

Progesterone Formulation

Versio 5.2	n	Revision Date: 06.04.2024		S Number: 5495-00011	Date of last issue: 30.09.2023 Date of first issue: 17.10.2019
		IDENTIFICATION			
Pi	roduct	name	:	Progesterone Fo	rmulation
М	anufa	cturer or supplier's d	etai	ls	
	ompar		:	Organon & Co.	
Ad	ddress	5	:	30 Hudson Stree Jersey City, New	t, 33nd floor Jersey, U.S.A 07302
Te	Telephone		:	+1-551-430-6000)
E	Emergency telephone number		÷	+1-215-631-6999)
E	E-mail address		:	EHSSTEWARD	⊉organon.com
R	ecom	mended use of the ch	nemi	ical and restrictio	ons on use
		mended use	:	Pharmaceutical	
R	estrict	ions on use		Not applicable	

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Carcinogenicity	:	Category 2
Reproductive toxicity	:	Category 1A
Effects on or via lactation		
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H351 Suspected of causing cancer. H360FD May damage fertility. May damage the unborn child. H362 May cause harm to breast-fed children.
Precautionary statements	:	 Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dust. P263 Avoid contact during pregnancy and while nursing.



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	5155495-00011	Date of first issue: 17.10.2019

P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

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 explosible dust-air mixture if dispersed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sunflower oil	8001-21-6	>= 30 -< 60
Progesterone	57-83-0	>= 10 -< 30
Glycerine	56-81-5	< 10
Titanium dioxide	13463-67-7	< 1

SECTION 4. FIRST AID MEASURES

General advice	 In the case of accident or if you feel unwell, seek medical a vice immediately. When symptoms persist or in all cases of doubt seek mediadvice. 	
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 pl of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. 	enty
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. 	



Version 5.2	Revision Date: 06.04.2024	-	0S Number: 55495-00011	Date of last issue: 30.09.2023 Date of first issue: 17.10.2019
and	Most important symptoms and effects, both acute and delayed		May cause harm to Contact with dust	sing cancer. lity. May damage the unborn child. to breast-fed children. can cause mechanical irritation or drying of
Pro	Protection of first-aiders		First Aid responde and use the recor	the eyes can lead to mechanical irritation. ers should pay attention to self-protection, nmended personal protective equipment I for exposure exists (see section 8).
No	tes to physician	:		cally and supportively.
SECTIC	N 5. FIREFIGHTING MEA	SU	RES	
Sui	table extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
	Unsuitable extinguishing media Specific hazards during fire- fighting		High volume wate	r jet
Spe			concentrations, ar potential dust exp Do not use a solic fire.	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. I water stream as it may scatter and spread pustion products may be a hazard to health.
Ha: uct	zardous combustion prod- s	:	Carbon oxides Nitrogen oxides (I	NOx)
Spe ods	ecific 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
for	Special protective equipment for firefighters Hazchem Code		In the event of fire	e, wear self-contained breathing apparatus. rective equipment.
SECTIC	N 6. ACCIDENTAL RELE	ASI	EMEASURES	
tive	rsonal precautions, protec- e equipment and emer- ncy procedures	:		ective equipment. ing advice (see section 7) and personal pro- 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.	



Progesterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	5155495-00011	Date of first issue: 17.10.2019
contai	nment and cleaning up	Avoid dispersal of with compressed Dust deposits sh es, as these may leased into the a Local or national posal of this mate employed in the mine which regul Sections 13 and	f dust in the air (i.e., clearing dust surfaces

SECTION 7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust
Advice on safe handling	:	ventilation. Avoid contact during pregnancy and while nursing. Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. 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. Do not eat, drink or smoke when using this product. 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 contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
Conditions for safe storage	:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types:



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	5155495-00011	Date of first issue: 17.10.2019

Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
Components	0A0-N0.		ters / Permissible	Dasis
		(Form of		
		exposure)	concentration	
Sunflower oil	8001-21-6	TWA (Mist)	10 mg/m3	AU OEL
Progesterone	57-83-0	TWA	6 µg/m3 (OEB 4)	Internal
		Wipe limit	60 µg/100 cm2	Internal
Glycerine	56-81-5	TWA (Mist)	10 mg/m3	AU OEL
Titanium dioxide	13463-67-7	TWA	10 mg/m3	AU OEL
		TWA (Res-	2.5 mg/m3	ACGIH
		pirable par-	(Titanium dioxide)	
		ticulate mat-		
		ter)		

This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Titanium dioxide

Engineering measures	:	Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.
Personal protective equipme	ent	
Respiratory protection Filter type Hand protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Combined particulates and organic vapour type
Material	:	Chemical-resistant gloves
Remarks Eye protection	:	Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat.



