SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

SECTION 1. IDENTIFICATION

Product name : Fluralaner / Moxidectin Liquid Formulation

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

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

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, sparks, open flame and hot surfaces. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical, ventilating and lighting
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P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P260 Do not breathe mist or vapors.
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:
P403 + P235 Store in a well-ventilated place. Keep cool.
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

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>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-</td>
<td>31692-85-0</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration 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 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.

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.
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Emergency equipment and emergency procedures
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.
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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
  - Self-reactive substances and mixtures
  - 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
  - Very acutely toxic substances and mixtures

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</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm 35 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm 35 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

Acetone
- TWA 250 ppm  ACGIH
- STEL 500 ppm ACGIH
- TWA 250 ppm 590 mg/m³  NIOSH REL
- TWA 1,000 ppm 2,400 mg/m³  OSHA Z-1

Moxidectin 113507-06-5
- TWA 10 µg/m³ (OEB 3)  Internal
- Wipe limit 100 µg/100 cm²  Internal

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-Methylacetamide</td>
<td>Urine</td>
<td>End of shift at end of work-</td>
<td>30 mg/g Creatinine</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>
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| Acetone | 67-64-1 | Acetone Urine | End of shift (As soon as possible after exposure ceases) | 25 mg/l | ACGIH BEI |

**Engineering measures**: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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**: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**

**Material**: Chemical-resistant gloves

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

**Eye protection**

**Material**: 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. 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: 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: 36 °F / 2 °C
   Method: closed cup
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
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

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: 3,547 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 national or regional regulation.

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
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<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
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</thead>
<tbody>
<tr>
<td>7.6</td>
<td>04/04/2023</td>
<td>656890-00019</td>
<td>10/01/2022</td>
<td>05/02/2016</td>
</tr>
</tbody>
</table>

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
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  
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 national or regional regulation.

**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

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

Test Type: Dendritic cell activation test  
Method: OECD Test Guideline 442E  
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  
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:

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
NOAEL: 4.5 mg/kg body weight
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 2 Years
NOAEL: 4.5 mg/kg body weight
Result: negative
Species: Dog
Application Route: Oral
Exposure time: 1 Years
NOAEL: 0.5 mg/kg body weight
Result: negative

IARC Group 2B: Possibly carcinogenic to humans
N,N-Dimethylacetamide 127-19-5

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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
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
<table>
<thead>
<tr>
<th>Exposure time</th>
<th>52 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Species</td>
<td>Juvenile dog</td>
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<tr>
<td>LOAEL</td>
<td>56 - 280 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>24 Weeks</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Diarrhea</td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>LOAEL</td>
<td>400 mg/kg</td>
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<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver, thymus gland</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**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 |
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**Fluralaner / Moxidectin Liquid Formulation**

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<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 10/01/2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.6</td>
<td>04/04/2023</td>
<td>656890-00019</td>
<td>Date of first issue: 05/02/2016</td>
</tr>
</tbody>
</table>

**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.

**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:** EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
plants
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)): 0.0736 µg/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
- 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)): 75 mg/l
  Exposure time: 48 h
- EC50 (Daphnia pulex (Water flea)): 8,800 mg/l
  Exposure time: 48 h
- NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 211
- NOEC (Daphnia magna (Water flea)): >= 79 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211

Toxicity to algae/aquatic plants:
- EC50 (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
- NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l
  Exposure time: 96 h
- EC50 (Pseudokirchneriella subcapitata (green algae)): 0.087 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: 4.1

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.
Do not dispose of waste into sewer.
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
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UN number : UN 1090
Proper shipping name : ACETONE SOLUTION (Fluralaner, Moxidectin)
Class : 3
Packing group : II
Labels : 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
49 CFR
UN/ID/NA number : UN 1090
Proper shipping name : Acetone SOLUTION
Class : 3
Packing group : II
Labels : FLAMMABLE LIQUID
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

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>5000</td>
<td>33333</td>
</tr>
</tbody>
</table>

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Flammable (gases, aerosols, liquids, or solids)
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations
Pennsylvania Right To Know
N,N-Dimethylacetamide 127-19-5
Fluralaner / Moxidectin Liquid Formulation

California Prop. 65
WARNING: This product can expose you to chemicals including N,N-Dimethylacetamide, which is/are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
N,N-Dimethylacetamide 127-19-5
Acetone 67-64-1

California Permissible Exposure Limits for Chemical Contaminants
N,N-Dimethylacetamide 127-19-5
Acetone 67-64-1

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
NFPA 704:

Health 2
Flammability 3
Instability 0

HMIS® IV:

HEALTH * 3
FLAMMABILITY 3
PHYSICAL HAZARD 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
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<td></td>
</tr>
</tbody>
</table>

NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average

All chemical acronyms, abbreviations, and initialisms are defined and explained in detail in the "Summary of Symbols, Abbreviations, and Acronyms" section of this SDS.


Revision Date : 04/04/2023

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...
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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.

US / Z8