SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version: 6.1
Revision Date: 08/27/2021
SDS Number: 656875-00013
Date of last issue: 04/21/2021
Date of first issue: 05/02/2016

SECTION 1. IDENTIFICATION

Product name: Fluralaner / Moxidectin Liquid Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
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
Flammable liquids: Category 2
Eye irritation: Category 2A
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Central nervous system)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements:
H225 Highly flammable liquid and vapor.
H319 Causes serious eye irritation.
H360D May damage the unborn child.
H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

Precautionary Statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 Do not breathe mist or vapors.
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P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical attention.
P337 + P313 IF eye irritation persists: Get medical attention.

Storage:
P405 Store locked up.

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

Other hazards
Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

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

<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>N,N-Dimethylacetamide</td>
<td>Acetamide, N,N-dimethyl-</td>
<td>127-19-5</td>
<td>&gt;= 30 - &lt; 60 *</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>No data available</td>
<td>864731-61-3</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl), α-[tetrahydro-2-furanyl]methyl]-ω-hydroxy-</td>
<td>Reaction products of tetrahydrofurfuryl alcohol with ethylene oxide</td>
<td>31692-85-0</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>Benzamide, N,N-diethyl-3-methyl-</td>
<td>134-62-3</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Acetone</td>
<td>2-Propanone</td>
<td>67-64-1</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>No data available</td>
<td>113507-06-5</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

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: Causes serious eye irritation. May damage the unborn child. Causes 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 firefighting: 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.

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.

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

### 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>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>TWA</td>
<td>10 ppm 36 mg/m³ CA AB OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm CA BC OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm CA QC OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV</td>
<td>10 ppm 36 mg/m³ CA ACGIH</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm ACGIH</td>
<td></td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEL 2) Internal</td>
<td></td>
</tr>
</tbody>
</table>

Further information:
- **Skin**
  - Wipe limit: 1000 µg/100 cm² Internal

<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>Acetone</td>
<td>67-64-1</td>
<td>TWA</td>
<td>500 ppm 1,200 mg/m³ CA AB OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>750 ppm 1,800 mg/m³ CA AB OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>250 ppm CA BC OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>500 ppm CA BC OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV</td>
<td>500 ppm 1,190 mg/m³ CA QC OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV</td>
<td>1,000 ppm 2,380 mg/m³ CA QC OEL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>250 ppm ACGIH</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>500 ppm ACGIH</td>
<td></td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>TWA</td>
<td>10 µg/m³ (OEL 3) Internal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm² Internal</td>
<td></td>
</tr>
</tbody>
</table>
Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</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>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>N-Methylaceta mide</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>30 mg/g Creatinine</td>
<td>ACGIH BEI</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>Acetone</td>
<td>Urine</td>
<td>End of shift (As soon as possible after exposure ceases)</td>
<td>25 mg/l</td>
<td>ACGIH BEI</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., sleevelts, 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. 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Colorless to pale yellow</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>2 °C</td>
</tr>
<tr>
<td>Method: closed cup</td>
<td></td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>1.06</td>
</tr>
<tr>
<td>Density</td>
<td>1.08 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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**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>
<tbody>
<tr>
<td>6.1</td>
<td>08/27/2021</td>
<td>656875-00013</td>
<td>04/21/2021</td>
<td>05/02/2016</td>
</tr>
</tbody>
</table>

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

Acute toxicity
Not classified based on available information.

Product:

Acute oral toxicity: Acute toxicity estimate: 3,548 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: 5.3 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: 2,827 mg/kg
Method: Calculation method
## Components:

### N,N-Dimethylacetamide:
- **Acute oral toxicity**: LD50 (Rat): 4,800 mg/kg
- **Acute inhalation toxicity**: LC50 (Rat): 2.2 mg/l  
  Exposure time: 4 h  
  Test atmosphere: dust/mist
- **Acute dermal toxicity**: Acute toxicity estimate: 1,100 mg/kg  
  Method: Expert judgment  
  Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

### Fluralaner:
- **Acute oral toxicity**: LD50 (Rat): > 2,000 mg/kg  
  Remarks: No mortality observed at this dose.  
  No significant adverse effects were reported
- **Acute dermal toxicity**: LD50 (Rat): > 2,000 mg/kg  
  Remarks: No significant adverse effects were reported

### Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-:
- **Acute oral toxicity**: LD50 (Rat, female): > 2,000 mg/kg  
  Method: OECD Test Guideline 423  
  Remarks: Based on data from similar materials

### N,N-Diethyl-m-toluamide:
- **Acute oral toxicity**: LD50 (Rat): 1,950 mg/kg
- **Acute inhalation toxicity**: LC50 (Rat): 5.95 mg/l  
  Exposure time: 4 h  
  Test atmosphere: dust/mist
- **Acute dermal toxicity**: LD50 (Rat): 5,000 mg/kg

### Acetone:
- **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

LC50 (Rat): 2.87 - 4.06 mg/l
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

Skin corrosion/irritation
Not classified based on available information.

Components:

N,N-Dimethylacetamide:
Species: Rabbit
Result: No skin irritation

Fluralaner:
Species: Rabbit
Result: No skin irritation

Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-:
Species: reconstructed human epidermis (RhE)
Method: OECD Test Guideline 439
Remarks: Based on data from similar materials
Result: No skin irritation

N,N-Diethyl-m-toluamide:
Species: Rabbit
Result: No skin irritation

Acetone:
Assessment: Repeated exposure may cause skin dryness or cracking.

Moxidectin:
Species: Rabbit
Result: Mild skin irritation
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**Serious eye damage/eye irritation**
Causes serious eye irritation.

