SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fenbendazole Premix Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Coronel Bento Soares, 530
          Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
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 in accordance with ABNT NBR 14725 Standard
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.
SAFETY DATA SHEET

Fenbendazole Premix Formulation

P260 Do not breathe dust.
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.

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>fenbendazole</td>
<td>43210-67-9</td>
<td>Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Oral) (Liver, Lymph nodes, Stomach, Nervous system), Category 2 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>Aspiration hazard, Category 1 Long-term (chronic) aquatic hazard, Category 4</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: If in eyes, rinse well with water. 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.
- Contact with dust can cause mechanical irritation or drying of the skin.
- Dust contact with the eyes can lead to mechanical irritation.

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: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Metal 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. 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:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- 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:
- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not breathe dust.
- 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.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.

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/PERSOAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameters / Permissible</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

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<table>
<thead>
<tr>
<th>Exposure</th>
<th>Concentration</th>
<th>Physical and Chemical Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>fenbendazole</td>
<td>43210-67-9 TWA</td>
<td>100 µg/m³ (OEB 2) Internal</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1 TWA (Inhalable particulate matter)</td>
<td>5 mg/m³ ACGIH</td>
</tr>
</tbody>
</table>

**Engineering measures**: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

**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.
- **Remarks**: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
- **Eye protection**: Wear the following personal protective equipment: Safety goggles.
- **Skin and body protection**: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: powder
- **Color**: light brown
- **Odor**: characteristic
- **Odor Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling**: No data available
Flash point : Not applicable
Evaporation rate : No data available
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
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
Density : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
- May form explosive dust-air mixture during processing, handling or other means.
- Can react with strong oxidizing agents.
Conditions to avoid
- Heat, flames and sparks.
- Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 1. 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

Paraffin oil:
- Acute oral toxicity:
  - LD50 (Rat): > 5.000 mg/kg
- Acute dermal toxicity:
  - LD50 (Rabbit): > 2.000 mg/kg
  - Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation
Not classified based on available information.

Components:
fenbendazole:
- Species: Rabbit
- Result: No skin irritation

Paraffin oil:
- 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

Paraffin oil:
- 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

Carcinogenicity
Not classified based on available information.

Components:

fenbendazole:
Species: Mouse
Application Route: Oral
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

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

Components:

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

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:
### SAFETY DATA SHEET

#### Fenbendazole Premix Formulation

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<tr>
<td>2.5</td>
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<td>1503376-00010</td>
<td>10.10.2020</td>
<td>31.03.2017</td>
</tr>
</tbody>
</table>

**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

#### Paraffin oil:

**Species**: Rat, female  
**LOAEL**: 161 mg/kg  
**Application Route**: Ingestion  
**Exposure time**: 90 Days

**Aspiration toxicity**  
Not classified based on available information.

**Components:**  
**fenbendazole:**  
No aspiration toxicity classification

**Paraffin oil:**  
The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

**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

#### Paraffin oil:
- **Toxicity to fish**: LL50 (Scophthalmus maximus (turbot)): > 100 mg/l  
  Exposure time: 96 h  
  Test substance: Water Accommodated Fraction  
  Remarks: Based on data from similar materials
- **Toxicity to daphnia and other aquatic invertebrates**: EL50 (Acartia tonsa): > 100 mg/l  
  Exposure time: 48 h  
  Test substance: Water Accommodated Fraction  
  Remarks: Based on data from similar materials
- **Toxicity to algae/aquatic plants**: EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l  
  Exposure time: 72 h  
  Test substance: Water Accommodated Fraction  
  Remarks: Based on data from similar materials  
  NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l  
  Exposure time: 72 h  
  Test substance: Water Accommodated Fraction  
  Remarks: Based on data from similar materials

### Persistence and degradability
No data available

### Bioaccumulative potential

#### Components:

#### fenbendazole:
- **Bioaccumulation**: Species: Lepomis macrochirus (Bluegill sunfish)  
  Bioconcentration factor (BCF): 240
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Partition coefficient: n-octanol/water

Paraffin oil:
Partition coefficient: n-octanol/water

Mobility in soil

Components:
fenbendazole:
Distribution among environmental compartments

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 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(fenbendazole)
Class: 9
Packing group: III
Labels:

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s.
(fenbendazole)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, 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.

Domestic regulation

ANTT
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (fenbendazole)

Class: 9
Packing group: III
Labels: 9
Hazard Identification Number: 90

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
National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

Brazil. List of chemicals controlled by the Federal Police: Calcium carbonate

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

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

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Sources of key data used to compile the Material Safety Data Sheet:

Full text of other abbreviations:
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average

All abbreviations are defined within the text.

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.

BR / Z8