according to GB/T 16483 and GB/T 17519



## **Etonogestrel Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
3.23	2024/04/06	16621-00027	Date of first issue: 2014/09/29

#### **1. PRODUCT AND COMPANY IDENTIFICATION**

Product name	:	Etonogestrel Formulation
Product code	:	NEXPLANON
Manufacturer or supplier's de	eta	ils
Company	:	Organon & Co.
Address	:	30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302
Telephone	:	+1-551-430-6000
Emergency telephone number	:	+1-215-631-6999
E-mail address	:	EHSSTEWARD@organon.com
Recommended use of the ch	ical and restrictions on use	
Recommended use Restrictions on use	:	Pharmaceutical Not applicable

#### 2. HAZARDS IDENTIFICATION

#### **Emergency Overview**

Appearance Colour Odour	:	Solid form No data available No data available
May damage fertility. Toxic to a	qu	atic life. Very toxic to aquatic life with long lasting effects.
GHS Classification		
Reproductive toxicity	:	Category 1A
Short-term (acute) aquatic hazard	:	Category 2
Long-term (chronic) aquatic hazard	:	Category 1
GHS label elements Hazard pictograms	:	

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Signa	l word	: Danger	
Hazar	Hazard statements		amage fertility. aquatic life. xic to aquatic life with long lasting effects.
Preca	utionary statements	P202 Do not and understo P273 Avoid re	elease to the environment. rotective gloves/ protective clothing/ eye protec-
		<b>Response:</b> P308 + P313 attention. P391 Collect	IF exposed or concerned: Get medical advice/
		<b>Storage:</b> P405 Store lo	cked up.
		<b>Disposal:</b> P501 Dispose disposal plant	e of contents/ container to an approved waste
-	ical and chemical haz assified based on avail		
	<b>h hazards</b> lamage fertility.		
	onmental hazards to aquatic life. Very tox	ic to aquatic life with	long lasting effects.

#### 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)
(17α)-13-Ethyl-17-hydroxy-11-methylene-	54048-10-1	>= 30 -< 50
18,19-dinorpregn-4-en-20-yn-3-one		
Barium sulfate	7727-43-7	>= 10 -< 20

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#### 4. FIRST AID MEASURES

General advice	<ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical</li> </ul>
If inhaled	advice. : If inhaled, remove to fresh air.
In case of skin contact	<ul> <li>Get medical attention.</li> <li>In case of contact, immediately flush skin with soap and plenty of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> </ul>
In case of eye contact	<ul> <li>Thoroughly clean shoes before reuse.</li> <li>If in eyes, rinse well with water.</li> <li>Cot medical attention if irritation develops and persists</li> </ul>
If swallowed	<ul> <li>Get medical attention if irritation develops and persists.</li> <li>If swallowed, DO NOT induce vomiting.</li> <li>Get medical attention.</li> <li>Rinse mouth thoroughly with water.</li> </ul>
Most important symptoms and effects, both acute and delayed	: May damage fertility. Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	<ul> <li>Dust contact with the eyes can lead to mechanical irritation.</li> <li>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).</li> </ul>
Notes to physician	: Treat symptomatically and supportively.
5. FIREFIGHTING MEASURES	
5. FIREFIGHTING MEASURES Suitable extinguishing media	Alcohol-resistant foam Carbon dioxide (CO2)
Suitable extinguishing media Unsuitable extinguishing	Alcohol-resistant foam
Suitable extinguishing media Unsuitable extinguishing media Specific hazards during fire-	Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Suitable extinguishing media Unsuitable extinguishing media	<ul> <li>Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical</li> <li>None known.</li> <li>Exposure to combustion products may be a hazard to health.</li> </ul>
Suitable extinguishing media Unsuitable extinguishing media Specific hazards during fire- fighting Hazardous combustion prod-	<ul> <li>Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical</li> <li>None known.</li> <li>Exposure to combustion products may be a hazard to health.</li> <li>Metal oxides Sulphur oxides</li> </ul>

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#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive 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 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 certain local or national requirements.

#### 7. HANDLING AND STORAGE

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 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.



