SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
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 in accordance with ABNT NBR 14725 Standard
Flammable liquids : Category 2
Acute toxicity (Oral) : Category 5
Acute toxicity (Inhalation) : Category 5
Acute toxicity (Dermal) : Category 5
Eye irritation : Category 2A
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 2 (Central nervous system)
Aspiration hazard : Category 2
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1
SAFETY DATA SHEET
Fluralaner / Moxidectin Liquid Formulation

Version: 8.1  Revision Date: 21.04.2021  SDS Number: 656874-00013  Date of last issue: 15.10.2020
Date of first issue: 02.05.2016

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms:
- Flammable
- Toxicity
- Health hazard
- Environmental hazard

Signal Word: Danger

Hazard Statements:
- H225 Highly flammable liquid and vapor.
- H303 + H313 + H333 May be harmful if swallowed, in contact with skin or if inhaled.
- H305 May be harmful if swallowed and enters airways.
- H319 Causes serious eye irritation.
- H360D May damage the unborn child.
- H373 May cause damage to organs (Central nervous system) through prolonged or repeated exposure.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements:

Prevention:
- P201 Obtain special instructions before use.
- P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
- P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
- P391 Collect spillage.

Other hazards which do not result in classification
Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>Flammable liquids, Acute toxicity (Oral), Category 4 Acute toxicity (Inhalation), Category 4 Acute toxicity (Dermal), Category 4 Eye irritation, Category 2A Reproductive toxicity, Category 1B</td>
<td>&gt;= 30 -&lt; 50</td>
</tr>
<tr>
<td>Substance</td>
<td>CAS Number</td>
<td>Hazard Category and Description</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
</tbody>
</table>
| Fluralaner                             | 864731-61-3| Reproductive toxicity, Category 2  
Long-term (chronic) aquatic hazard, Category 1 |
| Poly(oxy-1,2-ethanediyl), α-          | 31692-85-0| Eye irritation, Category 2A  
>= 25 < 30 |
| [(tetrahydro-2-furanyl)methyl]-        |            |                                                                                                 |
| ω-hydroxy-                             |            |                                                                                                 |
| N,N-Diethyl-m-toluamide                | 134-62-3   | Acute toxicity (Oral), Category 4  
Acute toxicity (Inhalation), Category 5  
Acute toxicity (Dermal), Category 5  
Eye irritation, Category 2A  
Short-term (acute) aquatic hazard, Category 3  
>= 10 < 20 |
| Acetone                                | 67-64-1    | Flammable liquids, Category 2  
Eye irritation, Category 2A  
Specific target organ toxicity - single exposure, Category 3  
Aspiration hazard, Category 2  
>= 10 < 20 |
| Moxidectin                             | 113507-06-5| Acute toxicity (Oral), Category 3  
Acute toxicity (Inhalation), Category 4  
Acute toxicity (Dermal), Category 5  
Eye irritation, Category 2B  
Reproductive toxicity, Category 2  
Specific target organ toxicity - repeated exposure (Central nervous system), Category 1  
Short-term (acute) aquatic hazard, Category 1  
Long-term (chronic) aquatic hazard, Category 1  
>= 1 < 2,5 |
| 2,6-Di-tert-butyl-p-cresol            | 128-37-0   | Short-term (acute) aquatic hazard,  
>= 0,1 < 0,25 |
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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: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control center immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: May be harmful if swallowed, in contact with skin or if inhaled. May be harmful if swallowed and enters airways. Causes serious eye irritation. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

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: High volume water jet

Specific hazards during fire fighting: Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Hazardous combustion products:
- Carbon oxides
- Chlorine compounds
- Fluorine compounds
- Nitrogen oxides (NOx)

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

Personal precautions, protective equipment and emergency procedures:
- Remove all sources of ignition.
- Ventilate the area.
- 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.
- Prevent spreading over a wide area (e.g., by containment or oil barriers).
- 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:
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapors/mists with a water spray jet.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- 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:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe mist or vapors.
- Do not swallow.
- Do not get in 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.
- Non-sparking tools should be used.
- Keep container tightly closed.
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- 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.

