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



# **Progesterone Formulation (Veterinary)**

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 2190086-00016
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### 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 the substance or mixture and uses advised against

Use of the Sub-

stance/Mixture

: Veterinary product

Recommended restrictions

on use

Not applicable

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)

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Hazard pictograms :





Signal word : Danger

Hazard statements : H350i May cause cancer by inhalation.

H351 Suspected of causing cancer.

H360FD May damage fertility. May damage the unborn

child.

H362 May cause harm to breast-fed children.

H372 Causes damage to organs through prolonged or

repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P263 Avoid contact during pregnancy and while nursing.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

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

attention.

P391 Collect spillage.

### Hazardous components which must be listed on the label:

Quartz

Progesterone

### **Additional Labelling**

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) peroxide	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.

Get medical attention.
Wash clothing before reuse.

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Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May cause cancer by inhalation.

Suspected of causing cancer.

May damage fertility. May damage the unborn child.

May cause harm to breast-fed children.

Causes damage to organs through prolonged or repeated

exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

### **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

SO.

Evacuate area.

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#### **SECTION 6: Accidental release measures**

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

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-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

### **SECTION 7: Handling and storage**

### 7.1 Precautions for safe handling

Technical measures : 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

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

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place. When using do not eat, drink or smoke. Wash contami-

nated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

### **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

### **Occupational Exposure Limits**

<u> </u>	0.4.0.11	LV L ( /E	0 1 1 1	l	
Components	CAS-No.	Value type (Form	Control parameters	Basis	
		of exposure)			
Quartz	14808-60-7	TWA (Respirable	0.1 mg/m3	2004/37/EC	
		dust)			
	Further inform	Further information: Carcinogens or mutagens			
		OELV - 8 hrs	0.1 mg/m3	IE OEL	
		(TWA) (Respira-	(Silica)		
		ble dust)			
	Further information: Carcinogenic, see List of Carcinogenic Substances, Mix-				
	tures and Processes				
Silicon dioxide	7631-86-9	OELV - 8 hrs	2.4 mg/m3	IE OEL	
		(TWA) (Respira-	(Silica)		
		ble dust)			
		OELV - 8 hrs	6 mg/m3	IE OEL	
		(TWA) (inhalable	(Silica)		
		dust)			
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 effects	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

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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 I.S. EN 166

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration and quantity of the hazardous substance 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

resistance data and an assessment of the local exposure

potential.

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 I.S. 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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : Not applicable

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : 1.1 g/cm<sup>3</sup>

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Relative vapour density : Not applicable

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : Not applicable

Molecular weight : Not applicable

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### **SECTION 11: Toxicological information**

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

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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Progesterone:

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Remarks: Based on data from similar materials

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 401

Assessment: The substance or mixture has no acute oral tox-

icity

Acute inhalation toxicity : LC50 (Rat): > 0.224 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Quartz:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Progesterone:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Result : Skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Quartz:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Remarks : Based on data from similar materials

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Progesterone:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Remarks : Based on data from similar materials

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Species : 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

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

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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Genotoxicity 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

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Carcinogenicity

May cause cancer by inhalation. Suspected of causing cancer.

**Components:** 

Quartz:

Species : Humans

Application Route : inhalation (dust/mist/fume)

Result : positive

Carcinogenicity - Assess-

ment

Positive evidence from human epidemiological studies (inhala-

tion)

Progesterone:

Species : Mouse, female
Application Route : Subcutaneous
Exposure time : 104 weeks
Result : positive

Carcinogenicity - Assess-

ment

Limited evidence of carcinogenicity in animal studies

Reproductive toxicity

May damage fertility. May damage the unborn child.

May cause harm to breast-fed children.

**Components:** 

Progesterone:

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



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Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Subcutaneous

Result: positive

Effects on foetal develop-

ment

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Subcutaneous

Result: positive

Reproductive toxicity - As-

sessment

Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies., Clear evidence of adverse effects on development, based on animal experiments., Studies indicating a hazard to babies during the lacta-

tion period

### Bis(alpha,alpha-dimethylbenzyl) peroxide:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 414

Result: positive

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

#### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

#### **Components:**

#### Quartz:

Exposure routes : inhalation (dust/mist/fume)

Target Organs : Lungs

Assessment : Shown to produce significant health effects in animals at con-

centrations of 0.02 mg/l/6h/d or less.

