

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

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

#### 1.1 Product identifier

Trade name : Fenbendazole Paste 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  
Walton Manor, Walton  
MK7 7AJ Milton Keynes - United Kingdom

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

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Reproductive toxicity, Category 2	H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



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Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
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- Hazard pictograms :  
- Signal word : Warning
- Hazard statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.  
H373 May cause damage to organs through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.
- Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P391 Collect spillage.
- Storage:**  
P405 Store locked up.

Hazardous components which must be listed on the label:

fenbendazole

### 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.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
fenbendazole	43210-67-9 256-145-7	Repr. 2; H361fd STOT RE 2; H373 (Liver, Stomach, Nervous system, Lymph nodes) Aquatic Acute 1; H400 Aquatic Chronic 1;	$\geq 10 - \leq 18.75$

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
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		H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 10	
Ethanol#	64-17-5 200-578-6 603-002-00-5	Flam. Liq. 2; H225 Eye Irrit. 2; H319 specific concentration limit Eye Irrit. 2; H319 >= 50 %	<= 0.04
Diethyl malonate#	105-53-3 203-305-9	Eye Irrit. 2; H319	<= 0.006
2-Furaldehyde#	98-01-1 202-627-7 605-010-00-4	Flam. Liq. 3; H226 Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 3; H311 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Carc. 2; H351 STOT SE 3; H335 Aquatic Chronic 3; H412	<= 0.006
Cinnamaldehyde#	104-55-2 203-213-9	Acute Tox. 4; H312 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1B; H317	<= 0.002
Isovaleraldehyde#	590-86-3 209-691-5	Flam. Liq. 2; H225 Eye Irrit. 2; H319 Skin Sens. 1B; H317 STOT SE 3; H335 Aquatic Chronic 2; H411	<= 0.002
Acetaldehyde#	75-07-0 200-836-8 605-003-00-6	Flam. Liq. 1; H224 Acute Tox. 4; H302 Eye Irrit. 2; H319 Muta. 2; H341 Carc. 1B; H350 STOT SE 3; H335	<= 0.0002
Trans-hex-2-en-1-ol#	928-95-0 213-191-2	Skin Corr. 1B; H314 Eye Dam. 1; H318	<= 0.0002
Substances with a workplace exposure limit :			
Propylene glycol	57-55-6 200-338-0		>= 15 - <= 15.16
Glycerine	56-81-5 200-289-5		10

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

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For explanation of abbreviations see section 16.  
#: Voluntarily-disclosed substance

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### 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.<br>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.<br>Get medical attention.  |
| In case of skin contact    | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact     | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.  |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |

#### 4.2 Most important symptoms and effects, both acute and delayed

- |       |   |  |
|-------|---|--|
| Risks | : | Suspected of damaging fertility. Suspected of damaging the unborn child.<br>May cause damage to organs through prolonged or repeated exposure. |
|-------|---|--|

#### 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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> ) |
|------------------------------|---|--|
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# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

---

Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Sulphur oxides

### 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.

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## 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. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

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      | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  |
| Local/Total ventilation | : | Use only with adequate ventilation.  |
| Advice on safe handling | : | Do not breathe vapours.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>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.<br>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. |

### 7.2 Conditions for safe storage, including any incompatibilities

- |   |   |  |
|---|---|--|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations. |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Gases                                   |

### 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
fenbendazole	43210-67-9	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Propylene glycol	57-55-6	TWA (Total vapour and particles)	150 ppm 474 mg/m <sup>3</sup>	GB EH40
		TWA (particles)	10 mg/m <sup>3</sup>	GB EH40
Glycerine	56-81-5	TWA (Mist)	10 mg/m <sup>3</sup>	GB EH40
Ethanol	64-17-5	TWA	1,000 ppm 1,920 mg/m <sup>3</sup>	GB EH40
2-Furaldehyde	98-01-1	TWA	2 ppm 8 mg/m <sup>3</sup>	GB EH40
	Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
		STEL	5 ppm 20 mg/m <sup>3</sup>	GB EH40
	Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
Acetaldehyde	75-07-0	TWA	20 ppm 37 mg/m <sup>3</sup>	GB EH40
	Further information: Capable of causing cancer and/or heritable genetic damage.			
		STEL	50 ppm 92 mg/m <sup>3</sup>	GB EH40
	Further information: Capable of causing cancer and/or heritable genetic damage.			

### Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term systemic effects	168 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term systemic effects	50 mg/m <sup>3</sup>
Glycerine	Workers	Inhalation	Long-term local effects	56 mg/m <sup>3</sup>
	Consumers	Ingestion	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	33 mg/m <sup>3</sup>
Ethanol	Workers	Inhalation	Long-term systemic effects	950 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	343 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic	114 mg/m <sup>3</sup>

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

			effects	
	Consumers	Skin contact	Long-term systemic effects	206 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	87 mg/kg bw/day
2-Furaldehyde	Workers	Inhalation	Long-term systemic effects	17.8 mg/m3
	Workers	Inhalation	Acute systemic effects	152 mg/m3
	Workers	Inhalation	Long-term local effects	8 mg/m3
	Workers	Inhalation	Acute local effects	20 mg/m3
	Workers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	8 mg/m3
	Consumers	Inhalation	Acute systemic effects	136 mg/m3
	Consumers	Inhalation	Long-term local effects	8 mg/m3
	Consumers	Inhalation	Acute local effects	20 mg/m3
	Consumers	Skin contact	Long-term systemic effects	2.4 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	2.4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	2.4 mg/kg bw/day
Cinnamaldehyde	Workers	Inhalation	Long-term systemic effects	2.204 mg/m3
	Workers	Skin contact	Long-term systemic effects	2.513 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0.543 mg/m3
	Consumers	Skin contact	Long-term systemic effects	0.625 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	2.5 mg/kg bw/day

### Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
fenbendazole		0.0001 mg/l
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57.2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)
Glycerine	Fresh water	0.885 mg/l



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

	Marine water	0.0885 mg/l
	Intermittent use/release	8.85 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	3.3 mg/kg dry weight (d.w.)
	Marine sediment	0.33 mg/kg dry weight (d.w.)
	Soil	0.141 mg/kg dry weight (d.w.)
Ethanol	Fresh water	0.96 mg/l
	Freshwater - intermittent	2.75 mg/l
	Marine water	0.79 mg/l
	Sewage treatment plant	580 mg/l
	Fresh water sediment	3.6 mg/kg dry weight (d.w.)
	Marine sediment	2.9 mg/kg dry weight (d.w.)
	Soil	0.63 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	380 mg/kg food
2-Furaldehyde	Fresh water	0.033 mg/l
	Freshwater - intermittent	0.027 mg/l
	Marine water	0.003 mg/l
	Sewage treatment plant	7.6 mg/l
	Fresh water sediment	0.12 mg/kg dry weight (d.w.)
	Marine sediment	0.012 mg/kg dry weight (d.w.)
	Soil	2.6 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	35.3 mg/kg food
Cinnamaldehyde	Fresh water	0.021 mg/l
	Marine water	0.002 mg/l
	Freshwater - intermittent	0.21 mg/l
	Sewage treatment plant	7.1 mg/l
	Fresh water sediment	0.021 mg/kg dry weight (d.w.)
	Marine sediment	0.002 mg/kg dry weight (d.w.)
	Soil	0.004 mg/kg dry weight (d.w.)

### 8.2 Exposure controls

#### 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

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

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.  
Equipment should conform to BS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Appearance : paste  
Colour : white to off-white  
Odour : cinnamon-like  
Odour Threshold : No data available

pH : 6 - 8

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available  
Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : insoluble  
Partition coefficient: n- : Not applicable

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

---

octanol/water  
Auto-ignition temperature : No data available  
  
Decomposition temperature : No data available  
  
Viscosity  
Viscosity, kinematic : No data available  
  
Explosive properties : Not explosive  
  
Oxidizing properties : The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Flammability (liquids) : No data available  
  
Molecular weight : No data available  
  
Particle size : No data available

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## 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 : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

---

### 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

#### **Ethanol:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 124.7 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour

#### **Diethyl malonate:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials

#### **2-Furaldehyde:**

Acute oral toxicity : LD50 (Rat): 108 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 1 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour

Acute dermal toxicity : Acute toxicity estimate: 300 mg/kg  
Method: Expert judgement

#### **Cinnamaldehyde:**

Acute oral toxicity : LD50 (Rat): 2,200 mg/kg  
Acute dermal toxicity : LD50 (Rabbit): 1,260 mg/kg

