SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fenbendazole (22.2%) Solid Formulation

Version 2.3 Revision Date: 23.03.2020 SDS Number: 2570039-00006 Date of last issue: 13.09.2019
Date of first issue: 27.02.2018

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

1.1 Product identifier
Trade name: Fenbendazole (22.2%) Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
Shotton Lane
NE23 3JU Cramlington - Great Britain

Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Reproductive toxicity, Category 2
Specific target organ toxicity - repeated exposure, Category 2
Short-term (acute) aquatic hazard, Category 1
Long-term (chronic) aquatic hazard, Category 1

H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms: 
Signal word: Warning
Hazard statements: H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

Hazardous components which must be listed on the label:
fenbendazole

2.3 Other hazards
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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>fenbendazole</td>
<td>43210-67-9</td>
<td></td>
<td></td>
<td></td>
<td>Repr.; H361fd STOT RE2; H373 Aquatic Acute1; H400 Aquatic Chronic1; H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 10</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
<tr>
<td></td>
<td>256-145-7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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: 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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Suspected of damaging fertility. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fenbendazole (22.2%) Solid Formulation

Version 2.3  Revision Date: 23.03.2020  SDS Number: 2570039-00006  Date of last issue: 13.09.2019
Date of first issue: 27.02.2018

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture
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
Nitrogen oxides (NOx)

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions : Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions
Environmental precautions : Discharge into the environment must be avoided.
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.

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.

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. 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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. 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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fenbendazole (22.2%) Solid Formulation

Version 2 Revision Date: 23.03.2020 SDS Number: 2570039-00006 Date of last issue: 13.09.2019
2.3 Date of first issue: 27.02.2018

Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
---|---|---|---|---|
fenbendazole | 43210-67-9 | TWA | 100 µg/m3 (OEB 2) | Internal |

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 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
Material: 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. Equipment should conform to NS EN 143
Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: granules
Colour: white to off-white
Odour: No data available
Odour Threshold: No data available
pH: 5 - 7
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): May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower: No data available
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fenbendazole (22.2%) Solid Formulation

Version 2.3  Revision Date: 23.03.2020  SDS Number: 2570039-00006  Date of last issue: 13.09.2019

Date of first issue: 27.02.2018

flammability limit

Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available

Solubility(ies)
Water solubility : insoluble
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

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

9.2 Other information

Flammability (liquids) : No data available
Molecular weight : No data available
Particle size : No data available

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.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity
Not classified based on available information.

Components:
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:
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.

Germ cell mutagenicity
Not classified based on available information.

Components:
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 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  
May cause damage to organs through prolonged or repeated exposure.  

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:  
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:
fenbendazole:
No aspiration toxicity classification

Experience with human exposure
Components:
fenbendazole:
Ingestion: Symptoms: Rapid respiration, Salivation, anorexia, Diarrhoea

SECTION 12: Ecological information

12.1 Toxicity
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

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
12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
Components:
fenbendazole:
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 240
Partition coefficient: n-octanol/water: log Pow: 2.3

12.4 Mobility in soil
Components:
fenbendazole:
Distribution among environmental compartments: log Koc: 4.37

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 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.
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
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,
Fenbendazole (22.2%) Solid Formulation

Version 2.3  Revision Date: 23.03.2020  SDS Number: 2570039-00006  Date of last issue: 13.09.2019  Date of first issue: 27.02.2018

N.O.S. (fenbendazole)

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

ADR :  9
RID :  9
IMDG :  9
IATA :  9

14.4 Packing group

ADR
Packing group :  III
Classification Code :  M7
Hazard Identification Number :  90
Labels :  9 (ENVIRONM.)

RID
Packing group :  III
Classification Code :  M7
Hazard Identification Number :  90
Labels :  9 (ENVIRONM.)
Tunnel restriction code :  (-)

IMDG
Packing group :  III
Hazard Identification Number :  90
Labels :  9 (ENVIRONM.)

IATA (Cargo)
Packing instruction (cargo aircraft) :  956
Packing instruction (LQ) :  Y956
Packing group :  III
Fenbendazole (22.2%) Solid Formulation

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

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : 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

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable. Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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
- 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.

Full text of other abbreviations
- Aquatic Acute: Short-term (acute) aquatic hazard
- Aquatic Chronic: Long-term (chronic) aquatic hazard
- Repr.: Reproductive toxicity
- STOT RE: Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - In-
Fenbendazole (22.2%) Solid Formulation

Further information


Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 2</td>
</tr>
<tr>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 2</td>
</tr>
<tr>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
</tr>
<tr>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
</tr>
<tr>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

NO / EN