

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Fenbendazole (0.5%) Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Veterinary product

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Drynam Road
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Serious eye damage, Category 1	H318: Causes serious eye damage.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 2	H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

Hazard statements : H318 Causes serious eye damage.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Calcium bis(dihydrogenorthophosphate) monohydrate

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Calcium bis(dihydrogenorthophosphate) monohydrate	10031-30-8	Eye Dam. 1; H318	>= 30 - < 50
Langbeinite	14977-37-8	Eye Irrit. 2; H319	>= 1 - < 10
Paraffin oil	8012-95-1 232-384-2	Asp. Tox. 1; H304 Aquatic Chronic 4; H413	>= 1 - < 2.5
fenbendazole	43210-67-9	Repr. 2; H361fd	>= 0.25 - < 1

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version 6.4	Revision Date: 14.04.2025	SDS Number: 1161530-00020	Date of last issue: 28.09.2024 Date of first issue: 19.12.2016
----------------	------------------------------	------------------------------	---

	256-145-7	STOT RE 2; H373 (Liver, Stomach, Nervous system, Lymph nodes) Aquatic Acute 1; H400 Aquatic Chronic 1; H410	
		M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 10	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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. |
| 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). |
| 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 | : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately. |
| If swallowed | : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water. |

4.2 Most important symptoms and effects, both acute and delayed

- | | |
|-------|--|
| Risks | : Contact with dust can cause mechanical irritation or drying of the skin. |
|-------|--|

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

Causes serious eye damage.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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 products : Oxides of phosphorus
Metal oxides
Carbon oxides
Chlorine compounds

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages
cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe dust. Do not swallow. Do not get in 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 Keep container tightly closed. 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.
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,

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Keep tightly closed.
Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

dusts non-specific 4 mg/m³
Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust)
Basis: IE OEL

10 mg/m³
Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust)
Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Paraffin oil	8012-95-1	OELV - 8 hrs (TWA) (inhalable fraction)	5 mg/m ³	IE OEL
fenbendazole	43210-67-9	TWA	100 µg/m ³ (OEB 2)	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Calcium carbonate	Workers	Inhalation	Long-term systemic effects	6.36 mg/m ³
	Consumers	Ingestion	Acute systemic effects	6.1 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1.06 mg/m ³
	Consumers	Ingestion	Long-term systemic effects	6.1 mg/kg bw/day
Sodium chloride	Workers	Inhalation	Long-term systemic effects	2068.62 mg/m ³
	Workers	Inhalation	Acute systemic effects	2068.62 mg/m ³

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version 6.4 Revision Date: 14.04.2025 SDS Number: 1161530-00020 Date of last issue: 28.09.2024
Date of first issue: 19.12.2016

	Workers	Skin contact	Long-term systemic effects	295.52 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	295.52 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	443.28 mg/m3
	Consumers	Inhalation	Acute systemic effects	443.28 mg/m3
	Consumers	Skin contact	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	126.65 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	126.65 mg/kg bw/day
Paraffin oil	Workers	Inhalation	Long-term systemic effects	5 mg/m3
	Workers	Inhalation	Short-term exposure	5 mg/m3
	Workers	Inhalation	Long-term local effects	5 mg/m3
	Workers	Inhalation	Acute local effects	5 mg/m3

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Calcium carbonate	Sewage treatment plant	100 mg/l
Sodium chloride	Fresh water	5 mg/l
	Sewage treatment plant	500 mg/l
	Soil	4.86 mg/kg dry weight (d.w.)
fenbendazole		0.0001 mg/l

8.2 Exposure controls

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

- Eye/face 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.
- Hand protection :
Material : Chemical-resistant gloves
- Skin and body protection : Work uniform or laboratory coat.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

Filter type	Filter should conform to I.S. EN 14387 : Combined particulates and organic vapour type (A-P)
-------------	---

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: powder
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Vapour pressure	: No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Particle characteristics		
Particle size	:	No data available

9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	No data available
Molecular weight	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
---------------------	---	--

10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
---------------------	---	---

10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
--------------------	---	------------------

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
--	---	--

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

Acute toxicity

Not classified based on available information.

Components:

Calcium bis(dihydrogenorthophosphate) monohydrate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 2.6 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 7,940 mg/kg

Langbeinite:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 425
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

Paraffin oil:

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

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:

Calcium bis(dihydrogenorthophosphate) monohydrate:

Species : Rabbit
Result : No skin irritation

Langbeinite:

Species : reconstructed human epidermis (RhE)
Method : Regulation (EC) No. 440/2008, Annex, B.46

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

Result	:	No skin irritation
Remarks	:	Based on data from similar materials

Paraffin oil:

Species	:	Rabbit
Result	:	No skin irritation

fenbendazole:

Species	:	Rabbit
Result	:	No skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Calcium bis(dihydrogenorthophosphate) monohydrate:

Species	:	Rabbit
Result	:	Irreversible effects on the eye

Langbeinite:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	Irritation to eyes, reversing within 7 days
Remarks	:	Based on data from similar materials

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.

