

Progesterone Formulation (Veterinary)

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
9.0	28.09.2024	2190082-00016	Date of first issue: 15.11.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier Trade name	:	Progesterone Formulation (Veterinary)	
1.2	Relevant identified uses of th	ne s	substance or mixture and uses advised against	
	Use of the Sub- stance/Mixture	:	Veterinary product	
	Recommended restrictions on use	:	Not applicable	
1.3	1.3 Details of the supplier of the safety data sheet			
	Company	:	MSD Kilsheelan Clonmel Tipperary, IE	
	Telephone	:	353-51-601000	
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com	

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Carcinogenicity, Category 2	H351: Suspected of causing cancer.
Carcinogenicity, Category 1A	H350i: May cause cancer by inhalation.
Reproductive toxicity, Category 1A	H360FD: May damage fertility. May damage the unborn child.
Effects on or via lactation	H362: May cause harm to breast-fed children.
Specific target organ toxicity - repeated	H372: Causes damage to organs through pro-
exposure, Category 1	longed or repeated exposure.
Long-term (chronic) aquatic hazard, Cat-	H410: Very toxic to aquatic life with long lasting
egory 1	effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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



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Hazaı	rd pictograms		¥2
Signa	l word	: Danger	•
Hazaı	rd statements	H351 Suspec H360FD child. H362 May ca H372 Causes peated exposu	use cancer by inhalation. ted of causing cancer. May damage fertility. May damage the unborn use harm to breast-fed children. a damage to organs through prolonged or re- re. xic to aquatic life with long lasting effects.
Preca	utionary statements	P263 Avoid o P273 Avoid r	special instructions before use. contact during pregnancy and while nursing. elease to the environment. rotective gloves/ protective clothing/ eye protec- ction.
		Response: P308 + P313 attention. P391 Collect	IF exposed or concerned: Get medical advice/ spillage.
Hazaı	rdous components whi	ch must be listed on	the label:

Hazardous components which must be listed on the label: Quartz Progesterone Restricted to professional users.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.



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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Quartz	14808-60-7 238-878-4	Carc. 1A; H350i STOT RE 1; H372 (Lungs)	>= 30 - < 50
Progesterone	57-83-0 200-350-6	Carc. 2; H351 Repr. 1A; H360FD Lact.H362 Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 1.000	>= 2,5 - < 10
Bis(alpha,alpha-dimethylbenzyl) per- oxide	80-43-3 201-279-3 617-006-00-X	Org. Perox. F; H242 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 1B; H360D Aquatic Chronic 2; H411	>= 0,3 - < 1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes.



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		Get medical att Wash clothing b Thoroughly clea	
In cas	e of eye contact		water as a precaution. ention if irritation develops and persists.
lf swa	llowed	Get medical att	O NOT induce vomiting. ention. oroughly with water.
4.2 Most ii	mportant symptoms	and effects, both acu	ite and delayed
Risks		Suspected of ca May damage fe May cause harr	cer by inhalation. ausing cancer. rrtility. May damage the unborn child. m to breast-fed children. e to organs through prolonged or repeated

4.3 Indication of any immediate medical attention and special treatment needed

exposure.

	•	
Treatment	: Treat symptomatically and sup	oortively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire- : fighting	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- : ucts	Carbon oxides Silicon oxides
5.3 Advice for firefighters	
Special protective equipment : for firefighters	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do
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according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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			so. Evacuate area.	
SECTION	N 6: Accidental rele	ease r	neasures	
6.1 Perso	nal precautions, prot	tective	e equipment an	d emergency procedures
Perso	onal precautions	:	Follow safe ha	protective equipment. Indling advice (see section 7) and personal pro- ent recommendations (see section 8).
6.2 Enviro	onmental precaution	S		
Envir	onmental precautions	:	Prevent further Retain and disp	o the environment. leakage or spillage if safe to do so. pose of contaminated wash water. es should be advised if significant spillages ained.
6.3 Metho	ods and material for o	contai	nment and clea	ning up
Meth	ods for cleaning up	·	tainer for dispo Local or nation posal of this ma employed in the mine which reg Sections 13 an	acuum up spillage and collect in suitable con- sal. al regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- julations are applicable. d 15 of this SDS provide information regarding national requirements.
6.4 Refere	ence to other section	IS		
See section	ons: 7, 8, 11, 12 and 1	3.		

