SAFETY DATA SHEET

Fenbendazole (4%) Solid Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

   Product name : Fenbendazole (4%) Solid Formulation

   Manufacturer or supplier’s details
   Company : MSD
   Address : Briahnager - Off Pune Nagar Road
             Wagholi - Pune - India 412 207
   Telephone : 908-740-4000
   Emergency telephone number : 1-908-423-6000
   E-mail address : EHSDATASTEWARD@msd.com
   Telefax : 908-735-1496

   Recommended use of the chemical and restrictions on use
   Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

   Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
   Classification
   Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

   GHS Classification
   Reproductive toxicity : Category 2
   Short-term (acute) aquatic hazard : Category 1
   Long-term (chronic) aquatic hazard : Category 1

   GHS label elements
   Hazard pictograms : 
   Signal word : Warning
   Hazard statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
                      H410 Very toxic to aquatic life with long lasting effects.
   Precautionary statements : Prevention:
P203 Obtain, read and follow all safety instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P318 IF exposed or concerned, get medical advice.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>fenbendazole</td>
<td>43210-67-9</td>
<td>&gt;= 3 - &lt; 5</td>
</tr>
</tbody>
</table>

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: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

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: Suspected of damaging fertility. Suspected of damaging the unborn child. Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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).

Treat symptomatically and supportively.

5. FIREFIGHTING 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: Carbon oxides
Metal oxides
Silicon oxides

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

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 spills 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.
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 contact with 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. 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 labelled containers. Store locked up. Store in accordance with the particular national regulations.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<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>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</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: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type

Hand protection: 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 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Colour: white

Odour: odourless

Odour Threshold: No data available

pH: 6 - 8

Melting point/freezing point: No data available

Initial boiling point and boiling range: Not applicable

Flash point: Not applicable

Evaporation rate: Not applicable

Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids): Not applicable

Self-ignition: No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: No data available
### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reactivity</strong></td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td><strong>Chemical stability</strong></td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td><strong>Possibility of hazardous reac-</strong></td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td><strong>Conditions to avoid</strong></td>
<td>Heat, flames and sparks. Avoid dust formation.</td>
</tr>
<tr>
<td><strong>Incompatible materials</strong></td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td><strong>Hazardous decomposition products</strong></td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Route of exposure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inhalation</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Skin contact</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Ingestion</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Eye contact</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Acute toxicity**  
Not classified based on available information.
Components:

Starch:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

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:

Fenbendazole:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Starch:
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:

Starch:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Germ cell mutagenicity
Not classified based on available information.
Components:

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

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

Components:

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 develop- : Test Type: Development
ment

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.

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, Lymph nodes, Stomach, Nervous system
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Starch:
Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact
Exposure time: 28 Days
Method: OECD Test Guideline 410

fenbendazole:
### SAFETY DATA SHEET

**Fenbendazole (4%) Solid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.4</td>
<td>10.10.2020</td>
<td>2726690-00006</td>
<td>23.03.2020</td>
<td>20.04.2018</td>
</tr>
</tbody>
</table>

#### Species

<table>
<thead>
<tr>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 mg/kg</td>
<td>Oral</td>
<td>2 Weeks</td>
<td>Kidney, Liver</td>
</tr>
<tr>
<td>&gt; 2,500 mg/kg</td>
<td>Oral</td>
<td>30 Days</td>
<td>Kidney, Liver</td>
</tr>
</tbody>
</table>

#### Remarks

- No significant adverse effects were reported
- Aspirations were not observed.

#### Aspiration toxicity

Not classified based on available information.

#### Components

- **fenbendazole:**
  - No aspiration toxicity classification

#### Experience with human exposure

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>1,600 mg/kg</td>
<td>Oral</td>
<td>90 Days</td>
<td>Central nervous system</td>
<td>Tremors</td>
</tr>
<tr>
<td>Dog</td>
<td>4 mg/kg</td>
<td>Oral</td>
<td>6 Months</td>
<td>Stomach, Lymph nodes, Nervous system</td>
<td></td>
</tr>
</tbody>
</table>

#### Ecotoxicity

**Components:**

- **fenbendazole:**
  - **Toxicity to fish:** LC50 (Oncorhynchus mykiss (rainbow trout)): > 7.5 mg/l
  - Exposure time: 96 h
  - Remarks: No toxicity at the limit of solubility
  - **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

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**12. ECOLOGICAL INFORMATION**

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SAFETY DATA SHEET

Fenbendazole (4%) Solid Formulation

Version 2.4  Revision Date: 10.10.2020  SDS Number: 2726690-00006  Date of last issue: 23.03.2020
Date of first issue: 20.04.2018

M-Factor (Acute aquatic toxicity) : 100

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: 0.0015 mg/l
Exposure time: 21 Days
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

Persistence and degradability
No data available

Bioaccumulative potential

Components:

fenbendazole:
Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 240

Partition coefficient: n-octanol/water : log Pow: 2.3

Mobility in soil

Components:

fenbendazole:
Distribution among environmental compartments : log Koc: 4.37

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
SAFETY DATA SHEET

Fenbendazole (4%) Solid Formulation

Version 2.4  Revision Date: 10.10.2020  SDS Number: 2726690-00006  Date of last issue: 23.03.2020
Date of first issue: 20.04.2018

(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 IMO instruments
Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

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

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

16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

Fenbendazole (4%) Solid Formulation

Version: 2.4  Revision Date: 10.10.2020  SDS Number: 2726690-00006  Date of last issue: 23.03.2020
Date of first issue: 20.04.2018

Sources of key data used to compile the Safety Data Sheet:

Date format: dd.mm.yyyy

Full text of other abbreviations:
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- TWA: 8-hour, time-weighted average

Full text of other abbreviations:
- All - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

IN / EN