

SAFETY DATA SHEET



Fenbendazole

Version 4.5 Revision Date: 01/15/2016 SDS Number: 18150-00007 Date of last issue: 09/22/2015
 Date of first issue: 10/02/2014

SECTION 1. IDENTIFICATION

Product name : Fenbendazole

Product code : Fenbendazole

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : One Merck Drive
 Whitehouse Station - New Jersey - USA 08889

Telephone : 908-423-1000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION


GHS Classification

Combustible dust

Reproductive toxicity : Category 2

Specific target organ systemic toxicity - repeated exposure (Oral) : Category 2 (Liver, lymph node, Stomach, Nervous system)

GHS label elements

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
 H361 Suspected of damaging fertility or the unborn child.
 H373 May cause damage to organs (Liver, lymph node, Stomach, Nervous system) through prolonged or repeated exposure if swallowed.

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Precautionary Statements : **Prevention:**
 P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
 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.

Other hazards

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance
 Substance name : Fenbendazole
 CAS-No. : 43210-67-9

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Fenbendazole	43210-67-9	>= 90 - <= 100

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.

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- | | | |
|---|---|--|
| 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 | : | Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
Suspected of damaging fertility or the unborn child.
May cause damage to organs through prolonged or repeated exposure if swallowed. |
| 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. |
| Notes to physician | : | Treat symptomatically and supportively. |
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SECTION 5. FIRE-FIGHTING MEASURES

- | | | |
|--|---|---|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
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 |
| 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. |
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SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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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.
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.
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.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Fenbendazole	43210-67-9	TWA	100 µg/m ³	Merck

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Engineering measures : Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
Material : Impervious gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:
Safety goggles

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : off-white

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Odor : odorless

Odor Threshold : No data available

pH : 7 - 7.5

Melting point/freezing point : 233 °C

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

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

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Solubility(ies)
Water solubility : 0.2 mg/l

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

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

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Possibility of hazardous reactions : Dust can form an explosive mixture in air.
Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

|| Not classified based on available information.

Ingredients:**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.

Ingredients:**Fenbendazole:**

Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

|| Not classified based on available information.

Ingredients:**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.

Ingredients:**Fenbendazole:**

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

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- : Test Type: DNA Repair
Result: negative
- : Test Type: Chromosomal aberration
Result: negative
- : Test Type: in vitro test
Species: mouse lymphoma cells
Metabolic activation: Metabolic activation
Result: Equivocal

Carcinogenicity

|| Not classified based on available information.

Ingredients:

Fenbendazole:

Species: Mouse

Application Route: oral (feed)

Exposure time: 2 Years

NOAEL: NOAEL (No observed adverse effect level): 405 mg/kg body weight

Result: negative

Species: Rat

Application Route: Oral

Exposure time: 2 Years

NOAEL: NOAEL (No observed adverse effect level): 5 mg/kg body weight

Result: negative

Target Organs: Lymph nodes, Liver

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

|| Suspected of damaging fertility or the unborn child.

Ingredients:

Fenbendazole:

Effects on fertility

- : Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: oral (feed)
General Toxicity Parent: NOAEL (No observed adverse effect level): 15 mg/kg body weight

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Fertility: LOAEL (Lowest observed adverse effect level): 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 (Lowest observed adverse effect level): 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 (No observed adverse effect level): 25 mg/kg body weight
 Result: Fetotoxicity.

Test Type: Embryo-fetal development
 Species: Rabbit
 Application Route: Oral
 Developmental Toxicity: LOAEL (Lowest observed adverse effect level): 63 mg/kg body weight

Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: NOAEL (No observed adverse effect level): 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, lymph node, Stomach, Nervous system) through prolonged or repeated exposure if swallowed.

Ingredients:

Fenbendazole:

Routes of exposure: Ingestion

Target Organs: Liver, lymph node, Stomach, Nervous system

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

Repeated dose toxicity

Ingredients:

Fenbendazole:

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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, lymph node, Nervous system

Aspiration toxicity

|| Not classified based on available information.

Ingredients:**Fenbendazole:**

No aspiration toxicity classification

Experience with human exposure**Ingredients:****Fenbendazole:**

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

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Ingredients:****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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M-Factor (Acute aquatic toxicity) : 100

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

M-Factor (Chronic aquatic toxicity) : 10

Persistence and degradability

No data available

Bioaccumulative potential

Ingredients:

Fenbendazole:

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

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

Mobility in soil

Ingredients:

Fenbendazole:

Distribution among environmental compartments : log Koc: 4.73

Other adverse effects

No data available

SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulation

UNRTDG

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

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(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

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

49 CFR

UN/ID/NA number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Fenbendazole)

Class : 9

Packing group : III

Labels : CLASS 9

ERG Code : 171

Marine pollutant : yes (Fenbendazole)

Remarks : Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards : Chronic Health Hazard
Fire Hazard

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

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New Jersey Right To Know

Fenbendazole	43210-67-9	90 - 100 %
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California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

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

AICS : not determined

DSL : not determined

IECSC : not determined

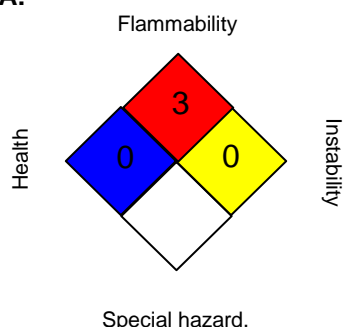
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SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	0*
FLAMMABILITY	3
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); EC_x - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL_x - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC_x - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations;

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UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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/>

Revision Date : 01/15/2016

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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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