7.1 Precautions for safe handling

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Avoid contact during pregnancy and while nursing. Do not get on skin or clothing.
		Do not breathe dust, fume, gas, mist, vapours or spray.
		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.
		Do not eat, drink or smoke when using this product.
		Take care to prevent spills, waste and minimize release to the



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Hygier	ne measures	:	flushing systems	emical is likely during typical use, provide eye and safety showers close to the working g do not eat, drink or smoke. Wash contami- fore re-use.
7.2 Conditi	ions for safe storage,	inc	luding any incom	patibilities
•	ements for storage and containers	:		labelled containers. Store locked up. Keep ore in accordance with the particular national
Advice	e on common storage	:	Strong oxidizing a	stances and mixtures
7.3 Specifi	c end use(s)			
Specif	ic use(s)	:	No data available	

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Quartz	14808-60-7	TWA (respirable	0,05 mg/m3	FOR-2011-
		dust)	(Silica)	12-06-1358
	Further inform	nation: Substances c	onsidered to be carcinogenio	Ç
		TWA (total dust)	0,3 mg/m3	FOR-2011-
			(Silica)	12-06-1358
	Further inform	nation: Substances c	onsidered to be carcinogenio	, ,
		TWA (Respirable	0,1 mg/m3	2004/37/EC
		dust)		
	Further inform	nation: Carcinogens	or mutagens	
Silicon dioxide	7631-86-9	TWA (respirable	1,5 mg/m3	FOR-2011-
		dust)	(Silica)	12-06-1358
Progesterone	57-83-0	TWA	6 µg/m3 (OEB 4)	Internal
		Wipe limit	60 µg/100 cm2	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Silicon dioxide	Workers	Inhalation	Long-term systemic effects	4 mg/m3
Bis(alpha,alpha- dimethylbenzyl) per-	Workers	Inhalation	Long-term systemic effects	5,6 mg/m3

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



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oxide					<u> </u>

oxide				
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1,4 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,4 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Bis(alpha,alpha-dimethylbenzyl)	Fresh water	2,34 µg/l
peroxide		
	Sewage treatment plant	100 mg/l
	Fresh water sediment	2,24 mg/kg
	Soil	0,447 mg/kg

8.2 Exposure controls

Engineering measures

Minimize workplace exposure concentrations. If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment

Eye/face protection	:	Wear the following personal protective equipment: Safety glasses Equipment should conform to NS EN 166
Hand protection		_ 1
Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Skin and body protection	:	Select appropriate protective clothing based on chemical re- sistance data and an assessment of the local exposure poten- tial. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to NS EN 137
Filter type	:	Self-contained breathing apparatus



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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	solid
Colour	:	light green
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not classified as a flammability hazard
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Flash point Auto-ignition temperature	:	Not applicable No data available
	:	
Auto-ignition temperature	:	No data available
Auto-ignition temperature Decomposition temperature	:	No data available No data available
Auto-ignition temperature Decomposition temperature pH Viscosity	:	No data available No data available No data available
Auto-ignition temperature Decomposition temperature pH Viscosity Viscosity, kinematic Solubility(ies)	:	No data available No data available No data available Not applicable
Auto-ignition temperature Decomposition temperature pH Viscosity Viscosity, kinematic Solubility(ies) Water solubility Partition coefficient: n-	: :: :: ::	No data available No data available No data available Not applicable soluble
Auto-ignition temperature Decomposition temperature pH Viscosity Viscosity, kinematic Solubility(ies) Water solubility Partition coefficient: n- octanol/water	: : : :	No data available No data available No data available Not applicable Soluble
Auto-ignition temperature Decomposition temperature pH Viscosity Viscosity, kinematic Solubility(ies) Water solubility Partition coefficient: n- octanol/water Vapour pressure	: : : :	No data available No data available No data available Not applicable Not applicable Not applicable No data available

