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



# Fenbendazole (0.5%) Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 1161530-00019 Date of first issue: 19.12.2016

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

1.1 Product identifier

Trade name : Fenbendazole (0.5%) Solid Formulation

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

Use of the Sub- : Veterinary product

stance/Mixture

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)

Serious eye damage, Category 1 H318: Causes serious eye damage. Short-term (acute) aquatic hazard, Cate-H400: Very toxic to aquatic life.

gory 1

Long-term (chronic) aquatic hazard, Cat- H411: To

H411: Toxic to aquatic life with long lasting effects.

egory 2

### 2.2 Label elements

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

Hazard pictograms :

\*\*\*

Signal word : Danger

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



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Hazard statements : H318 Causes serious eye damage.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P273 Avoid release to the environment. P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously

with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

P391 Collect spillage.

## Hazardous components which must be listed on the label:

Calcium bis(dihydrogenorthophosphate) monohydrate

#### 2.3 Other hazards

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

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

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

Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

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

## 3.2 Mixtures

Components

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

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

For explanation of abbreviations see section 16.

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

#### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical 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.

Get medical attention.

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

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention immediately.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

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

Risks : Causes serious eye damage.

Contact with dust can cause mechanical irritation or drying of

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



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the skin.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## **SECTION 5: Firefighting measures**

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

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

Specific hazards during fire-

fighting

 Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Oxides of phosphorus

Metal oxides Carbon oxides Chlorine compounds

### 5.3 Advice for firefighters

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing 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.

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



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Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

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

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to 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 : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres. Use only with adequate ventilation.

Local/Total ventilation Advice on safe handling

: Do not breathe dust.

Do not swallow. Do not get in eyes.

Avoid prolonged or repeated contact with skin.

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

sessment

Keep container tightly closed.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

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

environment.

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

flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash 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,

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



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industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Keep tightly closed.
 Store in accordance with the particular national regulations.

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

Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

## **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

### **Occupational Exposure Limits**

dusts non-specific 4 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable

dust)

Basis: IE OEL

10 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable

dust)

Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Paraffin oil	8012-95-1	OELV - 8 hrs (TWA) (inhalable fraction)	5 mg/m3	IE OEL
fenbendazole	43210-67-9	TWA	100 μg/m3 (OEB 2)	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Calcium carbonate	Workers	Inhalation	Long-term systemic effects	6.36 mg/m3
	Consumers	Ingestion	Acute systemic effects	6.1 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1.06 mg/m3
	Consumers	Ingestion	Long-term systemic effects	6.1 mg/kg bw/day
Sodium chloride	Workers	Inhalation	Long-term systemic effects	2068.62 mg/m3
	Workers	Inhalation	Acute systemic effects	2068.62 mg/m3

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

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

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

## 8.2 Exposure controls

## **Engineering measures**

Use feasible engineering controls to minimize exposure to compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

### Personal protective equipment

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material Chemical-resistant gloves

Skin and body protection

Work uniform or laboratory coat.

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

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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 : powder

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

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Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

## **SECTION 10: Stability and reactivity**

### 10.1 Reactivity

Not classified as a reactivity hazard.

## 10.2 Chemical stability

Stable under normal conditions.

# 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## **SECTION 11: Toxicological information**

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

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion
Eye contact

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



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**Acute toxicity** 

Not classified based on available information.

**Components:** 

Calcium bis(dihydrogenorthophosphate) monohydrate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 2.6 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Remarks: Based on data from similar materials

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

Langbeinite:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 425

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Remarks: Based on data from similar materials

Paraffin oil:

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

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

fenbendazole:

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

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

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Calcium bis(dihydrogenorthophosphate) monohydrate:

Species : Rabbit

Result : No skin irritation

Langbeinite:

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

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Result : No skin irritation

Remarks : Based on data from similar materials

Paraffin oil:

Species : Rabbit

Result : No skin irritation

fenbendazole:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

**Components:** 

Calcium bis(dihydrogenorthophosphate) monohydrate:

Species : Rabbit

Result : Irreversible effects on the eye

Langbeinite:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 7 days Remarks : Based on data from similar materials

Paraffin oil:

Species : Rabbit

Result : No eye irritation

fenbendazole:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Calcium bis(dihydrogenorthophosphate) monohydrate:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

Method : OECD Test Guideline 429

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Result : negative

Remarks : Based on data from similar materials

Langbeinite:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

Calcium bis(dihydrogenorthophosphate) monohydrate:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Test Type: in vitro micronucleus test Method: OECD Test Guideline 487

Result: negative

Remarks: Based on data from similar materials

Langbeinite:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

fenbendazole:

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

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Result: negative

Test Type: DNA Repair

Result: negative

Test Type: Chromosomal aberration

Result: negative

Test Type: in vitro assay

Test system: mouse lymphoma cells Metabolic activation: Metabolic activation

Result: equivocal

### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### fenbendazole:

Species : Mouse
Application Route : oral (feed)
Exposure time : 2 Years

NOAEL : 405 mg/kg body weight

Result : negative

Species : Rat
Application Route : Oral
Exposure time : 2 Years

NOAEL : 5 mg/kg body weight

Result : negative

Target Organs : Lymph nodes, Liver

### Reproductive toxicity

Not classified based on available information.

