

Etonogestrel Formulation (Implanon)

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
2.12	06.04.2024	16555-00026	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 th	ne s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture	:	Pharmaceutical
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	Organon & Co. 30 Hudson Street, 33nd floor 07302 Jersey City, New Jersey, U.S.A
	Telephone	:	+1-551-430-6000
	E-mail address of person responsible for the SDS	:	EHSSTEWARD@organon.com

1.4 Emergency telephone number

+1-215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1A	H360F: M
Long-term (chronic) aquatic hazard, Cat-	H410: Ve
egory 1	effects.

lay damage fertility. ery toxic to aquatic life with long lasting

2.2 Label elements

Laballin

Labelling (REGULATION Hazard pictograms	(EC) No 1272/2008)
Signal word	: Danger
Hazard statements	: H360F May damage fertility. H410 Very toxic to aquatic life with long lasting effects.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Preca	utionary statements	P273 Avoid rele	pecial instructions before use. ease to the environment. tective gloves/ protective clothing/ eye protec- on.		
		Response: P308 + P313 IF attention. P391 Collect sp	exposed or concerned: Get medical advice/		
		Storage: P405 Store locl	ked up.		
	Hazardous components which must be listed on the label:				

(17a)-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)
(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	

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For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measure	es
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.
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	offects both couts and delayed
4.2 Most important symptoms and Risks	
	Contact with dust can cause mechanical irritation or drying of the skin.
	Dust contact with the eyes can lead to mechanical irritation.
4.2 Indication of any immediate m	edical attention and special treatment needed
Treatment :	Treat symptomatically and supportively.
i realment .	Treat symptomatically and supportively.
SECTION 5: Firefighting measu	res
5.1 Extinguishing media	
Suitable extinguishing media :	Water spray Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical



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	Unsuitable extinguishing media	:	None known.	
5.2 S	pecial hazards arising fro	m the	e substance or mi	xture
	Specific hazards during fire- ighting	• :	Exposure to com	oustion products may be a hazard to health.
	Hazardous combustion products	d- :	Carbon oxides	
5.3 A	dvice for firefighters			
	Special protective equipment for firefighters	nt :		e, wear self-contained breathing apparatus. tective equipment.
	Specific extinguishing meth ods	- :	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do

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		Avoid release to the environment

Environmental precautions	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 surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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
Local/Total ventilation	:	and bonding, or inert atmospheres. 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 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
Hygiene measures	:	environment. 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,	incl	luding 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 Self-reactive substances and mixtures Organic peroxides

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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 of exposure)	Control parameters	Basis
(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 ²	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.

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/face protection Hand 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.
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Consider double gloving. 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. Equipment should conform to NS EN 143



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	Filter type	:	Particulates type	(P)
SECT	ION 9: Physical and che	mic	al properties	
	formation on basic physica	al an :	d chemical prope Solid form	erties
С	olour	:	No data available	9
С	dour	:	No data available	9
С	dour Threshold	:	No data available	9
N	lelting point/freezing point	:	No data available	9
	itial boiling point and boiling ange	:	No data available	9
F	lammability (solid, gas)	:	May form explosi dling or other me	ive dust-air mixture during processing, han- ans.
F	lammability (liquids)	:	No data available	9
	pper explosion limit / Upper ammability limit	:	No data available	9
	ower explosion limit / Lower ammability limit	:	No data available	9
F	lash point	:	No data available	9
A	uto-ignition temperature	:	No data available	9
D	ecomposition temperature	:	No data available	9
р	н	:	No data available	9
V	iscosity Viscosity, dynamic	:	No data available	9
	Viscosity, kinematic	:	No data available	9
S	olubility(ies) Water solubility	:	No data available	9
	artition coefficient: n- ctanol/water	:	No data available	
V	apour pressure	:	No data available	9

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Rela	ative density	: No data available	
Den	sity	: 1 g/cm ³	
Rela	ative vapour density	: No data available	
	icle characteristics Particle size	: No data available	
9.2 Othe	r information		
Exp	losives	: Not explosive	
Oxio	lizing properties	: The substance or mixture is not classi	fied as oxidizing.
Eva	poration rate	: No data available	
Mol	ecular 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

:	May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
:	Heat, flames and sparks. Avoid dust formation.
:	Oxidizing agents
	ucts ucts are known.
	: rod

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

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Acute toxicity

Not classified based on available information.

Components:

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

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:

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

Species Result	-	Mouse No skin irritation
Species Result		Guinea pig 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:

(17α) -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- As- sessment	:	Weight of evidence does not support classification as a germ cell mutagen.

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Carcinogenicity

Not classified based on available information.

Components:

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

Species Application Route Activity duration Result		Rat Oral 2 yr 0,5 mg/kg body weight negative
Species Application Route Activity duration Result	:	Rat Subcutaneous 2 yr 0,02 mg/kg body weight negative
Carcinogenicity - Assess- ment	:	Weight of evidence does not support classification as a car- cinogen

Reproductive toxicity

May damage fertility.

Components:

(17α)-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.					

STOT - single exposure

Not classified based on available information.