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F	Relative vapour density	: Not applicable	
F	Particle characteristics Particle size	: Not applicable	
	ther information Explosives	: Not explosive	
C	Dxidizing properties	: The substance or mixtu	re is not classified as oxidizing.
E	Evaporation rate	: Not applicable	
Ν	Aolecular weight	: Not applicable	

SECTION 10: Stability and reactivity

800

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

Acute toxicity

Not classified based on available information.

Components:

Quartz:

Acute oral toxicity

: LD50 (Rat): > 22.500 mg/kg



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Prog	esterone:		
Acute	e dermal toxicity	: LD50 (Rat): Remarks: Ba	> 2.000 mg/kg ased on data from similar materials
Bis(a	lpha,alpha-dimethylb	enzyl) peroxide:	
Acute	e oral toxicity		> 2.000 mg/kg CD Test Guideline 401 : The substance or mixture has no acute oral tox-
Acute	e inhalation toxicity	: LC50 (Rat): Exposure tin Test atmosp	
Acute	e dermal toxicity		> 2.000 mg/kg CD Test Guideline 402 : The substance or mixture has no acute dermal
Not c	corrosion/irritation lassified based on ava	ilable information.	
	ponents:		
Quar Spec Meth Resu Rema	ies od It	: No skin irrita	Guideline 404 tion ta from similar materials
Prog	esterone:		
Spec Resu Rema	ies It	: Rabbit : No skin irrita : Based on da	tion ta from similar materials
Ris(a	lpha,alpha-dimethylb	enzul) neroxide:	
Resu	• • •	: Skin irritation	1
Not c	ous eye damage/eye i lassified based on ava ponents:		
Quar	tz:		
Spec Mether	od	: Rabbit : OECD Test	Guideline 405

: No eye irritation

Result

Remarks

: Based on data from similar materials

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Progesterone:

Species Method Result Remarks	: Rabbit
Method	: OECD Test Guideline 405
Result	: No eye irritation
Remarks	: Based on data from similar materials

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Species Method Result	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	Irritation to eyes, reversing within 7 days

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Progesterone:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Rabbit
Method	:	OECD Test Guideline 406
Result	:	negative
Test Type Exposure routes Species Method Result Remarks	:	Based on data from similar materials

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact
Species	:	Mouse
Method	:	OECD Test Guideline 429
Test Type Exposure routes Species Method Result	:	negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Progesterone:

Genotoxicity 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 syn- thesis in mammalian cells (in vitro) Method: OECD Test Guideline 482 Result: negative

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ersion .0	Revision Date: 28.09.2024	SDS Number: 2190082-00016	Date of last issue: 06.04.2024 Date of first issue: 15.11.2017
II			
Genoto	oxicity in vivo	cytogenetic a Species: Mo Application F Result: nega Test Type: L mammalian Species: Rat	nkey Route: Subcutaneous tive Inscheduled DNA synthesis (UDS) test with liver cells in vivo Route: Ingestion
Bis(alp	ha,alpha-dimethylb	enzyl) peroxide:	
Genoto	oxicity in vitro	: Test Type: C Result: nega	hromosome aberration test in vitro
			n vitro mammalian cell gene mutation test CD Test Guideline 476 tive
May ca Suspec	ogenicity use cancer by inhala sted of causing cance onents:		
Quartz	:		
Specie Applica Result	s Ition Route	: Humans : inhalation (d : positive	ust/mist/fume)
Carcino ment	ogenicity - Assess-	: Positive evid tion)	ence from human epidemiological studies (inhala-
Proges	sterone:		
Specie Applica		: Mouse, fema : Subcutaneou : 104 weeks : positive	
Carcino ment	ogenicity - Assess-	: Limited evide	ence of carcinogenicity in animal studies
May da	ductive toxicity mage fertility. May da use harm to breast-fe		child.

