SAFETY DATA SHEET

Fenbendazole (0.5%) Solid Formulation

SECTION 1. IDENTIFICATION

Product name : Fenbendazole (0.5%) Solid Formulation

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
           Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
Serious eye damage : Category 1
Reproductive toxicity : Category 2

GHS label elements
Hazard pictograms : 

Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H318 Causes serious eye damage.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.

Precautionary Statements :
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves, protective clothing, eye protection and 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.
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium bis(dihydrogenorthophosphate) monohydrate</td>
<td>10031-30-8</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Langbeinite</td>
<td>14977-37-8</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Fenbendazole</td>
<td>43210-67-9</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

SECTION 4. 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.

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.

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin. Causes serious eye damage.
Suspected of damaging fertility. Suspected of damaging the unborn child.

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).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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

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.

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and 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.

SECTION 7. HANDLING AND STORAGE

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.
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.

Conditions for safe storage:
Keep in properly labeled containers.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid:
Do not store with the following product types:
Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Inert or nuisance dust</th>
<th>50 Million particles per cubic foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value type (Form of exposure):</td>
<td>TWA (total dust)</td>
</tr>
<tr>
<td>Basis:</td>
<td>OSHA Z-3</td>
</tr>
</tbody>
</table>

| 15 mg/m³ |
|------------------------|------------------------------------|
| Value type (Form of exposure): | TWA (total dust) |
| Basis: | OSHA Z-3 |

| 5 mg/m³ |
|------------------------|------------------------------------|
| Value type (Form of exposure): | TWA (respirable fraction) |
| Basis: | OSHA Z-3 |

| 15 Million particles per cubic foot |
|------------------------|------------------------------------|
| Value type (Form of exposure): | TWA (respirable fraction) |
| Basis: | OSHA Z-3 |

<table>
<thead>
<tr>
<th>Dust, nuisance dust and par- ticulates</th>
<th>10 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value type (Form of exposure):</td>
<td>PEL (Total dust)</td>
</tr>
</tbody>
</table>

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SAFETY DATA SHEET

Fenbendazole (0.5%) Solid Formulation

Version 7.0  Revision Date: 04/04/2023  SDS Number: 116114-00017  Date of last issue: 10/01/2022
Date of first issue: 12/19/2016

Basis: CAL PEL

5 mg/m³
Value type (Form of exposure): PEL (respirable dust fraction)
Basis: CAL PEL

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>TWA (Respirable)</td>
<td>5 mg/m³ (Calcium carbonate)</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³ (Calcium carbonate)</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ST (Mist)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>fenbendazole</td>
<td>43210-67-9</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

Respiratory protection
: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
Material
: Chemical-resistant gloves

Eye 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.

Skin and body protection
: Work uniform or laboratory coat.

Hygiene measures
: If exposure to chemical is likely during typical use, provide
Fenbendazole (0.5\%) Solid Formulation

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: powder

**Color**: No data available

**Odor**: No data available

**Odor 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**: 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

**Vapor pressure**: No data available

**Relative vapor density**: No data available

**Relative density**: No data available

**Density**: No data available

**Solubility(ies)**

- **Water solubility**: No data available

**Partition coefficient: n-octanol/water**: No data available

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, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
Fenbendazole (0.5%) Solid Formulation

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks. Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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
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Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

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

Calcium carbonate:

Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 420
Assessment: The substance or mixture has no acute oral toxicity

Acute inhalation toxicity: LC50 (Rat): > 3 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

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

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
**Calcium carbonate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Langbeinite:**

<table>
<thead>
<tr>
<th>Species</th>
<th>reconstructed human epidermis (RhE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Paraffin oil:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**fenbendazole:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Components:**

**Calcium bis(dihydrogenorthophosphate) monohydrate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irreversible effects on the eye</td>
</tr>
</tbody>
</table>

**Calcium carbonate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
</tbody>
</table>

**Langbeinite:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irritation to eyes, reversing within 7 days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Paraffin oil:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

**fenbendazole:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>
### Respiratory or skin sensitization

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

### Components:

#### Calcium bis(dihydrogenorthophosphate) monohydrate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 429</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### Calcium carbonate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 429</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Langbeinite:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 429</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### 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
Calcium carbonate:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative

- Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: negative

- Test Type: In vitro mammalian cell gene mutation test
  Method: OECD Test Guideline 476
  Result: negative

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)
  Result: negative

- Test Type: DNA Repair
  Result: negative

- Test Type: Chromosomal aberration
  Result: negative

- Test Type: in vitro test
  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
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<table>
<thead>
<tr>
<th>NOAEL : 405 mg/kg body weight</th>
<th>Result : negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species : Rat</td>
<td>Application Route : Oral</td>
</tr>
<tr>
<td>Exposure time : 2 Years</td>
<td>NOAEL : 5 mg/kg body weight</td>
</tr>
<tr>
<td>Result : negative</td>
<td>Target Organs : Lymph nodes, Liver</td>
</tr>
</tbody>
</table>

**NOAEL**

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

**NTP**

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

Suspected of damaging fertility. Suspected of damaging the unborn child.

