

Fenbendazole Paste Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 5.9
 28.09.2024
 899079-00023
 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 : H361fd Suspected of damaging fertility. Suspected of damag-

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.



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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 protec-

tion/ 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 -<= 18,75 |
| 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.



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> Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

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

Protection of first-aiders

Notes to physician

In case of eye contact

If swallowed

delayed

d

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

: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING 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 prod-

ucts

Carbon oxides

Nitrogen oxides (NOx)

Sulfur oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

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

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

so.

Evacuate area.

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 emer-

gency 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/m3 (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 un- | | | |
| | known relevance to humans | | | |
| | | С | 25 ppm | ACGIH |

Biological occupational exposure limits

| Components | CAS-No. | Control parameters | Biological specimen | Sam- pling time | Permissible concentra-tion | 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

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. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

Conditions to avoid None known.

Incompatible materials Oxidizing agents Hazardous decomposition No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of: Inhalation

Skin contact exposure 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

Glycerine:

Acute oral toxicity LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity LD50 (Guinea pig): > 5.000 mg/kg

Ethanol:

LD50 (Rat): 10.470 mg/kg Acute oral toxicity

Method: OECD Test Guideline 401

Acute inhalation toxicity LC50 (Rat, male): 116,9 mg/l

> Exposure time: 4 h Test atmosphere: vapor

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

Diethyl malonate:



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Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 402

Remarks: Based on data from similar materials

2-Furaldehyde:

Acute oral toxicity : LD50 (Rat): 108 mg/kg

Method: OECD Test Guideline 401

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

Exposure time: 4 h
Test atmosphere: 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

Result : No skin irritation



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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

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

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 syn-

thesis 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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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 syn-

thesis in mammalian cells (in vitro)

Result: positive

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

malian cells Result: positive

Genotoxicity in vivo : Test Type: Unscheduled DNA synthesis (UDS) test with

mammalian liver cells in vivo

Species: Rat

Application Route: Ingestion

Result: negative

Test Type: Transgenic rodent somatic cell gene mutation as-

say

Species: Mouse

Application Route: Ingestion

Result: negative

Cinnamaldehyde:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative



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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 syn-

thesis in mammalian cells (in vitro)

Result: positive

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: negative

Acetaldehyde:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: positive

Test Type: Chromosome aberration test in vitro

Result: positive

Test Type: in vitro micronucleus test



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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

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 - Assess-

ment

Limited evidence of carcinogenicity in animal studies

Cinnamaldehyde:

Species : Rat
Application Route : Ingestion
Exposure time : 106 weeks
Result : negative

Remarks : Based on data from similar materials

Species : Mouse

Application Route : Intraperitoneal injection

Exposure time : 24 weeks Result : negative

Isovaleraldehyde:

Species : Rat

Application Route : inhalation (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 - Assess-

ment

: 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 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 off-

spring 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 - 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

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 concentra-

tions 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

NOEC (Daphnia magna (Water flea)): 0,00113 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

M-Factor (Acute aquatic tox-

100

Toxicity to daphnia and other : aquatic invertebrates (Chron-

Exposure time: 21 Days

ic toxicity) 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 tox-

icity)

NOEC (Oryzias latipes (Japanese medaka)): >= 79 mg/l

Exposure time: 100 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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 tox-

icity)

NOEC (Danio rerio (zebra fish)): 0,33 mg/l

Exposure time: 12 d

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic 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 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.



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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)

ssen- : 964

Packing instruction (passenger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

964

(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

Registry.

Control of precursors and essential chemicals for the : Ethanol



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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

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Further information

Sources of key data used to compile the Material Safety

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

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

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 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, Bioaccumu-



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lative 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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