Components:

Progesterone:

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sion	Revision Date: 28.09.2024		OS Number: 90082-00016	Date of last issue: 06.04.2024 Date of first issue: 15.11.2017
Effect	s on fertility	:	Test Type: Fertili Species: Rat Application Route Result: positive	ty/early embryonic development e: Subcutaneous
Effect ment	s on foetal develop-	:	Test Type: Fertili Species: Rat Application Route Result: positive	ty/early embryonic development e: Subcutaneous
Repro sessn	eductive toxicity - As- nent	:	fertility from hum of adverse effect	e of adverse effects on sexual function and an epidemiological studies., Clear evidence s on development, based on animal experi ndicating a hazard to babies during the lac
Bis(al	lpha,alpha-dimethylb	enzy	I) peroxide:	
Effect ment	s on foetal develop-	:	Species: Rat Application Rout	yo-foetal development e: Ingestion est Guideline 414
Repro sessm	oductive toxicity - As- nent	:	Clear evidence o animal experime	f adverse effects on development, based c nts.
3101				
Not cl STOT Cause	 single exposure assified based on avail repeated exposure damage to organs the 			peated exposure.
Not cl STOT Cause <u>Comp</u>	assified based on avail - repeated exposure es damage to organs the conents:			peated exposure.
Not cl STOT Cause <u>Comp</u> Quart Expos Targe	assified based on avail - repeated exposure es damage to organs the conents:		h prolonged or rep inhalation (dust/r Lungs Shown to produc	
Not cl STOT Cause Comp Quart Expos Targe Asses	assified based on avail - repeated exposure es damage to organs the conents: sure routes t Organs	nroug : :	h prolonged or rep inhalation (dust/r Lungs Shown to produc centrations of 0.0	nist/fume) e significant health effects in animals at co
Not cl STOT Cause Comp Quart Expos Targe Asses Bis(al Expos	assified based on avail - repeated exposure es damage to organs the conents: sure routes t Organs ssment	nroug : :	inhalation (dust/r Lungs Shown to produc centrations of 0.0	nist/fume) e significant health effects in animals at co)2 mg/l/6h/d or less. alth effects observed in animals at concent
Not cl STOT Cause Comp Quart Expos Targe Asses Bis(al Expos Asses	assified based on avail - repeated exposure es damage to organs the conents: sure routes t Organs ssment hpha,alpha-dimethylbe sure routes	nroug : :	inhalation (dust/r Lungs Shown to produc centrations of 0.0 I) peroxide: Ingestion No significant he	nist/fume) e significant health effects in animals at co)2 mg/l/6h/d or less. alth effects observed in animals at concent
Not cl STOT Cause Comp Quart Expos Targe Asses Bis(al Expos Asses	assified based on avail - repeated exposure es damage to organs the conents: asure routes t Organs ssment Ipha,alpha-dimethylbe sure routes ssment	nroug : :	inhalation (dust/r Lungs Shown to produc centrations of 0.0 I) peroxide: Ingestion No significant he	nist/fume) e significant health effects in animals at co)2 mg/l/6h/d or less. alth effects observed in animals at concent
Not cl STOT Cause Comp Quart Expos Targe Asses Bis(al Expos Asses	assified based on avail - repeated exposure es damage to organs the conents: z: sure routes t Organs ssment lpha,alpha-dimethylbe sure routes ated dose toxicity conents: z: z: z: z: z: z: z: z: z: z	nroug : :	inhalation (dust/r Lungs Shown to produc centrations of 0.0 I) peroxide: Ingestion No significant he	nist/fume) e significant health effects in animals at co)2 mg/l/6h/d or less. alth effects observed in animals at concent