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	5155495-00011	Date of first issue: 17.10.2019

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Crystalline powder
Colour	:	white to off-white
Odour	:	odourless
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	126 °C
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	practically insoluble
Partition coefficient: n-	:	Not applicable
octanol/water Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		



Progesterone Formulation

Version 5.2	Revision Date: 06.04.2024		9S Number: 55495-00011	Date of last issue: 30.09.2023 Date of first issue: 17.10.2019
<i></i>			Net excProduce	
VI	scosity, kinematic	:	Not applicable	
Explo	osive properties	:	Not explosive	
Oxidi	zing properties	:	The substance o	r mixture is not classified as oxidizing.
Mole	cular weight	:	No data available	9
	cle characteristics cle size	:	No data available	e
SECTION	10. STABILITY AND RE	EAC	TIVITY	
	tivity nical stability ibility of hazardous reac-	:	Stable under nor	a reactivity hazard. mal conditions. a explosive mixture in air.
tions	litions to avoid		Avoid dust forma	tion
Incon	npatible materials irdous decomposition	:	None.	ecomposition products are known.
SECTION	11. TOXICOLOGICAL I	NFC	ORMATION	
Ехро	sure routes	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity lassified based on availa	ble	information.	
<u>Com</u>	ponents:			
Sunf	lower oil:			
Acute	e oral toxicity	:	LD50 (Rat): > 2,0 Method: OECD T Remarks: Based	
Proa	esterone:			
-	e dermal toxicity	:	LD50 (Rat): > 2,0 Remarks: Based	00 mg/kg on data from similar materials
Glyce	erine:			
Acute	e oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg

Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg



ersion 2	Revision Date: 06.04.2024	SDS Number: 5155495-00011	Date of last issue: 30.09.2023 Date of first issue: 17.10.2019			
	um dioxide:		<i>"</i>			
Acute	oral toxicity	: LD50 (Rat): > \$	5,000 mg/kg			
Acute inhalation toxicity		Exposure time: Test atmosphe	Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhala-			
-	corrosion/irritation assified based on ava	ailable information.				
Comp	oonents:					
Sunfl	ower oil:					
Speci	es	: Rabbit				
Resul	t	: No skin irritatio				
Rema	rks	: Based on data	from similar materials			
Proge	esterone:					
Speci	es	: Rabbit				
Resul		: No skin irritatio				
Rema	rks	: Based on data	from similar materials			
Glyce	erine:					
Speci		: Rabbit				
Resul	t	: No skin irritatio	n			
Titani	um dioxide:					
Speci		: Rabbit				
Resul	t	: No skin irritatio	n			
Serio	us eye damage/eye	irritation				
	assified based on ava					
<u>Comp</u>	oonents:					
Sunfl	ower oil:					
Speci		: Rabbit				
Resul		: No eye irritation				
Rema	ITKS	: Based on data	from similar materials			
Proge	esterone:					
Speci		: Rabbit				
Resul Metho		: No eye irritatio : OECD Test Gu				
N/IOTHO	DCI					



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ersion 2	Revision Date: 06.04.2024	SDS Number: 5155495-00011	Date of last issue: 30.09.2023 Date of first issue: 17.10.2019
Glyce	erine:		
Speci		: Rabbit	
Resul	t	: No eye irritation	
	ium dioxide:		
Speci		: Rabbit	
Resul	t	: No eye irritation	
Resp	iratory or skin sensi	tisation	
Skin	sensitisation		
Not cl	assified based on ava	ailable information.	
Resp	iratory sensitisation		
Not cl	assified based on ava	ailable information.	
<u>Comp</u>	oonents:		
Sunfl	ower oil:		
Test 7		: Maximisation Te	est
	sure routes	: Skin contact	
Speci		: Guinea pig	
Resul Rema		: negative : Based on data f	rom similar materials
_			
-	esterone:	· Movimination To	-
Test 7	•••	: Maximisation Te	est
Speci	sure routes	: Skin contact : Rabbit	
Metho		: OECD Test Gui	deline 406
Resul		: negative	
Rema	urks	: Based on data f	rom similar materials
Titani	ium dioxide:		
Test 7		: Local lymph noc	le assay (LLNA)
Expos	sure routes	: Skin contact	
Speci		: Mouse	
Resul	t	: negative	
Chro	nic toxicity		
	cell mutagenicity		
	assified based on ava	ailable information.	
	oonents:		
	ower oil:	· ·	n n sa sa
Geno	toxicity in vitro		ro mammalian cell gene mutation test Test Guideline 476



