according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fenbendazole Paste Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number: +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Reproductive toxicity : Category 2

Specific target organ toxicity - :

repeated exposure (Oral)

Category 2 (Liver, Stomach, Nervous system, Lymph nodes)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements

Hazard pictograms

Signal word : Warning

Hazard statements : H361fd Suspected of damaging fertility. Suspected of damag-

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

ing the unborn child.

H373 May cause damage to organs (Liver, Stomach, Nervous system, Lymph nodes) through prolonged or repeated expo-

sure if swallowed.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P203 Obtain, read and follow all safety instructions before use.

P260 Do not breathe vapours.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P318 IF exposed or concerned, get medical advice.

P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
fenbendazole	43210-67-9	>= 10 - <= 18.75
Ethanol#	64-17-5	<= 0.04
Diethyl malonate#	105-53-3	<= 0.006
2-Furaldehyde#	98-01-1	<= 0.006
Cinnamaldehyde#	104-55-2	<= 0.002
Isovaleraldehyde#	590-86-3	<= 0.002
Acetaldehyde#	75-07-0	<= 0.0002
Trans-hex-2-en-1-ol#	928-95-0	<= 0.0002

^{#:} Voluntarily-disclosed substance

4. 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.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

according to the Globally Harmonized System



Fenbendazole Paste Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.8 30.09.2023 899091-00021 Date of first issue: 16.09.2016

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

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.

In case of eye contact Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed

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

May cause damage to organs through prolonged or repeated

exposure if swallowed.

First Aid responders should pay attention to self-protection, Protection of first-aiders

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Hazardous combustion prod-

ucts

Carbon oxides

Nitrogen oxides (NOx)

Sulphur oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

Exposure to combustion products may be a hazard to health.

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

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

Evacuate area.

Special protective equipment:

for firefighters

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

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emergency procedures

Use personal protective equipment.

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

Environmental precautions Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items 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.

7. HANDLING AND STORAGE

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.

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.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
fenbendazole	43210-67-9	TWA	100 μg/m3 (OEB 2)	Internal
Ethanol	64-17-5	TWA	1,000 ppm 1,900 mg/m3	IN OEL
		STEL	1,000 ppm	ACGIH
2-Furaldehyde	98-01-1	TWA	0.2 ppm	ACGIH
Acetaldehyde	75-07-0	TWA	100 ppm 180 mg/m3	IN OEL
		STEL	150 ppm 270 mg/m3	IN OEL

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

C 25 ppm ACGIH

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentration	Basis
2-Furaldehyde	98-01-1	Furoic acid	Urine	End of shift (As soon as possible after exposure ceases)	200 mg/l	ACGIH BEI

Engineering measures : Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-less

quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Laboratory operations do not require special containment.

Personal protective equipment

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.
Filter type : Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Skin and body protection : Work uniform or laboratory coat.

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

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

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

use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : paste

Colour : white to off-white

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

Odour : cinnamon-like

Odour Threshold : No data available

pH : 6-8

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : insoluble

Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : No data available

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Fenbendazole Paste Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 5.8 30.09.2023 899091-00021 Date of first issue: 16.09.2016

10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac-

tions

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Components:

fenbendazole:

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

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

Ethanol:

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

Method: OECD Test Guideline 401

Acute inhalation toxicity LC50 (Rat): 124.7 mg/l

Exposure time: 4 h

Test atmosphere: vapour

Diethyl malonate:

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

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

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

LC50 (Rat): 1 mg/l Acute inhalation toxicity

> Exposure time: 4 h Test atmosphere: vapour

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

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:

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:

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

Species : Rabbit

Method : OECD Test Guideline 404

Result : Mild skin irritation

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

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:

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

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 : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse Result : negative

Diethyl malonate:

Test Type : Buehler Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

2-Furaldehyde:

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

Method : OECD Test Guideline 406

Result : negative

Cinnamaldehyde:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact

according to the Globally Harmonized System



Fenbendazole Paste Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.8 30.09.2023 899091-00021 Date of first issue: 16.09.2016

Species Mouse Result positive

Assessment Probability or evidence of low to moderate skin sensitisation

rate in humans

Isovaleraldehyde:

Test Type **Maximisation Test** Exposure routes Skin contact **Species** Guinea pig

Method **OECD Test Guideline 406**

positive Result

Remarks Based on data from similar materials

Probability or evidence of low to moderate skin sensitisation Assessment

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

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

according to the Globally Harmonized System



Fenbendazole Paste Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.8 30.09.2023 899091-00021 Date of first issue: 16.09.2016

Ethanol:

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

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)

Species: Mouse

Application Route: Ingestion

Result: equivocal

Diethyl malonate:

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

Method: Directive 67/548/EEC, Annex, B.13/14

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

2-Furaldehyde:

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

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: positive

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: positive

Test Type: DNA damage and repair, unscheduled DNA 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

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

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

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

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

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

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 -

Assessment

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

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

Carcinogenicity

Not classified based on available information.

Components:

fenbendazole:

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

NOAEL : 405 mg/kg body weight

Result : negative

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

NOAEL : 5 mg/kg body weight

Result : negative

Target Organs : Lymph nodes, Liver

2-Furaldehyde:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : positive

Remarks : The mechanism or mode of action is not relevant in humans.