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LOAE Applic	EL cation Route	: 0,053 mg/m3 : Inhalation	
Bis(a	Ipha,alpha-dimethyl	enzyl) peroxide:	
	EL EL cation Route sure time	 Rat 60 mg/kg 200 mg/kg Ingestion 28 Days OECD Test Guideline 407 	
•	ation toxicity		
Not cl	lassified based on ava	lable information.	
11.2 Infor	mation on other haz	rds	
Endo	oring discupting pro	ortion	

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Progesterone:

General Information	:	Target Organs: Endocrine system Symptoms: Effects on fertility	
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SECTION 12: Ecological information

12.1 Toxicity

Components:

Quartz:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): 508 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 731 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Progesterone: Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 1 - 10 mg/l Exposure time: 96 h

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			Method: OECD T	Vater Accommodated Fraction est Guideline 203 on data from similar materials
	city to daphnia and other atic invertebrates	:	Exposure time: 48 Test substance: V	nagna (Water flea)): > 1 mg/l 3 h Vater Accommodated Fraction on data from similar materials
Toxic icity)	city to fish (Chronic tox-	:	Exposure time: 2	
aqua	city to daphnia and other atic invertebrates (Chron- kicity)	:	NOEC: 0,1 mg/l Exposure time: 26 Species: Daphnia	6 d magna (Water flea)
M-Fa toxic	actor (Chronic aquatic ity)	:	1.000	
Bis(a	alpha,alpha-dimethylbei	nzv	I) peroxide:	
Toxi	city to daphnia and other atic invertebrates	-	EC50 (Daphnia m Exposure time: 48 Method: OECD T	
Toxic plant	city to algae/aquatic ts	:	mg/l Exposure time: 72 Method: OECD T	
			NOEC (Pseudoki Exposure time: 72 Method: OECD T	
Toxid	city to microorganisms	:	NOEC : > 1.000 r Exposure time: 30 Remarks: No toxi	
aqua	city to daphnia and other atic invertebrates (Chron- kicity)	:	NOEC: 0,177 mg, Exposure time: 2' Species: Daphnia Method: OECD T	1 d i magna (Water flea)
II 12.2 Pers	sistence and degradabil	ity		

Components:

Progesterone:

u	Result: Readily biodegradable. Remarks: Based on data from similar materials
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Bis(a	alpha,alpha-dimethylb	enzyl) peroxide:	
	egradability	: Result: Not i Biodegradat Exposure tin	
12.3 Bioa	ccumulative potential		
Com	ponents:		
Prog	esterone:		
	tion coefficient: n- nol/water	: Pow: 3,65 Method: OE	CD Test Guideline 117
Bis(a	alpha,alpha-dimethylb	enzyl) peroxide:	
Bioad	ccumulation	Bioconcentra	prinus carpio (Carp) ation factor (BCF): 137 - 1.470 CD Test Guideline 305C
	tion coefficient: n- nol/water	: log Pow: 5,6	
	ility in soil ata available		
12.5 Resu	ults of PBT and vPvB	assessment	
Prod	uct:		
Asse	ssment	to be either	nce/mixture contains no components considered persistent, bioaccumulative and toxic (PBT), or ent and very bioaccumulative (vPvB) at levels of ner.
12.6 Endo	ocrine disrupting prop	perties	
Prod	uct:		
Asse	ssment	ered to have REACH Artie	ce/mixture does not contain components consid- e endocrine disrupting properties according to cle 57(f) or Commission Delegated regulation 100 or Commission Regulation (EU) 2018/605 at % or higher.
	e r adverse effects ata available		

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

: Dispose of in accordance with local regulations.



