

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

---

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Etonogestrel Formulation (Nexplanon)  
Product code : NEXPLANON

#### 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 : EHSSTEWART@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)

Reproductive toxicity, Category 1A	H360F: May damage fertility.
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 : H360F May damage fertility.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P273 Avoid release to the environment.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version 2.5      Revision Date: 09.04.2021      SDS Number: 16628-00020      Date of last issue: 10.10.2020  
Date of first issue: 29.09.2014

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.

### Hazardous components which must be listed on the label:

(17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one

### 2.3 Other hazards

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

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

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

Dust contact with the eyes can lead to mechanical irritation.

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

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

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
(17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one	54048-10-1 258-936-2	Repr. 1A; H360F Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 10,000	$\geq 30$ - $< 50$
Substances with a workplace exposure limit :			
Barium sulfate	7727-43-7 231-784-4		$\geq 10$ - $< 20$

For explanation of abbreviations see section 16.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

---

---

### 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 damage fertility.
- Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.

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

- Treatment : Treat symptomatically and supportively.

---

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing : None known.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

---

media

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

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Metal oxides  
Sulphur oxides  
Carbon oxides

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

---

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

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

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

---

### 6.4 Reference to other sections

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

---

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

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

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

- |   |   |   |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Organic peroxides<br>Explosives<br>Gases                     |

### 7.3 Specific end use(s)

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version 2.5      Revision Date: 09.04.2021      SDS Number: 16628-00020      Date of last issue: 10.10.2020  
Date of first issue: 29.09.2014

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
(17 $\alpha$ )-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
		Wipe limit	0.5 $\mu\text{g}/100 \text{ cm}^2$	Internal
Barium sulfate	7727-43-7	OELV - 8 hrs (TWA) (Respirable dust)	5 $\text{mg}/\text{m}^3$	IE OEL
	Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used			
		TWA	0.5 $\text{mg}/\text{m}^3$ (Barium)	2006/15/EC
	Further information: Indicative			

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Barium sulfate	Workers	Inhalation	Long-term local effects	10 $\text{mg}/\text{m}^3$
	Workers	Inhalation	Long-term systemic effects	10 $\text{mg}/\text{m}^3$
	Consumers	Inhalation	Long-term systemic effects	10 $\text{mg}/\text{m}^3$
	Consumers	Ingestion	Long-term systemic effects	13000 $\text{mg}/\text{kg bw}/\text{day}$

##### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Barium sulfate	Fresh water	0.115 $\text{mg}/\text{l}$
	Sewage treatment plant	62.2 $\text{mg}/\text{l}$
	Fresh water sediment	600.4 $\text{mg}/\text{kg dry weight (d.w.)}$
	Soil	207.7 $\text{mg}/\text{kg dry weight (d.w.)}$

#### 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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

### Personal protective equipment

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. Equipment should conform to I.S. EN 143
Filter type	:	Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	:	Solid form
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

Decomposition temperature  
Decomposition temperature : No data available

pH : No data available

Viscosity  
Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Relative density : No data available

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

Relative vapour density : No data available

Particle characteristics  
Particle size : No data available

### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : 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.



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

---

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

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

#### Acute toxicity

Not classified based on available information.

#### Components:

##### **(17 $\alpha$ )-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

#### **Barium sulfate:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

#### **Skin corrosion/irritation**

Not classified based on available information.

#### Components:

##### **(17 $\alpha$ )-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

#### **Barium sulfate:**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439  
Remarks : Based on data from similar materials

Result : No skin irritation

#### **Serious eye damage/eye irritation**

Not classified based on available information.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

---

### Components:

#### **Barium sulfate:**

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : No eye irritation

#### **Respiratory or skin sensitisation**

##### **Skin sensitisation**

Not classified based on available information.

##### **Respiratory sensitisation**

Not classified based on available information.

### Components:

#### **Barium sulfate:**

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative  
Remarks : Based on data from similar materials

#### **Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### **(17 $\alpha$ )-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: negative

Test Type: in vitro assay  
Test system: Chinese hamster ovary cells  
Result: negative

Genotoxicity 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.

