# SAFETY DATA SHEET

# Fenbendazole (22.2%) Solid Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 30.09.2023 |
|---|---|---|---|
| 2.13 | 28.09.2024 | 2569769-00016 | Date of first issue: 27.02.2018 |

## SECTION 1. IDENTIFICATION

Product identifier : Fenbendazole (22.2%) Solid Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.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 ABNT NBR 14725 Standard**

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, Stomach, Nervous system, Lymph nodes)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

**GHS label elements in accordance with ABNT NBR 14725 Standard**

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H373 May cause damage to organs (Liver, Stomach, Nervous system, Lymph nodes) through prolonged or repeated exposure if swallowed.
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.

**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.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Classification | Concentration (% w/w) |
|---|---|---|---|
| Starch | 9005-25-8 | | >= 50 -< 70 |
| fenbendazole | 43210-67-9 | Repr., 2<br>STOT RE, (Oral)(Liver, Stomach, Nervous system, Lymph nodes) , 2<br>Aquatic Acute, 1<br>Aquatic Chronic, 1 | >= 20 -< 25 |

## 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 : 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.
May cause damage to organs through prolonged or repeated exposure if swallowed.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)
Sulfur 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 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.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>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.<br>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, fume, gas, mist, vapors or spray.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store locked up.<br>Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:<br>Strong oxidizing agents |

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| Starch | 9005-25-8 | TWA | 10 mg/m³ | ACGIH |
| fenbendazole | 43210-67-9 | TWA | 100 µg/m3 (OEB 2) | Internal |

**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

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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : granules

Color : white to off-white

Odor : No data available

Odor 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.

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 | : | Not applicable |
| Relative vapor density | : | Not applicable |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | insoluble |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Autoignition 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 characteristics | | |
| Particle size | : | No data available |

## 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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid | : | Heat, flames and sparks.<br>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<br>Skin contact |

Ingestion
Eye contact

**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 sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:**

**Starch:**

| | | |
|---|---|---|
| Test Type | : | Maximization Test |
| Routes of exposure | : | 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 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 |
| 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 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 off-spring 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**

May cause damage to organs (Liver, Stomach, Nervous system, Lymph nodes) through prolonged or repeated exposure if swallowed.

**Components:**

**fenbendazole:**

Routes of exposure : Ingestion
Target Organs : Liver, Stomach, Nervous system, Lymph nodes
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:**

| | | |
|---|---|---|
| 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:**

**fenbendazole:**

No aspiration toxicity classification

**Experience with human exposure**

**Components:**

**fenbendazole:**

| | | |
|---|---|---|
| Ingestion | : | Symptoms: Rapid respiration, Salivation, anorexia, Diarrhea |

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**fenbendazole:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,009 mg/l<br>Exposure time: 21 d |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 0,0088 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| M-Factor (Acute aquatic toxicity) | : | 100 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0,00113 mg/l<br>Exposure time: 21 Days<br>Method: OECD Test Guideline 211 |
| M-Factor (Chronic aquatic toxicity) | : | 10 |

**Persistence and degradability**

No data available

**Bioaccumulative potential**

**Components:**

**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<br>Method: FDA 3.08 |

**Other adverse effects**

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

| | | |
|---|---|---|
| Waste from residues | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>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 |
| Environmentally hazardous | : | yes |

**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**

**ANTT**

| | | |
|---|---|---|
| UN number | : | UN 3077 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (fenbendazole) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Hazard Identification Number | : | 90 |

**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

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

| | | |
|---|---|---|
| National List of Carcinogenic Agents for Humans - (LINACH) | : | Not applicable |

| | | |
|---|---|---|
| Brazil. List of chemicals controlled by the Federal Police | : | Not applicable |

**The ingredients of this product are reported in the following inventories:**

| | | |
|---|---|---|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

## SECTION 16. OTHER INFORMATION

| | | |
|---|---|---|
| Revision Date | : | 28.09.2024 |
| Date format | : | dd.mm.yyyy |

**Further information**

| | | |
|---|---|---|
| Sources of key data used to compile the Material Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ |

**Full text of other abbreviations**

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| ACGIH / TWA | : | 8-hour, time-weighted average |

AIIC - 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 - Transporta-

tion of Dangerous Goods; 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; 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.

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