SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Section 1: Identification

Product name: Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier's details

Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
        Upper Hutt - New Zealand
Telephone: +1-908-740-4000
Emergency telephone number: +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: Hazard identification

GHS Classification

Flammable liquids: Category 2
Serious eye damage/eye irritation: Category 2A
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 2 (Central nervous system)

GHS label elements

Hazard pictograms:

Signal word: Danger

Hazard statements:

H225 Highly flammable liquid and vapour.
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.

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.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use non-sparking tools.
P243 Take action to prevent static discharges.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ 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 advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Storage:
P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

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

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

Section 3: Composition/information on ingredients

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

<table>
<thead>
<tr>
<th>Components</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; 60</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl),.alpha.-(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-</td>
<td>31692-85-0</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>&gt;= 10 -&lt; 30</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; 3</td>
</tr>
</tbody>
</table>

Section 4: First-aid measures

<table>
<thead>
<tr>
<th>General advice</th>
<th>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.</th>
</tr>
</thead>
</table>
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 centre 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.
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 firefighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours 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 firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Hazchem Code : 2YE
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/vapours/mists with a water spray jet.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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 vapours.
- 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 decontamination and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.


Materials to avoid: Do not store with the following product types: Self-reactive substances and mixtures Organic peroxides Oxidizing agents Flammable gases Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Poisonous gases Explosives

Section 8: Exposure controls/personal protection

Components 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>WES-TWA</td>
<td>10 ppm 36 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
<td>ACGIH</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></td>
<td></td>
</tr>
<tr>
<td>Further information: Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>WES-TWA</td>
<td>500 ppm 1,185 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: Exposure can also be estimated by biological monitoring</td>
<td></td>
<td></td>
<td>WES-STE</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1,000 ppm 2,375 mg/m³</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: Exposure can also be estimated by biological monitoring</td>
<td></td>
<td></td>
<td>TWA</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>250 ppm</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STEL 500 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</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-Methylacetamide</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</td>
<td>50 mg/l</td>
<td>NZ BEI</td>
</tr>
<tr>
<td></td>
<td></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., 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: 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
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>Colour</td>
<td>Colorless to pale yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour 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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour 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>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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 vapour.
  - Vapours 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

Exposure routes :
  - Inhalation
  - Skin contact
  - Ingestion
  - Eye contact

Acute toxicity
Not classified based on available information.

Product:

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

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 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 judgement
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), .alpha.-[tetrahydro-2-furanyl)methyl]-.omega.-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: vapour

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), .alpha.-(tetrahydro-2-furanyl)methyll-.omega.-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), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-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 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 sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

N,N-Dimethylacetamide:
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Fluralaner:
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.
**Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl].omega.-hydroxy-:**
- **Test Type**: KeratinoSens assay
- **Method**: OECD Test Guideline 442D
- **Result**: negative
- **Remarks**: Based on data from similar materials
  - 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**: Maximisation Test
- **Exposure routes**: Skin contact
- **Species**: Guinea pig
- **Result**: negative

**Moxidectin:**
- **Test Type**: Buehler Test
- **Exposure routes**: Dermal
- **Species**: Guinea pig
- **Result**: Not a skin sensitizer.

**Chronic toxicity**
**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
### Fluralaner / Moxidectin Liquid Formulation

- **Test Type:** Chromosomal aberration  
  Result: negative

**Genotoxicity in vivo**:  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Oral  
Result: negative

---

#### Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

- **Test Type:** Micronucleus test  
  Species: Mouse  
  Cell type: Bone marrow  
  Application Route: Oral  
  Result: negative

**Remarks:** Based on data from similar materials

---

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

- **Test Type:** Bacterial reverse mutation assay (AMES)  
  Method: OECD Test Guideline 471  
  Result: negative

**Genotoxicity in vitro**:  
Result: negative

---

#### Acetone:

- **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**:  
Species: Mouse  
Application Route: Ingestion  
Result: negative

---

#### Moxidectin:

- **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 assay  
  Test system: Escherichia coli  
  Result: negative

**Genotoxicity in vivo**:  
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 (vapour)
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
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 foetal development : Test Type: Embryo-foetal 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 foetal 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:

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

- **Effects on foetal development**:
  - Test Type: Embryo-foetal 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 foetal development**:
  - Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Inhalation (vapour)
  - 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 foetal weight, foetal 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 foetal weight, foetal mortality
  - Result: No effects on fertility, Some evidence of adverse effects on development, based on animal experiments.

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

  - Test Type: Embryo-foetal 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
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.

Repeated dose toxicity

Components:

N,N-Dimethylacetamide:
Species: Rat
NOAEL: 90 mg/m3
LOAEL: 360 mg/m3
Application Route: inhalation (vapour)
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: Diarrhoea

Species: Rat
LOAEL: 400 mg/kg
Application Route: Oral
Exposure time: 90 Days
**SAFETY DATA SHEET**

**Fluralaner / Moxidectin Liquid Formulation**

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Liver, thymus gland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>NOAEL</td>
<td>500 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Dermal</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Acetone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>900 mg/kg</td>
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<tr>
<td>LOAEL</td>
<td>1,700 mg/kg</td>
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<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>45 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (vapour)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>8 Weeks</td>
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</table>

**Moxidectin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>3.9 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>15.4 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>4 Weeks</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Tremors</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>3.9 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>7.9 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Tremors, Salivation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.3 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.9 mg/kg</td>
</tr>
<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>Central nervous system</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Tremors, Lachrymation, Salivation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.3 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.87 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>52 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Tremors, Lachrymation</td>
</tr>
</tbody>
</table>
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 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
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), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-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
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC (Daphnia magna (Water flea)): 3.7 mg/l
  Exposure time: 21 d

Acetone:

- 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)): 0.0003 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), .alpha.-[[(tetrahydro-2-furanylmethyl]-omega.-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
Biocoencentration factor (BCF): 79.4
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water: log Pow: 4.5

Poly(oxy-1,2-ethanediyl), .alpha.-[tetrahydro-2-furanyl)methyl]-.omega.-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
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Fluralaner / Moxidectin Liquid Formulation

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.
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National Regulations

NZS 5433
UN number : UN 1090
Proper shipping name : ACETONE SOLUTION
Class : 3
Packing group : II
Labels : 3
Hazchem Code : 2YE

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

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

Section 16: Other information

Further information

Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
NZ BEI : New Zealand. Biological Exposure Indices
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version      Revision Date:    SDS Number:    Date of last issue: 21.04.2021
5.1          27.08.2021        656888-00014   Date of first issue: 02.05.2016

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average
NZ OEL / WES- STEL : Workplace Exposure Standard - Short-Term Exposure Limit

All - 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; ICS0 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

NZ / EN