

**Fenbendazole (0.5%) Crumbles Formulation**

Version 1.10      Revision Date: 30.09.2023      SDS Number: 6116961-00011      Date of last issue: 04.04.2023  
Date of first issue: 17.07.2020

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Fenbendazole (0.5%) Crumbles Formulation

**Manufacturer or supplier's details**

Company name of supplier : MSD  
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@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product  
Restrictions on use : Not applicable

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Reproductive toxicity : Category 2

**GHS label elements**

Hazard pictograms :



Signal Word : Warning

Hazard Statements : 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/ face protection.

**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

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

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**Other hazards**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Paraffin oil	8012-95-1	>= 1 -< 5
fenbendazole	43210-67-9	>= 0.1 -< 1

**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 : 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 : 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 (CO<sub>2</sub>)  
 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  
 Metal oxides
- Specific extinguishing meth- : Use extinguishing measures that are appropriate to local cir-

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ods cumstances 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.

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### 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.  
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.

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### SECTION 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.

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.

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

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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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Paraffin oil	8012-95-1	VLE-PPT (Mist)	5 mg/m <sup>3</sup>	NOM-010-STPS-2014
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
fenbendazole	43210-67-9	TWA	100 µg/m <sup>3</sup> (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 : Combined particulates and organic vapor 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

Appearance : pellets

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

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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

Vapor pressure : Not applicable

Relative vapor 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

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 size : No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

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Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****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
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**Skin corrosion/irritation**

Not classified based on available information.

**Components:****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:****Paraffin oil:**

Species	:	Rabbit
Result	:	No eye irritation

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**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.

**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 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.

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**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 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:**

Routes of exposure : Ingestion  
Target Organs : Liver, Stomach, Nervous system, Lymph nodes  
Assessment : May cause damage to organs through prolonged or repeated exposure.



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**Repeated dose toxicity****Components:****Paraffin oil:**

Species : Rat, female  
LOAEL : 161 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

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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:**

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

### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### 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

NOELR (*Skeletonema costatum* (marine diatom)): > 1 mg/l  
 Exposure time: 72 h  
 Test substance: Water Accommodated Fraction  
 Remarks: Based on data from similar materials

##### fenbendazole:

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)): 0.0088 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

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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

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
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.

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**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.  
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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****NOM-002-SCT**

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

**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.

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**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.	:	Not applicable
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**The ingredients of this product are reported in the following inventories:**

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

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**SECTION 16. OTHER INFORMATION**

Revision Date	:	30.09.2023
Date format	:	dd.mm.yyyy

**Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014	:	Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-	:	Time weighted average limit value

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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 - Transportation 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

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/>

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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