1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Manufacturer or supplier's details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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 : ![Hazard Pictogram]
Signal word : Danger
Hazard statements : H317 May cause an allergic skin reaction.
Precautionary statements:

**Prevention:**
P203 Obtain, read and follow all safety instructions before use.
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.
P318 IF exposed or concerned, get medical advice.
P333 + P317 If skin irritation or rash occurs: Get medical help.
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

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>lufenuron (ISO)</td>
<td>103055-07-8</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>Savorysel Bacon Flavor</td>
<td>Not Assigned</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
<td>57-50-1</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>praziquanet</td>
<td>55268-74-1</td>
<td>&gt;= 2.5 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<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 ad-
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: 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 if swallowed.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

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, 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.

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:
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>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</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>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

Hand protection: 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 task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>solid</td>
</tr>
<tr>
<td>Colour</td>
<td>brown</td>
</tr>
<tr>
<td>Odour</td>
<td>characteristic</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling</td>
<td>No data available</td>
</tr>
<tr>
<td>range</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during</td>
</tr>
<tr>
<td></td>
<td>processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>soluble</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Milbemycin Oxime / Lufenuron / Praziquantel
Formulation

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.
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.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:
Starch:
SAFETY DATA SHEET
Milbemycin Oxime / Lufenuron / Praziquantel
Formulation

Version 2.0  Revision Date: 11.03.2021  SDS Number: 7567911-00003  Date of last issue: 07.12.2020  Date of first issue: 20.11.2020

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 2,000 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

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.

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

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

Sodium chloride:
Acute oral toxicity: LD50 (Rat): 3,550 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 42 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

Milbemycin Oxime:
Acute oral toxicity: LD50 (Rat): 532 - 863 mg/kg
LD50 (Mouse): 722 - 946 mg/kg
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>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>11.03.2021</td>
<td>7567911-00003</td>
<td>07.12.2020</td>
<td>20.11.2020</td>
</tr>
</tbody>
</table>

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

Sodium chloride:
Species: Rabbit
Result: No skin 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

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

Sodium chloride:
Species: Rabbit
Result: No 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:

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.

Sodium chloride:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**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                                                    |

**lufenuron (ISO):**

| Genotoxicity in vitro          | Test Type: Ames test                                                |
|                                | Result: negative                                                    |

| Test Type: Mouse Lymphoma      | Result: negative                                                    |
| Test system: Chinese hamster cells |                                                         |

| Test Type: Cytogenetic assay   | Result: negative                                                    |
| Test system: Chinese hamster ovary cells |                                                  |

| Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) | Result: negative |
| Test system: rat hepatocytes    |                                                                |

| Test system: Human lymphocytes  | Result: negative                                                    |

**Genotoxicity in vivo**

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

| Test Type: Unscheduled DNA synthesis test (UDS) in testicular cells           | Result: negative |
| Species: Rat                                                                 |                                    |

**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.

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

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

Sodium chloride:
Genotoxicity in vitro:
Test Type: In vitro mammalian cell gene mutation test
Result: positive
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro)
Result: positive
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: positive
Test Type: Chromosome aberration test in vitro
Result: positive
Test Type: Chromosome aberration test in vitro
Result: negative
Genotoxicity in vivo:
Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative
Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Intraperitoneal injection
Result: positive

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

**Milbemycin Oxime:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Chromosome aberration test in vitro</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
</tr>
</tbody>
</table>

**Carcinogenicity**

Not classified based on available information.

**Components:**

**lufenuron (ISO):**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>18 month(s)</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

**praziquantel:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Hamster</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>80 weeks</td>
</tr>
<tr>
<td>NOAEL</td>
<td>100 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>104 weeks</td>
</tr>
<tr>
<td>NOAEL</td>
<td>250 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Sodium chloride:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
</tbody>
</table>
Exposure time: 2 Years
Result: negative

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

  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

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
Milbemycin Oxime / Lufenuron / Praziquantel
Formulation

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:
Species: Rat
Application Route: Ingestion
Result: negative
Species: Rabbit
Application Route: Ingestion
Result: negative
Species: Dog
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 |

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 |

| Species   | Rat |
| NOAEL     | 1.93 mg/kg |
| Application Route | oral (feed) |
| Exposure time   | 2 yr |
| Target Organs | Central nervous system effects, Convulsions |
| Symptoms      | central nervous system effects, Convulsions |

| Species   | Mouse |
| NOAEL     | 2.12 mg/kg |
| Application Route | oral (feed) |
| Exposure time   | 18 Months |
| Target Organs | Central nervous system, Liver, Prostate |
| Symptoms      | central nervous system effects, Convulsions |

| Species   | Dog |
| NOAEL     | 7.02 mg/kg |
| Application Route | oral (feed) |
| Exposure time   | 1 yr |
| Target Organs | Central nervous system, Liver, Lungs |
| Symptoms      | Convulsions, Fatality, Irregularities |

