

# SAFETY DATA SHEET

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



## Fenbendazole (0.5%) Solid Formulation

Version 6.1      Revision Date: 30.09.2023      SDS Number: 1161530-00017      Date of last issue: 04.04.2023  
Date of first issue: 19.12.2016

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

#### 1.1 Product identifier

Trade name : Fenbendazole (0.5%) Solid Formulation

#### 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

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

|  |  |
|--|--|
| Serious eye damage, Category 1                 | H318: Causes serious eye damage.                       |
| Short-term (acute) aquatic hazard, Category 1  | H400: Very toxic to aquatic life.                      |
| Long-term (chronic) aquatic hazard, Category 2 | H411: Toxic to aquatic life with long lasting effects. |

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

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Hazard statements : H318 Causes serious eye damage.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.  
P280 Wear eye protection/ face protection.

**Response:**  
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.  
P391 Collect spillage.

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

Calcium bis(dihydrogenorthophosphate) monohydrate

### 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.

Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name                                     | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                                  | Concentration<br>(% w/w) |
|---|---|---|--------------------------|
| Calcium bis(dihydrogenorthophosphate) monohydrate | 10031-30-8  | Eye Dam. 1; H318                                | >= 30 - < 50             |
| Langbeinite                                       | 14977-37-8  | Eye Irrit. 2; H319                              | >= 1 - < 10              |
| Paraffin oil                                      | 8012-95-1<br>232-384-2                                | Asp. Tox. 1; H304<br>Aquatic Chronic 4;<br>H413 | >= 1 - < 2.5             |
| fenbendazole                                      | 43210-67-9  | Repr. 2; H361fd                                 | >= 0.25 - < 1            |

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|  |           |  |  |
|--|-----------|--|--|
|  | 256-145-7 | STOT RE 2; H373<br>(Liver, Stomach,<br>Nervous system,<br>Lymph nodes)<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410 |  |
|  |           | M-Factor (Acute<br>aquatic toxicity): 100<br>M-Factor (Chronic<br>aquatic toxicity): 10  |  |

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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention immediately.
- 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 : Causes serious eye damage.

Contact with dust can cause mechanical irritation or drying of

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the skin.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Oxides of phosphorus  
Metal oxides  
Carbon oxides  
Chlorine compounds

### 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.

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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 container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
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.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.  
Do not swallow.  
Do not get in eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
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 contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures,

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industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. 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

### 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

dusts non-specific      4 mg/m<sup>3</sup>  
Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust)  
Basis: IE OEL

10 mg/m<sup>3</sup>  
Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust)  
Basis: IE OEL

| Components   | CAS-No.    | Value type (Form of exposure)           | Control parameters            | Basis    |
|--------------|------------|---|-------------------------------|----------|
| Paraffin oil | 8012-95-1  | OELV - 8 hrs (TWA) (inhalable fraction) | 5 mg/m <sup>3</sup>           | IE OEL   |
| fenbendazole | 43210-67-9 | TWA                                     | 100 µg/m <sup>3</sup> (OEB 2) | Internal |

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

| Substance name    | End Use   | Exposure routes | Potential health effects   | Value                     |
|-------------------|-----------|-----------------|----------------------------|---------------------------|
| Calcium carbonate | Workers   | Inhalation      | Long-term systemic effects | 6.36 mg/m <sup>3</sup>    |
|                   | Consumers | Ingestion       | Acute systemic effects     | 6.1 mg/kg bw/day          |
|                   | Consumers | Inhalation      | Long-term systemic effects | 1.06 mg/m <sup>3</sup>    |
| Sodium chloride   | Consumers | Ingestion       | Long-term systemic effects | 6.1 mg/kg bw/day          |
|                   | Workers   | Inhalation      | Long-term systemic effects | 2068.62 mg/m <sup>3</sup> |
|                   | Workers   | Inhalation      | Acute systemic effects     | 2068.62 mg/m <sup>3</sup> |

