SAFETY DATA SHEET

Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Version 2.1  Revision Date: 27.08.2021  SDS Number: 7567904-00004  Date of last issue: 11.03.2021
Date of first issue: 20.11.2020

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Manufacturer or supplier's details
Company: MSD
Address: 50 Tuas West Drive
Singapore - Singapore 638408
Telephone: +1-908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

GHS Classification
Skin sensitisation: Category 1
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Central nervous system, Lungs, Liver, Stomach)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms: 
Signal word: Danger
Hazard statements: H317 May cause an allergic skin reaction.
H360D May damage the unborn child.
H373 May cause damage to organs (Central nervous system, Lungs, Liver, Stomach) 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 dust/ fume/ gas/ mist/ vapours/ spray.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P302 + P352 IF ON SKIN: Wash with plenty of water.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
- P362 + P364 Take off contaminated clothing and wash it before reuse.
- 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**
- 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.

### 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>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 30 -&lt; 50</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
<tr>
<td>Lufenuron (ISO)</td>
<td>103055-07-8</td>
<td>&gt;= 2.5 -&lt; 10</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>&gt;= 1 -&lt; 10</td>
</tr>
<tr>
<td>Savorysel Bacon Flavor</td>
<td>Not Assigned</td>
<td>&gt;= 1 -&lt; 10</td>
</tr>
<tr>
<td>praziquantel</td>
<td>55268-74-1</td>
<td>&gt;= 1 -&lt; 10</td>
</tr>
<tr>
<td>Milbemycin Oxime</td>
<td>129496-10-2</td>
<td>&gt;= 0.25 -&lt; 1</td>
</tr>
</tbody>
</table>

### 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 immediately.
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:
May cause an allergic skin reaction.
May damage 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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.
Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Metal oxides
Chlorine compounds
Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protection: Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

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.

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: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not breathe dust, fume, gas, mist, vapours or spray. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. 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. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents.
### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Components 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>Starch</td>
<td>9005-25-8</td>
<td>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>PEL (long term) (Mist)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td>Lufenuron (ISO)</td>
<td>103055-07-8</td>
<td>TWA</td>
<td>OEB 3 (&gt;= 10 &lt; 100 µg/m³)</td>
<td>Internal</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Savorysel Bacon Flavor</td>
<td>Not Assigned</td>
<td>Wipe limit</td>
<td>OEB 2 (&gt;= 100 &lt; 1000 µg/m³)</td>
<td>Internal</td>
</tr>
<tr>
<td>Praziquantel</td>
<td>55268-74-1</td>
<td>TWA</td>
<td>0.5 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Milbemycin Oxime</td>
<td>129496-10-2</td>
<td>TWA</td>
<td>0.1 mg/m³ (OEB2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Engineering measures**

- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
- Minimize open handling.

**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 vapour type
  - Material: Chemical-resistant gloves
  - Remarks: Consider double gloving.

- **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. Additional body garments should be used based upon the
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.
- Contaminated work clothing should not be allowed out of the workplace.
- 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: solid
- **Colour**: brown
- **Odour**: characteristic
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: Not applicable
- **Evaporation rate**: Not applicable
- **Flammability (solid, gas)**: May form explosive dust-air mixture during processing, handling or other means.
- **Flammability (liquids)**: Not applicable
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: Not applicable
- **Relative vapour density**: Not applicable
- **Relative density**: No data available
Density : No data available

Solubility(ies)
- Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

 Decomposition temperature : No data available

Viscosity
- Viscosity, kinematic : Not applicable

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

### 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.
- Avoid oxidizing agents.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

**Components:**

**Starch:**
- Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
- Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Glycerine:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

lufenuron (ISO):
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
   LD50 (Mouse): > 2,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): 2,350 mg/m3
   Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Sucrose:
Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