Version 5.2	Revision Date: 06.04.2024	SDS Number:Date of last issue: 30.09.20235155495-00011Date of first issue: 17.10.2019
		Remarks: Based on data from similar materials
Prog	esterone:	
Genc	toxicity in vitro	 Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: Based on data from similar materials Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Method: OECD Test Guideline 482 Result: negative
Genc	otoxicity in vivo	 Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Monkey Application Route: Subcutaneous Result: negative Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo Species: Rat Application Route: Ingestion Result: negative
Glyce	erine:	
Genc	toxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test Result: negative
		Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Chromosome aberration test in vitro Result: negative
		Test Type: DNA damage and repair, unscheduled DNA syn- thesis in mammalian cells (in vitro) Result: negative
Titan	ium dioxide:	
	toxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Geno	otoxicity in vivo	: Test Type: In vivo micronucleus test Species: Mouse Result: negative



ersion 2	Revision Date: 06.04.2024	SDS Number: 5155495-00011	Date of last issue: 30.09.2023 Date of first issue: 17.10.2019
Carci	nogenicity		
Suspe	ected of causing cance	r.	
<u>Comp</u>	oonents:		
Proge	esterone:		
Specie	es	: Mouse, female	9
	ation Route	: Subcutaneous	3
	sure time	: 104 weeks	
Resul	t	: positive	
Carcir ment	nogenicity - Assess-	: Limited evider	nce of carcinogenicity in animal studies
Glyce	rine:		
Specie		: Rat	
	ation Route	: Ingestion	
Expos Resul	sure time	: 2 Years : negative	
Resul	L .	. negative	
Titani	um dioxide:		
Specie	es	: Rat	
	ation Route	: inhalation (due	st/mist/fume)
	sure time	: 2 Years	
Metho Result		: OECD Test G : positive	uideline 453
Rema			m or mode of action may not be relevant in hu-
		mans.	
			e(s) is not bioavailable and therefore does not dust inhalation hazard.
Carcir ment	nogenicity - Assess-	: Limited evider animals.	nce of carcinogenicity in inhalation studies with
Repro	oductive toxicity		
	lamage fertility. May da ause harm to breast-fe		ild.
<u>Comp</u>	oonents:		
Proge	esterone:		
-	s on fertility	: Test Type: Fe	rtility/early embryonic development
	,	Species: Rat	
		Application Ro	oute: Subcutaneous
		Result: positiv	e
Effect	s on foetal develop-	: Test Type: Fe	rtility/early embryonic development
ment		Species: Rat	
		Application Ro	oute: Subcutaneous
		Result: positiv	е
Repro	ductive toxicity - As-	: Positive evide	nce of adverse effects on sexual function and
	,		