**Components:**

**N,N-Dimethylacetamide:**
Species: Rabbit  
Result: Irritation to eyes, reversing within 21 days

**Fluralaner:**
Species: Rabbit  
Result: Mild eye irritation

**Poly(oxy-1,2-ethanediyl), α-[tetrahydro-2-furanyl)methyl]-ω-hydroxy-:**
Species: Tissue Culture  
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  
Method: OECD Test Guideline 405

**Moxidectin:**
Species: Rabbit  
Result: Moderate eye irritation

**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

**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.

**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
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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
- 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  
Species: Rat  
Cell type: Liver cells  
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

\textbf{N,N-Dimethylacetamide:}
Species: Rat  
Application Route: Inhalation (vapor)  
Exposure time: 18 month(s)  
Result: negative

\textbf{Fluralaner:}
Carcinogenicity - Assessment: No data available

\textbf{N,N-Diethyl-m-toluamide:}
Species: Rat  
Application Route: Ingestion  
Exposure time: 104 weeks  
Result: negative

\textbf{Acetone:}
Species: Mouse  
Application Route: Skin contact  
Exposure time: 424 days  
Result: negative

\textbf{Moxidectin:}
Species: Mouse  
Application Route: Oral  
Exposure time: 2 Years  
NOAEL: 4.5 mg/kg body weight  
Result: negative
## SAFETY DATA SHEET

### Fluralaner / Moxidectin Liquid Formulation

**Version**: 6.1  
**Revision Date**: 08/27/2021  
**SDS Number**: 656875-00013  
**Date of last issue**: 04/21/2021  
**Date of first issue**: 05/02/2016

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>4.5 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Species**: Dog  
**Application Route**: Oral  
**Exposure time**: 1 Years  
**NOAEL**: 0.5 mg/kg body weight  
**Result**: negative

### Reproductive toxicity
May damage the unborn child.

### Components:

#### N,N-Dimethylacetamide:
- **Effects on fertility**: Test Type: One-generation reproduction toxicity study  
  Species: Rat  
  Application Route: Inhalation  
  Result: negative

- **Effects on fetal development**: Test Type: Embryo-fetal development  
  Species: Rat  
  Application Route: Inhalation  
  Result: positive

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

#### Fluralaner:
- **Effects on fertility**: Test Type: Two-generation study  
  Species: Rat  
  Application Route: Oral  
  General Toxicity Parent: NOAEL: 50 mg/kg body weight  
  General Toxicity F1: LOAEL: 100 mg/kg body weight  
  Result: No effects on fertility., Postimplantation loss., Adverse neonatal effects.

  Test Type: One-generation reproduction toxicity study  
  Species: Dog  
  Application Route: Oral  
  Fertility: NOAEL: 75 mg/kg body weight  
  Result: No effects on fertility and early embryonic development were detected.

  Remarks: No significant adverse effects were reported

- **Effects on fetal development**: Test Type: Development  
  Species: Rat  
  Application Route: Oral  
  Developmental Toxicity: NOAEL: 100 mg/kg body weight  
  Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses,
No teratogenic effects.

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: Skeletal malformations., Visceral malformations.
Remarks: Maternal toxicity observed.

Test Type: Development
Species: Rabbit
Application Route: Dermal
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Skeletal malformations.

Reproductive toxicity - Assessment: Suspected of damaging the unborn child.

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

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

**Acetone:**

Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: inhalation (vapor)
Result: negative

**Moxidectin:**

Effects on fertility: Test Type: Two-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.

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
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

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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.

**STOT-single exposure**
Not classified based on available information.

**Components:**

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

**STOT-repeated exposure**
Causes 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.

**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  
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  
NOAEL: 45 mg/l  
Application Route: inhalation (vapor)  
Exposure time: 8 Weeks

Moxidectin:
Species: Mouse  
NOAEL: 3.9 mg/kg  
LOAEL: 15.4 mg/kg  
Application Route: Oral  
Exposure time: 4 Weeks  
Symptoms: Tremors

Species: Rat  
NOAEL: 3.9 mg/kg  
LOAEL: 7.9 mg/kg  
Application Route: Oral  
Exposure time: 13 Weeks  
Target Organs: Central nervous system  
Symptoms: Tremors, Salivation

Species: Dog  
NOAEL: 0.3 mg/kg  
LOAEL: 0.9 mg/kg  
Application Route: Oral  
Exposure time: 90 Days  
Target Organs: Central nervous system
Symptoms: Tremors, Lachrymation, Salivation

Species: Dog

NOAEL: 0.3 mg/kg
LOAEL: 0.87 mg/kg

Application Route: Oral
Exposure time: 52 Weeks
Target Organs: Central nervous system
Symptoms: Tremors, Lachrymation

**Aspiration toxicity**
Not classified based on available information.

**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.

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**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
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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

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:
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: 72 h
Method: OECD Test Guideline 201
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-furanyl)methyl]-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

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
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: Flammable Liquids

**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

TDG
UN number: UN 1090
Proper shipping name: ACETONE SOLUTION
Class: 3
Packing group: II
Labels: 3
ERG Code: 127
Marine pollutant: yes (Fluralaner, Moxidectin)

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)
ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
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
ACGIH / STEL: Short-term exposure limit
CA AB OEL / TWA: 8-hour Occupational exposure limit
CA AB OEL / STEL: 15-minute occupational exposure limit
CA BC OEL / TWA: 8-hour time weighted average
CA BC OEL / STEL: short-term exposure limit
CA QC OEL / TWA: Time-weighted average exposure value
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