

Versio 3.5		sion Date: 4.2021		S Number: 629-00020	Date of last issue: 10.10.2020 Date of first issue: 29.09.2014	
1. PR(	ODUCT ANI	D COMPANY ID	ENT	IFICATION		
Р	roduct name	e	:	Etonogestrel For	mulation (Nexplanon)	
Р	roduct code		:	NEXPLANON		
M	lanufacture	r or supplier's	detai	ils		
	ompany		:	Organon & Co.		
A	Address		:	30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302		
Т	Telephone		:	551-430-6000		
E	mergency te	elephone numbe	r:	215-631-6999		
E	-mail addres	SS	:	EHSSTEWARD	@organon.com	
R	ecommend	ed use of the c	hem	ical and restriction	ons on use	
R	ecommende	ed use	:	Pharmaceutical		
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#### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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	:	
Signal word	:	Danger
Hazard statements	:	H360F May damage fertility. H401 Toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	Prevention:



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		P273 Avoid rel	read and follow all safety i lease to the environment. otective gloves/ protective ection.			
<b>Response:</b> P318 IF exposed or concerned, get medical advice. P391 Collect spillage.						
	<b>Storage:</b> P405 Store locked up.					
		<b>Disposal:</b> P501 Dispose of contents/ container to an approved waste disposal plant.				
Dust Conta	contact with the eyes act with dust can caus	not result in classifica can lead to mechanica e mechanical irritation r mixture during proces	l irritation.	eans.		
3. COMPO	OSITION/INFORMATI	ON ON INGREDIENTS	6			
Subs	tance / Mixture	: Mixture				
Com	ponents					
Cherr	nical name		CAS-No.	Concentration (% w/w)		
· · ·	-13-Ethyl-17-hydroxy- pregn-4-en-20-yn-3-ol		54048-10-1	>= 30 - < 50		
	m sulfate		7727-43-7 >= 10 - < 20			

#### 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	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	May damage fertility. Contact with dust can cause mechanical irritation or drying of the skin.



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Protection of first-aiders		:	<ul> <li>Dust contact with the eyes can lead to mechanical irrita</li> <li>First Aid responders should pay attention to self-protection and use the recommended personal protective equipm when the potential for exposure exists (see section 8).</li> </ul>		
	Notes t	o physician	:		cally and supportively.
5. FI	REFIG	TING MEASURES			
	Suitable	e extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
	Unsuita media	able extinguishing	:	None known.	
	Specific fighting	c hazards during fire-	:	Exposure to comb	pustion products may be a hazard to health.
		ous combustion prod-	:	Metal oxides Sulphur oxides Carbon oxides	
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	Special protective equipment for firefighters		:	Evacuate area. In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.
6. A	CCIDEN	ITAL RELEASE MEAS	SUF	RES	
	tive equ	al precautions, protec- uipment and emer- procedures	:		ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).
	Enviror	nmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
		ls and materials for ment and cleaning up	:	tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may	dust in the air (i.e., clearing dust surfaces

leased 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-

Sections 13 and 15 of this SDS provide information regarding

mine which regulations are applicable.

certain local or national requirements.

#### SAFETY DATA SHEET



### **Etonogestrel Formulation (Nexplanon)**

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7. HAN	DLING AND STORAGE		
Technical measures		causing an exp Provide adequa	y may accumulate and ignite suspended dust losion. ate precautions, such as electrical grounding r inert atmospheres.
Local/Total ventilation			tilation is unavailable, use with local exhaust
Advice on safe handling		practice, based sessment Keep container Minimize dust g Keep container Keep away from Take precautio	dust. vapours. v. vith eyes. rdance with good industrial hygiene and safety on the results of the workplace exposure as-
Co	nditions for safe storage	Store locked up Keep tightly clo	
Ma	terials to avoid	: Do not store wi Strong oxidizin	th the following product types: g agents

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

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	TWA (Inhal- able particu- late matter)	5 mg/m3	ACGIH

**Engineering measures** Use closed processing systems or containment technologies : to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. No open handling permitted.