Savorysel Bacon Flavor:
Acute oral toxicity : Remarks: Based on available data, the classification criteria are not met.
Acute inhalation toxicity : Remarks: Not classified due to lack of data.
Acute dermal toxicity : Remarks: Based on available data, the classification criteria are not met.

praziquantel:
Acute oral toxicity : LD50 (Rat): 2,480 mg/kg
   LD50 (Mouse): 2,454 mg/kg
   LD50 (Dog): > 200 mg/kg
   LD50 (Rabbit): 1,050 mg/kg

Milbemycin Oxime:
Acute oral toxicity : LD50 (Rat): 532 - 863 mg/kg
   LD50 (Mouse): 722 - 946 mg/kg
Acute inhalation toxicity : LC50 (Rat): 1,200 mg/m3
   Exposure time: 4 h
   Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Skin corrosion/irritation
Not classified based on available information.

Components:

Glycerine:
Species: Rabbit
Result: No skin irritation

Lufenuron (ISO):
Species: Rabbit
Method: Draize Test
Result: No skin irritation

Savorysel Bacon Flavor:
Remarks: Based on data from similar materials
May irritate skin.

Praziquantel:
Species: Rabbit
Method: Draize Test
Remarks: slight irritation

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

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

Components:

Starch:
Species: Rabbit
Result: No eye irritation

Glycerine:
Species: Rabbit
Result: No eye irritation

Lufenuron (ISO):
Species: Rabbit
Result: No eye irritation
Method: Draize Test

Savorysel Bacon Flavor:
Remarks: Based on data from similar materials
May irritate eyes.

**praziquantel:**
Species: Rabbit
Result: Mild eye irritation
Method: Draize Test

**Milbemycin Oxime:**
Species: Rabbit
Result: No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
May cause an allergic skin reaction.

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

**Components:**

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

**Lufenuron (ISO):**
Test Type: Maximisation Test
Species: Guinea pig
Assessment: May cause sensitisation by skin contact.
Result: Sensitiser

**Savorysel Bacon Flavor:**
Remarks: Not classified due to lack of data.

**praziquantel:**
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

**Milbemycin Oxime:**
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
## Germ cell mutagenicity
Not classified based on available information.

### Components:

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

#### Glycerine:
Genotoxicity in vitro:
- Test Type: In vitro mammalian cell gene mutation test
  - Result: negative
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- Test Type: Chromosome aberration test in vitro
  - Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  - Result: negative

#### Lufenuron (ISO):
Genotoxicity in vitro:
- Test Type: Ames test
  - Result: negative
- Test Type: Mouse Lymphoma
  - Test system: Chinese hamster cells
  - Result: negative
- Test Type: Cytogenetic assay
  - Test system: Chinese hamster ovary cells
  - Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  - Test system: rat hepatocytes
  - Result: negative
- Test system: Human lymphocytes
  - Result: negative

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Result: negative
- Test Type: Unscheduled DNA synthesis test (UDS) in testicular cells
  - Species: Rat
  - Result: negative
SAFETY DATA SHEET

Milbemycin Oxime / Lufenuron / Praziquantel
Formulation

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

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

Savorysel Bacon Flavor:
Genotoxicity in vitro: Remarks: Not classified due to lack of data.
Genotoxicity in vivo: Remarks: Not classified due to lack of data.

Praziquantel:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Chinese hamster cells
  Result: negative

Genotoxicity in vivo:
- Test Type: Micronucleus test
  Species: Rat
  Result: negative

Milbemycin Oxime:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Chromosome aberration test in vitro
  Result: negative

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Result: negative

Carcinogenicity
Not classified based on available information.

