according to the Globally Harmonized System



Fenbendazole (20%) Solid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.09.2023

 4.0
 06.07.2024
 24668-00028
 Date of first issue: 22.10.2014

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fenbendazole (20%) Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number: +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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

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

Hazard pictograms

Signal word : Warning

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

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ing the unborn child.

H373 May cause damage to organs (Liver, Stomach, Nervous system, Lymph nodes) through prolonged or repeated expo-

sure if swallowed.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P203 Obtain, read and follow all safety instructions before use. P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P318 IF exposed or concerned, get medical advice.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% | |
|---------------|------------|------------------|--|
| | | w/w) | |
| Starch | 9005-25-8 | >= 20 - < 30 | |
| fenbendazole | 43210-67-9 | >= 10 - < 20 | |

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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.

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Get medical attention if irritation develops and persists.

: If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

If swallowed

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

he skin.

Dust contact with the eyes can lead to mechanical irritation. 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.

5. FIREFIGHTING MEASURES

Protection of first-aiders

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 prod-

ucts

Carbon oxides

Nitrogen oxides (NOx)

Sulphur oxides Metal 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 firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer for disposal.

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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.

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, fume, gas, mist, vapours or spray.

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 as-

sessment

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 labelled 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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

according to the Globally Harmonized System



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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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hygiene measures

Hand protection

Particulates type

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.

: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : granules

Colour : light yellow

Odour : odourless

Odour Threshold : No data available

pH : 6-8

Melting point/freezing point : No data available

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, han-

dling or other means.

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Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower :

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : insoluble

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Minimum ignition energy : > 500 mJ

Particle characteristics

Particle size : No data available

10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.
Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

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11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation 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 sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

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Components:

Starch:

Test Type : Maximisation Test Exposure routes 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 assay

Test system: mouse lymphoma cells Metabolic activation: Metabolic activation

Result: equivocal

Carcinogenicity

Not classified based on available information.

Components:

fenbendazole:

Species : Mouse Application Route : oral (feed) Exposure time : 2 Years

: 405 mg/kg body weight NOAEL

Result negative

: Rat Species Application Route
Exposure time
NOAEL Oral : 2 Years

: 5 mg/kg body weight

Result : negative

Target Organs : Lymph nodes, Liver

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Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

fenbendazole:

Effects on fertility : Test Type: Three-generation reproduction toxicity study

Species: Rat

Application Route: oral (feed)

General Toxicity - Parent: NOAEL: 15 mg/kg body weight

Fertility: LOAEL: 45 mg/kg body weight

Result: Effects on fertility

Effects on foetal develop-

ment

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-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 25 mg/kg body weight

Result: Fetotoxicity

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 63 mg/kg body weight

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 120 mg/kg body weight

Result: No effects on foetal development

Reproductive toxicity - 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 experi-

ments.

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:

Exposure routes : Ingestion

Target Organs : Liver, Stomach, Nervous system, Lymph nodes

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May cause damage to organs through prolonged or repeated Assessment

exposure.

Repeated dose toxicity

Components:

Starch:

Species : Rat

NOAEL
Application Route
Exposure time
Method >= 2,000 mg/kg: Skin contact 28 Days

OECD Test Guideline 410 Method

fenbendazole:

Rat Species

LOAEL 500 mg/kg Application Route
Exposure time
Target Organs Oral 2 Weeks Target Organs Kidney, Liver

Species Rat

> 2,500 mg/kg

NOAEL
Application Route Oral 30 Days

Remarks No significant adverse effects were reported

Species Rat

LOAEL 1,600 mg/kg

Application Route
Exposure time Oral : 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:

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Ingestion Symptoms: Rapid respiration, Salivation, anorexia, Diarrhoea

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

fenbendazole:

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.009 mg/l Toxicity to fish

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

M-Factor (Acute aquatic tox- :

icity)

100

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.00113 mg/l Exposure time: 21 Days

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

10

Persistence and degradability

No data available

Bioaccumulative potential

Components:

fenbendazole:

Partition coefficient: n-

log Pow: 3.32

octanol/water

Mobility in soil

Components:

fenbendazole:

Distribution among environ: log Koc: 3.8 - 4.7 mental compartments

Method: FDA 3.08

Other adverse effects

No data available

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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 han-Contaminated packaging

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN 3077 UN number

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

(fenbendazole)

Class 9 Packing group Ш 9 Labels Environmentally hazardous yes

IATA-DGR

UN/ID No. UN 3077

Proper shipping name Environmentally hazardous substance, solid, n.o.s.

(fenbendazole)

Class 9 Ш Packing group

Labels Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

956

Environmentally hazardous yes

IMDG-Code

UN number UN 3077

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

956

(fenbendazole)

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

Transport in bulk according to IMO instruments

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

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Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 06.07.2024

Further information

Sources of key data used to : compile the Safety Data

Sheet

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

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

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

Date format : dd.mm.yyyy

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 Develop-

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ment; 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 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.

IN / EN