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Avoi	dance of contact	Take care to environment : Oxidizing ag	-
Stor	age		
Conditions for safe storage		Store locked Keep tightly	•
Materials to avoid			with the following product types:
Pack	aging material	: Unsuitable n	naterial: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	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 <sup>2</sup>	Internal
Barium sulfate	7727-43-7	PC-TWA	10 mg/m3 (Barium)	CN OEL
		PC-TWA (Total dust)	5 mg/m3	CN OEL
		TWA (Inhal- able particu- late matter)	5 mg/m3	ACGIH

#### Components with workplace control parameters

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 are required. Operations require the use of appropriate containment tech- nology 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

: Particulates type

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Eye/f	ace protection	If the work en mists or aero Wear a faces	glasses with side shields or goggles. nvironment or activity involves dusty conditions, osols, wear the appropriate goggles. shield or other full face protection if there is a direct contact to the face with dusts, mists, or
Skin	and body protection	: Work uniforn Additional bo task being pe posable suits	n or laboratory coat. ody garments should be used based upon the erformed (e.g., sleevelets, apron, gauntlets, dis- s) to avoid exposed skin surfaces. late degowning techniques to remove potentially
Hand	protection	Containinated	a clothing.
M	aterial	: Chemical-res	sistant gloves
	emarks ene measures	eye flushing ing place. When using Wash contar The effective engineering appropriate o industrial hyg	uble gloving. o chemical is likely during typical use, provide systems and safety showers close to the work- do not eat, drink or smoke. ninated clothing before re-use. e operation of a facility should include review of controls, proper personal protective equipment, degowning and decontamination procedures, giene monitoring, medical surveillance and the histrative controls.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Solid form
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	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.

according to GB/T 16483 and GB/T 17519



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Fla	mmability (liquids)	:	No data available	9
	per explosion limit / Upper nmability limit	:	No data available	9
	ver explosion limit / Lower nmability limit	:	No data available	9
Vap	oour pressure	:	No data available	9
Rel	ative vapour density	:	No data available	9
Rel	ative density	:	No data available	9
Dei	nsity	:	1 g/cm <sup>3</sup>	
	ubility(ies) Water solubility	:	No data available	9
	tition coefficient: n-	:	No data available	9
	anol/water o-ignition temperature	:	No data available	9
Dee	composition temperature	:	No data available	9
	cosity Viscosity, dynamic	:	No data available	9
	Viscosity, kinematic	:	No data available	9
Exp	plosive properties	:	Not explosive	
Oxi	dizing properties	:	The substance o	r mixture is not classified as oxidizing.
Мо	lecular weight	:	No data available	9
	ticle characteristics ticle size	:	No data available	9

#### **10. STABILITY AND REACTIVITY**

Reactivity Chemical stability Possibility of hazardous reac- tions	::	Not classified as a reactivity hazard. Stable under normal conditions. 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.