Totally enclosed processes and materials transport systems



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			l. require the use of appropriate containment tech- gned to prevent leakage of compounds into the		
Perso	onal protective equip	ment			
Resp	iratory protection	sure assess	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.		
	Iter type protection	: Particulates			
Ma	aterial	: Chemical-re	sistant gloves		
	emarks protection	: Wear safety If the work e mists or aer Wear a face	puble gloving. glasses with side shields or goggles. environment or activity involves dusty conditions, osols, wear the appropriate goggles. eshield or other full face protection if there is a direct contact to the face with dusts, mists, or		
Skin a	and body protection	Additional b being perfor suits) to avo Use approp	Work uniform or laboratory coat. Additional body garments should be used based upon the ta being performed (e.g., sleevelets, apron, gauntlets, disposal suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.		
Hygie	ene measures	: If exposure flushing sys place. When using Wash conta The effective engineering appropriate industrial hy	to chemical is likely during typical use, provide eye tems and safety showers close to the working do not eat, drink or smoke. minated 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 nistrative 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



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	Flash point		:	No data available	9
	Evapora	ation rate	:	No data available	
	Flamma	ability (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.
	Flamma	ability (liquids)	:	No data available	9
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	No data available	)
	Relative	e vapour density	:	No data available	)
	Relative	e density	:	No data available	)
	Density		:	1 g/cm <sup>3</sup>	
	Solubili Wat	ty(ies) er solubility	:	No data available	9
	Partition octanol	n coefficient: n-	:	No data available	9
		nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty osity, dynamic	:	No data available	9
	Visc	osity, kinematic	:	No data available	)
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance of	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	
	Particle	size	:	No data available	

### 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	May form explosive dust-air mixture during processing, han-
tions		dling or other means.
		Can react with strong oxidizing agents.



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Incom	ions to avoid patible materials dous decomposition sts	: : :	Heat, flames and Avoid dust forma Oxidizing agents No hazardous d	ation.
1. TOXICO	DLOGICAL INFORMAT		1	
Inform exposi	ation on likely routes of ure	:	Inhalation Skin contact Ingestion Eye contact	
	toxicity			
	assified based on availa	ble	information.	
<u>Produ</u> Acute	<u>ct:</u> oral toxicity	:	Acute toxicity est Method: Calculat	imate: > 5,000 mg/kg ion method
<u>Comp</u>	onents:			
(17α)- <sup>-</sup>	13-Ethyl-17-hydroxy-1	1-m	ethylene-18,19-d	linorpregn-4-en-20-yn-3-one:
Acute	oral toxicity	:	LD50 (Rat): > 2,0	000 mg/kg
			LD50 (Mouse): >	2,000 mg/kg
	<b>n sulfate:</b> oral toxicity	:	LD50 (Rat): > 5,0	000 mg/kg
Claim a				
	orrosion/irritation assified based on availa	ble	information.	
	onents:			
		1-m	ethvlene-18,19-d	linorpregn-4-en-20-yn-3-one:
Specie		:	Mouse	
Result		:	No skin irritation	
Specie Result		:	Guinea pig No skin irritation	
Bariur	n sulfate:			
		:	OECD Test Guid	
Specie Metho Remar		:	Based on data fro	om similar materials

#### Serious eye damage/eye irritation

Not classified based on available information.



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<u>Com</u>	ponents:							
Bariu	ım sulfate:							
Speci	Species		abbit					
Metho			: OECD Test Guideline 405					
Resul	lt	: N	o eye irritati	on				
Resp	iratory or skin sens	itisation						
	sensitisation lassified based on av	ailable inf	ormation.					
Resp	iratory sensitisatior	n						
-	lassified based on av		ormation.					
<u>Com</u>	ponents:							
Bariu	ım sulfate:							
Test	Туре	: L	ocal lymph r	ode assay (LLNA)				
	sure routes	: S	kin contact					
Speci			louse					
Metho				buideline 429				
Resul Rema			egative ased on dat	a from similar materials				
	lassified based on av ponents:	ailable inf	ormation.					
• •		-	-	9-dinorpregn-4-en-20-yn-3-one:				
Geno	toxicity in vitro	Т		verse mutation assay Salmonella typhimurium ive				
		т	est Type: in	vitro assav				
		Т		Chinese hamster ovary cells				
Geno	toxicity in vivo			vivo micronucleus test				
		A	pecies: Mou pplication R esult: negat	oute: Oral				
	cell mutagenicity -		/eight of evidenter of evidente	dence does not support classification as a germ				
Bariu	ım sulfate:							
Geno	toxicity in vitro	R	esult: negat	acterial reverse mutation assay (AMES) ive sed on data from similar materials				

