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



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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

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

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)

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 pro-

longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate-

gory 1

H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

### 2.2 Label elements

### Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms :



¥2

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

### **Additional Labelling**

EUH208

Contains Cinnamaldehyde. May produce an allergic reaction.

#### 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.

### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

Components

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



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Chemical name	EC-No. Index-No. Registration number		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; H410	>= 10 - <= 18.75	
		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	<= 0.04	
		specific concentration limit Eye Irrit. 2; H319 >= 50 %		
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	
		Acute toxicity esti- mate		
		Acute oral toxicity: 108 mg/kg Acute inhalation tox- icity (vapour): 1 mg/l Acute dermal toxicity: 300 mg/kg		
Cinnamaldehyde#	104-55-2 203-213-9 606-155-00-6	Acute Tox. 4; H312 Skin Irrit. 2; H315 Eye Irrit. 2; H319	<= 0.002	

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<= 0.002

<= 0.0002

<= 0.0002

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Acute toxicity esti-

1,260 mg/kg

Acute dermal toxicity:

Flam. Liq. 2; H225

Flam. Liq. 1; H224

Eye Irrit. 2; H319 Muta. 2; H341 Carc. 1B; H350 STOT SE 3; H335

Acute toxicity esti-

Acute oral toxicity:

Skin Corr. 1B; H314

Eye Dam. 1; H318

Acute Tox. 4; H302

Skin Sens. 1B; H317 STOT SE 3; H335 Aquatic Chronic 2;

Eye Irrit. 2; H319

mate

H411

mate

661 mg/kg

**EUH071** 

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Isovaleraldehyde#

Acetaldehyde#

Skin Sens. 1A; H317
specific concentration limit
Skin Sens. 1A; H317 >= 0.01 %
>= 0.01 %

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590-86-3

209-691-5

75-07-0

200-836-8

928-95-0

213-191-2

605-003-00-6

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

#### **SECTION 4: First aid measures**

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

### 4.1 Description of first aid measures

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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.

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



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Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

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.

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

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

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Nitrogen oxides (NOx)

Sulphur oxides

Carbon 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.

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



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Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

#### **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 pro-

tective 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.

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 : 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 absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 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.

Do not swallow.

Avoid contact with eyes.

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



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Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

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

environment.

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 contami-

nated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

### 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:

Strong oxidizing agents

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**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
fenbendazole	43210-67-9	TWA	100 μg/m3 (OEB 2)	Internal
Propylene glycol	57-55-6	OELV - 8 hrs (TWA) (particles)	10 mg/m3	IE OEL
		OELV - 8 hrs	150 ppm	IE OEL
		(TWA) (total (va-	470 mg/m3	
		pour and parti-		
		cles))		
Ethanol	64-17-5	OELV - 15 min (STEL)	1,000 ppm	IE OEL
2-Furaldehyde	98-01-1	OELV - 15 min	5 ppm	IE OEL
		(STEL)	20 mg/m3	
	Further information: Substances which have the capacity to penetrate intact			
	skin when they come in contact with it, and be absorbed into the body			
		OELV - 8 hrs	2 ppm	IE OEL
		(TWA)	8 mg/m3	
	Further information: Substances which have the capacity to penetrate intact			

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



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11	skin when they come in contact with it, and be absorbed into the body			
Acetaldehyde	75-07-0	OELV - 15 min	25 ppm	IE OEL
II .		(STEL)	45 mg/m3	

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local ef- fects	10 mg/m3
	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Consumers	Inhalation	Long-term local effects	10 mg/m3
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3
Glycerine	Workers	Inhalation	Long-term local effects	56 mg/m3
	Consumers	Ingestion	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	33 mg/m3
Ethanol	Workers	Inhalation	Long-term systemic effects	380 mg/m3
	Workers	Skin contact	Long-term systemic effects	267 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	114 mg/m3
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 ef- fects	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

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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) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
fenbendazole		0.0001 mg/l
Propylene glycol	Fresh water	260 mg/l
g.yee.	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
	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
	0.1(0.1.5::.)	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
	Maria a a a disa a a f	weight (d.w.)
	Marine sediment	0.012 mg/kg dry
	Soil	weight (d.w.)
<u>J</u>	3011	2.6 mg/kg dry

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		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.