#### **Isovaleraldehyde:**

Acute oral toxicity : LD50 (Rat): 5,740 mg/kg  
Acute inhalation toxicity : LC50 (Rat): 42.7 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour  
Acute dermal toxicity : LD50 (Rabbit): 2,534 mg/kg

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

### Acetaldehyde:

Acute oral toxicity : LD50 (Rat): 661 mg/kg  
Acute dermal toxicity : LD50 (Rabbit): 3,540 mg/kg

### Trans-hex-2-en-1-ol:

Acute oral toxicity : LD50 (Rat): 3,500 mg/kg  
Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.  
Acute dermal toxicity : LD50 (Rabbit): 4,500 mg/kg

### Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

### Glycerine:

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

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### fenbendazole:

Species : Rabbit  
Result : No skin irritation

#### Ethanol:

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

#### Diethyl malonate:

Species : Rabbit  
Result : No skin irritation

#### 2-Furaldehyde:

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

Result : Skin irritation  
Remarks : Based on national or regional regulation.

### Cinnamaldehyde:

Species : human skin  
Result : Skin irritation

### Isovaleraldehyde:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : Mild skin irritation

### Acetaldehyde:

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

### Trans-hex-2-en-1-ol:

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431  
Result : Corrosive after 3 minutes to 1 hour of exposure

### Propylene glycol:

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

### Glycerine:

Species : Rabbit  
Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### fenbendazole:

Species : Rabbit  
Result : No eye irritation

#### Ethanol:

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : Irritation to eyes, reversing within 21 days

#### Diethyl malonate:

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days

### 2-Furaldehyde:

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : Irritation to eyes, reversing within 21 days

### Cinnamaldehyde:

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : Irritation to eyes, reversing within 21 days

### Isovaleraldehyde:

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days

### Acetaldehyde:

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days

### Trans-hex-2-en-1-ol:

Result : Irreversible effects on the eye  
Remarks : Based on skin corrosivity.

### Propylene glycol:

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

### Glycerine:

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:

#### Ethanol:

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

Result : negative

### Diethyl malonate:

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

### 2-Furaldehyde:

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

### Cinnamaldehyde:

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

### Isovaleraldehyde:

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : positive  
Remarks : Based on data from similar materials

Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

### Acetaldehyde:

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

### Trans-hex-2-en-1-ol:

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



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

---

Method : OECD Test Guideline 429  
Result : negative  
Remarks : Based on data from similar materials

### Propylene glycol:

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### fenbendazole:

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

Test Type: DNA Repair  
Result: negative

Test Type: Chromosomal aberration  
Result: negative

Test Type: in vitro assay  
Test system: mouse lymphoma cells  
Metabolic activation: Metabolic activation  
Result: equivocal

#### Ethanol:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)  
Species: Mouse  
Application Route: Ingestion  
Result: equivocal

#### Diethyl malonate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: Directive 67/548/EEC, Annex, B.13/14  
Result: negative

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

Remarks: Based on data from similar materials

### 2-Furaldehyde:

Genotoxicity in vitro

: Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: positive

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: positive

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: positive

Test Type: In vitro sister chromatid exchange assay in mammalian cells  
Result: positive

Genotoxicity in vivo

: Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo  
Species: Rat  
Application Route: Ingestion  
Result: negative

Test Type: Transgenic rodent somatic cell gene mutation assay  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### Cinnamaldehyde:

Genotoxicity in vitro

: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo

: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Mammalian erythrocyte micronucleus test (in vivo)

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow  
cytogenetic test, chromosomal analysis)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with  
mammalian liver cells in vivo  
Species: Rat  
Application Route: Ingestion  
Result: negative

### Isovaleraldehyde:

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: DNA damage and repair, unscheduled DNA syn-  
thesis in mammalian cells (in vitro)  
Result: positive  
Remarks: Based on data from similar materials

Genotoxicity in vivo

: Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative

### Acetaldehyde:

Genotoxicity in vitro

: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: positive

Test Type: Chromosome aberration test in vitro  
Result: positive

Test Type: in vitro micronucleus test  
Result: positive

Test Type: In vitro sister chromatid exchange assay in mam-  
malian cells  
Result: positive

