SAFETY DATA SHEET

Fenbendazole (0.5%) Crumbles Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fenbendazole (0.5%) Crumbles Formulation

Manufacturer or supplier's details

Company : MSD
Address : 50 Tuas West Drive
          Singapore - Singapore 638408
Telephone : +1-908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification

Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 2

GHS label elements

Hazard pictograms : 

Signal word : Warning
Hazard statements : H400 Very toxic to aquatic life.
                   H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:
                          P273 Avoid release to the environment.
                          Response:
                          P391 Collect spillage.
                          Disposal:
                          P501 Dispose of contents/ container to an approved waste disposal plant.
3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>fenbendazole</td>
<td>43210-67-9</td>
<td>&gt;= 0.25 - &lt; 1</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 : Flush eyes with water as a precaution. 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 : None known.

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.

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 : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Metal oxides
SAFETY DATA SHEET

Fenbendazole (0.5%) Crumbles Formulation

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 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. 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.

7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: 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. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labelled containers. 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 Control parameters / Permissible)</th>
<th>Basis</th>
</tr>
</thead>
</table>

3 / 15
9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : pellets

Colour : No data available

Odour : No data available

Odour Threshold : No data available
SAFETY DATA SHEET

Fenbendazole (0.5%) Crumbles Formulation

pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : Not applicable
Flammability (solid, gas) : No data available
Flammability (liquids) : Not applicable
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies)
   Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Components:

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

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 carbonate:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Paraffin oil:
Species: Rabbit
Result: No skin irritation

fenbendazole:
Species: Rabbit
Result: No skin irritation

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

Components:

Calcium carbonate:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

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 carbonate:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
Result: negative
Germ cell mutagenicity
Not classified based on available information.

Components:

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

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
Not classified based on available information.

Components:

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 foetal development:
Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

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.
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:

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

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, Lymph nodes, Nervous system

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, Diarrhoea

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
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

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): > 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

 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 211

M-Factor (Acute aquatic toxicity):

- 100

M-Factor (Chronic aquatic toxicity):

- NOEC (Daphnia magna (Water flea)): 0.0015 mg/l
  Exposure time: 21 Days
  Method: OECD Test Guideline 211

- 10

Persistence and degradability

No data available

Bioaccumulative potential

Components:

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

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. (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
SAFETY DATA SHEET

Fenbendazole (0.5%) Crumbles Formulation

Version 1.4
Revision Date: 27.08.2021
SDS Number: 6116964-00005
Date of last issue: 09.04.2021
Date of first issue: 17.07.2020

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.

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations : Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations : Not applicable

The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : dd.mm.yyyy

Full text of other abbreviations
SAFETY DATA SHEET

Fenbendazole (0.5%) Crumbles Formulation

Version: 1.4
Revision Date: 27.08.2021
SDS Number: 6116964-00005
Date of last issue: 09.04.2021
Date of first issue: 17.07.2020

ACGIH
ACGIH / TWA
SG OEL
SG OEL / PEL (long term)
SG OEL / PEL (short term)

SAFETY DATA SHEET.

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.

SG / EN