**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 fetal development**
  - Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

**Calcium carbonate:**

- **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

- **Effects on fetal development**
  - Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Ingestion
  - Method: OECD Test Guideline 414
  - Result: negative

**Langbeinite:**
## 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 fetal 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 fetal 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-fetal development
  - **Species:** Rabbit
  - **Application Route:** Oral
  - **Developmental Toxicity:** NOAEL: 25 mg/kg body weight
  - **Result:** Fetotoxicity.

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

- **Test Type:** Embryo-fetal development
  - **Species:** Rat
  - **Application Route:** Oral
  - **Developmental Toxicity:** NOAEL: 120 mg/kg body weight
  - **Result:** No effects on fetal 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.
STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.

Components:

fenbendazole:
<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Liver, Stomach, Nervous system, Lymph nodes</td>
</tr>
<tr>
<td>Assessment</td>
<td>May cause damage to organs through prolonged or repeated exposure</td>
</tr>
</tbody>
</table>

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 |

Calcium carbonate:
| Species  | Rat         |
| NOAEL    | > 1,000 mg/kg |
| Application Route | Ingestion |
| Exposure time  | 28 Days    |
| Method     | OECD Test Guideline 422 |

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
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

Experience with human exposure

Components:

fenbendazole:
Ingestion: Symptoms: Rapid respiration, Salivation, anorexia, Diarrhea

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

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: EC50 (Daphnia magna (Water flea)): > 100 mg/l
### Fenbendazole (0.5%) Solid Formulation

**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

---

### Calcium carbonate:

#### Toxicity to fish

- **LL50** (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
- Exposure time: 96 h
- Test substance: Water Accommodated Fraction
- Method: OECD Test Guideline 203

#### Toxicity to daphnia and other aquatic invertebrates

- **EL50** (Daphnia magna (Water flea)): > 100 mg/l
- Exposure time: 48 h
- Test substance: Water Accommodated Fraction
- Method: OECD Test Guideline 202

#### Toxicity to algae/aquatic plants

- **NOELR** (Pseudokirchneriella subcapitata (green algae)): 50 mg/l
- Exposure time: 72 h
- Test substance: Water Accommodated Fraction
- Method: OECD Test Guideline 201

- **EL50** (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
- Exposure time: 72 h
- Test substance: Water Accommodated Fraction
- Method: OECD Test Guideline 201

#### Toxicity to microorganisms

- **NOEC**: 1,000 mg/l
- Exposure time: 3 h
- Method: OECD Test Guideline 209

- **EC50**: > 1,000 mg/l
- Exposure time: 3 h
- Method: OECD Test Guideline 209

---

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

fenchazobole:

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

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.008 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

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

Persistence and degradability
No data available

Bioaccumulative potential

Components:

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

fenbendazole:
Partition coefficient n-octanol/water: log Pow: 3.32
Mobility in soil

Components:

fenbendazole:

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

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues: Dispose of in accordance with local regulations.
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

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(fenbendazole)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s.
(fenbendazole)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(fenbendazole)
Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant : yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**Domestic regulation**

49 CFR
UN/ID/NA number : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (fenbendazole)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : yes (fenbendazole)
Remarks : Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

**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.

**SECTION 15. REGULATORY INFORMATION**

**CERCLA Reportable Quantity**
This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**
This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**
This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards**
- Combustible dust
- Reproductive toxicity
- Serious eye damage or eye irritation

**SARA 313**
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**US State Regulations**

**Pennsylvania Right To Know**
- Calcium bis(dihydrogenorthophosphate) monohydrate 10031-30-8
- Calcium carbonate 471-34-1
- Sodium chloride 7647-14-5
- Paraffin oil 8012-95-1
California List of Hazardous Substances
Paraffin oil 8012-95-1

California Permissible Exposure Limits for Chemical Contaminants
Calcium carbonate 471-34-1
Paraffin oil 8012-95-1

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

SECTION 16. OTHER INFORMATION

Further information
NFPA 704:

HMIS® IV:

HEALTH ★ 3
FLAMMABILITY 3
PHYSICAL HAZARD 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The “★” represents a chronic hazard, while the “/” represents the absence of a chronic hazard.

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA : 8-hour, time-weighted average
CAL PEL / PEL : Permissible exposure limit
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
Fenbendazole (0.5%) Solid Formulation

OSHA Z-1 / TWA: 8-hour time weighted average
OSHA Z-3 / TWA: 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; EC - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSA - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EC - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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


Revision Date: 04/04/2023

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be 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.
# SAFETY DATA SHEET

**Fenbendazole (0.5%) Solid Formulation**

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US / Z8