

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.0	02/23/2024	10776693-00005	Date of first issue: 06/03/2022

SECTION 1. IDENTIFICATION

Product name : Fenbendazole (10%) Aqueous Solution (NZ)
Other means of identification : PANACUR 100 (A007154)

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.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 in accordance with the Hazardous Products Regulations

Reproductive toxicity : Category 2
Specific target organ toxicity : Category 2 (Liver, Stomach, Nervous system, Lymph nodes)
- repeated exposure (Oral)

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H373 May cause damage to organs (Liver, Stomach, Nervous system, Lymph nodes) through prolonged or repeated exposure if swallowed.

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 mist or vapors.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical attention.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version 2.0 Revision Date: 02/23/2024 SDS Number: 10776693-00005 Date of last issue: 09/30/2023
Date of first issue: 06/03/2022

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
fenbendazole	No data available	43210-67-9	$\geq 9.6 - \leq 10.52$
Silicon dioxide	Silica	7631-86-9	3

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Suspected of damaging fertility. Suspected of damaging the unborn child.
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 (see section 8).
- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.0	02/23/2024	10776693-00005	Date of first issue: 06/03/2022

- | | | |
|--|---|---|
| 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
Nitrogen oxides (NO _x)
Sulfur oxides
Metal 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. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

- | | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
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 | : | Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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 | : | See Engineering measures under EXPOSURE |
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Fenbendazole (10%) Aqueous Solution (NZ)

Version 2.0 Revision Date: 02/23/2024 SDS Number: 10776693-00005 Date of last issue: 09/30/2023
Date of first issue: 06/03/2022

Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.
Advice on safe handling : Use only with adequate ventilation.
Do not breathe mist or vapors.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the environment.
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
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
fenbendazole	43210-67-9	TWA	100 µg/m ³ (OEB 2)	Internal
Silicon dioxide	7631-86-9	TWAEV (respirable dust)	6 mg/m ³	CA QC OEL

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type : Particulates 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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.0	02/23/2024	10776693-00005	Date of first issue: 06/03/2022

Skin and body protection : Work uniform or laboratory coat.
Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Color : white
off-white

Odor : No data available

Odor Threshold : No data available

pH : 6.0 - 7.0

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) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.0	02/23/2024	10776693-00005	Date of first issue: 06/03/2022

Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	50 - 300 mm ² /s
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
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.

Components:

fenbendazole:

Acute oral toxicity	:	LD50 (Rat): > 10,000 mg/kg
	:	LD50 (Mouse): > 10,000 mg/kg

Silicon dioxide:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
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SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.0	02/23/2024	10776693-00005	Date of first issue: 06/03/2022

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 2.08 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

fenbendazole:

Species : Rabbit
Result : No skin irritation

Silicon dioxide:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

fenbendazole:

Species : Rabbit
Result : No eye irritation

Silicon dioxide:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

fenbendazole:

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.0	02/23/2024	10776693-00005	Date of first issue: 06/03/2022

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

Silicon dioxide:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
Genotoxicity in vivo	: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative

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

Silicon dioxide:

Species	: Rat
Application Route	: Ingestion
Exposure time	: 103 weeks
Result	: negative

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version 2.0 Revision Date: 02/23/2024 SDS Number: 10776693-00005 Date of last issue: 09/30/2023
Date of first issue: 06/03/2022

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 fetal development	: Test Type: Development Species: Dog, female Application Route: Oral Developmental Toxicity: LOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects. Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 25 mg/kg body weight Result: Fetotoxicity. Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 63 mg/kg body weight Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 120 mg/kg body weight Result: No effects on fetal development.
Reproductive toxicity - Assessment	: Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

Silicon dioxide:

Effects on fetal development	: Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative
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STOT-single exposure

Not classified based on available information.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.0	02/23/2024	10776693-00005	Date of first issue: 06/03/2022

STOT-repeated exposure

May cause damage to organs (Liver, Stomach, Nervous system, Lymph nodes) through prolonged or repeated exposure if swallowed.

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:

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

Silicon dioxide:

Species	: Rat
NOAEL	: 1.3 mg/m ³
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 13 Weeks

Aspiration toxicity

Not classified based on available information.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.0	02/23/2024	10776693-00005	Date of first issue: 06/03/2022

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
aquatic invertebrates : Exposure time: 48 h
Method: OECD Test Guideline 202

|| Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 0.00113 mg/l
aquatic invertebrates (Chronic toxicity) : Exposure time: 21 Days
Method: OECD Test Guideline 211

Silicon dioxide:

|| Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

|| Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
aquatic invertebrates : Exposure time: 24 h
Method: OECD Test Guideline 202

|| Toxicity to algae/aquatic : EC50 (Desmodesmus subspicatus (green algae)): > 10,000
plants : mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): 10,000
mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.0	02/23/2024	10776693-00005	Date of first issue: 06/03/2022

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.
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 Regulations

UNRTDG

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(fenbendazole)
Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(fenbendazole)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.0	02/23/2024	10776693-00005	Date of first issue: 06/03/2022

Packing instruction (passenger aircraft) : 964

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, 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

TDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (fenbendazole)

Class : 9

Packing group : III

Labels : 9

ERG Code : 171

Marine pollutant : yes(fenbendazole)

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (10%) Aqueous Solution (NZ)

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.0	02/23/2024	10776693-00005	Date of first issue: 06/03/2022

CA QC OEL / TWA EV : Time-weighted average exposure 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

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 : 02/23/2024
Date format : mm/dd/yyyy

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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Fenbendazole (10%) Aqueous Solution (NZ)

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2.0	02/23/2024	10776693-00005	Date of first issue: 06/03/2022

CA / Z8