

Fenbendazole Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.0	17.06.2025	899079-00024	Date of first issue: 16.09.2016

SECTION 1. IDENTIFICATION

Product name : Fenbendazole Paste Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 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

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)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms



Signal Word : Warning

Hazard Statements : H361Df 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.
H410 Very toxic to aquatic life with long lasting effects.

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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 vapors.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.
Storage:
P405 Store locked up.
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 -< 20
Glycerine	56-81-5	≥ 10 -< 20
Ethanol#	64-17-5	< 0,1
Diethyl malonate#	105-53-3	$\geq 0,0025$ -< 0,025
2-Furaldehyde#	98-01-1	$\geq 0,0025$ -< 0,025
Cinnamaldehyde#	104-55-2	$\geq 0,0003$ -< 0,0025
Isovaleraldehyde#	590-86-3	$\geq 0,0003$ -< 0,0025
Acetaldehyde#	75-07-0	< 0,0003
Trans-hex-2-en-1-ol#	928-95-0	< 0,1

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.

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In case of eye contact	: Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
If swallowed	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
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. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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 (NO _x) Sulfur 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 fire-fighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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).

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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 diking or other appropriate containment to keep material from spreading. If diked 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 vapors.
 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.
 Conditions for safe storage : Keep in properly labeled 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
 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
fenbendazole	43210-67-9	TWA	100 µg/m ³ (OEB 2)	Internal
Glycerine	56-81-5	CMP (Mist)	10 mg/m ³	AR OEL
Ethanol	64-17-5	CMP	1.000 ppm	AR OEL
Further information: A4 - Not classifiable as a human carcinogen				
		STEL	1.000 ppm	ACGIH

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2-Furaldehyde	98-01-1	CMP	2 ppm	AR OEL
	Further information: A3 - Confirmed animal carcinogen with unknown relevance to humans, Skin			
		TWA	0,2 ppm	ACGIH
Acetaldehyde	75-07-0	CMP-C	25 ppm	AR OEL
	Further information: A3 - Confirmed animal carcinogen with unknown relevance to humans			
		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	total furoic acid	Urine	End of shift	200 mg/g creatinine	AR BEI
		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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapor type

Hand protection : Chemical-resistant gloves

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,

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industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	paste
Color	:	white to off-white
Odor	:	cinnamon-like
Odor 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
Vapor pressure	:	No data available
Relative vapor 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
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive

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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

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

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: vapor
Acute dermal toxicity	:	LD50 (Rabbit): > 15.800 mg/kg

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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: vapor
Acute dermal toxicity	: Acute toxicity estimate: 300 mg/kg Method: Expert judgment

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: vapor
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
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|| 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

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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 sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Ethanol:**

Test Type	: Mouse ear swelling test (MEST)
Routes of exposure	: Skin contact
Species	: Mouse
Result	: negative

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Diethyl malonate:

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

2-Furaldehyde:

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative

Cinnamaldehyde:

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: positive

Assessment	: Probability or evidence of high skin sensitization rate in humans
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Isovaleraldehyde:

Test Type	: Maximization Test
Routes of exposure	: 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 sensitization rate in humans
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Acetaldehyde:

Test Type	: Maximization Test
Routes of exposure	: 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)
Routes of exposure	: Skin contact
Species	: Mouse
Method	: OECD Test Guideline 429
Result	: negative

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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 test
Test system: mouse lymphoma cells
Metabolic activation: Metabolic activation
Result: equivocal

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

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II**Diethyl malonate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: Directive 67/548/EEC, Annex V, 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

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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

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	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
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Application Route	: Oral
Exposure time	: 2 Years
NOAEL	: 5 mg/kg body weight
Result	: negative
Target Organs	: Lymph nodes, Liver

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 (vapor)
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
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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 (vapor)
Exposure time	: 2 Years
Result	: negative
Remarks	: Based on data from similar materials

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Acetaldehyde:

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

Carcinogenicity - Assessment	: Sufficient evidence of carcinogenicity in animal experiments
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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 fetal 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-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 25 mg/kg body weight Result: Fetotoxicity. Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 63 mg/kg body weight Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 120 mg/kg body weight Result: No effects on fetal 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.

Glycerine:

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

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

Cinnamaldehyde:

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

Acetaldehyde:

Effects on fetal development : Test Type: Embryo-fetal 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

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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 fetal development : Test Type: Embryo-fetal 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:**

Routes of exposure : 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

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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

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 y
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

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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 (vapor)
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, Diarrhea

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****fenbendazole:**

|| Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,009 mg/l
Exposure time: 21 d

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Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,0088 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

M-Factor (Acute aquatic toxicity) : 100

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0,00113 mg/l
Exposure time: 21 Days
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

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.

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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

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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:****Glycerine:**

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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

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|||octanol/water

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 environ-
|||mental compartments : log Koc: 3,8 - 4,7
Method: FDA 3.08**Ethanol:**|||Distribution among environ-
|||mental compartments : log Koc: 0,2**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.

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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.

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**

Argentina. Carcinogenic Substances and Agents	: Not applicable
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Registry.

Control of precursors and essential chemicals for the : Ethanol
preparation of drugs.

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

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

SECTION 16. OTHER INFORMATION

Revision Date	: 17.06.2025
Date format	: dd.mm.yyyy

Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD
compile the Material Safety eChem Portal search results and European Chemicals Agen-
Data Sheet cy, <http://echa.europa.eu/>

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 other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	: ACGIH - Biological Exposure Indices (BEI)
AR BEI	: Argentina. Biological Exposure Indices
AR OEL	: Argentina. Occupational Exposure Limits
ACGIH / TWA	: 8-hour, time-weighted average
ACGIH / STEL	: Short-term exposure limit
ACGIH / C	: Ceiling limit
AR OEL / CMP	: TLV (Threshold Limit Value)
AR OEL / CMP-C	: Ceiling value

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

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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; TECL - 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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