

# **Etonogestrel Formulation (Implanon)**

Version Revision Date: SDS Number: Date of last issue: 10.10.2020 2.5 09.04.2021 16562-00019 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 (Implanon)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Pharmaceutical

stance/Mixture

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.

30 Hudson Street, 33nd floor

07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS

: EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1A H360F: May damage fertility.

Long-term (chronic) aquatic hazard, Cat- H410: Very toxic to aquatic life with long lasting

egory 1 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.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.



# **Etonogestrel Formulation (Implanon)**



Version Revision Date: SDS Number: Date of last issue: 10.10.2020 2.5 09.04.2021 16562-00019 Date of first issue: 29.09.2014

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:

(17α)-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.

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)
(17α)-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	>= 50 - < 70
		M-Factor (Chronic aquatic toxicity): 10.000	

For explanation of abbreviations see section 16.

# **SECTION 4: First aid measures**

# 4.1 Description of first aid measures

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

vice 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.



# **Etonogestrel Formulation (Implanon)**



Version **Revision Date:** SDS Number: Date of last issue: 10.10.2020 09.04.2021 16562-00019 Date of first issue: 29.09.2014 2.5

In case of skin contact In case of contact, immediately flush skin with soap and plenty

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 (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

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 prod- : Carbon oxides

ucts

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Use water spray to cool unopened containers.



# **Etonogestrel Formulation (Implanon)**



Version Revision Date: SDS Number: Date of last issue: 10.10.2020 2.5 09.04.2021 16562-00019 Date of first issue: 29.09.2014

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 pro-

tective 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 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.

#### 6.4 Reference to other sections

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

#### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe dust. Do not breathe vapours.

Do not swallow.

Avoid contact with eyes.

Handle in accordance with good industrial hygiene and safety



# **Etonogestrel Formulation (Implanon)**

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16562-00019	Date of first issue: 29.09.2014

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 contami-

nated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

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

Requirements for storage areas and containers

Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

## **SECTION 8: Exposure controls/personal protection**

# 8.1 Control parameters

## **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form	Control parameters	Basis
		of exposure)		
(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

#### 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.



# **Etonogestrel Formulation (Implanon)**



Version Revision Date: SDS Number: Date of last issue: 10.10.2020 2.5 09.04.2021 16562-00019 Date of first issue: 29.09.2014

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems are required.

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

### Personal protective equipment

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Particulates type (P)

# **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

Appearance : 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.

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower : No data available



# **Etonogestrel Formulation (Implanon)**

♣ ORGANON

Version Revision Date: SDS Number: Date of last issue: 10.10.2020 2.5 09.04.2021 16562-00019 Date of first issue: 29.09.2014

flammability limit

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- : No data available

octanol/water

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.

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : No data available

# **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents



# **Etonogestrel Formulation (Implanon)**



Version Revision Date: SDS Number: Date of last issue: 10.10.2020 2.5 09.04.2021 16562-00019 Date of first issue: 29.09.2014

## 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

# **SECTION 11: Toxicological information**

# 11.1 Information on toxicological effects

Information on likely routes of : Inhalation exposure 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

#### 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

# Serious eye damage/eye irritation

Not classified based on available information.

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

# Respiratory sensitisation

Not classified based on available information.

# 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



# **Etonogestrel Formulation (Implanon)**



Version Revision Date: SDS Number: Date of last issue: 10.10.2020 2.5 09.04.2021 16562-00019 Date of first issue: 29.09.2014

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- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

## 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 - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

#### 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



ORGANON

# **Etonogestrel Formulation (Implanon)**

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

 2.5
 09.04.2021
 16562-00019
 Date of first issue: 29.09.2014

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.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

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

**Aspiration toxicity** 

Not classified based on available information.

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



ORGANON

# **Etonogestrel Formulation (Implanon)**

Version Revision Date: SDS Number: Date of last issue: 10.10.2020 2.5 09.04.2021 16562-00019 Date of first issue: 29.09.2014

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

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 tox-

icity)

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 (Chron-

ic toxicity)

NOEC: 1,2 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic

toxicity)

10.000

#### 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



# **Etonogestrel Formulation (Implanon)**

Version Revision Date: SDS Number: Date of last issue: 10.10.2020 2.5 09.04.2021 16562-00019 Date of first issue: 29.09.2014

## 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 environ- : log Koc: 2,84 mental compartments : Method: FDA 3.08

#### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered

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

0.1% or higher.

#### 12.6 Other adverse effects

# **Product:**

Endocrine disrupting poten-

tial

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation

(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### **SECTION 13: Disposal considerations**

## 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

# **SECTION 14: Transport information**

#### 14.1 UN number

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

14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.



# **Etonogestrel Formulation (Implanon)**

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	16562-00019	Date of first issue: 29.09.2014

 $((17\alpha)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-$ 

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,

N.O.S

 $((17\alpha)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-$ 

en-20-yn-3-one)

IMDG : 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.

((17α)-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 : 956



# **Etonogestrel Formulation (Implanon)**

♣ ORGANON

Version Revision Date: SDS Number: Date of last issue: 10.10.2020 2.5 09.04.2021 16562-00019 Date of first issue: 29.09.2014

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 956

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 Transport in bulk according to Annex II of Marpol and the IBC Code

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

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**



# **Etonogestrel Formulation (Implanon)**

Version **Revision Date:** SDS Number: Date of last issue: 10.10.2020 09.04.2021 16562-00019 Date of first issue: 29.09.2014 2.5

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

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; AIIC - 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 test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL -International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA -Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

Sheet

Sources of key data used to compile the Safety Data

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

Classification of the mixture: Classification procedure:

Repr. 1A H360F Calculation method Aquatic Chronic 1 H410 Calculation method



# **Etonogestrel Formulation (Implanon)**

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

 2.5
 09.04.2021
 16562-00019
 Date of first issue: 29.09.2014

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.

ZA / EN