SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Milbemycin Oxime / Lufenuron / Praziquantel
Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Milbemycin Oxime / Lufenuron / Praziquantel Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
              Walton Manor, Walton
             MK7 7AJ Milton Keynes - United Kingdom
   Telephone : +1-908-740-4000
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   +1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

   Classification (REGULATION (EC) No 1272/2008)
   Skin sensitisation, Category 1
   Reproductive toxicity, Category 1B
   Specific target organ toxicity - repeated exposure, Category 2
   Short-term (acute) aquatic hazard, Category 1
   Long-term (chronic) aquatic hazard, Category 1

   H317: May cause an allergic skin reaction.
   H360D: May damage the unborn child.
   H373: May cause damage to organs through prolonged or repeated exposure.
   H400: Very toxic to aquatic life.
   H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

   Labelling (REGULATION (EC) No 1272/2008)
   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 through prolonged or
repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P201 Obtain special instructions before use.
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.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:
lufenuron (ISO)

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>lufenuron (ISO)</td>
<td>103055-07-8 410-690-9 616-050-00-7</td>
<td>Skin Sens. 1; H317 Repr. 1B; H360D STOT RE 1; H372 (Central nervous system, Lungs, Liver, Stomach) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10,000 M-Factor (Chronic aquatic toxicity): 10</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
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Milbemycin Oxime / Lufenuron / Praziquantel
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<table>
<thead>
<tr>
<th>Savorysel Bacon Flavor</th>
<th>Not Assigned</th>
<th>Aquatic Chronic 3; H412</th>
<th>&gt;= 1 - &lt; 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>praziquantel</td>
<td>55268-74-1</td>
<td>Aquatic Chronic 3; H412</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>259-559-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Milbemycin Oxime</td>
<td>129496-10-2</td>
<td>Acute Tox. 4; H302</td>
<td>&gt;= 0.25 - &lt; 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute Tox. 4; H332</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT RE 1; H372</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Central nervous system)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Acute 1; H400</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Chronic 1; H410</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 10,000</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 10,000</td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks:
- Contact with dust can cause mechanical irritation or drying of the skin.
- Dust contact with the eyes can lead to mechanical irritation.
- May cause an allergic skin reaction.
- May damage the unborn child.
- May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

 Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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 as-
Hygiene measures: 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.

7.2 Conditions for safe storage, including any incompatibilities

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

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA (inhalable dust)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols., The COSH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m⁻³ 8-hour TWA of inhalable dust or 4
mg·m⁻³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed ‘inhalable’ and ‘respirable’. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with. Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.

<table>
<thead>
<tr>
<th>Substance</th>
<th>TWA (Mist)</th>
<th>STEL</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td></td>
<td>GB EH40</td>
</tr>
<tr>
<td>Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lufenuron (ISO)</td>
<td>103055-07-8</td>
<td></td>
<td>Internal</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
<tr>
<td>Savorysel Bacon Flavor</td>
<td>Not Assigned</td>
<td>Wipe limit</td>
<td>OEB 2 (≥ 100 µg/m³)</td>
</tr>
<tr>
<td>Praziquantel</td>
<td>55268-74-1</td>
<td>0.5 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Milbemycin Oxime</td>
<td>129496-10-0</td>
<td>0.1 mg/m³ (OEB2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>2068.62 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>2068.62 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>295.52 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>295.52 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>443.28 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>443.28 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
<tr>
<td>Glycerine</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>56 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>229 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>33 mg/m³</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lufenuron (ISO)</td>
<td>Water</td>
<td>0.2 µg/l</td>
</tr>
<tr>
<td>Praziquantel</td>
<td>Fresh water</td>
<td>0.3 mg/l</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>Fresh water</td>
<td>5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>500 mg/l</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>4.86 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Glycerine</td>
<td>Fresh water</td>
<td>0.885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>8.85 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>3.3 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.33 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.141 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>
Exposure controls

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

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 face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Skin and body protection: Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to BS EN 14387

Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
**SAFETY DATA SHEET**

(according to Regulation (EC) No. 1907/2006)

### 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>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>11.03.2021</td>
<td>7602781-00003</td>
<td>07.12.2020</td>
<td>20.11.2020</td>
</tr>
</tbody>
</table>

- **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.

### 9.2 Other information

- **Molecular weight:** No data available
- **Particle size:** No data available

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity
Not classified as a reactivity hazard.

#### 10.2 Chemical stability
Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions
- **Hazardous reactions:** May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
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SDS Number: 7602781-00003  Date of last issue: 07.12.2020
Date of first issue: 20.11.2020

10.4 Conditions to avoid
Conditions to avoid:
- Heat, flames and sparks.
- Avoid dust formation.

10.5 Incompatible materials
Materials to avoid:
- Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

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

Acute toxicity
Not classified based on available information.

Components:

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

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
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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:**

### 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:**

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

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

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

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:
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:
lufenuron (ISO):
Genotoxicity in vitro: Test Type: Ames test
### Genotoxicity in vitro

**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

### Germ cell mutagenicity- Assessment

: Weight of evidence does not support classification as a germ cell mutagen.

### 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)
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Milbemycin Oxime / Lufenuron / Praziquantel
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Version 2.0 Revision Date: 11.03.2021 SDS Number: 7602781-00003 Date of last issue: 07.12.2020
Date of first issue: 20.11.2020

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:

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:

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

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
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<table>
<thead>
<tr>
<th>Application Route: Ingestion</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Embryo-foetal development</td>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td>Result: negative</td>
</tr>
<tr>
<td>Test Type: Embryo-foetal development</td>
<td>Species: Dog</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

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 through prolonged or repeated exposure.