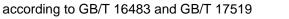


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Incomp	atible materials	: Oxidizing age	nts
Hazard product	ous decomposition s	: No hazardous	s decomposition products are known.
. TOXICO	LOGICAL INFORM	ATION	
Exposu	re routes	: Inhalation Skin contact Ingestion Eye contact	
Acute t	•		
	ssified based on avai	ilable information.	
Produc Acute o	: <u>t:</u> ral toxicity	: Acute toxicity e Method: Calcu	estimate: > 5,000 mg/kg Ilation method
<u>Compo</u>	onents:		
(17α)-1	3-Ethyl-17-hydroxy	-11-methylene-18,19	9-dinorpregn-4-en-20-yn-3-one:
	3-Ethyl-17-hydroxy ral toxicity	-11-methylene-18,19 : LD50 (Rat): >	
		: LD50 (Rat): >	
Acute o		: LD50 (Rat): >	2,000 mg/kg
Acute o Barium	ral toxicity	: LD50 (Rat): >	2,000 mg/kg : > 2,000 mg/kg
Acute o Barium Acute o Skin co	ral toxicity sulfate: ral toxicity prrosion/irritation	: LD50 (Rat): > LD50 (Mouse) : LD50 (Rat): >	2,000 mg/kg : > 2,000 mg/kg
Acute o Barium Acute o Skin co Not clas	ral toxicity sulfate: ral toxicity prrosion/irritation ssified based on avai	: LD50 (Rat): > LD50 (Mouse) : LD50 (Rat): >	2,000 mg/kg : > 2,000 mg/kg
Acute o Barium Acute o Skin co Not clas <u>Compo</u>	ral toxicity sulfate: ral toxicity prrosion/irritation ssified based on avai enents:	: LD50 (Rat): > LD50 (Mouse) : LD50 (Rat): >	2,000 mg/kg : > 2,000 mg/kg 5,000 mg/kg
Acute o Barium Acute o Skin co Not clas <u>Compo</u> (17α)-1	ral toxicity sulfate: ral toxicity prrosion/irritation ssified based on avai <u>ments:</u> 3-Ethyl-17-hydroxy	: LD50 (Rat): > LD50 (Mouse) : LD50 (Rat): > ilable information. -11-methylene-18,19	2,000 mg/kg : > 2,000 mg/kg
Acute o Barium Acute o Skin co Not clas <u>Compo</u>	ral toxicity sulfate: ral toxicity prrosion/irritation ssified based on avai <u>ments:</u> 3-Ethyl-17-hydroxy	: LD50 (Rat): > LD50 (Mouse) : LD50 (Rat): >	2,000 mg/kg : > 2,000 mg/kg 5,000 mg/kg 9-dinorpregn-4-en-20-yn-3-one:
Acute o Barium Acute o Skin co Not clas <u>Compo</u> (17α)-1 Species	ral toxicity sulfate: ral toxicity prrosion/irritation ssified based on avai <u>enents:</u> 3-Ethyl-17-hydroxy	<ul> <li>: LD50 (Rat): &gt;</li> <li>LD50 (Mouse)</li> <li>: LD50 (Rat): &gt;</li> <li>ilable information.</li> <li>-11-methylene-18,19</li> <li>: Mouse</li> </ul>	2,000 mg/kg : > 2,000 mg/kg 5,000 mg/kg 9-dinorpregn-4-en-20-yn-3-one:
Acute o Barium Acute o Skin co Not clas <u>Compo</u> (17α)-1 Species Result	ral toxicity sulfate: ral toxicity prrosion/irritation ssified based on avai <u>enents:</u> 3-Ethyl-17-hydroxy	<ul> <li>: LD50 (Rat): &gt;</li> <li>LD50 (Mouse)</li> <li>: LD50 (Rat): &gt;</li> <li>ilable information.</li> <li>-11-methylene-18,19         <ul> <li>: Mouse</li> <li>: No skin irritatio</li> <li>: Guinea pig</li> </ul> </li> </ul>	2,000 mg/kg : > 2,000 mg/kg 5,000 mg/kg 9-dinorpregn-4-en-20-yn-3-one:
Acute of Barium Acute of Skin co Not clas Compo (17α)-1 Species Result Species Result Barium Species	ral toxicity sulfate: ral toxicity prrosion/irritation ssified based on avai <u>ments:</u> 3-Ethyl-17-hydroxy s s sulfate:	<ul> <li>: LD50 (Rat): &gt; LD50 (Mouse)</li> <li>: LD50 (Rat): &gt;</li> <li>ilable information.</li> <li>-11-methylene-18,19</li> <li>: Mouse</li> <li>: No skin irritation</li> <li>: Guinea pig</li> <li>: No skin irritation</li> <li>: reconstructed</li> </ul>	2,000 mg/kg : > 2,000 mg/kg 5,000 mg/kg <b>9-dinorpregn-4-en-20-yn-3-one:</b> on on
Acute of Barium Acute of Skin co Not clas Compo (17α)-1 Species Result Species Result	ral toxicity sulfate: ral toxicity prrosion/irritation ssified based on avaionents: 3-Ethyl-17-hydroxy s sulfate:	<ul> <li>: LD50 (Rat): &gt; LD50 (Mouse)</li> <li>: LD50 (Rat): &gt;</li> <li>ilable information.</li> <li>-11-methylene-18,19</li> <li>: Mouse</li> <li>: No skin irritation</li> <li>: Guinea pig</li> <li>: No skin irritation</li> <li>: reconstructed</li> <li>: OECD Test Got</li> </ul>	2,000 mg/kg : > 2,000 mg/kg 5,000 mg/kg <b>9-dinorpregn-4-en-20-yn-3-one:</b> on on

## Serious eye damage/eye irritation

Not classified based on available information.





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#### 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.