Version 5.2	Revision Date: 06.04.2024	SDS Number: 5155495-00011	Date of last issue: 30.09.2023 Date of first issue: 17.10.2019
sessn	nent	of adverse e	human epidemiological studies., Clear evidence effects on development, based on animal experi- dies indicating a hazard to babies during the lacta-
Glyce	erine:		
-	s on fertility	Species: Ra	Route: Ingestion
Effect ment	s on foetal develop-	Species: Ra	Route: Ingestion
	- single exposure assified based on ava	ilable information.	
	- repeated exposure assified based on ava		
Repe	ated dose toxicity		
-	oonents:		
-	ponents:		
<u>Comp</u> Glyce Speci	oonents: erine: es	: Rat	
<u>Com</u> Glyce Speci NOAE	oonents: erine: es EL	: 0.167 mg/l	
Comp Glyce Speci NOAE LOAE Applic	oonents: erine: es EL EL cation Route	: 0.167 mg/l : 0.622 mg/l : inhalation (d	lust/mist/fume)
Comp Glyce Speci NOAE LOAE Applic	oonents: erine: es EL EL	: 0.167 mg/l : 0.622 mg/l	lust/mist/fume)
Comp Glyce Speci NOAE LOAE Applic Expos	oonents: erine: es EL EL cation Route sure time es	: 0.167 mg/l : 0.622 mg/l : inhalation (d : 13 Weeks : Rat	
Comp Glyce Speci NOAE LOAE Applic Expos	ponents: erine: es EL EL cation Route sure time es EL	: 0.167 mg/l : 0.622 mg/l : inhalation (d : 13 Weeks : Rat : 8,000 - 10,0	
Comp Glyce Speci NOAE LOAE Applic Expos Speci NOAE Applic	oonents: erine: es EL EL cation Route sure time es	: 0.167 mg/l : 0.622 mg/l : inhalation (d : 13 Weeks : Rat	
Comp Glyce Speci NOAE LOAE Applic Expos Speci NOAE Applic Expos	erine: es EL EL cation Route sure time es EL cation Route sure time	 0.167 mg/l 0.622 mg/l inhalation (d 13 Weeks Rat 8,000 - 10,0 Ingestion 2 yr 	
Comp Glyce Speci NOAE LOAE Applic Expos Speci NOAE Speci NOAE	ponents: erine: es EL EL cation Route sure time es EL cation Route sure time es EL cation Route sure time	 0.167 mg/l 0.622 mg/l inhalation (d 13 Weeks Rat 8,000 - 10,0 Ingestion 2 yr Rabbit 5,040 mg/kg 	00 mg/kg
Comp Glyce Speci NOAE LOAE Applic Expos Speci NOAE Applic Expos	erine: es EL EL cation Route sure time es EL cation Route sure time es EL cation Route sure time	 0.167 mg/l 0.622 mg/l inhalation (d 13 Weeks Rat 8,000 - 10,0 Ingestion 2 yr Rabbit 5,040 mg/kg Skin contact 	00 mg/kg
Comp Glyce Speci NOAE LOAE Applic Expos Speci NOAE Applic Expos	ponents: erine: es EL EL cation Route sure time es EL cation Route sure time es EL cation Route sure time	 0.167 mg/l 0.622 mg/l inhalation (d 13 Weeks Rat 8,000 - 10,0 Ingestion 2 yr Rabbit 5,040 mg/kg 	00 mg/kg
Comp Glyce Speci NOAE LOAE Applic Expos Speci NOAE Applic Expos	erine: es EL EL cation Route sure time es EL cation Route sure time es EL cation Route sure time	 0.167 mg/l 0.622 mg/l inhalation (d 13 Weeks Rat 8,000 - 10,0 Ingestion 2 yr Rabbit 5,040 mg/kg Skin contact 	00 mg/kg
Comp Glyce Speci NOAE LOAE Applic Expos Speci NOAE Applic Expos Speci NOAE Applic Expos	erine: es EL EL EL EL EXATION ROUTE sure time es EL EXATION ROUTE sure time es EL EXATION ROUTE sure time es EL EXATION ROUTE sure time es EL EXATION ROUTE sure time	 0.167 mg/l 0.622 mg/l inhalation (d 13 Weeks Rat 8,000 - 10,0 Ingestion 2 yr Rabbit 5,040 mg/kg Skin contact 45 Weeks Rat 	00 mg/kg
Comp Glyce Speci NOAE LOAE Applic Expos Speci NOAE Applic Expos Speci NOAE Applic Expos Titan Speci NOAE	es EL es EL cation Route sure time es EL cation Route sure time es EL cation Route sure time es EL cation Route sure time	 0.167 mg/l 0.622 mg/l inhalation (d 13 Weeks Rat 8,000 - 10,0 Ingestion 2 yr Rabbit 5,040 mg/kg Skin contact 45 Weeks Rat 24,000 mg/kg 	00 mg/kg
Comp Glyce Speci NOAE LOAE Applic Expos Speci NOAE Applic Expos Speci NOAE Applic Expos Speci NOAE Applic Expos	erine: es EL EL EL EL EXATION ROUTE sure time es EL EXATION ROUTE sure time es EL EXATION ROUTE sure time es EL EXATION ROUTE sure time es EL EXATION ROUTE sure time	 0.167 mg/l 0.622 mg/l inhalation (d 13 Weeks Rat 8,000 - 10,0 Ingestion 2 yr Rabbit 5,040 mg/kg Skin contact 45 Weeks Rat 	00 mg/kg
Comp Glyce Speci NOAE LOAE Applic Expos Speci NOAE Applic Expos Speci NOAE Applic Expos Speci NOAE Applic Expos	erine: es EL EL cation Route sure time es EL cation Route sure time es EL cation Route sure time ium dioxide: es EL cation Route sure time	 0.167 mg/l 0.622 mg/l inhalation (d 13 Weeks Rat 8,000 - 10,0 Ingestion 2 yr Rabbit 5,040 mg/kg Skin contact 45 Weeks Rat 24,000 mg/kg Ingestion 	00 mg/kg