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.
- 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.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store locked up.
- Keep tightly closed.
- Keep in a cool, well-ventilated place.
- Store in accordance with the particular national regulations.
- Keep away from heat and sources of ignition.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Flammable solids
  - Pyrophoric liquids
  - Pyrophoric solids
  - Self-heating substances and mixtures
  - Substances and mixtures which in contact with water emit flammable gases
  - Explosives
  - Gases

### 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>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>LT</td>
<td>8 ppm</td>
<td>BR OEL</td>
</tr>
</tbody>
</table>

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Further information: Absorption through the skin, Degree of harmfulness: maximum

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>Urine</td>
<td>End of workday at end of work-week</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>LT</td>
<td>Urine</td>
<td>780 ppm 1.870 mg/m³</td>
<td></td>
<td>Internal</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>TWA</td>
<td>Urine</td>
<td>10 µg/m³ (OEB 3)</td>
<td></td>
<td>Internal</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>TWA (Inhalable fraction and vapor)</td>
<td></td>
<td>2 mg/m³</td>
<td></td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

**Engineering measures**: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

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.
Use explosion-proof electrical, ventilating and lighting equipment.

**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**
- Self-contained breathing apparatus

**Hand protection**
- Chemical-resistant gloves

**Remarks**: Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

**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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: liquid

**Color**: Colorless to pale yellow

**Odor**: No data available

**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**: 2 °C
  - Method: closed cup

**Evaporation rate**: No data available

**Flammability (solid, gas)**: Not applicable
SAFETY DATA SHEET

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Flammability (liquids): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: No data available
Relative vapor density: No data available
Relative density: 1.06
Density: 1.08 g/cm³
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity
  Viscosity, kinematic: 7.5 mm²/s
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Particle size: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions
  Highly flammable liquid and vapor.
  Vapors may form explosive mixture with air.
  Can react with strong oxidizing agents.
Conditions to avoid: Heat, flames and sparks.
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
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid 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>
</table>

**Acute toxicity**

May be harmful if swallowed, in contact with skin or if inhaled.

**Product:**

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>3.548 mg/kg</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>5.3 mg/l</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>2.827 mg/kg</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity Estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 4.800 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): 2.2 mg/l</td>
<td></td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): 1.100 mg/kg</td>
<td>Expert judgment</td>
</tr>
</tbody>
</table>

Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity Estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 2.000 mg/kg</td>
<td>No mortality observed at this dose. No significant adverse effects were reported</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2.000 mg/kg</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity Estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poly(oxy-1,2-ethanediyl, α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-</td>
<td>LD50 (Rat, female): &gt; 2.000 mg/kg</td>
<td>OECD Test Guideline 423</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity Estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 1.950 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): 5.95 mg/l</td>
<td></td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): 5.000 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity Estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Acute oral toxicity: LD50 (Rat): 5.800 mg/kg

Acute inhalation toxicity: LC50 (Rat): 76 mg/l
  Exposure time: 4 h
  Test atmosphere: vapor

Acute dermal toxicity: LD50 (Rabbit): 7.426 mg/kg

**Moxidectin:**

Acute oral toxicity: LD50 (Rat): 106 mg/kg
  LD50 (Mouse): 42 - 84 mg/kg

Acute inhalation toxicity: LC50 (Rat): 3,28 mg/l
  Exposure time: 5 h
  Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
  Remarks: No significant adverse effects were reported

Acute toxicity (other routes of administration): LD50 (Rat): 394 mg/kg
  Application Route: Intraperitoneal

  LD50 (Mouse): 84 mg/kg
  Application Route: Intraperitoneal

  LD50 (Rat): > 640 mg/kg
  Application Route: Subcutaneous

  LD50 (Mouse): 263 mg/kg
  Application Route: Subcutaneous

2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity: LD50 (Rat): > 6.000 mg/kg
  Method: OECD Test Guideline 401

Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
  Method: OECD Test Guideline 402
  Assessment: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**N,N-Dimethylacetamide:**

Species: Rabbit

Result: No skin irritation
**Fluralaner / Moxidectin Liquid Formulation**

**Version**: 8.1  
**Revision Date**: 21.04.2021  
**SDS Number**: 656874-00013  
**Date of last issue**: 15.10.2020  
**Date of first issue**: 02.05.2016

<table>
<thead>
<tr>
<th><strong>Fluralaner</strong></th>
</tr>
</thead>
</table>
| **Species** | Rabbit  
| **Result** | No skin irritation |

<table>
<thead>
<tr>
<th><strong>Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-</strong></th>
</tr>
</thead>
</table>
| **Species** | reconstructed human epidermis (RhE)  
| **Method** | OECD Test Guideline 439  
| **Remarks** | Based on data from similar materials |

| **Result** | No skin irritation |

<table>
<thead>
<tr>
<th><strong>N,N-Diethyl-m-toluamide</strong></th>
</tr>
</thead>
</table>
| **Species** | Rabbit  
| **Result** | No skin irritation |