#### Components:

#### Barium sulfate:

Local lymph node assay (LLNA)
Skin contact
Mouse
OECD Test Guideline 429
negative
Based on data from similar materials

#### 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 - 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

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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.

#### **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-
ment	cinogen
Barium sulfate:	
Species	: Rat
Application Route	Ingestion
Exposure time	: 2 Years
Result	negative
Remarks	Based on data from similar materials
Komano	
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

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		-		
		S A D	est Type: Fertility pecies: Rabbit, f pplication Route pose: 0.05 milligra result: Effects on	emale : Oral am per kilogram
Effects on foetal develop- ment		D G	: Species: Rat, female Duration of Single Treatment: 14 d General Toxicity Maternal: NOAEL: 1.8 mg/kg body we Result: No teratogenic effects	
	Reproductive toxicity - As- sessment			of adverse effects on sexual function and n epidemiological studies.
Bar	ium sulfate:			
Effe	cts on fertility	S A R	pecies: Rat pplication Route esult: negative	y/early embryonic development : Ingestion on data from similar materials
Effe mer	cts on foetal develop- nt	S A N R	pecies: Rat pplication Route lethod: OECD Te esult: negative	o-foetal development : Ingestion est Guideline 414 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:

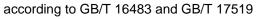
Assessment

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

#### Repeated dose toxicity

#### **Components:**

mg/kg
1
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Targe	et Organs	:	Reproductive	organs, Endocrine system				
Speci	ies		Dog					
LÒAE	EL	:	0.625 mg/kg					
	cation Route	:	: Oral					
	sure time et Organs	:	26 Weeks Reproductive	organs, Endocrine system				
Bariu	ım sulfate:							
Spec		:	Rat					
NOA!	EL cation Route	:	61.1 mg/kg Ingestion					
	sure time	:	90 Days					
Rema		:		a from similar materials				
•	r <b>ation toxicity</b> lassified based on ava	ailable	information.					
		isonxe	ure					
Expe	rience with human e	,vbogr						
-								
Com	ponents:			0 dinemprogra 4 on 20 yrs 2 onor				
Com	ponents: -13-Ethyl-17-hydrox		<b>nethylene-18,1</b> Symptoms: H Skin disorder	s, effects on menstruation, vaginitis, breast te				
<u>Com</u> (17α) Inhala	ponents: -13-Ethyl-17-hydrox	y-11-m	<b>nethylene-18,1</b> Symptoms: H Skin disorder	<b>9-dinorpregn-4-en-20-yn-3-one:</b> leadache, Dizziness, Abdominal pain, Nausea s, effects on menstruation, vaginitis, breast te od swings, male reproductive effects, Sweatin				
<u>Com</u> (17α) Inhala	ponents: -13-Ethyl-17-hydrox ation	y-11-m	<b>nethylene-18,1</b> Symptoms: H Skin disorder	leadache, Dizziness, Abdominal pain, Nausea s, effects on menstruation, vaginitis, breast te				
<u>Com</u> (17α) Inhala . ECOL	ponents: -13-Ethyl-17-hydrox ation OGICAL INFORMAT	y-11-m	<b>nethylene-18,1</b> Symptoms: H Skin disorder	leadache, Dizziness, Abdominal pain, Nausea s, effects on menstruation, vaginitis, breast te				
<u>Com</u> (17α) Inhala . ECOL Ecoto <u>Com</u>	ponents: -13-Ethyl-17-hydrox ation OGICAL INFORMAT oxicity ponents:	y-11-m ION	<b>nethylene-18,1</b> Symptoms: H Skin disorder derness, moo	leadache, Dizziness, Abdominal pain, Nausea s, effects on menstruation, vaginitis, breast te				
<u>Com</u> (17α) Inhala ECOL Ecoto <u>Com</u> (17α)	ponents: -13-Ethyl-17-hydrox ation OGICAL INFORMAT oxicity ponents:	y-11-m ION	nethylene-18,1 Symptoms: H Skin disorder derness, mod	leadache, Dizziness, Abdominal pain, Nauses s, effects on menstruation, vaginitis, breast te od swings, male reproductive effects, Sweatin <b>9-dinorpregn-4-en-20-yn-3-one:</b> hynchus mykiss (rainbow trout)): 4.0 mg/l e: 96 h				
<u>Com</u> (17α) Inhala ECOL Ecoto <u>Com</u> (17α)	ponents: -13-Ethyl-17-hydrox ation OGICAL INFORMAT oxicity ponents: -13-Ethyl-17-hydrox	y-11-m ION	nethylene-18,1 Symptoms: H Skin disorder derness, mod hethylene-18,1 LC50 (Oncorl Exposure tim Method: FDA LC50 (Leporr Exposure tim Method: OEC	leadache, Dizziness, Abdominal pain, Nauser s, effects on menstruation, vaginitis, breast te od swings, male reproductive effects, Sweatin <b>9-dinorpregn-4-en-20-yn-3-one:</b> hynchus mykiss (rainbow trout)): 4.0 mg/l e: 96 h 4.11 his macrochirus (Bluegill sunfish)): > 1.3 mg/l				
<u>Com</u> (17α) Inhala Ecoto <u>Com</u> (17α) Toxic	ponents: -13-Ethyl-17-hydrox ation OGICAL INFORMAT oxicity ponents: -13-Ethyl-17-hydrox	y-11-m ION y-11-m	hethylene-18,1 Symptoms: H Skin disorder derness, mod hethylene-18,1 LC50 (Oncorl Exposure tim Method: FDA LC50 (Leporr Exposure tim Method: OEC Remarks: No EC50 (Daphr Exposure tim Method: FDA	leadache, Dizziness, Abdominal pain, Nauser s, effects on menstruation, vaginitis, breast te od swings, male reproductive effects, Sweatin <b>9-dinorpregn-4-en-20-yn-3-one:</b> hynchus mykiss (rainbow trout)): 4.0 mg/l e: 96 h 4.11 his macrochirus (Bluegill sunfish)): > 1.3 mg/l e: 96 h D Test Guideline 203 toxicity at the limit of solubility hia magna (Water flea)): > 3.9 mg/l e: 48 h				