Result: negative

Test Type: Chromosome aberration test in vitro



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		Remarks: Base	d on data from similar materials
		Method: OECD	tro mammalian cell gene mutation test Test Guideline 476
		Result: negative Remarks: Base	e d on data from similar materials
Carci	nogenicity		
-	lassified based on ava	ilable information.	
<u>Com</u>	ponents:		
(17α) <sup>,</sup>	-13-Ethyl-17-hydroxy	-11-methylene-18,19-	dinorpregn-4-en-20-yn-3-one:
Speci		: Rat	
	cation Route	: Oral	
Activi	ty duration	: 2 yr	
Resu	14	: 0.5 mg/kg body	weight
Resu	11	: negative	
Speci	ies	: Rat	
	cation Route	: Subcutaneous	
	ty duration	: 2 yr	
_		: 0.02 mg/kg bod	y weight
Resu	lt	: negative	
Carci	nogenicity - Assess-	: Weight of evide	nce does not support classification as a ca
ment		cinogen	
Bariu	ım sulfate:		
Speci		: Rat	
•	cation Route	: Ingestion	
	sure time	: 2 Years	
Resu	lt	: negative	
Rema	arks	: Based on data	from similar materials
-	oductive toxicity		
May o	damage fertility.		
<u>Com</u>	ponents:		
(17α) <sup>,</sup>	-13-Ethyl-17-hydroxy	-11-methylene-18,19-	dinorpregn-4-en-20-yn-3-one:
Effect	ts on fertility	: Test Type: Fert	ility
_		Species: Rat, fe	emale
		Application Rou	
			.: 0.012 mg/kg body weight
		Result: Effects	on fertility
		Test Type: Fert	ility
		Species: Rabbi	
		Application Rou	
		Dose: 0.05 milli	gram per kilogram
		Result: Effects	on fertility
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Effects on foetal develop- ment Reproductive toxicity - As- sessment		:	General Toxic	female ngle Treatment: 14 d ity Maternal: NOAEL: 1.8 mg/kg body weigh atogenic effects
		:		nce of adverse effects on sexual function an uman epidemiological studies.
Bariu	m sulfate:			
Effect	s on fertility	:	Species: Rat Application Ro Result: negati	rtility/early embryonic development oute: Ingestion ve ed on data from similar materials
Effect ment	s on foetal develop-	:	Species: Rat Application Ro Method: OEC Result: negati	D Test Guideline 414
STOT	- single exposure			
Not cl STOT	<ul> <li>single exposure</li> <li>assified based on avai</li> <li>repeated exposure</li> </ul>	•		
Not cl <b>STOT</b> Not cl	assified based on avai - repeated exposure assified based on avai	•		
Not cl STOT Not cl <u>Com</u> r	assified based on avai - repeated exposure assified based on avai ponents:	•		
Not cl STOT Not cl Comp Bariu	assified based on avai - repeated exposure assified based on avai	•	information. No significant	health effects observed in animals at concer g/kg bw or less.
Not cl STOT Not cl Comp Bariu Asses	assified based on avai - repeated exposure assified based on avai <u>ponents:</u> m sulfate:	lable	information. No significant	
Not cl STOT Not cl Comp Bariu Asses Repe	assified based on avai - repeated exposure assified based on avai <u>conents:</u> m sulfate: assment	lable	information. No significant	
Not cl STOT Not cl Comp Bariu Asses Repe	assified based on avai - repeated exposure assified based on avai <u>conents:</u> m sulfate: assment ated dose toxicity <u>conents:</u>	lable	information. No significant tions of 100 m	
Not cl STOT Not cl Comp Bariu Asses Repe Comp (17α) Speci	assified based on avai - repeated exposure assified based on avai <u>conents:</u> m sulfate: assment ated dose toxicity <u>conents:</u> -13-Ethyl-17-hydroxy- es	lable	information. No significant tions of 100 m <b>nethylene-18,1</b> 9 Rat	g/kg bw or less.
Not cl STOT Not cl Comp Bariu Asses Repea Comp (17α) Speci LOAE	assified based on avai - repeated exposure assified based on avai <u>conents:</u> m sulfate: ated dose toxicity <u>conents:</u> -13-Ethyl-17-hydroxy- es -14	lable	information. No significant tions of 100 m <b>nethylene-18,1</b> 9 Rat 0.5 mg/kg	