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:

Lufenuron (ISO):
- Species: Rat
- NOAEL: 5.34 mg/kg
- Application Route: oral (feed)
- Exposure time: 4 Months
- Target Organs: Central nervous system, digestive system
- Symptoms: central nervous system effects
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</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</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 effects, Convulsions</td>
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<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>
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<tr>
<td>Dog</td>
<td>7.02 mg/kg</td>
<td>oral (feed)</td>
<td>1 yr</td>
<td>Central nervous system effects, Convulsions</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Convulsions, Fatality, Irregularities</td>
</tr>
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</table>

**Savorysel Bacon Flavor:**

<table>
<thead>
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<th>Remarks</th>
</tr>
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<tr>
<td>Not classified due to lack of data.</td>
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</table>

**praziquantel:**

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<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td>Rat</td>
<td>1,000 mg/kg</td>
<td>Oral</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Dog</td>
<td>60 mg/kg</td>
<td>Oral</td>
<td>No significant adverse effects were reported</td>
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**Milbemycin Oxime:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>3 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Liver disorders, Blood disorders</td>
</tr>
<tr>
<td>Dog</td>
<td>8.6 mg/kg</td>
<td>Ingestion</td>
<td>3 Days</td>
<td>Tremors</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
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.

Savorysel Bacon Flavor:
General Information : Remarks: Based on data from similar materials 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:

Savorysel Bacon Flavor:
Remarks : No toxicology information is available.

SECTION 12: Ecological information

12.1 Toxicity

Components:

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
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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: 80 µg/l
Exposure time: 33 d
Species: Oncorhynchus mykiss (rainbow trout)
Method: OECD Test Guideline 210

NOEC: 20 µg/l
Exposure time: 359 d
Species: Oncorhynchus mykiss (rainbow trout)
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
NOEC: 8.38 µg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

NOEC: 90 µg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

NOEC: 2 µg/l
Exposure time: 21 d
Species: Chironomus riparius (harlequin fly)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 10

praziquantel:

Toxicity to fish
LC50 (Carassius auratus (goldfish)): 29.2 mg/l
Exposure time: 96 hrs
Method: OECD Test Guideline 203

LC50 (Danio rerio (zebra fish)): 31.6 mg/l
Exposure time: 96 hrs
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates
EC50 (Daphnia magna (Water flea)): 35 mg/l
Exposure time: 48 h
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Method: OECD Test Guideline 202
Toxicity to microorganisms: EC50 (activated sludge): > 1,000 mg/l
Exposed time: 3 h
Test Type: Respiration inhibition of activated sludge
Method: OECD Test Guideline 209

Milbemycin Oxime:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 0.16 µg/l
Exposed time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.03 µg/l
Exposed time: 48 h
Toxicity to algae/aquatic plants: EC50: > 87 µg/l
Exposed time: 72 h
M-Factor (Acute aquatic toxicity): 10,000
M-Factor (Chronic aquatic toxicity): NOEC: 0.01 µg/l
Species: Daphnia magna (Water flea)
M-Factor (Chronic aquatic toxicity): 10,000

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential

Components:

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

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
12.4 Mobility in soil

Components:

lufenuron (ISO):

Distribution among environmental compartments: log Koc: 5.38
Method: OECD Test Guideline 106

12.5 Results of PBT and vPvB assessment

Product: Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product: Endocrine disrupting potential: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number

ADN: UN 3077
ADR: UN 3077
RID: UN 3077
IMDG: UN 3077
IATA: UN 3077

14.2 UN proper shipping name
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</table>

**ADN**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Milbemycin Oxime, lufenuron (ISO))

**ADR**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Milbemycin Oxime, lufenuron (ISO))

**RID**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Milbemycin Oxime, lufenuron (ISO))

**IMDG**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Milbemycin Oxime, lufenuron (ISO))

**IATA**: Environmentally hazardous substance, solid, n.o.s. (Milbemycin Oxime, lufenuron (ISO))

### 14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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<tr>
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</tbody>
</table>

### 14.4 Packing group

**ADN**

- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

**ADR**

- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)

**RID**

- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

**IMDG**

- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F

**IATA (Cargo)**

- Packing instruction (cargo): 956
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</tbody>
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aircraft)
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
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Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

<table>
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<tr>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
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<tr>
<td>100 t</td>
<td>200 t</td>
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Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information
Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
H302: Harmful if swallowed.
H317: May cause an allergic skin reaction.
H322: Harmful if inhaled.
H360D: May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H372: Causes damage to organs through prolonged or repeated exposure if swallowed.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
H412: Harmful to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox.: Acute toxicity
Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Repr.: Reproductive toxicity
Skin Sens.: Skin sensitisation
STOT RE: Specific target organ toxicity - repeated exposure
GB EH40: UK. EH40 WEL - Workplace Exposure Limits
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GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; KECl - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

Skin Sens. 1 H317 Calculation method
Repr. 1B H360D Calculation method
STOT RE 2 H373 Calculation method
Aquatic Acute 1 H400 Calculation method
Aquatic Chronic 1 H410 Calculation method

Classification procedure:

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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.

GB / EN