Components:

Calcium bis(dihydrogenorthophosphate) monohydrate:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact
Species	:	Mouse
Method	:	OECD Test Guideline 429

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

Result : negative
Remarks : Based on data from similar materials

Langbeinite:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

Calcium bis(dihydrogenorthophosphate) monohydrate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: in vitro micronucleus test
Method: OECD Test Guideline 487
Result: negative
Remarks: Based on data from similar materials

Langbeinite:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

fenbendazole:

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

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:

Calcium bis(dihydrogenorthophosphate) monohydrate:

Effects on fertility	: Test Type: Reproduction/Developmental toxicity screening test
	Species: Rat
	Application Route: Ingestion
	Method: OECD Test Guideline 421
	Result: negative
	Remarks: Based on data from similar materials

Effects on foetal development	: Test Type: Embryo-foetal development
	Species: Rat
	Application Route: Ingestion
	Result: negative

Langbeinite:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

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 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-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 - 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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

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:

Calcium bis(dihydrogenorthophosphate) monohydrate:

Species	: Rat
NOAEL	: > 300 mg/kg
Application Route	: Ingestion
Exposure time	: 28 Days
Method	: OECD Test Guideline 407
Remarks	: Based on data from similar materials

Langbeinite:

Species	: Rat
NOAEL	: > 100 mg/kg
Application Route	: Ingestion
Exposure time	: 28 d
Method	: OECD Test Guideline 422
Remarks	: Based on data from similar materials

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
Exposure time	: 2 Weeks
Target Organs	: Kidney, Liver

Species	: Rat
NOAEL	: > 2,500 mg/kg

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

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:

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

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

fenbendazole:

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

SECTION 12: Ecological information

12.1 Toxicity

Components:

Calcium bis(dihydrogenorthophosphate) monohydrate:

- | | |
|---|--|
| Toxicity to fish | : LC50 (<i>Oryzias latipes</i> (Japanese medaka)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (<i>Daphnia magna</i> (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | : ErC50 (<i>Pseudokirchneriella subcapitata</i> (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials |
| Toxicity to microorganisms | : EC50 : > 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials |

Langbeinite:

- | | |
|---|---|
| Toxicity to fish | : LC50 (<i>Oncorhynchus mykiss</i> (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (<i>Daphnia magna</i> (Water flea)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials |

Paraffin oil:

- | | |
|---|--|
| Toxicity to fish | : LL50 (<i>Scophthalmus maximus</i> (turbot)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : EL50 (<i>Acartia tonsa</i> (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 (<i>Skeletonema costatum</i> (marine diatom)): > 100 mg/l
Exposure time: 72 h |

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

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 : EC50 (Daphnia magna (Water flea)): 0.0088 mg/l
aquatic invertebrates : Exposure time: 48 h
Method: OECD Test Guideline 202

M-Factor (Acute aquatic tox- : 100
icity)

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

M-Factor (Chronic aquatic : 10
toxicity)

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

Paraffin oil:

Partition coefficient: n- : log Pow: > 4
octanol/water : Remarks: Calculation

fenbendazole:

Partition coefficient: n- : log Pow: 3.32
octanol/water

12.4 Mobility in soil

Components:

fenbendazole:

Distribution among environ- : log Koc: 3.8 - 4.7
mental compartments : Method: FDA 3.08

12.5 Results of PBT and vPvB assessment

Product:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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

14.1 UN number or ID number

ADN	: UN 3077
ADR	: UN 3077
RID	: UN 3077
IMDG	: UN 3077
IATA	: UN 3077

14.2 UN proper shipping name

ADN	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (fenbendazole)
ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (fenbendazole)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (fenbendazole)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (fenbendazole)
IATA	:	Environmentally hazardous substance, solid, n.o.s. (fenbendazole)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9
ADR	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9
Tunnel restriction code	: (-)
RID	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9
IMDG	
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
IATA (Cargo)	
Packing instruction (cargo aircraft)	: 956
Packing instruction (LQ)	: Y956
Packing group	: III
Labels	: Miscellaneous

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

IATA (Passenger)

Packing instruction (passenger aircraft)	: 956
Packing instruction (LQ)	: Y956
Packing group	: III
Labels	: Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	: Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	: Not applicable
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	: Not applicable
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	: Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	: Not applicable

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
----	--------------------------	---------------------	---------------------

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H304	: May be fatal if swallowed and enters airways.
H318	: Causes serious eye damage.
H319	: Causes serious eye irritation.
H361fd	: Suspected of damaging fertility. Suspected of damaging the unborn child.
H373	: May cause damage to organs through prolonged or repeated exposure if swallowed.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.
H413	: May cause long lasting harmful effects to aquatic life.

Full text of other abbreviations

Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Asp. Tox.	: Aspiration hazard
Eye Dam.	: Serious eye damage
Eye Irrit.	: Eye irritation
Repr.	: Reproductive toxicity
STOT RE	: Specific target organ toxicity - repeated exposure
IE OEL	: Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA)	: Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regula-

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fenbendazole (0.5%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.4	14.04.2025	1161530-00020	Date of first issue: 19.12.2016

tion (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

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 Agency, <http://echa.europa.eu/>

Classification of the mixture:

Eye Dam. 1	H318
Aquatic Acute 1	H400
Aquatic Chronic 2	H411

Classification procedure:

Calculation method
Calculation method
Calculation method

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.

IE / EN