Not cl STOT Not cl Comp Bariu Asses Repea Comp (17α) Speci LOAE Applic	assified based on avai - repeated exposure assified based on avai <u>conents:</u> m sulfate: ated dose toxicity <u>conents:</u> -13-Ethyl-17-hydroxy- es EL cation Route	lable	information. No significant tions of 100 m <b>nethylene-18,1</b> 9 Rat 0.5 mg/kg Oral	g/kg bw or less.
Not cl STOT Not cl Comp Bariu Asses Reper Comp (17a) Speci LOAE Applic Expos	assified based on avai - repeated exposure assified based on avai <u>conents:</u> m sulfate: ated dose toxicity <u>conents:</u> -13-Ethyl-17-hydroxy- es -14	lable	information. No significant tions of 100 m <b>nethylene-18,1</b> 9 Rat 0.5 mg/kg Oral 1 yr	g/kg bw or less.
Not cl STOT Not cl Comp Bariu Asses Repea Comp (17α) Speci LOAE Applic Expos Targe	assified based on avai - repeated exposure assified based on avai <u>conents:</u> m sulfate: ssment ated dose toxicity <u>conents:</u> -13-Ethyl-17-hydroxy- es EL cation Route sure time et Organs es	lable	information. No significant tions of 100 m <b>nethylene-18,1</b> 9 Rat 0.5 mg/kg Oral 1 yr	g/kg bw or less. 9-dinorpregn-4-en-20-yn-3-one:
Not cl STOT Not cl Comp Bariu Asses Repea (17α) Speci LOAE Applic Expos Targe	assified based on avai - repeated exposure assified based on avai <u>conents:</u> m sulfate: assment ated dose toxicity <u>conents:</u> -13-Ethyl-17-hydroxy- es -13-Ethyl-17-hydroxy- es -14 cation Route sure time to Organs es -14	lable	information. No significant tions of 100 m <b>nethylene-18,1</b> Rat 0.5 mg/kg Oral 1 yr Reproductive Dog 0.625 mg/kg	g/kg bw or less. 9-dinorpregn-4-en-20-yn-3-one:
Not cl STOT Not cl Comp Bariu Asses Repea (17α) Speci LOAE Applic Expos Targe	assified based on avai - repeated exposure assified based on avai <u>conents:</u> m sulfate: assment ated dose toxicity <u>conents:</u> -13-Ethyl-17-hydroxy- es L cation Route sure time to Organs es L cation Route	lable	information. No significant tions of 100 m <b>nethylene-18,1</b> Rat 0.5 mg/kg Oral 1 yr Reproductive Dog 0.625 mg/kg Oral	g/kg bw or less. 9-dinorpregn-4-en-20-yn-3-one:
Not cl STOT Not cl Comp Bariu Asses Repea (17α) Speci LOAE Applic Expos Targe Speci LOAE Applic Expos	assified based on avai - repeated exposure assified based on avai <u>conents:</u> m sulfate: assment ated dose toxicity <u>conents:</u> -13-Ethyl-17-hydroxy- es -13-Ethyl-17-hydroxy- es -14 cation Route sure time to Organs es -14	lable	information. No significant tions of 100 m <b>hethylene-18,1</b> Rat 0.5 mg/kg Oral 1 yr Reproductive Dog 0.625 mg/kg Oral 26 Weeks	g/kg bw or less. 9-dinorpregn-4-en-20-yn-3-one:
Not cl STOT Not cl Comp Bariu Asses Repea Comp (17α) Speci LOAE Applic Expos Targe Speci LOAE Applic Expos Targe	assified based on avai - repeated exposure assified based on avai <u>conents:</u> m sulfate: assment ated dose toxicity <u>conents:</u> -13-Ethyl-17-hydroxy- es -13-Ethyl-17-hydroxy- es -14 cation Route sure time to Organs es -12 cation Route sure time to Organs	lable	information. No significant tions of 100 m <b>hethylene-18,1</b> Rat 0.5 mg/kg Oral 1 yr Reproductive Dog 0.625 mg/kg Oral 26 Weeks	g/kg bw or less. 9-dinorpregn-4-en-20-yn-3-one: organs, Endocrine system
Not cl STOT Not cl Comp Bariu Asses Repea Comp (17α) Speci LOAE Applic Expos Targe Speci LOAE Applic Expos Targe	assified based on avai - repeated exposure assified based on avai <u>conents:</u> m sulfate: assment ated dose toxicity <u>conents:</u> -13-Ethyl-17-hydroxy- es EL cation Route sure time at Organs es EL cation Route sure time at Organs m sulfate:	lable	information. No significant tions of 100 m <b>hethylene-18,1</b> Rat 0.5 mg/kg Oral 1 yr Reproductive Dog 0.625 mg/kg Oral 26 Weeks	g/kg bw or less. 9-dinorpregn-4-en-20-yn-3-one: organs, Endocrine system