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STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

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

Species LOAEL Application Route Exposure time Target Organs	 Rat 0,5 mg/kg Oral 1 yr Reproductive organs, Endocrine system
Species LOAEL Application Route Exposure time Target Organs	 Dog 0,625 mg/kg Oral 26 Weeks Reproductive organs, Endocrine system

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:

(17α)-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 ten-
derness, mood swings, male reproductive effects, Sweating

SECTION 12: Ecological information

12.1 Toxicity

Components:

(17a)-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

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				Exposure time: 96 Method: OECD Te		
		to daphnia and other invertebrates	:	Exposure time: 48 Method: FDA 4.08		
Toxicity to microorganisms		:	NOEC : 70,8 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209			
				EC50 : > 1.000 m Exposure time: 3 Test Type: Respir Method: OECD Te	h ration inhibition	
	oxicity city)	to fish (Chronic tox-	:	NOEC: 0,059 mg/ Exposure time: 32 Species: Pimepha Method: OECD To	2 d ales promelas (fathead minnow)	
				NOEC: 0,0000027 Exposure time: 18 Species: Oryzias Method: OECD Te	33 d latipes (Japanese medaka)	
a		to daphnia and other invertebrates (Chron- ty)	:	NOEC: 1,2 mg/l Exposure time: 21 Species: Daphnia	l d magna (Water flea)	
	/I-Facto oxicity)	or (Chronic aquatic	:	10.000		
12.2 F	Persist	ence and degradabil	ity			
<u>C</u>	Components:					
(*	(17a)-13-Ethyl-17-hydroxy-11-methylene-18 19-dinorpregn-4-en-20-yn-3-one:					

(17α) -13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:					
Stability in water	:	Hydrolysis: < 10 %(5 d)			
		Method: FDA 3.09			

12.3 Bioaccumulative potential

Components:

(17α)-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



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		Method: OEC	CD Test Guideline 305				
	ion coefficient: n- ol/water	: log Pow: 3,5					
12.4 Mobi	lity in soil						
<u>Com</u>	oonents:						
(17α) [,]	-13-Ethyl-17-hydroxy-	11-methylene-18, ²	19-dinorpregn-4-en-20-yn-3-one:				
	bution among environ- al compartments	: log Koc: 2,84 Method: FDA					
12.5 Resu	lts of PBT and vPvB a	ssessment					
Produ	uct:						
Assessment		to be either p very persiste	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 Endo	ocrine disrupting prop	erties					
Produ	uct:						
Asses	ssment	 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	SECTION 13: Disposal considerations						
13.1 Wast	e treatment methods						
Produ Conta	uct aminated packaging	 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. Do not dispose of waste into sewer. Empty containers should be taken to an approved waste han- 					

SECTION 14: Transport information

14.1 UN number or ID number

ADN	:	UN 3077
ADR	:	UN 3077

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

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RID			UN 3077	
IMD	2		UN 3077	
IATA	_		UN 3077	
	broper shipping name	•	011 0077	
-				
ADN		:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, SOLID, 7-hydroxy-11-methylene-18,19-dinorpregn-4-
ADR		:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, SOLID, 7-hydroxy-11-methylene-18,19-dinorpregn-4-
RID		:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, SOLID, 7-hydroxy-11-methylene-18,19-dinorpregn-4-
IMDG		:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. ((17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4- en-20-yn-3-one)	
ΙΑΤΑ	ΙΑΤΑ			hazardous substance, solid, n.o.s. 7-hydroxy-11-methylene-18,19-dinorpregn-4-
14.3 Trar	sport hazard class(es)			
			Class	Subsidiary risks
ADN	l	:	9	
ADR		:	9	
RID		:	9	
IMD	G	:	9	
ΙΑΤΑ	N	:	9	
14.4 Pacl	king group			
Clas Haza Labe Pack Clas Haza	king group sification Code ard Identification Number els king group sification Code ard Identification Number	:	III M7 90 9 9 III M7 90	
Labe Tunr	els nel restriction code	:	9 (-)	

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P C H	Classifi	g group cation Code Identification Number	:	III M7 90 9	
P L	MDG Packing abels EmS Co	g group ode	:	III 9 F-A, S-F	
P a P P	Packing aircraft) Packing	Cargo) g instruction (cargo g instruction (LQ) g group	:	956 Y956 III Miscellaneous	
P g P P	Packing Jer airc Packing	Passenger) g instruction (passen- raft) g instruction (LQ) g group	:	956 Y956 III Miscellaneous	
14.5 E	Enviro	nmental hazards			
	ADN Environ	mentally hazardous	:	yes	
	ADR Environ	mentally hazardous	:	yes	
	RID Environ	mentally hazardous	:	yes	
	MDG /larine	pollutant	:	yes	
		Passenger) mentally hazardous	:	yes	
		Cargo) mentally hazardous	:	yes	
14.6 S	14.6 Special precautions for user				

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.



of

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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, mixtures and articles (Annex XVII)	:	Not applicable	
REACH - Candidate List of Substances of Very High	:	Not applicable	
Concern for Authorisation (Article 59). REACH - List of substances subject to authorisation	:	Not applicable	
(Annex XIV)			
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable	
Regulation (EU) 2019/1021 on persistent organic pollu-	:	Not applicable	
tants (recast)			
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import	:	Not applicable	
of dangerous chemicals			
Seveso III: Directive 2012/18/EU of the European Parliam major-accident hazards involving dangerous substances.		and of the Counci	ii on the control
, 314 31		Quantity 1	Quantity 2

		Quantity I	
E1	ENVIRONMENTAL	100 t	200 t
	HAZARDS		

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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.



Etonogestrel Formulation (Implanon)

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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 - 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; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:	Classification procedure:
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/

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



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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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