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

---

- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: positive
- Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Rat  
Application Route: Intraperitoneal injection  
Result: positive
- Test Type: Mammalian bone marrow sister chromatid exchange  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: positive
- Germ cell mutagenicity- Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.
- Trans-hex-2-en-1-ol:**
- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative
- Test Type: in vitro micronucleus test  
Method: OECD Test Guideline 487  
Result: negative
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials
- Propylene glycol:**
- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative
- Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative
- Glycerine:**
- Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

---

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
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

#### 2-Furaldehyde:

Species : Mouse  
Application Route : Ingestion  
Exposure time : 103 weeks  
Method : OECD Test Guideline 451  
Result : positive  
Remarks : The mechanism or mode of action is not relevant in humans.

Species : Hamster  
Application Route : inhalation (vapour)  
Exposure time : 52 weeks  
Result : negative

Species : Mouse  
Application Route : Skin contact  
Exposure time : 47 weeks  
Result : positive

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

### **Cinnamaldehyde:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 106 weeks  
Result : negative  
Remarks : Based on data from similar materials

Species : Mouse  
Application Route : Intraperitoneal injection  
Exposure time : 24 weeks  
Result : negative

### **Isovaleraldehyde:**

Species : Rat  
Application Route : inhalation (vapour)  
Exposure time : 2 Years  
Result : negative  
Remarks : Based on data from similar materials

### **Acetaldehyde:**

Species : Rat  
Application Route : Inhalation  
Exposure time : 121 weeks  
Result : positive

Carcinogenicity - Assessment : Sufficient evidence of carcinogenicity in animal experiments

### **Propylene glycol:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

### **Glycerine:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

### **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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

- 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.
- Ethanol:**  
Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion  
Result: negative
- Diethyl malonate:**  
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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

Result: negative  
Remarks: Based on data from similar materials

### 2-Furaldehyde:

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

### Cinnamaldehyde:

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

### Acetaldehyde:

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

### Trans-hex-2-en-1-ol:

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: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative  
Remarks: Based on data from similar materials

### Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion  
Result: negative

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

### Glycerine:



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

---

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

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

### STOT - single exposure

Not classified based on available information.

#### Components:

##### **2-Furaldehyde:**

Assessment : May cause respiratory irritation.

##### **Isovaleraldehyde:**

Assessment : May cause respiratory irritation.

##### **Acetaldehyde:**

Assessment : May cause respiratory irritation.

### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

#### Components:

##### **fenbendazole:**

Exposure routes : Ingestion  
Target Organs : Liver, Stomach, Nervous system, Lymph nodes  
Assessment : May cause damage to organs through prolonged or repeated exposure.

##### **2-Furaldehyde:**

Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

### Repeated dose toxicity

#### Components:

##### **fenbendazole:**

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

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

### Ethanol:

Species : Rat  
NOAEL : 1,280 mg/kg  
LOAEL : 3,156 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

### 2-Furaldehyde:

Species : Rat  
NOAEL : 53 mg/kg  
Application Route : Ingestion  
Exposure time : 13 Weeks

### Cinnamaldehyde:

Species : Rat  
NOAEL : 200 mg/kg  
Application Route : Ingestion  
Exposure time : 12 Weeks

### Acetaldehyde:

Species : Rat  
NOAEL : 125 mg/kg  
LOAEL : 675 mg/kg  
Application Route : Ingestion  
Exposure time : 28 Days

Species : Rat  
NOAEL : 0.3 mg/kg  
LOAEL : 1 mg/kg

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

---

Application Route : inhalation (vapour)  
Exposure time : 13 Weeks

### Trans-hex-2-en-1-ol:

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Ingestion  
Exposure time : 98 Days  
Remarks : Based on data from similar materials

### Propylene glycol:

Species : Rat, male  
NOAEL : >= 1,700 mg/kg  
Application Route : Ingestion  
Exposure time : 2 yr

### Glycerine:

Species : Rat  
NOAEL : 0.167 mg/l  
LOAEL : 0.622 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 13 Weeks

Species : Rat  
NOAEL : 8,000 - 10,000 mg/kg  
Application Route : Ingestion  
Exposure time : 2 yr

Species : Rabbit  
NOAEL : 5,040 mg/kg  
Application Route : Skin contact  
Exposure time : 45 Weeks

### Aspiration toxicity

Not classified based on available information.

