SAFETY DATA SHEET

Fenbendazole Paste Formulation

SECTION 1. PRODUCT AND COMPANY 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
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, Lymph nodes, Stomach, Nervous system)
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 damaging the unborn child.
H373 May cause damage to organs (Liver, Lymph nodes, Stomach, Nervous system) through prolonged or repeated exposure if swallowed.
H410 Very toxic to aquatic life with long lasting effects.
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 mist or 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**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>fenbendazole</td>
<td>43210-67-9</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

### 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. 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 products: Carbon 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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.
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 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: Avoid inhalation of vapor or mist. 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>fenbendazole</td>
<td>43210-67-9</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>CMP (Mist)</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
</tbody>
</table>

Further information: Irritation

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, 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: No data available
- Autoignition temperature: No data available
- Decomposition temperature: No data available
- Viscosity: No data available
- Explosive properties: Not explosive
- Oxidizing properties: The substance or mixture is not classified as oxidizing.
- Molecular weight: No data available
- Particle size: No data available

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

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
Skin corrosion/irritation
Not classified based on available information.

**Components:**

fenbendazole:
Species: Rabbit
Result: No skin irritation

Glycerine:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

**Components:**

fenbendazole:
Species: Rabbit
Result: No eye irritation

Glycerine:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitization

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**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

**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

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

**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
  Result: negative

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

STOT-single exposure
Not classified based on available information.

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

Components:
fenbendazole:
Routes of exposure: Ingestion
Target Organs: Liver, Lymph nodes, Stomach, Nervous system
Assessment: May cause damage to organs through prolonged or repeated exposure
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, Lymph nodes, Nervous system

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

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 (Oncorhynchus mykiss (rainbow trout)): > 7.5 mg/l
Exposure time: 96 h
Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.008 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)): 0.0015 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

Persistence and degradability
Components:
Glycerine:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 92%

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

Bioaccumulative potential

Components:

fenbendazole:
Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): 240

Partition coefficient: n-octanol/water : log Pow: 2,3

Glycerine:
Partition coefficient: n-octanol/water : log Pow: -1,75

Mobility in soil

Components:

fenbendazole:
Distribution among environmental compartments : log Koc: 4,37

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : 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

IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(fenbendazole)

Class : 9
Packing group : III
Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents Registry: Not applicable

Control of precursors and essential chemicals for the preparation of drugs: Sodium hydroxide

International Regulations

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

Further information
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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