### Bis(alpha,alpha-dimethylbenzyl) peroxide:

Exposure routes : Ingestion

Assessment : No significant health effects observed in animals at concentra-

tions of 100 mg/kg bw or less.

#### Repeated dose toxicity

### **Components:**

Quartz:

Species : Humans

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LOAEL : 0.053 mg/m3
Application Route : Inhalation

### Bis(alpha,alpha-dimethylbenzyl) peroxide:

Species: RatNOAEL: 60 mg/kgLOAEL: 200 mg/kgApplication Route: IngestionExposure time: 28 Days

Method : OECD Test Guideline 407

### **Aspiration toxicity**

Not classified based on available information.

#### 11.2 Information on other hazards

### **Endocrine disrupting properties**

### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered 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

### **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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Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.000010 mg/l Exposure time: 21 d

Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.1 mg/l Exposure time: 26 d

Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic

toxicity)

1,000

### Bis(alpha,alpha-dimethylbenzyl) peroxide:

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 0.397 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 20

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 8 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC: > 1,000 mg/l Toxicity to microorganisms

Exposure time: 30 min

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.177 mg/l

Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

#### 12.2 Persistence and degradability

### **Components:**

Progesterone:

Result: Readily biodegradable. Biodegradability

Remarks: Based on data from similar materials

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### Bis(alpha,alpha-dimethylbenzyl) peroxide:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 20.2 % Exposure time: 28 d

Method: OECD Test Guideline 301F

#### 12.3 Bioaccumulative potential

#### **Components:**

#### Progesterone:

Partition coefficient: n- : Pow: 3.65

octanol/water Method: OECD Test Guideline 117

### Bis(alpha,alpha-dimethylbenzyl) peroxide:

Bioaccumulation : Species: Cyprinus carpio (Carp)

Bioconcentration factor (BCF): 137 - 1,470

Method: OECD Test Guideline 305C

Partition coefficient: n- : log Pow: 5.6

octanol/water

#### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

### 12.6 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered 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.

#### 12.7 Other adverse effects

No data available

### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

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



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are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

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**

#### 14.1 UN number or ID number

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : 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)

IATA : 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
IATA : 9

#### 14.4 Packing group

**ADN** 

Packing group : III

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



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Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

rid

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**IMDG** 

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 956

ger aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

**ADN** 

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

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

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



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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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Conditions of restriction for the following entries should be considered: Number on list 30: Bis(alpha,alphadimethylbenzyl) peroxide

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Bis(alpha,alpha-dimethylbenzyl)

peroxide

Regulation (EC) on substances that deplete the ozone

Not applicable

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

Not applicable

REACH - List of substances subject to authorisation (Annex XIV)

Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2 E1 **ENVIRONMENTAL** 100 t 200 t **HAZARDS** 

## Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

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



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Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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**

H360D

H242 Heating may cause a fire. H315 Causes skin irritation. H319 Causes serious eye irritation. H350i May cause cancer by inhalation. Suspected of causing cancer. H351 May damage the unborn child.

May damage fertility. May damage the unborn child. H360FD

H362 May cause harm to breast-fed children.

Causes damage to organs through prolonged or repeated H372

exposure if inhaled.

H410 Very toxic to aquatic life with long lasting effects. H411 Toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Aquatic Chronic Long-term (chronic) aquatic hazard

Carcinogenicity Carc. Eve Irrit. Eve irritation

Effects on or via lactation Lact. Organic peroxides Org. Perox. Reproductive toxicity Repr.

Skin Irrit. Skin irritation

STOT RE Specific target organ toxicity - repeated exposure

Europe. Directive 2004/37/EC on the protection of workers 2004/37/EC

from the risks related to exposure to carcinogens or mutagens

IE OEL Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

2004/37/EC / TWA Long term exposure limit

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

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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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### **Further information**

Sources of key data used to compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Classification procedure:

### Classification of the mixture:

#### 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 H410 Aquatic Chronic 1 Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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

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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.

IE / EN