### Components:

#### fenbendazole:

No aspiration toxicity classification

### Experience with human exposure

### Components:

#### fenbendazole:

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Components:

##### **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 toxicity) : 100

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

M-Factor (Chronic aquatic toxicity) : 10

##### **Ethanol:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l  
Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l  
Exposure time: 72 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): 6,500 mg/l  
Exposure time: 16 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 9.6 mg/l  
Exposure time: 9 d  
Species: Daphnia magna (Water flea)

##### **Diethyl malonate:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 12 - 17 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 179 mg/l  
Exposure time: 48 h  
Method: Directive 67/548/EEC, Annex V, C.2.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 800 mg/l  
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 115 mg/l  
Exposure time: 72 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): 3,097 mg/l  
Exposure time: 16 h  
Method: DIN 38 412 Part 8

### 2-Furaldehyde:

Toxicity to fish : EC50 (Leuciscus idus (Golden orfe)): 29 mg/l  
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 29 mg/l  
Exposure time: 24 h

Toxicity to algae/aquatic plants : NOEC (Microcystis aeruginosa (blue-green algae)): 2.7 mg/l  
Exposure time: 8 d

Toxicity to microorganisms : EC50 : 760 mg/l  
Exposure time: 30 min  
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 0.33 mg/l  
Exposure time: 12 d  
Species: Danio rerio (zebra fish)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1.9 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### Cinnamaldehyde:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 4.15 mg/l  
Exposure time: 96 h  
Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 3.21 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Chlorella vulgaris (Fresh water algae)): 16.09 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 : 71 mg/l  
Exposure time: 3 h  
Method: ISO 8192

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

### Isovaleraldehyde:

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 3.25 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 177 mg/l  
Exposure time: 48 h
- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 137.37 mg/l  
Exposure time: 96 h
- EC10 (Desmodesmus subspicatus (green algae)): 101.83 mg/l  
Exposure time: 96 h
- Toxicity to microorganisms : EC10 (Pseudomonas putida): 310 mg/l  
Exposure time: 17 h  
Method: DIN 38 412 Part 8

### Acetaldehyde:

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 30.8 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 57.4 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- EC10 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

### Trans-hex-2-en-1-ol:

- Toxicity to fish : LC50 (Oncorhynchus mykiss (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 (Daphnia magna (Water flea)): 163 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 226 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

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### Propylene glycol:

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l  
Exposure time: 48 h
- Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l  
Exposure time: 18 h
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 13,020 mg/l  
Exposure time: 7 d  
Species: Ceriodaphnia dubia (water flea)

### Glycerine:

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,955 mg/l  
Exposure time: 48 h
- Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10,000 mg/l  
Exposure time: 16 h  
Method: DIN 38 412 Part 8

## 12.2 Persistence and degradability

### Components:

#### Ethanol:

- Biodegradability : Result: Readily biodegradable.  
Biodegradation: 84 %  
Exposure time: 20 d

#### Diethyl malonate:

- Biodegradability : Result: Readily biodegradable.  
Biodegradation: 99 %  
Exposure time: 28 d  
Method: Regulation (EC) No. 440/2008, Annex, C.4-A

#### 2-Furaldehyde:

- Biodegradability : Result: Readily biodegradable.  
Biodegradation: 93.5 %  
Exposure time: 14 d

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

### **Cinnamaldehyde:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 100 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### **Isovaleraldehyde:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 49.5 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301D

### **Acetaldehyde:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 80 %  
Exposure time: 14 d  
Method: OECD Test Guideline 301C

### **Trans-hex-2-en-1-ol:**

Biodegradability : Result: Readily biodegradable.  
Remarks: Based on data from similar materials

### **Propylene glycol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

### **Glycerine:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 %  
Exposure time: 30 d  
Method: OECD Test Guideline 301D

## 12.3 Bioaccumulative potential

### **Components:**

#### **fenbendazole:**

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

#### **Ethanol:**

Partition coefficient: n-octanol/water : log Pow: -0.35

#### **Diethyl malonate:**

Partition coefficient: n-octanol/water : log Pow: 0.96



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 9372763-00008      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