according to GB/T 16483 and GB/T 17519



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			Method: OECD	Test Guideline 210		
			Exposure time:	s latipes (Japanese medaka)): 0.0000027 mg/l 183 d 9 Test Guideline 229		
	ity to daphnia and other ic invertebrates (Chron-	:	NOEC (Daphni Exposure time:	a magna (Water flea)): 1.2 mg/l 21 d		
M-Fac	ctor (Chronic aquatic	:	10,000			
	toxicity) Toxicity to microorganisms		<ul> <li>NOEC: 70.8 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</li> </ul>			
Bariu	m sulfate:					
Toxici	ity to fish	:	Exposure time: Method: OECD	erio (zebra fish)): > 100 mg/l 96 h 9 Test Guideline 203 ed on data from similar materials		
	ity to daphnia and other ic invertebrates	:	Exposure time:	a magna (Water flea)): > 10 - 100 mg/l 48 h ed on data from similar materials		
Toxici plants	ity to algae/aquatic	:	mg/l Exposure time: Method: OECD	okirchneriella subcapitata (green algae)): > 1 72 h 9 Test Guideline 201 ed on data from similar materials		
			mg/l Exposure time: Method: OECD	okirchneriella subcapitata (green algae)): > 100 72 h 9 Test Guideline 201 ed on data from similar materials		
	ity to daphnia and other ic invertebrates (Chron- icity)	:	Exposure time:	a magna (Water flea)): > 1 mg/l 21 d ed on data from similar materials		
Toxici	ity to microorganisms	:				

according to GB/T 16483 and GB/T 17519



## **Etonogestrel Formulation**

/ersion 3.23	Revision Date: 2024/04/06	SDS Number: 16621-00027	Date of last issue: 2023/09/26 Date of first issue: 2014/09/29
		NOEC: > 6 Exposure 1 Method: O	
		Remarks:	Based on data from similar materials
Persi	stence and degrada	bility	
Com	ponents:		
(17α)	-13-Ethyl-17-hydrox	y-11-methylene-1	8,19-dinorpregn-4-en-20-yn-3-one:
Stabi	lity in water	: Hydrolysis Method: Fl	: < 10 %(5 d) DA 3.09
Bioa	ccumulative potentia	al	
Com	ponents:		
(17α)	-13-Ethyl-17-hydrox	y-11-methylene-1	8,19-dinorpregn-4-en-20-yn-3-one:
Bioac	cumulation	Bioconcen	epomis macrochirus (Bluegill sunfish) tration factor (BCF): 128 ECD Test Guideline 305
	ion coefficient: n- ol/water	: log Pow: 3	.5
	ım sulfate:		
Bioac	cumulation		epomis macrochirus (Bluegill sunfish) tration factor (BCF): < 500

