

Fenbendazole (4%) Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 2726686-00013
 Date of first issue: 20.04.2018

SECTION 1. IDENTIFICATION

Product name : Fenbendazole (4%) Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

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

Reproductive toxicity : Category 2

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements

Hazard pictograms





Signal Word : Warning

Hazard Statements : H361fd Suspected of damaging fertility. Suspected of damag-

ing the unborn child.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P273 Avoid release to the environment.



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P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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

attention.

P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

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.	Concentration (% w/w)
Starch	9005-25-8	>= 30 -< 50
fenbendazole	43210-67-9	>= 3 -< 5

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 contact, immediately flush skin with soap and plenty In case of skin contact

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

If in eyes, rinse well with water. In case of eye contact

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.

Contact with dust can cause mechanical irritation or drying of

Dust contact with the eyes can lead to mechanical irritation.



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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 None known.

media

Specific hazards during fire

fighting

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 prod-

ucts

Carbon oxides

Nitrogen oxides (NOx)

Sulfur oxides Metal oxides Silicon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency 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.

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



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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 Advice on safe handling Use only with adequate ventilation.

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.

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Starch	9005-25-8	CMP	10 mg/m ³	AR OEL	
	Further information: A4 - Not classifiable as a human carcinogen				
		TWA	10 mg/m ³	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.



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Filter type

Hand protection Material

: Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.

Particulates type

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

Hygiene measures

Work uniform or laboratory coat.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : white

Odor : odorless

Odor Threshold : No data available

pH : 6-8

Melting point/freezing point : No data available

Initial boiling point and boiling

range

Not applicable

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) : Not applicable

Self-ignition : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available



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Vapor pressure No data available

Relative vapor density Not applicable

No data available Relative density

Density No data available

Solubility(ies)

insoluble Water solubility

Solubility in other solvents 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

SECTION 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Stable under normal conditions.

Chemical stability

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

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 Skin contact

Ingestion Eye contact



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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



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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



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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 - As-

sessment

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.

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



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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

Exposure time: 21 d

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 0,0088 mg/l



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Exposure time: 48 h aquatic invertebrates

Method: OECD Test Guideline 202

Exposure time: 21 Days

M-Factor (Acute aquatic tox- :

NOEC (Daphnia magna (Water flea)): 0,00113 mg/l Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

Method: OECD Test Guideline 211

100

M-Factor (Chronic aquatic 10

toxicity)

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 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.

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste Contaminated packaging

handling site for recycling or disposal.

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 Ш Labels 9



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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)

Packing instruction (passen: 956

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

956

(fenbendazole)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents : Not applicable

Registry.

Control of precursors and essential chemicals for the : Not applicable

preparation of drugs.

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

DSL : not determined

AICS : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION



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Further information

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet cy, http://echa.europa.eu/

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average AR OEL / CMP : TLV (Threshold Limit Value)

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

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



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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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