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Version 5.2	Revision Date: 06.04.2024		OS Number: 55495-00011	Date of last issue: 30.09.2023 Date of first issue: 17.10.2019
	cation Route sure time	:	inhalation (dust 2 yr	/mist/fume)
-	ration toxicity classified based on availa	ıble	information.	
	erience with human exp			
<u>Com</u>	ponents:			
-	esterone: eral Information	:	Target Organs: Symptoms: Effe	Endocrine system
SECTION	12. ECOLOGICAL INFO	ORI	• •	
Ecot	oxicity			
<u>Com</u>	ponents:			
	lower oil: bity to fish	:	Exposure time:	ıs idus (Golden orfe)): > 100 mg/l 48 h d on data from similar materials
	city to daphnia and other tic invertebrates	:	Exposure time: Method: Directi Remarks: Base	magna (Water flea)): > 32 mg/l 48 h ve 67/548/EEC, Annex V, C.2. d on data from similar materials e limit of solubility
Τοχία	city to microorganisms	:	Exposure time:	nonas putida): 883 mg/l 18 h d on data from similar materials
Prog	esterone:			
-	city to fish	:	Exposure time: Test substance Method: OECD	rio (zebra fish)): > 1 - 10 mg/l 96 h : Water Accommodated Fraction Test Guideline 203 d on data from similar materials
	city to daphnia and other tic invertebrates	:	Exposure time: Test substance	magna (Water flea)): > 1 mg/l 48 h : Water Accommodated Fraction d on data from similar materials



rsion	Revision Date: 06.04.2024	-	S Number: 55495-00011	Date of last issue: 30.09.2023 Date of first issue: 17.10.2019
	ty to daphnia and other ic invertebrates (Chron- city)		NOEC (Daphnia Exposure time: 2	magna (Water flea)): 0.1 mg/l 26 d
Glyce	rine:			
Toxici	ty to fish	:	LC50 (Oncorhyn Exposure time: 9	nchus mykiss (rainbow trout)): 54,000 mg/l 96 h
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia Exposure time: 4	magna (Water flea)): 1,955 mg/l 48 h
Toxici	ty to microorganisms	:	NOEC (Pseudor Exposure time: 7 Method: DIN 38	
Titani	um dioxide:			
	ty to fish	:	Exposure time: 9	nchus mykiss (rainbow trout)): > 100 mg/l 96 h Test Guideline 203
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia Exposure time: 4	magna (Water flea)): > 100 mg/l 48 h
Toxici plants	ty to algae/aquatic	:	EC50 (Skeletone Exposure time: 7	ema costatum (marine diatom)): > 10,000 m 72 h
Toxici	ty to microorganisms	:	EC50: > 1,000 n Exposure time: 3 Method: OECD	
Persi	stence and degradabil	ity		
<u>Comp</u>	oonents:			
Proge	esterone:			
Biode	gradability	:	Result: Readily I Remarks: Based	biodegradable. I on data from similar materials
Glyce	rine:			
Biode	gradability	:	Result: Readily I Biodegradation: Exposure time: 3 Method: OECD	92 %
Bioac	cumulative potential			
Comp	oonents:			



Progesterone Formulation

sion	Revision Date: 06.04.2024	SDS Number: 5155495-00011	Date of last issue: 30.09.2023 Date of first issue: 17.10.2019
octan	ol/water	Method: OECD	Test Guideline 117
	erine: ion coefficient: n- ol/water	: log Pow: -1.75	
	lity in soil ata available		
	r adverse effects ata available		

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

International Regulations

UNRTDG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Progesterone)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR		
UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Progesterone)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passen- ger aircraft)	:	956
Environmentally hazardous	:	yes
IMDG-Code		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.



Progesterone Formulation

	Version 5.2	Revision Date: 06.04.2024	SDS Number: 5155495-00011	Date of last issue: 30.09.2023 Date of first issue: 17.10.2019	
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		(Progesterone)
Class	:	9
Packing group	:	111
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

ADG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Progesterone)
Class	:	9
Packing group	:	III
Labels	:	9
Hazchem Code	:	2Z
Environmentally hazardous	:	yes

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mix- ture				
Therapeutic Goods (Poisons : Standard) Instrument		the original publication to check for onditions or threshold limits that might		
Prohibition/Licensing Requirements		There is no applicable prohibition, authorisation and restricted use requirements, including for carcino-		

There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

IECSC	:	not determined
AICS	:	not determined
DSL	:	not determined



Version	Revision Date:
5.2	06.04.2024

SDS Number: 5155495-00011 Date of last issue: 30.09.2023 Date of first issue: 17.10.2019

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information		
Revision Date Sources of key data used to compile the Safety Data Sheet	:	06.04.2024 Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/
Date format	:	dd.mm.yyyy
Full text of other abbreviation	ns	
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AU OEL	:	Australia. Workplace Exposure Standards for Airborne Con- taminants.
ACGIH / TWA	:	8-hour, time-weighted average
AU OEL / TWA	:	Exposure standard - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association: IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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

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



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	5155495-00011	Date of first issue: 17.10.2019

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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