Savorysel Bacon Flavor:

| Remarks                  | Not classified due to lack of data. |

praziquantel:

| Species   | Rat |
| NOAEL     | 1,000 mg/kg |
| Application Route | Oral |
| Remarks      | No significant adverse effects were reported |

| Species   | Dog |
| NOAEL     | 60 mg/kg |
### Sodium chloride:
- **Species**: Rat
- **LOAEL**: 2,533 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 2 yr

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

### 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.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

lufenuron (ISO):

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 73,100 µg/l Exposure time: 96 h Method: OECD Test Guideline 203</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 29,000 µg/l Exposure time: 96 h Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td></td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): 370 µg/l Exposure time: 96 h Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Americamysis): 0.042 µg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Raphidocelis subcapitata (freshwater green alga)): 209 µg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>EC50 (Scenedesmus subspicatus): 17 µg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity)</td>
<td>10,000</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC: 80 µg/l Exposure time: 33 d Species: Oncorhynchus mykiss (rainbow trout) Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td></td>
<td>NOEC: 20 µg/l Exposure time: 359 d Species: Oncorhynchus mykiss (rainbow trout) Method: OECD Test Guideline 229</td>
</tr>
</tbody>
</table>
### toxicity to daphnia and other aquatic invertebrates (chronic toxicity)

<table>
<thead>
<tr>
<th>NOEC: 8.38 µg/l</th>
<th>Exposure time: 21 d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Daphnia magna (Water flea)</td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC: 90 µg/l</th>
<th>Exposure time: 21 d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Daphnia magna (Water flea)</td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC: 2 µg/l</th>
<th>Exposure time: 21 d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Chironomus riparius (harlequin fly)</td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

### m-factor (chronic aquatic toxicity)

| m-factor: 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 |
| Method: OECD Test Guideline 202 |

#### toxicity to microorganisms

| EC50 (activated sludge): > 1,000 mg/l |
| Exposure time: 3 h |
| Test Type: Respiration inhibition of activated sludge |
| Method: OECD Test Guideline 209 |

### sodium chloride:

#### toxicity to fish

| LC50 (Lepomis macrochirus (Bluegill sunfish)): 5,840 mg/l |
| Exposure time: 96 h |

#### toxicity to daphnia and other aquatic invertebrates

| EC50 (Daphnia magna (Water flea)): 4,136 mg/l |
| Exposure time: 48 h |

#### toxicity to algae/aquatic plants

| EC50: > 2,000 mg/l |
| Exposure time: 96 h |

#### toxicity to microorganisms

| EC10: > 1,000 mg/l |

#### toxicity to fish (chronic toxicity)

| NOEC: 252 mg/l |
| Exposure time: 33 d |
| Species: Pimephales promelas (fathead minnow) |
**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**  
**NOEC:** 314 mg/l  
**Exposure time:** 21 d  
**Species:** Daphnia pulex (Water flea)

**Milbemycin Oxime:**

**Toxicity to fish**:  
**LC50** (Oncorhynchus mykiss (rainbow trout)): 0.16 µg/l  
**Exposure time:** 96 h

**Toxicity to daphnia and other aquatic invertebrates**:  
**EC50** (Daphnia magna (Water flea)): 0.03 µg/l  
**Exposure time:** 48 h

**Toxicity to algae/aquatic plants**:  
**EC50**: > 87 µg/l  
**Exposure time:** 72 h

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

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**:  
**NOEC:** 0.01 µg/l  
**Species:** Daphnia magna (Water flea)

**M-Factor (Chronic aquatic toxicity)**:  
10,000

**Persistence and degradability**
No data available

**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

**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
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
SAFETY DATA SHEET

Milbemycin Oxime / Lufenuron / Praziquantel
Formulation

Version 2.0  Revision Date: 11.03.2021  SDS Number: 7567911-00003  Date of last issue: 07.12.2020
Date of first issue: 20.11.2020

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

Transport in bulk according to IMO instruments
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

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

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

Date format: dd.mm.yyyy

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

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA
**SAFETY DATA SHEET**

**Milbemycin Oxime / Lufenuron / Praziquantel**

**Formulation**

<table>
<thead>
<tr>
<th>Version</th>
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<td>2.0</td>
<td>11.03.2021</td>
<td>7567911-00003</td>
<td>07.12.2020</td>
<td>20.11.2020</td>
</tr>
</tbody>
</table>

- International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, 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; 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.