

ORGANON

# **Etonogestrel Formulation (Nexplanon)**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

 4.16
 09.04.2021
 16609-00020
 Date of first issue: 29.09.2014

#### **SECTION 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, 33nd 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

## **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Reproductive toxicity : Category 1A

**GHS label elements** 

Hazard pictograms :

Signal word : Danger

Hazard statements : H360F May damage fertility.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P281 Use personal protective equipment as required.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste



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disposal plant.

#### Other hazards which do not result in classification

Dust contact with the eves 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)
(17α)-13-Ethyl-17-hydroxy-11-methylene-	54048-10-1	>= 30 -< 60
18,19-dinorpregn-4-en-20-yn-3-one		
Barium sulfate	7727-43-7	>= 10 -< 30

#### **SECTION 4. FIRST AID MEASURES**

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

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).

Treat symptomatically and supportively.

Notes to physician

### **SECTION 5. FIREFIGHTING MEASURES**

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

delayed

None known.



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Specific hazards during fire-

fighting

Hazardous combustion prod-

ucts

•

Metal oxides Sulphur oxides

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

Exposure to combustion products may be a hazard to health.

cumstances 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.

Hazchem Code : 2Z

## **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer 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 deter-

mine 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. Do not breathe vapours.

Do not swallow.







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Avoid contact with eyes.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

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.

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.

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

### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis	
		exposure)	concentration		
(17α)-13-Ethyl-17-hydroxy-11- methylene-18,19-dinorpregn-4- en-20-yn-3-one	54048-10-1	TWA	0.05 µg/m3 (OEB 5)	Internal	
		Wipe limit	0.5 µg/100 cm <sup>2</sup>	Internal	
Barium sulfate	7727-43-7	TWA	10 mg/m3	AU OEL	
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica				
		TWA (Inhal-	5 mg/m3	ACGIH	
		able particu-			
		late matter)			

**Engineering measures** : Use closed processing systems or containment technologies

to control at source (e.g., glove boxes/isolators) and to pre-

vent 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



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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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

#### **SECTION 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-

dling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper : No data available



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flammability limit

Lower explosion limit / Lower :

flammability limit

No data available

No data available Vapour pressure

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

# **SECTION 10. STABILITY AND REACTIVITY**

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Avoid dust formation. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

Exposure routes Inhalation

Skin contact



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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.

Respiratory sensitisation

Not classified based on available information.



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#### **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

### **Chronic toxicity**

# 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
Regult: pagetive

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.



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#### Components:

(17α)-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 - Assess-

Weight of evidence does not support classification as a car-

cinogen

**Barium sulfate:** 

ment

**Species** Rat Inaestion **Application Route** Exposure time 2 Years Result negative

Based on data from similar materials Remarks

### 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 develop-

ment

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 - As-

sessment

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



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Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

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 concentra-

tions 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.



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#### **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**

#### **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 tox-

icity)

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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 1.2 mg/l

Exposure time: 21 d

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:** 

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l

Exposure time: 96 h



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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 tox-

icity)

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 (Chron-

in the inverte

ic 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:**

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

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)

Bioconcentration factor (BCF): 128 Method: OECD Test Guideline 305



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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

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

### **Disposal methods**

Waste from residues

Dispose of in accordance with local regulations.

Contaminated packaging : E

Empty containers should be taken to an approved waste han-

dling 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.

((17α)-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

Packing instruction (cargo

aircraft)

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Packing instruction (passen: :

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

956

((17α)-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.

## **National Regulations**

**ADG** 

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
Hazchem Code : 2Z

### 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

Prohibition/Licensing Requirements : There is no applicable prohibition,

authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regula-

tions.

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

AICS : not determined

DSL : not determined



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**IECSC** not determined

#### **SECTION 16. OTHER INFORMATION**

#### **Further information**

09.04.2021 **Revision Date** 

Sources of key data used to Internal technical data, data from raw material SDSs, OECD compile the Safety Data

eChem Portal search results and European Chemicals Agen-

Sheet cy, http://echa.europa.eu/

Date format dd.mm.yyyy

Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV)

AU OEL Australia. Workplace Exposure Standards for Airborne Con-

taminants.

ACGIH / TWA 8-hour, time-weighted average

AU OEL / TWA Exposure standard - time weighted average

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



# **Etonogestrel Formulation (Nexplanon)**

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

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