NOAEL : 61.1 mg/kg						
Application Route: IngestionExposure time: 90 DaysRemarks: Based on data from similar materials						
Aspiration toxicity Not classified based on available information.						
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, Naus Skin disorders, effects on menstruation, vaginitis, breas derness, mood swings, male reproductive effects, Swea	ten-					
12. ECOLOGICAL INFORMATION						
Ecotoxicity						
Components:						
(17α)-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/lExposure time: 96 hMethod: FDA 4.11						
LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1.3 mg Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility	ı/I					
Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 3.9 mg/l aquatic invertebrates 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						



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				Species: Oryzias Method: OECD Te	latipes (Japanese medaka) est Guideline 229
		to daphnia and other invertebrates (Chron- ty)	:	NOEC: 1.2 mg/l Exposure time: 21 Species: Daphnia	d magna (Water flea)
	M-Facto toxicity)	or (Chronic aquatic	:	10,000	
	Barium	sulfate:			
	Toxicity		:	Exposure time: 96 Method: OECD Te	
		to daphnia and other invertebrates	:	Exposure time: 48	agna (Water flea)): > 10 - 100 mg/l 3 h on data from similar materials
	Toxicity plants	to algae/aquatic	:	mg/l Exposure time: 72 Method: OECD Te	
				mg/l Exposure time: 72 Method: OECD Te	
	Toxicity	to microorganisms	:	EC50: > 600 mg/l Exposure time: 3 Method: OECD Te Remarks: Based o	h
				NOEC: > 600 mg/ Exposure time: 3 Method: OECD Te Remarks: Based of	h
	Toxicity icity)	to fish (Chronic tox-	:	NOEC: > 1 mg/l Exposure time: 33 Species: Danio re Method: OECD Te Remarks: Based of	rio (zebra fish)
		to daphnia and other invertebrates (Chron- ty)	:		l d magna (Water flea) on data from similar materials



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Per	sistence and degradabil	lity		
<u>Cor</u>	nponents:			
(170	α)-13-Ethyl-17-hydroxy-1	l1-n	nethylene-18,19-c	linorpregn-4-en-20-yn-3-one:
Stal	pility in water	:	Hydrolysis: < 10 Method: FDA 3.0	
Bio	accumulative potential			
<u>Cor</u>	nponents:			
(170	x)-13-Ethyl-17-hydroxy-1	l1-n	nethylene-18,19-c	linorpregn-4-en-20-yn-3-one:
Bioa	accumulation	:	Bioconcentration	s macrochirus (Bluegill sunfish) factor (BCF): 128 Fest Guideline 305
	tition coefficient: n- anol/water	:	log Pow: 3.5	
Bar	ium sulfate:			
Bioa	accumulation	:		s macrochirus (Bluegill sunfish) factor (BCF): < 500
	tition coefficient: n- anol/water	:	: log Pow: -1.03 Remarks: Calculation	
Mol	pility in soil			
<u>Cor</u>	nponents:			
(170	x)-13-Ethyl-17-hydroxy-1	l1-n	nethylene-18,19-d	linorpregn-4-en-20-yn-3-one:
	ribution among environ- ntal compartments	:	log Koc: 2.84 Method: FDA 3.0	)8
• • • •	<b>er adverse effects</b> data available			
13. DISF	POSAL CONSIDERATION	NS		
Dis	posal methods			
Was	ste from residues Itaminated packaging	:	Empty containers dling site for recy	cordance with local regulations. s should be taken to an approved waste han- cling or disposal. specified: Dispose of as unused product.
14. TRA	NSPORT INFORMATION	I		
Inte	rnational Regulations			
	RTDG number	:	UN 3077	



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Proper shipping name		:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, SOLID, 7-hydroxy-11-methylene-18,19-dinorpregn- )	
	Class Packing Labels	g group	:	9 111 9	
	IATA-E UN/ID Proper		:		nazardous substance, solid, n.o.s. 7-hydroxy-11-methylene-18,19-dinorpregn-
	Labels	g group g instruction (cargo	: : :	9 III Miscellaneous 956	)
	Packing ger airc	g instruction (passen-	:	956 yes	
	IMDG- UN nur	Code	:	UN 3077 ENVIRONMENTA N.O.S.	ALLY HAZARDOUS SUBSTANCE, SOLID, 7-hydroxy-11-methylene-18,19-dinorpregn-4-
	Labels EmS C	g group ode pollutant	:	9 III 9 F-A, S-F yes	

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### **15. REGULATORY INFORMATION**

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

The components of this pro-	duo	t are reported in the following inventories:
AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined



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16. (	OTHER INFORMATION			
	Further information Sources of key data used to compile the Safety Data Sheet	:		data, data from raw material SDSs, OECD arch results and European Chemicals Agen- ropa.eu/
	Date format		dd.mm.yyyy	
	Full text of other abbreviat	ions		
	ACGIH	÷		eshold Limit Values (TLV)
	ACGIH / TWA	:	8-hour, time-weig	hted 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 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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