

Fenbendazole (0.5%) Crumbles Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 6.0 2024/09/28 6116960-00014 Date of first issue: 2020/07/17

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Fenbendazole (0.5%) Crumbles Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 2

GHS label elements

Hazard pictograms

¥2>

Signal word : Warning

Hazard statements : H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P273 Avoid release to the environment.

Response:

P391 Collect spillage.



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Disposal:

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

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|---------------|------------|-----------------------|----------|
| Paraffin oil | 8012-95-1 | >= 1 - < 10 | |
| | | | |
| fenbendazole | 43210-67-9 | >= 0.25 - < 1 | |

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.

: Flush eyes with water as a precaution.

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

In case of eye contact

delayed

: None known.

Destantion of C

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical



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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 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, protec- :

tive 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.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Handling

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.



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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

Take care to prevent spills, waste and minimize release to the

environment.

Avoidance of contact

Hygiene measures

Oxidizing agents

If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

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.

Storage

Conditions for safe storage

Keep in properly labelled containers.

Store in accordance with the particular national regulations.

Materials to avoid

Do not store with the following product types:

Strong oxidizing agents

Unsuitable material: None known. Packaging material

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Concentration standard / Permissible concentration | Basis |
|--------------|--|--|---|----------------|
| Paraffin oil | 8012-95-1 | OEL-M (Mist) | 3 mg/m3 | JP OEL JSOH |
| | Further information: Group 1: carcinogenic to humans | | | |
| | | TWA (Inhal- able particu- late matter) | 5 mg/m3 | ACGIH |
| fenbendazole | 43210-67-9 | TWA | 100 μg/m3 (OEB 2) | Internal |

Use feasible engineering controls to minimize exposure to **Engineering measures**

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



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Respiratory protection If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Combined particulates and organic vapour type

Filter 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state pellets

Colour No data available

Odour No data available

Odour Threshold No data available

Melting point/freezing point No data available

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) No data available

Flammability (liquids) Not applicable

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit / Lower flammability limit No data available

Flash point Not applicable

No data available Decomposition temperature

No data available pΗ

Evaporation rate Not applicable

No data available Auto-ignition temperature

Viscosity

Viscosity, kinematic Not applicable



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Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : Not applicable

Density and / or relative density

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics

Particle size : No data available

10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac- :

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition

No hazardous decomposition products are known.

products

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



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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

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

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.

Germ cell mutagenicity

Not classified based on available information.

Components:

fenbendazole:



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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

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

Not classified based on available information.

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



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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

Not classified based on available information.

Components:

fenbendazole:

Exposure routes : Ingestion

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

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Paraffin oil:

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

fenbendazole:

Species : Rat LOAEL : 500 mg/kg

Application Route : Oral



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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: DogNOAEL: 4 mg/kgLOAEL: 8 mg/kgExposure 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:

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Paraffin oil:

Toxicity to fish : LL50 (Scophthalmus maximus (turbot)): > 100 mg/l

Exposure time: 96 h



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> 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

M-Factor (Acute aquatic tox- :

100

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.00113 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

Components:

Paraffin oil:

Partition coefficient: n-

octanol/water

log Pow: > 4

Remarks: Calculation

fenbendazole:

Partition coefficient: n-

octanol/water

: log Pow: 3.32



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Mobility in soil

Components:

fenbendazole:

Distribution among environ-

mental compartments

: log Koc: 3.8 - 4.7 Method: FDA 3.08

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

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 yes

Environmentally hazardous

IATA-DGR

UN/ID No. UN 3077

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

(fenbendazole)

9 Class Packing group Ш

Labels Miscellaneous

Packing instruction (cargo 956

aircraft)

Packing instruction (passen-956

ger aircraft)

Environmentally hazardous yes

IMDG-Code

UN number UN 3077



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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.

National Regulations

Refer to section 15 for specific national regulation.

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.

ERG Code : 171

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable



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Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

| Chemical name | Concentration (%) | Remarks |
|---------------|-------------------|---------|
| Mineral oil | >=1 - <10 | - |

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

| Chemical name | Remarks |
|---------------|---------|
| Mineral oil | _ |

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)



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Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS not determined

DSL not determined

IECSC not determined

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

Further information

Sources of key data used to : compile the Safety Data

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

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

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH USA. ACGIH Threshold Limit Values (TLV)

JP OEL JSOH Japan. The Japan Society for Occupational Health. Recom-

mendation of Occupational Exposure Limits

ACGIH / TWA 8-hour, time-weighted average JP OEL JSOH / OEL-M Occupational Exposure Limit-Mean

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 Sys-



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tem; 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 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.

JP / EN