## **Components:**

### Calcium bis(dihydrogenorthophosphate) monohydrate:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening

test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 421

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

## Langbeinite:

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



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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: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

fenbendazole:

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

Species: Rat

Application Route: oral (feed)

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

Fertility: LOAEL: 45 mg/kg body weight

Result: Effects on fertility

Effects on foetal 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.

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



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## STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

#### Components:

#### fenbendazole:

Exposure routes : Ingestion

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

Assessment : May cause damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

## **Components:**

### Calcium bis(dihydrogenorthophosphate) monohydrate:

Species : Rat

NOAEL : > 300 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Method : OECD Test Guideline 407

Remarks : Based on data from similar materials

### Langbeinite:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 28 d

Method : OECD Test Guideline 422

Remarks : Based on data from similar materials

## Paraffin oil:

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

### fenbendazole:

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

Species : Rat

NOAEL : > 2,500 mg/kg

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Application Route : Oral Exposure time : 30 Days

Remarks : No significant adverse effects were reported

Species : Rat

LOAEL : 1,600 mg/kg

Application Route : Oral Exposure time : 90 Days

Target Organs : Central nervous system

Symptoms : Tremors

Species : Dog
NOAEL : 4 mg/kg
LOAEL : 8 mg/kg
Exposure time : 6 Months

Target Organs : Stomach, Nervous system, Lymph nodes

### **Aspiration toxicity**

Not classified based on available information.

#### **Components:**

### Paraffin oil:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

### fenbendazole:

No aspiration toxicity classification

#### 11.2 Information on other hazards

## **Endocrine disrupting properties**

## **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

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



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### **SECTION 12: Ecological information**

## 12.1 Toxicity

### **Components:**

Calcium bis(dihydrogenorthophosphate) monohydrate:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50 : > 100 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

Langbeinite:

Toxicity to fish : LC50 (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)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Paraffin oil:

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

Exposure time: 96 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Acartia tonsa (Calanoid copepod)): > 100 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l

Exposure time: 72 h

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



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Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

fenbendazole:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.009 mg/l

Exposure time: 21 d

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.0088 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

M-Factor (Acute aquatic tox- :

icity)

100

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

#### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

## **Components:**

Paraffin oil:

Partition coefficient: n- : log Pow: > 4

octanol/water Remarks: Calculation

fenbendazole:

Partition coefficient: n-

octanol/water

log Pow: 3.32

## 12.4 Mobility in soil

### **Components:**

fenbendazole:

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

## 12.5 Results of PBT and vPvB assessment

#### **Product:**

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



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

## 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(fenbendazole)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(fenbendazole)

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



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**RID** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(fenbendazole)

**IMDG** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(fenbendazole)

Environmentally hazardous substance, solid, n.o.s. **IATA** 

(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 Ш Classification Code M7 Hazard Identification Number : 90 Labels 9

**ADR** 

Packing group Ш Classification Code M7 Hazard Identification Number : 90 Labels 9 Tunnel restriction code (-)

**RID** 

Ш Packing group Classification Code M7 Hazard Identification Number : 90 Labels 9

**IMDG** 

Packing group Ш Labels 9 F-A, S-F **EmS Code** 

IATA (Cargo)

Packing instruction (cargo

aircraft)

956

Packing instruction (LQ) Y956 Packing group Ш

Labels Miscellaneous

IATA (Passenger)

Packing instruction (passen-956

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



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ger aircraft)

Packing instruction (LQ) Y956 Packing group Ш

Labels Miscellaneous

14.5 Environmental hazards

Environmentally hazardous yes

Environmentally hazardous yes

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 Not applicable

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High Not applicable

Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone Not applicable

Regulation (EU) 2019/1021 on persistent organic pollu-Not applicable

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia-Not applicable

ment 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.

Quantity 2 Quantity 1

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



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E1 ENVIRONMENTAL 100 t 200 t

**HAZARDS** 

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

## **Full text of H-Statements**

H304 : May be fatal if swallowed and enters airways.

H318 : Causes serious eye damage. H319 : Causes serious eye irritation.

H361fd : Suspected of damaging fertility. Suspected of damaging the

unborn child.

H373 : May cause damage to organs through prolonged or repeated

exposure if swallowed.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.
H413 : May cause long lasting harmful effects to aquatic life.

### Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard Aquatic Chronic : Long-term (chronic) aquatic hazard

Asp. Tox. : Aspiration hazard Eye Dam. : Serious eye damage

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure

IE OEL : Ireland. List of Chemical Agents and Carcinogens with 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)

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

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



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associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

Sources of key data used to compile the Safety Data

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

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

## Classification of the mixture: Classification procedure:

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

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

IE / EN