<table>
<thead>
<tr>
<th><strong>Acetone</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assessment</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Moxidectin</strong></th>
</tr>
</thead>
</table>
| **Species** | Rabbit  
| **Result** | Mild skin irritation |

<table>
<thead>
<tr>
<th><strong>2,6-Di-tert-butyl-p-cresol</strong></th>
</tr>
</thead>
</table>
| **Species** | Rabbit  
| **Method** | OECD Test Guideline 404  
| **Result** | No skin irritation  
| **Remarks** | Based on data from similar materials |

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:**

<table>
<thead>
<tr>
<th><strong>N,N-Dimethylacetamide</strong></th>
</tr>
</thead>
</table>
| **Species** | Rabbit  
| **Result** | Irritation to eyes, reversing within 21 days |

<table>
<thead>
<tr>
<th><strong>Fluralaner</strong></th>
</tr>
</thead>
</table>
| **Species** | Rabbit  
| **Result** | Mild eye irritation |

<table>
<thead>
<tr>
<th><strong>Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-</strong></th>
</tr>
</thead>
</table>
| **Species** | Tissue Culture  
| **Method** | OECD Test Guideline 492  
| **Remarks** | Based on data from similar materials |

| **Species** | Bovine cornea  
| **Method** | OECD Test Guideline 437  
| **Remarks** | Based on data from similar materials |
Result : Irritation to eyes, reversing within 21 days

N,N-Diethyl-m-toluamide:
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Remarks : Based on harmonised classification in EU regulation 1272/2008, Annex VI

Acetone:
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

Moxidectin:
Species : Rabbit
Result : Moderate eye irritation

2,6-Di-tert-butyl-p-cresol:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

N,N-Dimethylacetamide:
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

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

Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-:
Test Type : KeratinoSens assay
Method : OECD Test Guideline 442D
Result : negative
Remarks : Based on data from similar materials
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Remarks:

Direct Peptide Reactivity Assay (DPRA):
OECD Test Guideline 442C: positive
Remarks: Based on data from similar materials

Dendritic cell activation test:
OECD Test Guideline 442E: negative
Remarks: Based on data from similar materials

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

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

2,6-Di-tert-butyl-p-cresol:
Test Type: Human repeat insult patch test (HRIPT)
Routes of exposure: Skin contact
Species: Humans
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

N,N-Dimethylacetamide:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Rat
Application Route: Inhalation
Method: OECD Test Guideline 478
Result: negative

Fluralaner:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Result: negative
Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Poly(oxy-1,2-ethanediyl), α-[tetrahydro-2-furanyl)methyl]-ω-hydroxy-:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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

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
Application Route: Ingestion
Result: negative

Moxidectin:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Result: negative

Test Type: in vitro test
Test system: Escherichia coli
Result: negative

Genotoxicity in vivo:
Test Type: Chromosomal aberration
Species: Rat
Cell type: Bone marrow
Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
### 2,6-Di-tert-butyl-p-cresol:

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

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

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

### Carcinogenicity

Not classified based on available information.

### Components:

#### N,N-Dimethylacetamide:

- **Species**: Rat
- **Application Route**: Inhalation (vapor)
- **Exposure time**: 18 month(s)
- **Result**: negative

#### Fluralaner:

- **Carcinogenicity - Assessment**: No data available

#### N,N-Diethyl-m-toluamide:

- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 104 weeks
- **Result**: negative

#### Acetone:

- **Species**: Mouse
- **Application Route**: Skin contact
- **Exposure time**: 424 days
- **Result**: negative

#### Moxidectin:

- **Species**: Mouse
- **Application Route**: Oral
- **Exposure time**: 2 Years
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>4,5 mg/kg body weight</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>2 Years</td>
<td>4,5 mg/kg body weight</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>Oral</td>
<td>1 Years</td>
<td>0,5 mg/kg body weight</td>
<td>negative</td>
</tr>
</tbody>
</table>

2,6-Di-tert-butyl-p-cresol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>22 Months</td>
<td>negative</td>
</tr>
</tbody>
</table>

Reproductive toxicity
May damage the unborn child.