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to I.S. 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

Physical state : paste

Colour : white to off-white

Odour : cinnamon-like

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling : No data available

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range

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower :

flammability limit

No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 6-8

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : insoluble

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

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

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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.

### **SECTION 11: Toxicological information**

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

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

### **Acute toxicity**

Not classified based on available information.

## **Components:**

## fenbendazole:

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

LD50 (Mouse): > 10,000 mg/kg

**Ethanol:** 

Acute oral toxicity : LD50 (Rat): 10,470 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat, male): 116.9 mg/l

Exposure time: 4 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 15,800 mg/kg

### **Diethyl malonate:**

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



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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

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

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

fenbendazole:

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



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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:

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

Serious eye damage/eye irritation

Not classified based on available information.

Components:

fenbendazole:

Species : Rabbit

Result : No eye irritation

**Ethanol:** 

Species : Rabbit

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



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Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Diethyl malonate:

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.

## Respiratory or skin sensitisation

### Skin sensitisation

Not classified based on available information.

## Respiratory sensitisation

Not classified based on available information.

## **Components:**

**Ethanol:** 

Test Type : Mouse ear swelling test (MEST)

Exposure routes : Skin contact
Species : Mouse
Result : negative

Diethyl malonate:

Test Type : Buehler Test

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



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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 : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : positive

Assessment : Probability or evidence of high skin sensitisation rate in hu-

mans

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

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

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



## Fenbendazole Paste Formulation

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### 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: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

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: Rat

Application Route: Ingestion

Result: negative

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

Remarks: Based on data from similar materials

2-Furaldehyde:

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

Method: OECD Test Guideline 471

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



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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 syn-

thesis in mammalian cells (in vitro)

Result: positive

Test Type: In vitro sister chromatid exchange assay in mam-

malian 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 as-

say

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

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



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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

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: positive

Genotoxicity in vivo : Test Type: In vivo micronucleus test

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



### Fenbendazole Paste Formulation

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Species: Rat

Application Route: Intraperitoneal injection

Result: positive

Test Type: Mammalian bone marrow sister chromatid ex-

change

Species: Mouse

Application Route: Intraperitoneal injection

Result: positive

Germ cell mutagenicity- As-

sessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity 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

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

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



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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 - Assess-

ment

: Limited evidence of carcinogenicity in animal studies

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 - Assess-

ment

: Sufficient evidence of carcinogenicity in animal experiments

Reproductive toxicity

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

**Components:** 

fenbendazole:

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



### Fenbendazole Paste Formulation

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

Species: Rat

Application Route: oral (feed)

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

Fertility: LOAEL: 45 mg/kg body weight

Result: Effects on fertility

Effects on foetal develop-

ment

Test Type: Development

Species: Dog, female Application Route: Oral

Developmental Toxicity: LOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the off-

spring were detected., No teratogenic effects

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 25 mg/kg body weight

Result: Fetotoxicity

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 63 mg/kg body weight

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 120 mg/kg body weight

Result: No effects on foetal development

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and

fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experi-

ments.

**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 develop- : Test Type: Combined repeated dose toxicity study with the

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



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ment reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

2-Furaldehyde:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Cinnamaldehyde:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Acetaldehyde:

Effects on foetal develop-

ment

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

**Components:** 

2-Furaldehyde:

Assessment : May cause respiratory irritation.

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



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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

: May cause damage to organs through prolonged or repeated Assessment

exposure.

2-Furaldehyde:

Assessment No significant health effects observed in animals at concentra-

tions of 100 mg/kg bw or less.

Repeated dose toxicity

**Components:** 

fenbendazole:

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

: Rat Species

> 2,500 mg/kg

NOAEL Application Route Exposure time Remarks : Oral : 30 Days

Remarks No significant adverse effects were reported

Species Rat

Species
LOAEL
Application Route
Exposure time
The Croans 1,600 mg/kg : Oral : 90 Days

: 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

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



### **Fenbendazole Paste Formulation**

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Ethanol:

Species : Rat

NOAEL : 1,730 mg/kg LOAEL : 3,200 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: RatNOAEL: 125 mg/kgLOAEL: 675 mg/kgApplication Route: IngestionExposure time: 28 Days

 Species
 : Rat

 NOAEL
 : 0.3 mg/kg

 LOAEL
 : 1 mg/kg

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

**Aspiration toxicity** 

Not classified based on available information.