Components:

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

Lufenuron (ISO):
Species: Rat
Application Route: Ingestion
Exposure time: 18 month(s)
Result: negative

Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen

**praziquantel:**
Species: Hamster
Application Route: Oral
Exposure time: 80 weeks
NOAEL: 100 mg/kg body weight
Result: negative
Remarks: No significant adverse effects were reported

Species: Rat
Application Route: Oral
Exposure time: 104 weeks
NOAEL: 250 mg/kg body weight
Result: negative
Remarks: No significant adverse effects were reported

**Reproductive toxicity**
May damage the unborn child.

**Components:**

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

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

**lufenuron (ISO):**
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
General Toxicity - Parent: NOAEL: 8.3 mg/kg wet weight
Early Embryonic Development: NOAEL: 20.9 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on foetal development: Test Type: Development
Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: 500 mg/kg body weight
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Symptoms: No adverse effects
Remarks: No significant adverse effects were reported

Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
General Toxicity Maternal: NOAEL: 20.9 mg/kg body weight
Embryo-foetal toxicity: 8.3 mg/kg body weight
Result: foetal abnormalities

Reproductive toxicity - Assessment:
: Clear evidence of adverse effects on development, based on animal experiments.

Savorysel Bacon Flavor:
Effects on fertility:
: Remarks: No data available

Effects on foetal development:
: Remarks: No data available

praziquantel:
Effects on fertility:
: Test Type: Fertility
Species: Rat
Remarks: No significant adverse effects were reported

Test Type: Fertility
Species: Mouse
Remarks: No significant adverse effects were reported

Effects on foetal development:
: Test Type: Development
Species: Rat
Remarks: No significant adverse effects were reported

Test Type: Development
Species: Mouse
Remarks: No significant adverse effects were reported

Milbemycin Oxime:
Effects on fertility:
: Test Type: One-generation reproduction toxicity study
Species: Dog
Application Route: Ingestion
Result: negative

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

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Result: negative
STOT - single exposure
Not classified based on available information.

Components:

Lufenuron (ISO):
Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure
May cause damage to organs (Central nervous system, Lungs, Liver, Stomach) through prolonged or repeated exposure if swallowed.

Components:

Lufenuron (ISO):
Exposure routes: Oral
Target Organs: Central nervous system, Lungs, Liver, Stomach
Assessment: Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Milbemycin Oxime:
Exposure routes: Ingestion
Target Organs: Central nervous system
Assessment: Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Starch:
Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact
Exposure time: 28 Days
Method: OECD Test Guideline 410

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
### SAFETY DATA SHEET

**Milbemycin Oxime / Lufenuron / Praziquantel**  
**Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>27.08.2021</td>
<td>7567904-00004</td>
<td>11.03.2021</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>8,000 - 10,000 mg/kg</td>
<td>Ingestion</td>
<td>2 yr</td>
<td>Rabbit</td>
<td>5,040 mg/kg</td>
<td>Skin contact</td>
<td>45 Weeks</td>
<td>Central nervous system, digestive system</td>
<td>central nervous system effects</td>
</tr>
</tbody>
</table>

**lufenuron (ISO):**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>5.34 mg/kg</td>
<td>oral (feed)</td>
<td>4 Months</td>
<td>Central nervous system, digestive system</td>
<td>central nervous system effects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>1.93 mg/kg</td>
<td>oral (feed)</td>
<td>2 yr</td>
<td>Central nervous system, digestive system</td>
<td>central nervous system effects, Convulsions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>2.12 mg/kg</td>
<td>oral (feed)</td>
<td>18 Months</td>
<td>Central nervous system, Liver, Prostate</td>
<td>central nervous system effects, Convulsions</td>
</tr>
</tbody>
</table>

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<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>7.02 mg/kg</td>
<td>oral (feed)</td>
<td>1 yr</td>
<td>Central nervous system, Liver, Lungs</td>
<td>Convulsions, Fatality, Irregularities</td>
</tr>
</tbody>
</table>

**Savorysel Bacon Flavor:**

**Remarks:** Not classified due to lack of data.

**praziquantel:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>1,000 mg/kg</td>
<td>Oral</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>60 mg/kg</td>
<td>Oral</td>
<td>Gastrointestinal tract</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Milbemycin Oxime / Lufenuron / Praziquantel
Formulation