Components:

N,N-Dimethylacetamide:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: One-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Application Route: Inhalation</td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Application Route: Inhalation</td>
</tr>
<tr>
<td>Result: positive</td>
<td></td>
</tr>
</tbody>
</table>

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

Fluralaner:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Two-generation study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>General Toxicity Parent: NOAEL: 50 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>General Toxicity F1: LOAEL: 100 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: No effects on fertility., Postimplantation loss., Adverse neonatal effects.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: One-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Dog</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Fertility: NOAEL: 75 mg/kg body weight</td>
</tr>
<tr>
<td>Test Type</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>Development</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>NOAEL: 10 mg/kg body weight</th>
<th>Result: Skeletal malformations., Visceral malformations. Remarks: Maternal toxicity observed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>NOAEL: 100 mg/kg body weight</td>
<td>Result: Skeletal malformations.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reproductive toxicity - Assessment</th>
<th>N,N-Diethyl-m-toluamide:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type</td>
<td>Species</td>
</tr>
<tr>
<td>-----------</td>
<td>---------</td>
</tr>
<tr>
<td>Development</td>
<td>Rat</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>NOAEL: 100 mg/kg body weight</th>
<th>Result: no effects on fertility., Some evidence of adverse effects on development, based on animal experiments.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL: 0,8 mg/kg body weight</td>
<td>General Toxicity F1: LOAEL: 0,8 mg/kg body weight</td>
<td>Reduced fetal weight., Fetal mortality.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>NOAEL: 100 mg/kg body weight</th>
<th>Result: no effects on fertility., Some evidence of adverse effects on development, based on animal experiments.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL: 0,8 mg/kg body weight</td>
<td>General Toxicity F1: LOAEL: 0,8 mg/kg body weight</td>
<td>Reduced fetal weight., Fetal mortality.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>NOAEL: 100 mg/kg body weight</th>
<th>Result: no effects on fertility., Some evidence of adverse effects on development, based on animal experiments.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL: 0,8 mg/kg body weight</td>
<td>General Toxicity F1: LOAEL: 0,8 mg/kg body weight</td>
<td>Reduced fetal weight., Fetal mortality.</td>
</tr>
</tbody>
</table>
Test Type: Three-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
General Toxicity F1: LOAEL: 0.8 mg/kg body weight  
Symptoms: Reduced fetal weight, Fetal mortality.  
Result: No effects on fertility, Some evidence of adverse effects on development, based on animal experiments.

Effects on fetal development:  
Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
General Toxicity Maternal: LOAEL: 10 mg/kg body weight  
Embryo-fetal toxicity: LOAEL: 10 mg/kg body weight  
Result: Skeletal malformations.  
Remarks: The effects were seen only at maternally toxic doses.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
General Toxicity Maternal: LOAEL: 5 mg/kg body weight  
Developmental Toxicity: NOAEL: 10 mg/kg body weight  
Result: No teratogenic effects, No embryotoxic effects.

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

2,6-Di-tert-butyl-p-cresol:  
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

STOT-single exposure  
Not classified based on available information.

Components:  
Acetone:  
Assessment: May cause drowsiness or dizziness.

STOT-repeated exposure  
May cause damage to organs (Central nervous system) through prolonged or repeated exposure.

Components:  
Moxidectin:  
Target Organs: Central nervous system  
Assessment: Causes damage to organs through prolonged or repeated exposure
2,6-Di-tert-butyl-p-cresol:
Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

N,N-Dimethylacetamide:
Species: Rat
NOAEL: 90 mg/m³
LOAEL: 360 mg/m³
Application Route: Inhalation (vapor)
Exposure time: 24 Months

Fluralaner:
Species: Dog
NOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 52 Weeks
Target Organs: Liver
Remarks: No significant adverse effects were reported

Species: Juvenile dog
LOAEL: 56 - 280 mg/kg
Application Route: Oral
Exposure time: 24 Weeks
Symptoms: Diarrhea

Species: Rat
LOAEL: 400 mg/kg
Application Route: Oral
Exposure time: 90 Days
Target Organs: Liver, thymus gland

Species: Rat
NOAEL: 500 mg/kg
Application Route: Dermal
Exposure time: 90 Days
Target Organs: Liver
Remarks: No significant adverse effects were reported

Acetone:
Species: Rat
NOAEL: 900 mg/kg
LOAEL: 1.700 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Species: Rat
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version: 8.1
Revision Date: 21.04.2021
SDS Number: 656874-00013
Date of last issue: 15.10.2020
Date of first issue: 02.05.2016

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOAEL</strong></td>
<td>45 mg/l</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>inhalation (vapor)</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>8 Weeks</td>
</tr>
</tbody>
</table>

