

## Etonogestrel Formulation (Nexplanon)

Version 3.16      Revision Date: 09.04.2021      SDS Number: 16642-00020      Date of last issue: 10.10.2020  
Date of first issue: 29.09.2014

---

**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Etonogestrel Formulation (Nexplanon)

Product code : NEXPLANON

**Manufacturer or supplier's details**

Company : Organon & Co.

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

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

---

**2. HAZARDS IDENTIFICATION****GHS Classification**

Reproductive toxicity : Category 1A

Long-term (chronic) aquatic hazard : Category 1

**GHS label elements**

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.  
P202 Do not handle until all safety precautions have been read and understood.  
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.

---

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.16	09.04.2021	16642-00020	Date of first issue: 29.09.2014

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.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
(17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one	54048-10-1	>= 30 -< 50
Barium sulfate	7727-43-7	>= 10 -< 20

**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.
- 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 damage fertility.  
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.

**5. FIREFIGHTING MEASURES**

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.16	09.04.2021	16642-00020	Date of first issue: 29.09.2014

---

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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 : Metal oxides  
Sulphur oxides  
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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
- 

**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 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.
- 

**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

## Etonogestrel Formulation (Nexplanon)

Version 3.16      Revision Date: 09.04.2021      SDS Number: 16642-00020      Date of last issue: 10.10.2020  
Date of first issue: 29.09.2014

- ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not breathe vapours.  
Do not swallow.  
Avoid contact with eyes.  
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.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labelled 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

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	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	PEL (long term)	10 $\text{mg}/\text{m}^3$	SG OEL
		TWA (Inhalable particulate matter)	5 $\text{mg}/\text{m}^3$	ACGIH

- 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.

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.16	09.04.2021	16642-00020	Date of first issue: 29.09.2014

---

**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.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

- Appearance : Solid form
- Colour : No data available
- 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 : No data available
- Evaporation rate : No data available
- Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

# SAFETY DATA SHEET



## Etonogestrel Formulation (Nexplanon)



Version 3.16      Revision Date: 09.04.2021      SDS Number: 16642-00020      Date of last issue: 10.10.2020  
Date of first issue: 29.09.2014

---

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

---

### 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.

## Etonogestrel Formulation (Nexplanon)

Version            Revision Date:            SDS Number:            Date of last issue: 10.10.2020  
3.16                09.04.2021                16642-00020            Date of first issue: 29.09.2014

---

**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 $\alpha$ )-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.

**Components:****Barium sulfate:**

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

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

Not classified based on available information.

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.16	09.04.2021	16642-00020	Date of first issue: 29.09.2014

---

**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 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.



## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.16	09.04.2021	16642-00020	Date of first issue: 29.09.2014

---

**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

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

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.16	09.04.2021	16642-00020	Date of first issue: 29.09.2014

---

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

**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.

## Etonogestrel Formulation (Nexplanon)

Version 3.16      Revision Date: 09.04.2021      SDS Number: 16642-00020      Date of last issue: 10.10.2020  
Date of first issue: 29.09.2014

**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

**12. ECOLOGICAL INFORMATION****Ecotoxicity****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 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  
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

**Barium sulfate:**

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.16	09.04.2021	16642-00020	Date of first issue: 29.09.2014

---

- 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 fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): > 1 mg/l  
Exposure time: 33 d  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): > 1 mg/l  
Exposure time: 21 d  
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  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials

**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

**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)

## Etonogestrel Formulation (Nexplanon)

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.16	09.04.2021	16642-00020	Date of first issue: 29.09.2014

---

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

**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

**Other adverse effects**

No data available

---

**13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : 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.

---

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

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
((17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)  
Class : 9  
Packing group : III  
Labels : 9

**IATA-DGR**

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
((17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)  
Class : 9  
Packing group : III  
Labels : Miscellaneous

# SAFETY DATA SHEET



## Etonogestrel Formulation (Nexplanon)



Version 3.16      Revision Date: 09.04.2021      SDS Number: 16642-00020      Date of last issue: 10.10.2020  
Date of first issue: 29.09.2014

---

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.  
((17 $\alpha$ )-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.

---

## 15. REGULATORY INFORMATION

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

#### Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations : Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

# SAFETY DATA SHEET



## Etonogestrel Formulation (Nexplanon)



Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.16	09.04.2021	16642-00020	Date of first issue: 29.09.2014

---

### 16. OTHER INFORMATION

#### 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/>

Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
SG OEL : Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances

ACGIH / TWA : 8-hour, time-weighted average  
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AIIC - 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; 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 SDS material is used in combination with any other materials or in any process, unless specified in the text.

# SAFETY DATA SHEET



## Etonogestrel Formulation (Nexplanon)



Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.16	09.04.2021	16642-00020	Date of first issue: 29.09.2014

---

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.

SG / EN