Species : Hamster

Application Route : inhalation (vapour)

Exposure time : 52 weeks
Result : negative

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

Carcinogenicity - 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

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

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-

neni

: Sufficient evidence of carcinogenicity in animal experiments

Reproductive toxicity

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

Components:

fenbendazole:

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

Species: Rat

Application Route: oral (feed)

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

Fertility: LOAEL: 45 mg/kg body weight

Result: Effects on fertility

Effects on 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

according to the Globally Harmonized System



Fenbendazole Paste Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.8 30.09.2023 899091-00021 Date of first issue: 16.09.2016

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-

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

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

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

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.

Isovaleraldehyde:

Assessment : May cause respiratory irritation.

Acetaldehyde:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

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

Components:

fenbendazole:

Exposure routes : Ingestion

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

Assessment : May cause damage to organs through prolonged or repeated

exposure.

2-Furaldehyde:

Assessment : No significant health effects observed in animals at concentra-

tions of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

fenbendazole:

Species : Rat

LOAEL : 500 mg/kg
Application Route : Oral
Exposure time : 2 Weeks

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

Target Organs : Kidney, Liver

Species : Rat

NOAEL : > 2,500 mg/kg

Application Route : Oral Exposure time : 30 Days

Remarks : No significant adverse effects were reported

Species : Rat

LOAEL : 1,600 mg/kg

Application Route : Oral Exposure time : 90 Days

Target Organs : Central nervous system

Symptoms : Tremors

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

Target Organs : Stomach, Nervous system, Lymph nodes

Ethanol:

Species : Rat

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

2-Furaldehyde:

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

Cinnamaldehyde:

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

Acetaldehyde:

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

Species : Rat NOAEL : 0.3 mg/kg

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

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

Experience with human exposure

Components:

fenbendazole:

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

fenbendazole:

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

Exposure time: 21 d

Toxicity to daphnia and other :

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-

aquatic invertebrates (Cirior

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:

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

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

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

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

Exposure time: 72 h

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

Exposure time: 72 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): 6,500 mg/l

Exposure time: 16 h

Toxicity to daphnia and other :

aquatic invertebrates (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

mq/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- : NOEC: 0.33 mg/l

according to the Globally Harmonized System



Fenbendazole Paste Formulation

Revision Date: Version SDS Number: Date of last issue: 04.04.2023 5.8 30.09.2023 899091-00021 Date of first issue: 16.09.2016

icity) Exposure time: 12 d

Species: Danio rerio (zebra fish)

Toxicity to daphnia and other : aquatic 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

: EC50: 71 mg/l Toxicity to microorganisms

> 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

Exposure time: 96 h

EC10 (Desmodesmus subspicatus (green algae)): 101.83

ErC50 (Desmodesmus subspicatus (green algae)): 137.37

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

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

Toxicity to algae/aquatic

plants

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

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 163 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): 226

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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 the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

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

Bioaccumulative potential

Components:

fenbendazole:

Partition coefficient: n-

octanol/water

log Pow: 3.32

Ethanol:

Partition coefficient: n-

octanol/water

log Pow: -0.35

Diethyl malonate:

Partition coefficient: n-

octanol/water

log Pow: 0.96

2-Furaldehyde:

Partition coefficient: n-

log Pow: 0.83

octanol/water

Remarks: Calculation

Cinnamaldehyde:

Partition coefficient: n-

octanol/water

log Pow: 2.107

Isovaleraldehyde:

Partition coefficient: n-

octanol/water

log Pow: 1.5

Acetaldehyde:

Partition coefficient: n-

octanol/water

log Pow: 0.45

according to the Globally Harmonized System



Fenbendazole Paste Formulation

Revision Date: SDS Number: Version Date of last issue: 04.04.2023 5.8 30.09.2023 899091-00021 Date of first issue: 16.09.2016

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

log Pow: 1.61 Partition coefficient: n-

octanol/water Remarks: Calculation

Mobility in soil

Components:

fenbendazole:

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

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number UN 3082

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, Proper shipping name

N.O.S.

(fenbendazole)

Class 9 Ш Packing group Labels 9 Environmentally hazardous yes

IATA-DGR

UN/ID No. UN 3082

Environmentally hazardous substance, liquid, n.o.s. Proper shipping name

(fenbendazole)

Class 9 Packing group Ш

Labels Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen-

964

964

ger aircraft)

Environmentally hazardous yes

IMDG-Code

UN number UN 3082

according to the Globally Harmonized System



Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 5.8
 30.09.2023
 899091-00021
 Date of first issue: 16.09.2016

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(fenbendazole)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 30.09.2023

Further information

Sources of key data used to compile the Safety Data

Olympia the Salety Data

Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

IN OEL : India. Permissible levels of certain chemical substances in

work environment.

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit

ACGIH / C : Ceiling limit

IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)

IN OEL / STEL : Short-term exposure Limit STEL (15 min)

according to the Globally Harmonized System



Fenbendazole Paste Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 5.8 30.09.2023 899091-00021 Date of first issue: 16.09.2016

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate: NOM - Official Mexican Norm: NTP - National Toxicology Program: NZIoC - New Zealand Inventory of Chemicals: OECD - Organization for Economic Co-operation and Development: OPPTS - Office of Chemical Safety and Pollution Prevention: PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

IN / EN