**Moxidectin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOAEL</strong></td>
<td>3,9 mg/kg</td>
</tr>
<tr>
<td><strong>LOAEL</strong></td>
<td>15,4 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>4 Weeks</td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
<td>Tremors</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOAEL</strong></td>
<td>3,9 mg/kg</td>
</tr>
<tr>
<td><strong>LOAEL</strong></td>
<td>7,9 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>13 Weeks</td>
</tr>
<tr>
<td><strong>Target Organs</strong></td>
<td>Central nervous system</td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
<td>Tremors, Salivation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOAEL</strong></td>
<td>0,3 mg/kg</td>
</tr>
<tr>
<td><strong>LOAEL</strong></td>
<td>0,9 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>90 Days</td>
</tr>
<tr>
<td><strong>Target Organs</strong></td>
<td>Central nervous system</td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
<td>Tremors, Lachrymation, Salivation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOAEL</strong></td>
<td>0,3 mg/kg</td>
</tr>
<tr>
<td><strong>LOAEL</strong></td>
<td>0,87 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>52 Weeks</td>
</tr>
<tr>
<td><strong>Target Organs</strong></td>
<td>Central nervous system</td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
<td>Tremors, Lachrymation</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2,6-Di-tert-butyl-p-cresol:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Species</strong></td>
<td>Rat</td>
</tr>
<tr>
<td><strong>NOAEL</strong></td>
<td>25 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Ingestion</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>22 Months</td>
</tr>
</tbody>
</table>

**Aspiration toxicity**

May be harmful if swallowed and enters airways.

**Components:**

**Fluralaner:**
Not applicable
Acetone:
The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

Experience with human exposure

Components:

**Fluralaner:**
- **Skin contact**: Remarks: May irritate skin.
- **Eye contact**: Remarks: May cause eye irritation.

**Moxidectin:**
- **Inhalation**: Remarks: No human information is available.
- **Skin contact**: Remarks: No human information is available.
- **Eye contact**: Remarks: No human information is available.
- **Ingestion**: Remarks: No human information is available.

SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

Components:

**N,N-Dimethylacetamide:**
- **Toxicity to fish**: LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 500 mg/l
  Exposure time: 48 h
- **Toxicity to algae/aquatic plants**: EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
  Exposure time: 72 h
  EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l
  Exposure time: 72 h
- **Toxicity to microorganisms**: EC10: > 1.995 mg/l
  Exposure time: 30 min

**Fluralaner:**
- **Toxicity to fish**: LC50 (Oncorhynchus mykiss (rainbow trout)): > 0,0488 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203
  Remarks: No toxicity at the limit of solubility.
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 0,015 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202
  Remarks: No toxicity at the limit of solubility.
- **Toxicity to algae/aquatic plants**: NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0,08 mg/l
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity):  
NOEC (Zebrafish): >= 0.049 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 204  
Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):  
NOEC (Daphnia magna (Water flea)): 0,000047 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity):  
1.000

**Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-:**

Toxicity to daphnia and other aquatic invertebrates:  
EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:  
EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

**N,N-Diethyl-m-toluamide:**

Toxicity to fish:  
LC50 (Oncorhynchus mykiss (rainbow trout)): 97 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:  
EC50 (Daphnia magna (Water flea)): 75 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants:  
ErC50 (Selenastrum capricornutum (green algae)): 41 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Selenastrum capricornutum (green algae)): 7,6 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):  
NOEC (Daphnia magna (Water flea)): 3,7 mg/l  
Exposure time: 21 d

**Acetone:**
### Fluralaner / Moxidectin Liquid 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>
</table>

**Toxicity to fish**
- LC50 (Oncorhynchus mykiss (rainbow trout)): 5.540 mg/l  
  Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Daphnia pulex (Water flea)): 8.800 mg/l  
  Exposure time: 48 h

**Toxicity to algae/aquatic plants**
- NOEC (Pseudokirchneriella subcapitata (green algae)): 7.000 mg/l  
  Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- NOEC (Daphnia magna (Water flea)): >= 79 mg/l  
  Exposure time: 21 d  
  Method: OECD Test Guideline 211

**Toxicity to microorganisms**
- EC50: 61.150 mg/l  
  Exposure time: 30 min  
  Method: ISO 8192

**Moxidectin:**

**Toxicity to fish**
- LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,0006 mg/l  
  Exposure time: 96 h  
  Method: OECD Test Guideline 203