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|--------------|-----------|--------------|----------------------------|--------------------------|
|              | Workers   | Skin contact | Long-term systemic effects | 295.52 mg/kg bw/day      |
|              | Workers   | Skin contact | Acute systemic effects     | 295.52 mg/kg bw/day      |
|              | Consumers | Inhalation   | Long-term systemic effects | 443.28 mg/m <sup>3</sup> |
|              | Consumers | Inhalation   | Acute systemic effects     | 443.28 mg/m <sup>3</sup> |
|              | Consumers | Skin contact | Long-term systemic effects | 126.65 mg/kg bw/day      |
|              | Consumers | Skin contact | Acute systemic effects     | 126.65 mg/kg bw/day      |
|              | Consumers | Ingestion    | Long-term systemic effects | 126.65 mg/kg bw/day      |
|              | Consumers | Ingestion    | Acute systemic effects     | 126.65 mg/kg bw/day      |
| Paraffin oil | Workers   | Inhalation   | Long-term systemic effects | 5 mg/m <sup>3</sup>      |
|              | Workers   | Inhalation   | Short-term exposure        | 5 mg/m <sup>3</sup>      |
|              | Workers   | Inhalation   | Long-term local effects    | 5 mg/m <sup>3</sup>      |
|              | Workers   | Inhalation   | Acute local effects        | 5 mg/m <sup>3</sup>      |

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

| Substance name    | Environmental Compartment | Value                        |
|-------------------|---------------------------|------------------------------|
| Calcium carbonate | Sewage treatment plant    | 100 mg/l                     |
| Sodium chloride   | Fresh water               | 5 mg/l                       |
|                   | Sewage treatment plant    | 500 mg/l                     |
|                   | Soil                      | 4.86 mg/kg dry weight (d.w.) |
| fenbendazole      |                           | 0.0001 mg/l                  |

## 8.2 Exposure controls

### Engineering measures

Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

### Personal protective equipment

- Eye/face protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Hand protection  
Material : Chemical-resistant gloves
- Skin and body protection : Work uniform or laboratory coat.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

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|             |  |
|-------------|--|
| Filter type | Equipment should conform to I.S. EN 14387<br>: Combined particulates and organic vapour type (A-P) |
|-------------|--|

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

|  |   |
|--|---|
| Physical state                                   | : powder  |
| Colour   | : No data available   |
| 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)                        | : May form explosive dust-air mixture during processing, handling or other means. |
| 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                             | : No data available   |
| Solubility(ies)                                  |   |
| Water solubility                                 | : No data available   |
| Partition coefficient: n-octanol/water           | : No data available   |
| Vapour pressure                                  | : No data available   |



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Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : No data available

### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

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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 : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

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

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

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### Acute toxicity

Not classified based on available information.

### Components:

#### Calcium bis(dihydrogenorthophosphate) monohydrate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 2.6 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 7,940 mg/kg

#### Langbeinite:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 425  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials

#### Paraffin oil:

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

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

#### fenbendazole:

Acute oral toxicity : LD50 (Rat): > 10,000 mg/kg  
LD50 (Mouse): > 10,000 mg/kg

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Calcium bis(dihydrogenorthophosphate) monohydrate:

Species : Rabbit  
Result : No skin irritation

#### Langbeinite:

Species : reconstructed human epidermis (RhE)  
Method : Regulation (EC) No. 440/2008, Annex, B.46

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Result : No skin irritation  
Remarks : Based on data from similar materials

### Paraffin oil:

Species : Rabbit  
Result : No skin irritation

### fenbendazole:

Species : Rabbit  
Result : No skin irritation

### Serious eye damage/eye irritation

Causes serious eye damage.

