SAFETY DATA SHEET

Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.7	28.09.2024	887492-00023	Date of first issue: 16.09.2016

SECTION 1: IDENTIFICATION

Product name : Fenbendazole Paste Formulation

Manufacturer or supplier's details

Company : Intervet Australia Pty Limited (trading as MSD Animal Health)

Address : 91-105 Harpin Street
Bendigo 3550, Victoria Austrailia

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, Stomach, Nervous system, Lymph nodes)

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H373 May cause damage to organs (Liver, Stomach, Nervous system, Lymph nodes) through prolonged or repeated exposure if swallowed.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe vapours.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
fenbendazole	43210-67-9	>= 10 -<= 18.75
Propylene glycol	57-55-6	>= 15 -<= 15.16
Glycerine	56-81-5	10
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

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

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 : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed	:	If swallowed, DO NOT induce vomiting. 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.
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).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 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	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NOx) Sulphur oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Hazchem Code	:	•3Z

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective 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 barriers). Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages 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 determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 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 assessment Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
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

SECTION 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
Propylene glycol	57-55-6	TWA (particulate)	10 mg/m3	AU OEL
		TWA (Total (vapour and particles))	150 ppm 474 mg/m3	AU OEL
Glycerine	56-81-5	TWA (Mist)	10 mg/m3	AU OEL
Ethanol	64-17-5	TWA	1,000 ppm 1,880 mg/m3	AU OEL
		STEL	1,000 ppm	ACGIH
2-Furaldehyde	98-01-1	TWA	2 ppm 7.9 mg/m3	AU OEL
	Further information: Skin absorption			
		TWA	0.2 ppm	ACGIH
Acetaldehyde	75-07-0	STEL	50 ppm 91 mg/m3	AU OEL
	Further information: Category 2 (Carc. 2) Suspected human carcinogen			
		TWA	20 ppm 36 mg/m3	AU OEL
	Further information: Category 2 (Carc. 2) Suspected human carcinogen			
		C	25 ppm	ACGIH

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling 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., dripless 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 exposure 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	paste
Colour	:	white to off-white
Odour	:	cinnamon-like
Odour Threshold	:	No data available
pH	:	6 - 8
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
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 characteristics		
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : 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

Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

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

Glycerine:

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

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:

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:

Species	:	Rabbit
Result	:	No skin irritation

Propylene glycol:

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

Glycerine:

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:

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

Propylene glycol:

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

Glycerine:

Species : Rabbit
Result : No eye irritation

Ethanol:

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

Diethyl malonate:

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

2-Furaldehyde:

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

Cinnamaldehyde:

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

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:

Propylene glycol:

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

Ethanol:

Test Type	:	Mouse ear swelling test (MEST)
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	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	positive
Assessment	:	Probability or evidence of high skin sensitisation rate in humans

Isovaleraldehyde:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	positive
Remarks	:	Based on data from similar materials
Assessment	:	Probability or evidence of low to moderate skin sensitisation rate in humans

Acetaldehyde:

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

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

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

Result : negative
Remarks : Based on data from similar materials

Chronic toxicity

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

Propylene glycol:

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

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

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

Glycerine:

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

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

Test Type: Chromosome aberration test in vitro
Result: negative

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

Result: negative

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
Result: negative

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

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

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

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

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

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

Cinnamaldehyde:

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

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

Test Type: Chromosome aberration test in vitro
Result: negative

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

Test Type: Mammalian erythrocyte micronucleus test (in vivo 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 synthesis 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 mammalian cells
Result: positive

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

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Rat
Application Route: Intraperitoneal injection
Result: positive

Test Type: Mammalian bone marrow sister chromatid exchange
Species: Mouse
Application Route: Intraperitoneal injection
Result: positive

Germ cell mutagenicity - Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

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

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

Method: OECD Test Guideline 471
Result: negative

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

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

Propylene glycol:

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

Glycerine:

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

2-Furaldehyde:

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

Method	:	OECD Test Guideline 451
Result	:	positive
Remarks	:	The mechanism or mode of action is not relevant in humans.

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

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

Carcinogenicity - Assessment	:	Limited evidence of carcinogenicity in animal studies

Cinnamaldehyde:

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

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

Isovaleraldehyde:

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

Acetaldehyde:

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

Carcinogenicity - Assessment	:	Sufficient evidence of carcinogenicity in animal experiments

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 development : Test Type: Development
Species: Dog, female
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 25 mg/kg body weight
Result: Fetotoxicity

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 63 mg/kg body weight

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 120 mg/kg body weight
Result: No effects on foetal development

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

Propylene glycol:

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

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

Glycerine:

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

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

Ethanol:

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

Diethyl malonate:

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

2-Furaldehyde:

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

Cinnamaldehyde:

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

Acetaldehyde:

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

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

Effects on fertility	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative Remarks: Based on data from similar materials

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 concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

fenbendazole:

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

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

Propylene glycol:

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

Glycerine:

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

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

Species	:	Rabbit
NOAEL	:	5,040 mg/kg
Application Route	:	Skin contact

Exposure time	:	45 Weeks

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

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

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

Propylene glycol:

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

Glycerine:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l Exposure time: 96 h

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

Ethanol:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 5,012 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 fish (Chronic toxicity)	:	NOEC (Oryzias latipes (Japanese medaka)): >= 79 mg/l Exposure time: 100 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 9.6 mg/l Exposure time: 9 d
Toxicity to microorganisms	:	EC50 (Protozoa): 5,800 mg/l Exposure time: 4 h

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 fish (Chronic toxicity)	:	NOEC (Danio rerio (zebra fish)): 0.33 mg/l Exposure time: 12 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 1.9 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	EC50: 760 mg/l Exposure time: 30 min Method: OECD Test Guideline 209

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 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:

Propylene glycol:

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

Glycerine:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 92 %

Exposure time: 30 d
Method: OECD Test Guideline 301D

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

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- : log Pow: 3.32

octanol/water

Propylene glycol:

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

Glycerine:

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

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-octanol/water : log Pow: 0.83
Remarks: Calculation

Cinnamaldehyde:

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

Isovaleraldehyde:

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

Acetaldehyde:

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

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

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

Mobility in soil

Components:

fenbendazole:

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

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (fenbendazole)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

IATA-DGR

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (fenbendazole)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passenger aircraft)	:	964
Environmentally hazardous	:	yes

IMDG-Code

UN number	:	UN 3082
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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

ADG

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (fenbendazole)
Class	:	9
Packing group	:	III
Labels	:	9
Hazchem Code	:	•3Z
Environmentally hazardous	:	yes

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.

SECTION 15. REGULATORY INFORMATION

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

Therapeutic Goods (Poisons Standard) Instrument	:	Schedule 5 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)
Prohibition/Licensing Requirements	:	There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

Revision Date	:	28.09.2024
Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Date format	:	dd.mm.yyyy

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
AU OEL	:	Australia. Workplace Exposure Standards for Airborne Con-

taminants.

ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
ACGIH / C	:	Ceiling limit
AU OEL / TWA	:	Exposure standard - time weighted average
AU OEL / STEL	:	Exposure standard - short term exposure limit

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.

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