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Conta	aminated packaging	are not product Waste codes s discussion with Do not dispose : Empty containe dling site for re	te European Waste Catalogue, Waste Codes t specific, but application specific. hould be assigned by the user, preferably in the waste disposal authorities. of waste into sewer. ers should be taken to an approved waste han- cycling or disposal. e specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	:	UN 3077
ADR	:	UN 3077
RID	:	UN 3077
IMDG	:	UN 3077
ΙΑΤΑ	:	UN 3077
14.2 UN proper shipping name		
ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Progesterone)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Progesterone)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Progesterone)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Progesterone)
ΙΑΤΑ	:	Environmentally hazardous substance, solid, n.o.s. (Progesterone)
14.3 Transport hazard class(es)		
		Class Subsidiary risks
ADN	:	9
ADR	:	9
RID	:	9
IMDG	:	9
ΙΑΤΑ	:	9
14.4 Packing group		
ADN		



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Class	ng group ification Code rd Identification Number s	: III : M7 : 90 : 9	
Class Haza Label	ng group ification Code rd Identification Number s el restriction code	: III : M7 : 90 : 9 : (-)	
Class	ng group ification Code rd Identification Number s	: III : M7 : 90 : 9	
IMDG Packi Label EmS	ng group s	: III : 9 : F-A, S-F	
Packi aircra Packi	ng instruction (LQ) ng group	: 956 : Y956 : III : Miscellane	ous
IATA Packi ger ai Packi	(Passenger) ng instruction (passen- ircraft) ng instruction (LQ) ng group	: 956 : Y956 : III : Miscellane	
14.5 Envii	onmental hazards		
ADR	onmentally hazardous	: yes	
RID	onmentally hazardous	: yes : yes	
IMDG	-	: yes	
	(Passenger)	: yes	
	(Cargo) onmentally hazardous	: yes	



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14.6 Special precautions for user

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

14.7 Maritime transport in bulk according to IMO instruments

Remarks

: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Substance(s) or mixture(s) are liste here according to their appearance in the regulation, irrespective of the use/purpose or the conditions of the restriction. Please refer to the cond tions in corresponding Regulation to determine whether an entry is appli cable to the placing on the market or not.REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).: Bis(alpha,alpha-dimethylbenzyl) peroxideREACH - List of substances subject to authorisation (Annex XIV): Not applicable	
) -) -
(Annex AIV)	
Regulation (EC) on substances that deplete the ozone : Not applicable layer	
Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable tants (recast)	
Regulation (EU) No 649/2012 of the European Parlia- : Not applicable ment and the Council concerning the export and import of dangerous chemicals Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.	
E1 ENVIRONMENTAL 100 t 200 t	

HAZARDS

Commission Regulation (EU) 2020/878



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

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

The components of this product are reported in the following inventories:			
AICS	:	not determined	
DSL	:	not determined	
IECSC	:	not determined	

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.	
Full text of H-Statements H242 H315 H319 H350i H351 H360D H360FD H362 H372 H410 H411	· · · · · · · · · · · · · · · · · · ·	Heating may cause a fire. Causes skin irritation. Causes serious eye irritation. May cause cancer by inhalation. Suspected of causing cancer. May damage the unborn child. May damage fertility. May damage the unborn child. May cause harm to breast-fed children. Causes damage to organs through prolonged or repeated exposure if inhaled. Very toxic to aquatic life with long lasting effects. Toxic to aquatic life with long lasting effects.	
Full text of other abbreviations			
Aquatic Chronic Carc. Eye Irrit. Lact. Org. Perox. Repr. Skin Irrit. STOT RE 2004/37/EC		Long-term (chronic) aquatic hazard Carcinogenicity Eye irritation Effects on or via lactation Organic peroxides Reproductive toxicity Skin irritation Specific target organ toxicity - repeated exposure Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work	
FOR-2011-12-06-1358 2004/37/EC / TWA FOR-2011-12-06-1358 / TWA		Norway. Occupational Exposure limits Long term exposure limit Long term exposure limit	



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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:	Classification procedure:
Sources of key data used to	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data	eChem Portal search results and European Chemicals Agen-
Sheet	cy, http://echa.europa.eu/

Classification of the h	Classification proced	
Carc. 2	H351	Calculation method
Carc. 1A	H350i	Calculation method
Repr. 1A	H360FD	Calculation method
Lact.	H362	Calculation method
STOT RE 1	H372	Calculation method
Aquatic Chronic 1	H410	Calculation method

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NO / EN