### Components:

#### Calcium bis(dihydrogenorthophosphate) monohydrate:

Species : Rabbit  
Result : Irreversible effects on the eye

#### Langbeinite:

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : Irritation to eyes, reversing within 7 days  
Remarks : Based on data from similar materials

### Paraffin oil:

Species : Rabbit  
Result : No eye irritation

### fenbendazole:

Species : Rabbit  
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:

#### Calcium bis(dihydrogenorthophosphate) monohydrate:

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

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Result : negative  
Remarks : Based on data from similar materials

### Langbeinite:

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative  
Remarks : Based on data from similar materials

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Calcium bis(dihydrogenorthophosphate) monohydrate:

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: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

Test Type: in vitro micronucleus test  
Method: OECD Test Guideline 487  
Result: negative  
Remarks: Based on data from similar materials

### Langbeinite:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

### fenbendazole:

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

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Result: negative

Test Type: DNA Repair  
Result: negative

Test Type: Chromosomal aberration  
Result: negative

Test Type: in vitro assay  
Test system: mouse lymphoma cells  
Metabolic activation: Metabolic activation  
Result: equivocal

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **fenbendazole:**

Species : Mouse  
Application Route : oral (feed)  
Exposure time : 2 Years  
NOAEL : 405 mg/kg body weight  
Result : negative

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
NOAEL : 5 mg/kg body weight  
Result : negative  
Target Organs : Lymph nodes, Liver

### **Reproductive toxicity**

Not classified based on available information.

### **Components:**

#### **Calcium bis(dihydrogenorthophosphate) monohydrate:**

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 421  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### **Langbeinite:**

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Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

### **fenbendazole:**

Effects on fertility : Test Type: Three-generation reproduction toxicity study  
Species: Rat  
Application Route: oral (feed)  
General Toxicity - Parent: NOAEL: 15 mg/kg body weight  
Fertility: LOAEL: 45 mg/kg body weight  
Result: Effects on fertility

Effects on foetal development : Test Type: Development  
Species: Dog, female  
Application Route: Oral  
Developmental Toxicity: LOAEL: 100 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 25 mg/kg body weight  
Result: Fetotoxicity

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 63 mg/kg body weight

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 120 mg/kg body weight  
Result: No effects on foetal development

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

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### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### fenbendazole:

Exposure routes : Ingestion  
Target Organs : Liver, Stomach, Nervous system, Lymph nodes  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Calcium bis(dihydrogenorthophosphate) monohydrate:

Species : Rat  
NOAEL : > 300 mg/kg  
Application Route : Ingestion  
Exposure time : 28 Days  
Method : OECD Test Guideline 407  
Remarks : Based on data from similar materials

#### Langbeinite:

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Ingestion  
Exposure time : 28 d  
Method : OECD Test Guideline 422  
Remarks : Based on data from similar materials

#### Paraffin oil:

Species : Rat, female  
LOAEL : 161 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

#### fenbendazole:

Species : Rat  
LOAEL : 500 mg/kg  
Application Route : Oral  
Exposure time : 2 Weeks  
Target Organs : Kidney, Liver

Species : Rat  
NOAEL : > 2,500 mg/kg

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Application Route : Oral  
Exposure time : 30 Days  
Remarks : No significant adverse effects were reported

Species : Rat  
LOAEL : 1,600 mg/kg  
Application Route : Oral  
Exposure time : 90 Days  
Target Organs : Central nervous system  
Symptoms : Tremors

Species : Dog  
NOAEL : 4 mg/kg  
LOAEL : 8 mg/kg  
Exposure time : 6 Months  
Target Organs : Stomach, Nervous system, Lymph nodes

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Paraffin oil:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

#### fenbendazole:

No aspiration toxicity classification

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

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

### Experience with human exposure

#### Components:

#### fenbendazole:

Ingestion : Symptoms: Rapid respiration, Salivation, anorexia, Diarrhoea



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### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Components:

##### **Calcium bis(dihydrogenorthophosphate) monohydrate:**

- Toxicity to fish : LC50 (*Oryzias latipes* (Japanese medaka)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants : ErC50 (*Pseudokirchneriella subcapitata* (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials
- Toxicity to microorganisms : EC50 : > 100 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials

