SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Manufacturer or supplier's details

Company: MSD
Address: Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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

GHS label elements

Hazard pictograms:

Signal Word: Danger
Hazard Statements:
H317 May cause an allergic skin reaction.
H360D May damage the unborn child.
H373 May cause damage to organs (Central nervous system, Lungs, Liver, Stomach) through prolonged or repeated exposure if swallowed.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary Statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 30 -&lt; 50</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
<tr>
<td>Lufenuron (ISO)</td>
<td>103055-07-8</td>
<td>&gt;= 5 -&lt; 10</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>&gt;= 5 -&lt; 10</td>
</tr>
<tr>
<td>Savorysel Bacon Flavor</td>
<td>Not Assigned</td>
<td>&gt;= 5 -&lt; 10</td>
</tr>
<tr>
<td>Praziquantel</td>
<td>55268-74-1</td>
<td>&gt;= 2,5 -&lt; 5</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>&gt;= 1 -&lt; 5</td>
</tr>
<tr>
<td>Milbemycin Oxime</td>
<td>129496-10-2</td>
<td>&gt;= 0,25 -&lt; 1</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical
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.

SECTION 5. FIRE-FIGHTING 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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES
SAFETY DATA SHEET
Milbemycin Oxime / Lufenuron / Praziquantel
Formulation

Version 2.0  Revision Date: 11.03.2021  SDS Number: 7567881-00003  Date of last issue: 07.12.2020
Date of first issue: 20.11.2020

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 spills 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:
SAFETY DATA SHEET

Milbemycin Oxime / Lufenuron / Praziquantel
Formulation

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>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: A4 - Not classifiable as a human carcinogen, lung, Dermatitis</td>
<td></td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Irritation</td>
<td></td>
</tr>
<tr>
<td>Iufenuron (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>CMP (Mist)</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: A4 - Not classifiable as a human carcinogen, lung</td>
<td></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 vapor type

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the 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
Color: brown
Odor: characteristic
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
SAFETY DATA SHEET

Milbemycin Oxime / Lufenuron / Praziquantel
Formulation

Version 2.0  Revision Date: 11.03.2021  SDS Number: 7567881-00003  Date of last issue: 07.12.2020
Date of first issue: 20.11.2020

Vapor pressure : Not applicable
Relative vapor density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies)
   Water solubility : soluble
Partition coefficient: n-octanol/water : Not applicable
Autoignition 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

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: > 5.000 mg/kg
  - Method: Calculation method

**Acute dermal toxicity**
- Acute toxicity estimate: > 5.000 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):**
- **Acute oral toxicity**: LD50 (Rat): > 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
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
- **Acute inhalation toxicity**: LC50 (Rat): 1.200 mg/m³
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
- **Acute dermal toxicity**: LD50 (Rat): > 2.000 mg/kg

Skin corrosion/irritation
- Not classified based on available information.

**Components:**

**Glycerine:**
- **Species**: Rabbit
- **Result**: No skin irritation

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

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

**Praziquantel:**
- **Species**: Rabbit
- **Method**: Draize Test
- **Remarks**: Slight irritation

**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

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

Sodium chloride:  
Species: Rabbit  
Result: No eye irritation

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:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Lufenuron (ISO):
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Assessment</td>
<td>May cause sensitization by skin contact.</td>
</tr>
<tr>
<td>Result</td>
<td>Sensitizer</td>
</tr>
</tbody>
</table>

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

Praziquantel:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

Sodium chloride:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</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:
<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>Skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

| Genotoxicity in vitro | Test Type: Bacterial reverse mutation assay (AMES)
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td>Test Type</td>
<td>Result</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>negative</td>
</tr>
<tr>
<td>DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</td>
<td>negative</td>
</tr>
</tbody>
</table>

**lufenuron (ISO):**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ames test</td>
<td>negative</td>
</tr>
<tr>
<td></td>
<td>Mouse Lymphoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test system: Chinese hamster cells</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cytogenetic assay</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test system: Chinese hamster ovary cells</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test system: rat hepatocytes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cytogenetic assay</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test system: Human lymphocytes</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unscheduled DNA synthesis test (UDS) in testicular cells</td>
<td>negative</td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**Sucrose:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

**Savorysel Bacon Flavor:**

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

Genotoxicity in vivo: Remarks: Not classified due to lack of data.

**Praziquantel:**
### 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>7567881-00003</td>
<td>07.12.2020</td>
<td>20.11.2020</td>
</tr>
</tbody>
</table>

| **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:

| **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

Sodium chloride:
- Species: Rat
- Application Route: Ingestion
- Exposure time: 2 Years
- Result: negative

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

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
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):

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**: \( \geq 2.000 \text{ mg/kg} \)  
- **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  
  - **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
# SAFETY DATA SHEET

## Milbemycin Oxime / Lufenuron / Praziquantel Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>SDS Number: 7567881-00003</th>
<th>Date of last issue: 07.12.2020</th>
<th>Date of first issue: 20.11.2020</th>
</tr>
</thead>
</table>

### 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

### Savorysel Bacon Flavor:

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

### Praziquantel:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>1.000 mg/kg</td>
<td>Oral</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>60 mg/kg</td>
<td>180 mg/kg</td>
<td>Oral</td>
<td>Gastrointestinal tract</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

### Sodium chloride:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>2.533 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Milbemycin Oxime:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</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>15 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Liver disorders, Blood disorders</td>
</tr>
</tbody>
</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>Dog</td>
<td>8.6 mg/kg</td>
<td>Ingestion</td>
<td>3 Days</td>
<td>Tremors</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, 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

M-Factor (Acute aquatic toxicity): 10.000

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

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

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

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:
EC50 (Daphnia magna (Water flea)): 35 mg/l
aquatic invertebrates  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 fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 252 mg/l  Exposure time: 33 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia pulex (Water flea)): 314 mg/l  Exposure time: 21 d
Toxicity to microorganisms: EC10: > 1.000 mg/l

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 (Daphnia magna (Water flea)): 0,01 µg/l
M-Factor (Chronic aquatic toxicity): 10.000

Persistence and degradability

Components:

Glycerine:

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

Components:

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

Lufenuron (ISO):
- Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
  - Bioconcentration factor (BCF): 28
  - Method: OECD Test Guideline 305
- Partition coefficient: n-octanol/water: log Pow: 5.12

Sucrose:
- Partition coefficient: n-octanol/water: log 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: 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

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

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Milbemycin Oxime, lufenuron (ISO))
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

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

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents : Not applicable Registry.
Control of precursors and essential chemicals for the preparation of drugs.

International Regulations

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

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

SECTION 16. OTHER INFORMATION

Further information

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

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 other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- AR OEL: Argentina. Occupational Exposure Limits
- ACGIH / TWA: 8-hour, time-weighted average
- AR OEL / CMP: TLV (Threshold Limit Value)

ABBREVIATIONS:
- AICL - 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 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 Substanc-
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.