According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

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- : Veterinary product

stance/Mixture

Recommended restrictions : Not applicable

on use

1.3 Details of the supplier of the safety data sheet

Company : MSD

Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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
Specific target organ toxicity - repeated

Specific target organ toxicity - repeated H372: Causes damage to orga

exposure, Category 1

Long-term (chronic) aquatic hazard, Cat-

egory 1

H362: May cause harm to breast-fed children. H372: Causes damage to organs through pro-

longed or repeated exposure.

H410: Very toxic to aquatic life with long lasting

effects.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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

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.

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 | Carc. 1A; H350i | >= 30 - < 50 |

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 7.0 28.09.2024 9373417-00008 Date of first issue: 27.08.2021

| | 238-878-4 | STOT RE 1; H372 (Lungs) | |
|--|--------------------------------------|--|---------------|
| 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 |
| Substances with a workplace exposure limit : | | | |
| Silicon dioxide | 7631-86-9 231-545-4 | | >= 20 - < 30 |

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.

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.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

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.

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-

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

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.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

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 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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

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

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis | |
|---------------------------|--|-------------------------------|--------------------------------|---|--|
| Quartz | 14808-60-7 | TWA (Respirable | 0.1 mg/m3 | GB EH40 | |
| | | fraction) | (Silica) | | |
| | Further inform | nation: Capable of ca | nusing cancer and/or heritable | ng cancer and/or heritable genetic dam- | |
| | age. | | | | |
| | | TWA (Respirable | 0.1 mg/m3 | 2004/37/EC | |
| | | dust) | | | |
| | Further information: Carcinogens or mutagens | | | | |
| Silicon dioxide 7631-86-9 | | TWA (inhalable | 6 mg/m3 | GB EH40 | |
| | | dust) | (Silica) | | |
| | | TWA (Respirable | 2.4 mg/m3 | GB EH40 | |
| dust) ` | | dust) | (Silica) | | |
| Progesterone | Progesterone 57-83-0 TWA | | 6 μg/m3 (OEB 4) | Internal | |
| | | Wipe limit | 60 μg/100 cm2 | Internal | |

Derived No Effect Level (DNEL)

| 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- oxide | Workers | Inhalation | Long-term systemic effects | 5.6 mg/m3 |
| | 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 |

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

Predicted No Effect Concentration (PNEC)

| 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 BS 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 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 BS EN 137

Filter type : Self-contained breathing apparatus

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : solid
Colour : light green
Odour : No data available
Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : Not classified as a flammability hazard

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 : 1.1 g/cm³

Solubility(ies)

Water solubility : soluble

Partition coefficient: n- : Not applicable

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : Not applicable

Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

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 toxicological effects

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

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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

Silicon dioxide:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 2.08 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhala-

tion toxicity

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

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

Silicon dioxide:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No 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

Progesterone:

Species : Rabbit

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

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

Silicon dioxide:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

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-

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 7.0 28.09.2024 9373417-00008 Date of first issue: 27.08.2021

thesis in mammalian cells (in vitro) Method: OECD Test Guideline 482

Result: negative

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

Silicon dioxide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

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)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

Progesterone:

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

Carcinogenicity - Assess-

ment

: Limited evidence of carcinogenicity in animal studies

Silicon dioxide:

Species : Rat
Application Route : Ingestion
Exposure time : 103 weeks
Result : negative

Reproductive toxicity

May damage fertility. May damage the unborn child. May cause harm to breast-fed children.

Components:

Progesterone:

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.

Silicon dioxide:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 7.0 28.09.2024 9373417-00008 Date of first issue: 27.08.2021

Application Route: Ingestion

Result: negative

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 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

Silicon dioxide:

Species : Rat

NOAEL : 1.3 mg/m3

Application Route : inhalation (dust/mist/fume)

Exposure time : 13 Weeks

Aspiration toxicity

Not classified based on available information.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 7.0 28.09.2024 9373417-00008 Date of first issue: 27.08.2021

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

aquatic invertebrates

Toxicity to daphnia and other : 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

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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 9373417-00008 Date of first issue: 27.08.2021 7.0

Toxicity to algae/aquatic

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 20 mg/l

plants

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

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

Exposure time: 30 min

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other : aquatic invertebrates (Chron-

NOEC: 0.177 mg/l Exposure time: 21 d

ic toxicity)

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

Silicon dioxide:

Toxicity to fish LC50 (Danio rerio (zebra fish)): > 10,000 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 1,000 mg/l

Exposure time: 24 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Desmodesmus subspicatus (green algae)): > 10,000

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): 10,000

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

12.2 Persistence and degradability

Components:

Progesterone:

Biodegradability Result: Readily biodegradable.

Remarks: Based on data from similar materials

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Biodegradability Result: Not readily biodegradable.

Biodegradation: 20.2 %

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 7.0 28.09.2024 9373417-00008 Date of first issue: 27.08.2021

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 Other adverse effects

Product:

Endocrine disrupting poten-

tial

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

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

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.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

SECTION 14: Transport information

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

ADR

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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 7.0 28.09.2024 9373417-00008 Date of first issue: 27.08.2021

956

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

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 Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable

UK REACH Candidate list of substances of very high : Not applicable

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained : Not applicable

Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EC) on substances that deplete the ozone : Not applicable

layer

UK REACH List of substances subject to authorisation : Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior : Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

HAZARDS

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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 : Heating may cause a fire.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

| | Version 7.0 | Revision Date: 28.09.2024 | SDS Number 9373417-000 | |
|------|---|---------------------------|---|---|
| | H315 H319 H350i H351 H360D H360F H362 H372 | | : May caus : Suspecte : May dam : May dam : May caus : Causes o | kin irritation. erious eye irritation. se cancer by inhalation. d of causing cancer. age the unborn child. age fertility. May damage the unborn child. se harm to breast-fed children. lamage to organs through prolonged or repeated if inhaled. |
| H410 | | : Very toxic | to aquatic life with long lasting effects. | |

Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

H411

Aquatic Chronic : Long-term (chronic) aquatic hazard

Carc. : Carcinogenicity
Eye Irrit. : Eye irritation

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

Skin Irrit. : Skin irritation

STOT RE : Specific target organ toxicity - repeated exposure

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

from the risks related to exposure to carcinogens or mutagens

at work

GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

2004/37/EC / TWA : Long term exposure limit

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

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 Re-

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Progesterone Formulation (Veterinary)

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 7.0
 28.09.2024
 9373417-00008
 Date of first issue: 27.08.2021

striction 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

Aquatic Chronic 1

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:

Calculation method

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

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

GB / EN