##### **Langbeinite:**

- Toxicity to fish : LC50 (*Oncorhynchus mykiss* (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

##### **Paraffin oil:**

- Toxicity to fish : LL50 (*Scophthalmus maximus* (turbot)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EL50 (*Acartia tonsa* (Calanoid copepod)): > 100 mg/l  
Exposure time: 48 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants : EL50 (*Skeletonema costatum* (marine diatom)): > 100 mg/l  
Exposure time: 72 h

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

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

### fenbendazole:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.009 mg/l  
Exposure time: 21 d

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 0.0088 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Method: OECD Test Guideline 202

M-Factor (Acute aquatic tox- : 100  
icity)

Toxicity to daphnia and other : NOEC: 0.00113 mg/l  
aquatic invertebrates (Chron- : Exposure time: 21 Days  
ic toxicity) : Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic : 10  
toxicity)

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

#### Components:

##### Paraffin oil:

Partition coefficient: n- : log Pow: > 4  
octanol/water : Remarks: Calculation

##### fenbendazole:

Partition coefficient: n- : log Pow: 3.32  
octanol/water

### 12.4 Mobility in soil

#### Components:

##### fenbendazole:

Distribution among environ- : log Koc: 3.8 - 4.7  
mental compartments : Method: FDA 3.08

### 12.5 Results of PBT and vPvB assessment

#### Product:

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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 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.

### 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 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 handling 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. (fenbendazole)  
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (fenbendazole)

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**RID** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(fenbendazole)

**IMDG** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(fenbendazole)

**IATA** : Environmentally hazardous substance, solid, n.o.s.  
(fenbendazole)

### 14.3 Transport hazard class(es)

|             | Class | Subsidiary risks |
|-------------|-------|------------------|
| <b>ADN</b>  | : 9   |                  |
| <b>ADR</b>  | : 9   |                  |
| <b>RID</b>  | : 9   |                  |
| <b>IMDG</b> | : 9   |                  |
| <b>IATA</b> | : 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  
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 (passen- : 956

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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 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) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) 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

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|    |                          |       |       |
|----|--------------------------|-------|-------|
| E1 | ENVIRONMENTAL<br>HAZARDS | 100 t | 200 t |
|----|--------------------------|-------|-------|

### 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

|        |   |   |
|--------|---|---|
| H304   | : | May be fatal if swallowed and enters airways.                                   |
| H318   | : | Causes serious eye damage.  |
| H319   | : | Causes serious eye irritation.  |
| H361fd | : | Suspected of damaging fertility. Suspected of damaging the unborn child.        |
| H373   | : | May cause damage to organs through prolonged or repeated exposure if swallowed. |
| H400   | : | Very toxic to aquatic life.   |
| H410   | : | Very toxic to aquatic life with long lasting effects.                           |
| H413   | : | May cause long lasting harmful effects to aquatic life.                         |

### Full text of other abbreviations

|                             |   |  |
|-----------------------------|---|--|
| Aquatic Acute               | : | Short-term (acute) aquatic hazard  |
| Aquatic Chronic             | : | Long-term (chronic) aquatic hazard   |
| Asp. Tox.                   | : | Aspiration hazard  |
| Eye Dam.                    | : | Serious eye damage   |
| Eye Irrit.                  | : | Eye irritation   |
| Repr.                       | : | Reproductive toxicity  |
| STOT RE                     | : | Specific target organ toxicity - repeated exposure   |
| IE OEL                      | : | List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2 |
| IE OEL / OELV - 8 hrs (TWA) | : | Occupational exposure limit value (8-hour 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 - Emergen-

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cy 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 of the mixture:

|                   |      |
|-------------------|------|
| Eye Dam. 1        | H318 |
| Aquatic Acute 1   | H400 |
| Aquatic Chronic 2 | H411 |

### Classification procedure:

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

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.

IE / EN