#### Distribution among environ- : log Koc: 2.84 mental compartments

Other adverse effects

Partition coefficient: n-

octanol/water

Mobility in soil

**Components:** 

No data available

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

Disposal i	methods
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Waste from residues	:	Do not dispose of waste into sewer.
		Dispose of in accordance with local regulations.

log Pow: -1.03

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

Method: FDA 3.08

**Remarks: Calculation** 

:





# **Etonogestrel Formulation**

Version 3.23	Revision Date: 2024/04/06		DS Number: 621-00027	Date of last issue: 2023/09/26 Date of first issue: 2014/09/29
Conta	aminated packaging	:	dling site for red	rs should be taken to an approved waste han- cycling or disposal. specified: Dispose of as unused product.
14. TRAN	SPORT INFORMATION			
Interr	national Regulations			
	<b>FDG</b> umber er shipping name	:	N.O.S.	TALLY HAZARDOUS SUBSTANCE, SOLID, I-17-hydroxy-11-methylene-18,19-dinorpregn-
Label	ng group	:	9 III 9 yes	
<b>IATA</b> UN/IE Prope		:		/ hazardous substance, solid, n.o.s. I-17-hydroxy-11-methylene-18,19-dinorpregn- ne)
Label Packi aircra Packi ger ai	ng group s ng instruction (cargo		9 III Miscellaneous 956 956 yes	
UN ni	<b>-Code</b> umber er shipping name	:	N.O.S. ((17α)-13-Ethyl-	TALLY HAZARDOUS SUBSTANCE, SOLID, -17-hydroxy-11-methylene-18,19-dinorpregn-4
Label EmS	ng group s		en-20-yn-3-one 9 III 9 F-A, S-F yes	)
	sport in bulk according pplicable for product as	-		RPOL 73/78 and the IBC Code
Natio	nal Regulations			
UN ni	<b>944/12268</b> umber er shipping name	:	UN 3077 ENVIRONMEN	TALLY HAZARDOUS SUBSTANCE, SOLID,

Version



Date of last issue: 2023/09/26

according to GB/T 16483 and GB/T 17519

## **Etonogestrel Formulation**

Revision Date:

SDS Number:

3.23	2024/04/06	16621-	00027	Date of first issue: 2014/09/29				
Label	ing group	((1	).S. 7α)-13-Eth n-20-yn-3-α	yl-17-hydroxy-11-methylene-18,19-dinorpregn- one)				
Spec	ial precautions for u	ser						
based Shee	d upon the properties	of the unpa ifications r	ackaged ma nay vary by	e for informational purposes only, and solely aterial as it is described within this Safety Data aterial of transportation, package sizes, and var-				
15. REGU	LATORY INFORMAT	ION						
Law	onal regulatory inform on the Prevention an Ilation on the Admini	d Control	•					
-								
	ogue and Classificatio		rsor Chemi	cals : Not listed				
-	tze River Protection			amigala prohibited for inland river transport				
		-	•	emicals prohibited for inland river transport. in the following inventories:				
AICS	•		determine	_				
DSL		: not	determine	d				
IECS	С	: not	determine	d				
16. OTHE	R INFORMATION							
Revis	ion Date	: 202	24/04/06					
Furth	er information							
	ces of key data used to ile the Safety Data t	eC	hem Portal	cal data, data from raw material SDSs, OECD search results and European Chemicals Agen- .europa.eu/				
Date	format	: ууу	y/mm/dd					
Full t	Full text of other abbreviations							
ACGI CN O		: Oc	cupational	Threshold Limit Values (TLV) exposure limits for hazardous agents in the hemical hazardous agents.				
	H / TWA EL / PC-TWA			reighted average oncentration - time weighted average				

according to GB/T 16483 and GB/T 17519



## Etonogestrel Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/26
3.23	2024/04/06	16621-00027	Date of first issue: 2014/09/29

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; 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; WHMIS - Workplace Hazardous Materials Information System

#### Disclaimer

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.

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