**Components:** 

fenbendazole:

No aspiration toxicity classification

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



## Fenbendazole Paste Formulation

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#### 11.2 Information on other hazards

### **Endocrine disrupting properties**

**Product:** 

Assessment The substance/mixture does not contain components consid-

ered 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

**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

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 0.0088 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

M-Factor (Acute aquatic tox- : 100

icity)

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.00113 mg/l Exposure time: 21 Days

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

M-Factor (Chronic aquatic

toxicity)

: 10

**Ethanol:** 

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l

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



### Fenbendazole Paste Formulation

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plants Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC50 (Protozoa): 5,800 mg/l

Exposure time: 4 h

Toxicity to fish (Chronic tox-

icity)

NOEC: >= 79 mg/l Exposure time: 100 d

Species: Oryzias latipes (Japanese medaka)

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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.

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 tox-

icity)

NOEC: 0.33 mg/l

Exposure time: 12 d

Species: Danio rerio (zebra fish)

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



### Fenbendazole Paste Formulation

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Toxicity to daphnia and other : aguatic invertebrates (Chron-

ic 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

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

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



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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/

Exposure time: 72 h

Method: OECD Test Guideline 201

## 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

Cinnamaldehyde:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 100 %

Exposure time: 28 d

Method: OECD Test Guideline 301B

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



## Fenbendazole Paste Formulation

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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

12.3 Bioaccumulative potential

**Components:** 

fenbendazole:

Partition coefficient: n-: log Pow: 3.32

octanol/water

Ethanol:

Partition coefficient: nlog Pow: -0.35

octanol/water

Diethyl malonate:

Partition coefficient: nlog Pow: 0.96

octanol/water

2-Furaldehyde:

Partition coefficient: n-: log Pow: 0.83

octanol/water Remarks: Calculation

Cinnamaldehyde:

Isovaleraldehyde:

Partition coefficient: nlog Pow: 2.107

octanol/water

log Pow: 1.5 Partition coefficient: n-

octanol/water

Acetaldehyde:

Partition coefficient: n-

log Pow: 0.45

octanol/water

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

Partition coefficient: nlog Pow: 1.61

octanol/water Remarks: Calculation

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



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### 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 consid-

ered 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 han-

dling 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 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082

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



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IATA : UN 3082

14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(fenbendazole)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(fenbendazole)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(fenbendazole)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(fenbendazole)

IATA : Environmentally hazardous substance, liquid, 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 : M6
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

**RID** 

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

**IMDG** 

Packing group : III

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



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Labels : 9

EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 964

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 964

ger aircraft)

Packing instruction (LQ) : Y964
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)

 Conditions of restriction for the following entries should be considered: Number on list 3

Number on list 75: If you intend to use this product as tattoo ink, please

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



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contact your vendor.

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. Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone

laver

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation Not applicable

(Annex XIV)

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

**HAZARDS** 

Quantity 1

Not applicable

Not applicable

Not applicable

Quantity 2

**ENVIRONMENTAL** 200 t 100 t

### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

### 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.

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#### **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.

EUH071 : Corrosive to the respiratory tract.

#### 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 irritation Eye Irrit. Flam. Liq. Flammable liquids Muta. Germ cell mutagenicity Reproductive toxicity Repr. Skin Corr. Skin corrosion Skin Irrit. Skin irritation

Skin Irrit. : Skin Irritation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure

STOT SE : Specific target organ toxicity - single exposure IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min : Occupational exposure limit value (15-minute reference period)

(STEL) od

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 Test-

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ing 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

Sheet

Sources of key data used to : compile the Safety Data

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:

#### Classification procedure:

Aquatia Aquata 4	on method
Aquatic Acute 1 H400 Calculation	on method
Aquatic Chronic 1 H410 Calculation	on method

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their

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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