: Oral
Fertility: LOAEL: 0,012 mg/kg body weight
Result: Effects on fertility.

Test Type: Fertility
Species: Rabbit, female
Application Route: Oral
Dose: 0.05 milligram per kilogram
Result: Effects on fertility.

Effects on fetal development : Species: Rat, female
Duration of Single Treatment: 14 d
General Toxicity Maternal: NOAEL: 1,8 mg/kg body weight
Result: No teratogenic effects.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies.

Ethinylestradiol:

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

Effects on fetal 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.

Etonogestrel / Ethinyl Estradiol Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 7.9 | 26.09.2023 | 16762-00023 | Date of first issue: 29.09.2014 |

STOT-repeated exposure

Causes damage to organs (Liver, Blood) through prolonged or repeated exposure.

Components:**Ethinylestradiol:**

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

Repeated dose toxicity**Components:****(17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

| | | |
|-------------------|---|---------------------------------------|
| Species | : | Rat |
| LOAEL | : | 0,5 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 1 y |
| Target Organs | : | Reproductive organs, Endocrine system |

| | | |
|-------------------|---|---------------------------------------|
| Species | : | Dog |
| LOAEL | : | 0,625 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 26 Weeks |
| Target Organs | : | Reproductive organs, Endocrine system |

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 y |
| Target Organs | : | Reproductive organs, Mammary gland, Liver, Uterus (includ- |

Etonogestrel / Ethinyl Estradiol Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 7.9 | 26.09.2023 | 16762-00023 | Date of first issue: 29.09.2014 |

ing cervix)

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****(17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

Inhalation : Symptoms: Headache, Dizziness, Abdominal pain, Nausea, Skin disorders, effects on menstruation, vaginitis, breast tenderness, mood swings, male reproductive effects, Sweating

Ethinylestradiol:

Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea, Headache, Dizziness, mood swings, Edema, liver function change, water retention, hair loss, gynecomastia, effects on menstruation

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****(17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4,0 mg/l
Exposure time: 96 h
Method: FDA 4.11

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.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 3,9 mg/l
Exposure time: 48 h
Method: FDA 4.08
Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0,059 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

NOEC (Oryzias latipes (Japanese medaka)): 0,0000027 mg/l
Exposure time: 183 d
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1,2 mg/l
Exposure time: 21 d

M-Factor (Chronic aquatic toxicity) : 10.000

Toxicity to microorganisms : NOEC: 70,8 mg/l

Etonogestrel / Ethinyl Estradiol Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 7.9 | 26.09.2023 | 16762-00023 | Date of first issue: 29.09.2014 |

Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

EC50: > 1.000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

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 fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0,01 µg/l
 Exposure time: 35 d
 Method: OECD Test Guideline 210
- NOEC (Zebrafish): 0,00031 µg/l
 Exposure time: 339 d
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0,75 mg/l
 Exposure time: 21 d
 Method: OECD Test Guideline 211
- M-Factor (Chronic aquatic toxicity) : 100.000
- 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

Persistence and degradability**Components:****(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

- Stability in water : Hydrolysis: < 10 %(5 d)
 Method: FDA 3.09

Etonogestrel / Ethinyl Estradiol Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 7.9 | 26.09.2023 | 16762-00023 | Date of first issue: 29.09.2014 |

Bioaccumulative potential**Components:****(17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 128
Method: OECD Test Guideline 305

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

Mobility in soil**Components:****(17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

Distribution among environmental compartments : log Koc: 2,84
Method: FDA 3.08

Ethinylestradiol:

Distribution among environmental compartments : log Koc: 3,86

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ethinylestradiol, (17 α)-13-Ethyl-17-hydroxy-11-methylene-

Etonogestrel / Ethinyl Estradiol Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 7.9 | 26.09.2023 | 16762-00023 | Date of first issue: 29.09.2014 |

18,19-dinorpregn-4-en-20-yn-3-one)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Ethinylestradiol, (17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)

Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ethinylestradiol, (17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)

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

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

Not applicable for product as supplied.

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

Etonogestrel / Ethinyl Estradiol Formulation

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|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023 |
| 7.9 | 26.09.2023 | 16762-00023 | Date of first issue: 29.09.2014 |

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 26.09.2023
Date format : dd.mm.yyyy

Further information

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

Full text of other abbreviations

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the

SAFETY DATA SHEET



Etonogestrel / Ethinyl Estradiol Formulation



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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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