---

### 2-Furaldehyde:

Partition coefficient: n-octanol/water : log Pow: 0.83  
Remarks: Calculation

### Cinnamaldehyde:

Partition coefficient: n-octanol/water : log Pow: 2.107

### Isovaleraldehyde:

Partition coefficient: n-octanol/water : log Pow: 1.5

### Acetaldehyde:

Partition coefficient: n-octanol/water : log Pow: 0.45

### Trans-hex-2-en-1-ol:

Partition coefficient: n-octanol/water : log Pow: 1.61  
Remarks: Calculation

### Propylene glycol:

Partition coefficient: n-octanol/water : log Pow: -1.07  
Method: Regulation (EC) No. 440/2008, Annex, A.8

### Glycerine:

Partition coefficient: n-octanol/water : log Pow: -1.75

## 12.4 Mobility in soil

### Components:

#### fenbendazole:

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

## 12.5 Results of PBT and vPvB assessment

### Product:

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

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.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.  |

## SECTION 14: Transport information

### 14.1 UN number

- |      |   |         |
|------|---|---------|
| ADN  | : | UN 3082 |
| ADR  | : | UN 3082 |
| RID  | : | UN 3082 |
| IMDG | : | UN 3082 |
| IATA | : | UN 3082 |

### 14.2 UN proper shipping name

- |      |   |   |
|------|---|---|
| ADN  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(fenbendazole) |
| ADR  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(fenbendazole) |
| RID  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(fenbendazole) |
| IMDG | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(fenbendazole) |
| IATA | : | Environmentally hazardous substance, liquid, n.o.s.<br>(fenbendazole) |

### 14.3 Transport hazard class(es)

Class	Subsidiary risks
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# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

---

<b>ADN</b>	:	9
<b>ADR</b>	:	9
<b>RID</b>	:	9
<b>IMDG</b>	:	9
<b>IATA</b>	:	9

### 14.4 Packing group

<b>ADN</b>		
Packing group	:	III
Classification Code	:	M6
Hazard Identification Number	:	90
Labels	:	9

<b>ADR</b>		
Packing group	:	III
Classification Code	:	M6
Hazard Identification Number	:	90
Labels	:	9
Tunnel restriction code	:	(-)

<b>RID</b>		
Packing group	:	III
Classification Code	:	M6
Hazard Identification Number	:	90
Labels	:	9

<b>IMDG</b>		
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F

<b>IATA (Cargo)</b>		
Packing instruction (cargo aircraft)	:	964
Packing instruction (LQ)	:	Y964
Packing group	:	III
Labels	:	Miscellaneous

<b>IATA (Passenger)</b>		
Packing instruction (passenger aircraft)	:	964
Packing instruction (LQ)	:	Y964
Packing group	:	III
Labels	:	Miscellaneous

### 14.5 Environmental hazards

<b>ADN</b>		
Environmentally hazardous	:	yes

<b>ADR</b>		
Environmentally hazardous	:	yes

**RID**

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

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 Transport in bulk according to Annex II of Marpol and the IBC Code

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the following entries should be considered: Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH)

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

---

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

### 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.

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### 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

H224	:	Extremely flammable liquid and vapour.
H225	:	Highly flammable liquid and vapour.
H226	:	Flammable liquid and vapour.
H301	:	Toxic if swallowed.
H302	:	Harmful if swallowed.
H311	:	Toxic in contact with skin.
H312	:	Harmful in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H315	:	Causes skin irritation.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H319	:	Causes serious eye irritation.
H330	:	Fatal if inhaled.
H335	:	May cause respiratory irritation.
H341	:	Suspected of causing genetic defects.
H350	:	May cause cancer.
H351	:	Suspected of causing cancer.
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.
H411	:	Toxic to aquatic life with long lasting effects.
H412	:	Harmful to aquatic life with long lasting effects.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

### Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Carc.	:	Carcinogenicity
Eye Dam.	:	Serious eye damage
Eye Irrit.	:	Eye irritation
Flam. Liq.	:	Flammable liquids
Muta.	:	Germ cell mutagenicity
Repr.	:	Reproductive toxicity
Skin Corr.	:	Skin corrosion
Skin Irrit.	:	Skin irritation
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure
STOT SE	:	Specific target organ toxicity - single exposure
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	:	Short-term exposure limit (15-minute 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; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (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; 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

### Further information

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	9372763-00008	Date of first issue: 27.08.2021

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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:

Repr. 2	H361fd
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
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.

GB / EN