

SAFETY DATA SHEET

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



Progesterone Formulation (Veterinary)

Version 8.0 Revision Date: 14.04.2025 SDS Number: 9373417-00009 Date of last issue: 28.09.2024
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 Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

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 H362: May cause harm to breast-fed children.

Specific target organ toxicity - repeated exposure, Category 1 H372: Causes damage to organs through prolonged or repeated exposure.

Long-term (chronic) aquatic hazard, Cat- H410: Very toxic to aquatic life with long lasting

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egory 1 effects.

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. | Classification | Concentration (% w/w) |
|---------------|-------------------|----------------|--------------------------|
| | | | |

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| | Index-No. Registration number | | |
|---|--------------------------------------|--|---------------|
| 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 |
| 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 advice 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.

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Get medical attention if irritation develops and persists.

If swallowed : 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 products : 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 methods : Use extinguishing measures that are appropriate to local circumstances 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 protective 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 container 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 determine 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 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 assessment. 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-

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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

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|-----------------|---|-------------------------------|--------------------------------|------------|
| Quartz | 14808-60-7 | TWA (Respirable fraction) | 0.1 mg/m ³ (Silica) | GB EH40 |
| | Further information: Capable of causing cancer and/or heritable genetic damage. | | | |
| | | TWA (Respirable dust) | 0.1 mg/m ³ | 2004/37/EC |
| | Further information: Carcinogens or mutagens | | | |
| Silicon dioxide | 7631-86-9 | TWA (inhalable dust) | 6 mg/m ³ (Silica) | GB EH40 |
| | | TWA (Respirable dust) | 2.4 mg/m ³ (Silica) | GB EH40 |
| Progesterone | 57-83-0 | TWA | 6 µg/m ³ (OEB 4) | Internal |
| | | Wipe limit | 60 µg/100 cm ² | 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/m ³ |
| Bis(alpha,alpha-dimethylbenzyl) peroxide | Workers | Inhalation | Long-term systemic effects | 5.6 mg/m ³ |
| | Workers | Skin contact | Long-term systemic effects | 8 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic | 1.4 mg/m ³ |

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| | | | effects | |
|--|-----------|--------------|----------------------------|------------------|
| | 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)

| Substance name | Environmental Compartment | Value |
|--|---------------------------|-------------|
| Bis(alpha,alpha-dimethylbenzyl) peroxide | Fresh water | 2.34 µg/l |
| | 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 | : Chemical-resistant gloves |
| Material | |
| 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 exposure assessment demonstrates exposures outside the recommended 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 |

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| | | |
|--|---|--|
| Odour Threshold | : | No data available |
| pH | : | No data available |
| Melting point/freezing point | : | No data available |
| 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 |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | Not applicable |
| Relative vapour density | : | Not applicable |
| Relative density | : | No data available |
| Density | : | 1.1 g/cm ³ |
| Solubility(ies) | | |
| Water solubility | : | soluble |
| Partition coefficient: n-octanol/water | : | Not applicable |
| 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

| | | |
|------------------|---|----------------|
| Molecular weight | : | Not applicable |
| Particle size | : | Not applicable |

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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 toxicological effects

Information on likely routes of exposure : Skin contact
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 toxicity

Acute inhalation toxicity : LC50 (Rat): > 0.224 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

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||| Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

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 inhalation 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

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

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

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.

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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 synthesis 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.

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Components:

Quartz:

| | | |
|------------------------------|---|---|
| Species | : | Humans |
| Application Route | : | inhalation (dust/mist/fume) |
| Result | : | positive |
| Carcinogenicity - Assessment | : | Positive evidence from human epidemiological studies (inhalation) |

Progesterone:

| | | |
|------------------------------|---|---|
| Species | : | Mouse, female |
| Application Route | : | Subcutaneous |
| Exposure time | : | 104 weeks |
| Result | : | positive |
| Carcinogenicity - Assessment | : | 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 development | : | Test Type: Fertility/early embryonic development Species: Rat Application Route: Subcutaneous Result: positive |
| Reproductive toxicity - Assessment | : | 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 lactation period |

Bis(alpha,alpha-dimethylbenzyl) peroxide:

| | | |
|-------------------------------|---|--|
| Effects on foetal development | : | Test Type: Embryo-foetal development Species: Rat |
|-------------------------------|---|--|

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Application Route: Ingestion
Method: OECD Test Guideline 414
Result: positive

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

Silicon dioxide:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
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 concentrations 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 concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

Quartz:

Species : Humans
NOAEL : 0.053 mg/m³
Application Route : Inhalation

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Species : Rat
NOAEL : 60 mg/kg
LOAEL : 200 mg/kg
Application Route : Ingestion
Exposure time : 28 Days
Method : OECD Test Guideline 407

Silicon dioxide:

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| | | |
|-------------------|---|-----------------------------|
| 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.

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 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 toxicity) | : | NOEC: 0.000010 mg/l Exposure time: 21 d Species: Pimephales promelas (fathead minnow) |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0.1 mg/l Exposure time: 26 d Species: Daphnia magna (Water flea) |
| M-Factor (Chronic aquatic | : | 1,000 |

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1.1 | toxicity

Bis(alpha,alpha-dimethylbenzyl) peroxide:

| | |
|--|---|
| Toxicity to daphnia and other aquatic invertebrates | : 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 |
| 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 (Chronic toxicity) | : NOEC: 0.177 mg/l Exposure time: 21 d 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:

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Biodegradability : Result: Readily biodegradable.
Remarks: Based on data from similar materials

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-octanol/water : Pow: 3.65
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-octanol/water : log Pow: 5.6

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 potential : 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

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Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

discussion with the waste disposal authorities.
Do not dispose of waste into sewer.

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

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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 aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 956
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.

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

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

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 concern (SVHC) for Authorisation | : Not applicable |
| The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) | : Not applicable |
| Regulation (EU) No 2024/590 on substances that deplete the ozone layer | : Not applicable |
| UK REACH List of substances subject to authorisation (Annex XIV) | : Not applicable |
| GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation | : Not applicable |
| Control of Major Accident Hazards Regulations 2015 (COMAH) | |
| E1 | ENVIRONMENTAL HAZARDS |
| | Quantity 1 100 t |
| | Quantity 2 200 t |

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. |
|-------------------|--|

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Full text of H-Statements

| | |
|--------|--|
| H242 | : Heating may cause a fire. |
| H315 | : Causes skin irritation. |
| H319 | : Causes serious eye irritation. |
| H350i | : May cause cancer by inhalation. |
| H351 | : Suspected of causing cancer. |
| H360D | : May damage the unborn child. |
| 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 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 |
| 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, mutagens or reprotoxic substances at work - Annex III |
| 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; KECL - 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.

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tative) 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

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 of the mixture:

| | |
|-------------------|--------|
| Carc. 2 | H351 |
| Carc. 1A | H350i |
| Repr. 1A | H360FD |
| Lact. | H362 |
| STOT RE 1 | H372 |
| Aquatic Chronic 1 | H410 |

Classification procedure:

| |
|--------------------|
| Calculation method |

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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