- LC50 (Oncorhynchus mykiss (rainbow trout)): 0,0002 mg/l  
  Exposure time: 96 h  
  Method: OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Daphnia magna (Water flea)): 0,00003 mg/l  
  Exposure time: 48 h  
  Method: OECD Test Guideline 202

**Toxicity to algae/aquatic plants**
- EC50 (Pseudokirchneriella subcapitata (green algae)): 0,087 mg/l  
  Exposure time: 96 h  
  Method: OECD Test Guideline 201

**M-Factor (Acute aquatic toxicity)**
- 10.000

**M-Factor (Chronic aquatic toxicity)**
- 10.000

**2,6-Di-tert-butyl-p-cresol:**

**Toxicity to fish**
- LC50 (Danio rerio (zebra fish)): > 0,57 mg/l  
  Exposure time: 96 h  

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Daphnia magna (Water flea)): 0,48 mg/l  
  Exposure time: 48 h  
  Method: OECD Test Guideline 202

**Toxicity to algae/aquatic plants**
- ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0,24 mg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 0,24 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 1  
Toxicity to fish (Chronic toxicity): NOEC (Oryzias latipes (Japanese medaka)): 0,053 mg/l  
Exposure time: 30 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0,316 mg/l  
Exposure time: 21 d  
M-Factor (Chronic aquatic toxicity): 1  
Toxicity to microorganisms: EC50: > 10.000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

Persistence and degradability

Components:

N,N-Dimethylacetamide:  
Biodegradability: Result: Not readily biodegradable.  
Biodegradation: 70 %  
Exposure time: 28 d  
Remarks: The 10 day time window criterion is not fulfilled.

Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanylmethyl]-ω-hydroxy-:  
Biodegradability: Result: Not readily biodegradable.  
Method: OECD Test Guideline 301F  
Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:  
Biodegradability: Result: Readily biodegradable.  
Biodegradation: 83,8 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

Acetone:  
Biodegradability: Result: Readily biodegradable.  
Biodegradation: 91 %  
Exposure time: 28 d

2,6-Di-tert-butyl-p-cresol:  
Biodegradability: Result: Not readily biodegradable.  
Biodegradation: 4,5 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C
Bioaccumulative potential

Components:

Fluralaner:
- Bioaccumulation: Species: Zebrafish
  Bioconcentration factor (BCF): 79.4
  Method: OECD Test Guideline 305
- Partition coefficient: n-octanol/water: log Pow: 4.5

Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-:
- Partition coefficient: n-octanol/water: log Pow: < 4
  Remarks: Calculation

N,N-Diethyl-m-toluamide:
- Partition coefficient: n-octanol/water: log Pow: 2.02

Acetone:
- Partition coefficient: n-octanol/water: log Pow: -0.27 - -0.23

Moxidectin:
- Partition coefficient: n-octanol/water: log Pow: 4.7

2,6-Di-tert-butyl-p-cresol:
- Bioaccumulation: Species: Cyprinus carpio (Carp)
  Bioconcentration factor (BCF): 330 - 1.800
- Partition coefficient: n-octanol/water: log Pow: 5.1

Mobility in soil

Components:

Fluralaner:
- Distribution among environmental compartments: log Koc: 3.4

Other adverse effects

Components:

Fluralaner:
- Results of PBT and vPvB assessment: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

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. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 1090
Proper shipping name : ACETONE SOLUTION
Class : 3
Packing group : II
Labels : 3

IATA-DGR
UN/ID No. : UN 1090
Proper shipping name : Acetone solution
Class : 3
Packing group : II
Labels : Flammable Liquids
Packing instruction (cargo aircraft) : 364
Packing instruction (passenger aircraft) : 353

IMDG-Code
UN number : UN 1090
Proper shipping name : ACETONE SOLUTION (Fluralaner, Moxidectin)
Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
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

ANTT
UN number : UN 1090
Proper shipping name : ACETONE, SOLUTION
Class : 3
Packing group : II
Labels : 3
Hazard Identification Number : 33

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
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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
National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

Brazil. List of chemicals controlled by the Federal Police: Not applicable

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

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
BR BEI: Brazil. NR7. Parameters for Biological Control of Occupational Exposure to Some Chemical Agents
BR OEL: Brazil. NR 15 - Unhealthy activities and operations
ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
BR OEL / LT: Up to 48 hours /week

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 Chemi-
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**Fluralaner / Moxidectin Liquid Formulation**

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<tr>
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<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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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.

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