Version: 2.1  Revision Date: 27.08.2021  SDS Number: 7567904-00004  Date of last issue: 11.03.2021  Date of first issue: 20.11.2020

Remarks: No significant adverse effects were reported

**Milbemycin Oxime:**

Species: Rat
NOAEL: 3 mg/kg
LOAEL: 15 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Symptoms: Liver disorders, Blood disorders

Species: Dog
LOAEL: 8.6 mg/kg
Application Route: Ingestion
Exposure time: 3 Days
Symptoms: Tremors

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

**Experience with human exposure**

**Components:**

**Lufenuron (ISO):**
General Information: Remarks: May be harmful if swallowed. May cause neurotoxic effects.

**Savoreysel Bacon Flavor:**
Remarks: May irritate skin. May irritate eyes.

**praziquantel:**
Inhalation: Symptoms: Headache, Tiredness, Dizziness, Gastrointestinal discomfort, decrease body temperature, Allergic reactions

**Milbemycin Oxime:**
Ingestion: Symptoms: Salivation, Convulsions, Diarrhoea, Weakness, Vomiting, Tremors, Coma
Remarks: Based on Animal Evidence

**Further information**

**Components:**

**Savoreysel Bacon Flavor:**
Remarks: No toxicology information is available.
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

lufenuron (ISO):
Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 73,100 µg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): > 29,000 µg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 370 µg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Americamysis): 0.042 µg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic plants : EC50 (Raphidocelis subcapitata (freshwater green alga)): 209 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Scenedesmus subspicatus): 17 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 10,000

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 80 µg/l
Exposure time: 33 d
Method: OECD Test Guideline 210

NOEC (Oncorhynchus mykiss (rainbow trout)): 20 µg/l
Exposure time: 359 d
Method: OECD Test Guideline 229
### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milbemycin Oxime</td>
<td>8.38 µg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td>Lufenuron</td>
<td>90 µg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td>Praziquantel</td>
<td>2 µg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

### M-Factor (Chronic aquatic toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>M-Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milbemycin Oxime</td>
<td>10,000</td>
</tr>
</tbody>
</table>

### Toxicity to fish

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50 (Carassius auratus (goldfish))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milbemycin Oxime</td>
<td>29.2 mg/l</td>
<td>96 hrs</td>
<td>OECD Test Guideline 203</td>
</tr>
<tr>
<td>Lufenuron</td>
<td>31.6 mg/l</td>
<td>96 hrs</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

### Toxicality to algae/aquatic plants

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milbemycin Oxime</td>
<td>&gt; 87 µg/l</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

### M-Factor (Acute aquatic toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>M-Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milbemycin Oxime</td>
<td>10,000</td>
</tr>
</tbody>
</table>
Persistence and degradability

Components:

Glycerine:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 92 %
Exposure time: 30 d
Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:

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

Lufenuron (ISO):
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 28
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water: log Pow: 5.12

Sucrose:
Partition coefficient: n-octanol/water: Pow: < 1

Praziquantel:
Partition coefficient: n-octanol/water: log Pow: 2.012
pH: 7

Milbemycin Oxime:
Bioaccumulation: Bioconcentration factor (BCF): 440
Partition coefficient: n-octanol/water: log Pow: 7

Mobility in soil

Components:

Lufenuron (ISO):
Distribution among environmental compartments: log Koc: 5.38
Method: OECD Test Guideline 106

Other adverse effects
No data available
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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Milbemycin Oxime, lufenuron (ISO))
- Class: 9
- Packing group: III
- Labels: 9

IATA-DGR
- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Milbemycin Oxime, lufenuron (ISO))
- 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. (Milbemycin Oxime, lufenuron (ISO))
- 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.
15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

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

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

16. OTHER INFORMATION

Further information

Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AIIIC - 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 con-
SAFETY DATA SHEET

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centration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

SG / EN