#### **Barium sulfate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

---

Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

### Carcinogenicity

Not classified based on available information.

#### Components:

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

Species : Rat  
Application Route : Oral  
Activity duration : 2 yr  
: 0.5 mg/kg body weight  
Result : negative

Species : Rat  
Application Route : Subcutaneous  
Activity duration : 2 yr  
: 0.02 mg/kg body weight  
Result : negative

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

#### **Barium sulfate:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative  
Remarks : Based on data from similar materials

### Reproductive toxicity

May damage fertility.

#### Components:

##### **(17 $\alpha$ )-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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version 2.5      Revision Date: 09.04.2021      SDS Number: 16628-00020      Date of last issue: 10.10.2020  
Date of first issue: 29.09.2014

---

Effects on foetal 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.

### Barium sulfate:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative  
Remarks: Based on data from similar materials

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### Barium sulfate:

Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

### Repeated dose toxicity

#### Components:

#### (17 $\alpha$ )-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 yr  
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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

### Barium sulfate:

Species	:	Rat
NOAEL	:	61.1 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Remarks	:	Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

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

### Experience with human exposure

#### Components:

#### **(17 $\alpha$ )-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
------------	---	--

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

#### **(17 $\alpha$ )-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 microorganisms	:	NOEC : 70.8 mg/l Exposure time: 3 h
----------------------------	---	--

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version 2.5      Revision Date: 09.04.2021      SDS Number: 16628-00020      Date of last issue: 10.10.2020  
Date of first issue: 29.09.2014

---

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

Toxicity to fish (Chronic toxicity) : NOEC: 0.059 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

NOEC: 0.0000027 mg/l  
Exposure time: 183 d  
Species: Oryzias latipes (Japanese medaka)  
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1.2 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity) : 10,000

**Barium sulfate:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10 - 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50 : > 600 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials

NOEC : > 600 mg/l  
Exposure time: 3 h

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC: > 1 mg/l  
Exposure time: 33 d  
Species: Danio rerio (zebra fish)  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: > 1 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Remarks: Based on data from similar materials

### 12.2 Persistence and degradability

#### Components:

##### **(17 $\alpha$ )-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

### 12.3 Bioaccumulative potential

#### Components:

##### **(17 $\alpha$ )-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

#### **Barium sulfate:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): < 500

Partition coefficient: n-octanol/water : log Pow: -1.03  
Remarks: Calculation

### 12.4 Mobility in soil

#### Components:

##### **(17 $\alpha$ )-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

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

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

### 12.7 Other adverse effects

No data available

## 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.

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

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADN : UN 3077  
ADR : UN 3077  
RID : UN 3077  
IMDG : UN 3077  
IATA : UN 3077

### 14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
((17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
((17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

---

**IMDG** : N.O.S.  
((17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)  
: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
((17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)

**IATA** : Environmentally hazardous substance, solid, n.o.s.  
((17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)

### 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  
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 (passen- : 956

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

ger aircraft)  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

### 14.5 Environmental hazards

**ADN**  
Environmentally hazardous : yes

**ADR**  
Environmentally hazardous : yes

**RID**  
Environmentally hazardous : yes

**IMDG**  
Marine pollutant : yes

**IATA (Passenger)**  
Environmentally hazardous : yes

**IATA (Cargo)**  
Environmentally hazardous : yes

### 14.6 Special precautions for user

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

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
----	-----------------------	---------------------	---------------------

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

### 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

H360F : May damage fertility.

H410 : Very toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard

Repr. : Reproductive toxicity

2006/15/EC : Europe. Indicative occupational exposure limit values

IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1

2006/15/EC / TWA : Limit Value - eight hours

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

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; 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16628-00020	Date of first issue: 29.09.2014

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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; 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:

Repr. 1A	H360F
Aquatic Chronic 1	H410

### Classification procedure:

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.

IE / EN