SAFETY DATA SHEET
according to the Hazardous Products Regulations

Milbemycin Oxime / Lufenuron / Praziquantel
Formulation

Version 3.2  Revision Date: 09/30/2023  SDS Number: 7567906-00009  Date of last issue: 04/04/2023
Date of first issue: 11/20/2020

SECTION 1. IDENTIFICATION

Product name: Milbemycin Oxime / Lufenuron / Praziquantel Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A.  07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Skin sensitization: Category 1
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure (Oral): Category 1 (Central nervous system, Lungs, Liver, Stomach)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements:
H317 May cause an allergic skin reaction.
H360D May damage the unborn child.
H372 Causes damage to organs (Central nervous system, Lungs, Liver, Stomach) through prolonged or repeated exposure if swallowed.

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, vapors or spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

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

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

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

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>Sago starch</td>
<td>9005-25-8</td>
<td>31.94</td>
</tr>
<tr>
<td>Glycerine</td>
<td>1,2,3-Propanetriol</td>
<td>56-81-5</td>
<td>12</td>
</tr>
<tr>
<td>Lufenuron (ISO)</td>
<td>No data available</td>
<td>103055-07-8</td>
<td>7.67</td>
</tr>
<tr>
<td>Sucrose</td>
<td>.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl</td>
<td>57-50-1</td>
<td>5</td>
</tr>
<tr>
<td>Savorysel Bacon Flavor</td>
<td>No data available</td>
<td>Not Assigned</td>
<td>5</td>
</tr>
<tr>
<td>Praziquantel</td>
<td>4H-pyrazino-[2,1-a]-isoquinolin-4-one, 2-(cyclohexylcarbonyl)-1,2,3,6,7,11b-hexahydro-</td>
<td>55268-74-1</td>
<td>3.8</td>
</tr>
</tbody>
</table>
SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: May cause an allergic skin reaction. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure if swallowed. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

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

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during 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.
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Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: 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, vapors 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 labeled 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
- Self-reactive substances and mixtures
- Organic peroxides
- Explosives
- Gases

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (total dust)</td>
<td>10 mg/m³</td>
<td>CA QC 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>TWA (Mist)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable mist)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Mist)</td>
<td>10 mg/m³</td>
<td>CA QC 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>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV</td>
<td>10 mg/m³</td>
<td>CA QC 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)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
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<td></td>
</tr>
</tbody>
</table>

| Milbemycin Oxime | 129496-10-2 | TWA | 0.1 mg/m3 | Internal (OEB2) |

**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 vapor type

**Hand protection**: Chemical-resistant gloves

**Eye protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**: Work uniform or laboratory coat. 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: solid
### Milbemycin Oxime / Lufenuron / Praziquantel

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<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Color</strong></td>
<td>brown</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>characteristic</td>
</tr>
<tr>
<td><strong>Odor Threshold</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td><strong>Flammability (liquids)</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Lower explosion limit / Lower flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Vapor pressure</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Relative vapor density</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Solubility(ies)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Water solubility</strong></td>
<td>soluble</td>
</tr>
<tr>
<td><strong>Partition coefficient: n-octanol/water</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Autoignition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Viscosity, kinematic</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Explosive properties</strong></td>
<td>Not explosive</td>
</tr>
<tr>
<td><strong>Oxidizing properties</strong></td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
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Molecular weight : No data available
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

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

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 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: > 2,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

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):
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</tr>
</tbody>
</table>

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

Respiratory sensitization
Not classified based on available information.

Components:
Starch:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Lufenuron (ISO):
Test Type: Maximization Test
Species: Guinea pig
Assessment: May cause sensitization by skin contact.
Result: Sensitizer

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

Praziquantel:
Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Milbemycin Oxime:
Routes of exposure: 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)
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</tr>
</tbody>
</table>

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

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 fetal development: Test Type: Embryo-fetal 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 fetal 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-fetal toxicity: 8.3 mg/kg body weight  
Result: Fetal 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 fetal 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 fetal 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 fetal development:** Test Type: Embryo-fetal development  
  Species: Rat  
  Application Route: Ingestion  
  Result: negative
  
  Test Type: Embryo-fetal development  
  Species: Rabbit  
  Application Route: Ingestion  
  Result: negative
  
  Test Type: Embryo-fetal development  
  Species: Dog
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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
Causes damage to organs (Central nervous system, Lungs, Liver, Stomach) through prolonged or repeated exposure if swallowed.

Components:
Lufenuron (ISO):
Routes of exposure : 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:
Routes of exposure : 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
NOAEL : 8,000 - 10,000 mg/kg
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Application Route: Ingestion
Exposure time: 2 y
Species: Rabbit
NOAEL: 5,040 mg/kg
Application Route: Skin contact
Exposure time: 45 Weeks

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 y
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 y
Target Organs: Central nervous system, Liver, Lungs
Symptoms: Convulsions, Fatality, Irregularities

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
LOAEL: 180 mg/kg
Application Route: Oral
Target Organs: Gastrointestinal tract
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.

**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, Diarrhea, 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

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

- 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
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**Milbemycin Oxime / Lufenuron / Praziquantel**

**Formulation**

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#### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

- **NOEC (Daphnia magna (Water flea)):** 8.38 µg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211
- **NOEC (Daphnia magna (Water flea)):** 90 µg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211
- **NOEC (Chironomus riparius (harlequin fly)):** 2 µg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

#### 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

#### 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

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

- **NOEC (Daphnia magna (Water flea)):** 0.01 µg/l

#### Persistence and degradability

**Components:**

**Glycerine:**

- **Biodegradability:** Result: Readily biodegradable.
  - Biodegradation: 92 %
  - Exposure time: 30 d
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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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues
: Do not dispose of waste into sewer.
  Dispose of in accordance with local regulations.

Contaminated packaging
: Empty containers should be taken to an approved waste handling site for recycling or disposal.
  If not otherwise specified: Dispose of as unused product.
SECTION 14. TRANSPORT INFORMATION

International Regulations

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

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.

Domestic regulation

TDG
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
ERG Code : 171
Marine pollutant : yes(Milbemycin Oxime, Lufenuron (ISO))
Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **CA AB OEL**: Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
- **CA BC OEL**: Canada. British Columbia OEL
- **CA QC OEL**: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
- **ACGIH / TWA**: 8-hour, time-weighted average
- **CA AB OEL / TWA**: 8-hour Occupational exposure limit
- **CA BC OEL / TWA**: 8-hour time weighted average
- **CA QC OEL / TWAEV**: Time-weighted average exposure value

Additional abbreviations:

- **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** - 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 Chemical Substances
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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


Revision Date: 09/30/2023
Date format: mm/dd/yyyy

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.

CA / Z8