SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version 6.1 Revision Date: 2021/08/27 SDS Number: 656881-00014 Date of last issue: 2021/04/21
Date of first issue: 2016/05/02

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier’s details
Company : MSD
Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone : 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

2. HAZARDS 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)
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

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.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
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/ shower.
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.
P391 Collect spillage.

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.

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; 60</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 25 - &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>
</tbody>
</table>
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 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.

5. FIREFIGHTING 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.

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.

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.

Conditions for safe storage:
Keep in properly labelled 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:
- Self-reactive substances and mixtures
- Organic peroxides
- Oxidizing agents
- Flammable gases
- Pyrophoric liquids
- Pyrophoric solids
- Self-heating substances and mixtures
- Poisonous gases
- Explosives

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>NAB</td>
<td>10 ppm / 36 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals, Skin</td>
<td></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>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>NAB</td>
<td>250 ppm / 1,187.12 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>PSD</td>
<td>500 ppm / 1,780 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Not classified as carcinogenic to humans. Not</td>
<td></td>
</tr>
</tbody>
</table>
enough data to classify these materials as carcinogenic to humans or animals

<table>
<thead>
<tr>
<th>Component</th>
<th>TWA</th>
<th>STEL</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moxidectin</td>
<td>250 ppm</td>
<td>500 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>10 µg/m3 (OEB 3)</td>
<td>100 µg/100 cm²</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 (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 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.

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</td>
<td>closed cup</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>
</tbody>
</table>
Relative vapour 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
Auto-ignition 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

10. STABILITY AND REACTIVITY
Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions
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.

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: > 2,000 mg/kg
  Method: Calculation method
Acute inhalation toxicity
  Acute toxicity estimate: > 5 mg/l
  Exposure time: 4 h
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<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>2021/08/27</td>
<td>656881-00014</td>
<td>2021/04/21</td>
<td>2016/05/02</td>
</tr>
</tbody>
</table>

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

2,6-Di-tert-butyl-p-cresol:
Acute oral toxicity: LD50 (Rat): > 6,000 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation
Not classified based on available information.

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

Fluralaner:
Species: Rabbit
Result: No skin irritation

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

2,6-Di-tert-butyl-p-cresol:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

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
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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

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

Respiratory or skin 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

Remarks: Direct Peptide Reactivity Assay (DPRA)
Species: Guinea pig
Result: positive
Remarks: Based on data from similar materials

Remarks: Dendritic cell activation test
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials
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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.

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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 assay
    - 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

**2,6-Di-tert-butyl-p-cresol:**
- **Genotoxicity in vitro:**
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
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

2,6-Di-tert-butyl-p-cresol:
Species: Rat
Application Route: Ingestion
Exposure time: 22 Months
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.

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

Effects on fertility:

- Test Type: Two-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

Effects on foetal development:

- Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

STOT - single exposure

Not classified based on available information.

Components:

Acetone:

Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure

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

Components:

Moxidectin:

Target Organs: Central nervous system
Assessment: Causes damage to organs through prolonged or repeated exposure.

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

Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.
Repeated dose toxicity

Components:

N,N-Dimethylacetamide:
Species: Rat
NOAEL: 90 mg/m3
LOAEL: 360 mg/m3
Application Route: Inhalation (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
Target Organs: Liver, thymus gland

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

Acetone:
Species: Rat
NOAEL: 900 mg/kg
LOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Species: Rat
NOAEL: 45 mg/l
Application Route: Inhalation (vapour)
Exposure time: 8 Weeks

Moxidectin:
Species: Mouse
NOAEL: 3.9 mg/kg
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

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

2,6-Di-tert-butyl-p-cresol:
Species : Rat
NOAEL : 25 mg/kg
Application Route : Ingestion
Exposure time : 22 Months

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.

### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**N,N-Dimethylacetamide:**
- Toxicity to fish: EC50 (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: > 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: NOEC (Daphnia magna (Water flea)): 0.000047 mg/l
aquatic invertebrates (Chronic toxicity) Exposure time: 21 d
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 1,000

**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

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

Toxicity to fish: LC50 (Onkorhynchus 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: 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

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 (Onkorhynchus 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
**SAFETY DATA SHEET**

**Fluralaner / Moxidectin Liquid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
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<td>656881-00014</td>
<td>2021/04/21</td>
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- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**
  - NOEC (Daphnia magna (Water flea)): $\geq 79 \text{ mg/l}$
  - 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

- **M-Factor (Acute aquatic toxicity):**
  - 10,000

- **M-Factor (Chronic aquatic toxicity):**
  - 10,000

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

- **Toxicity to fish:**
  - LC50 (Danio rerio (zebra fish)): $> 0.57 \text{ mg/l}$
    - Exposure time: 96 h

- **Toxicity to daphnia and other aquatic invertebrates:**
  - EC50 (Daphnia magna (Water flea)): 0.48 mg/l
    - Exposure time: 48 h
    - Method: OECD Test Guideline 202

- **Toxicity to algae/aquatic plants:**
  - ErC50 (Pseudokirchneriella subcapitata (green algae)): $> 0.24 \text{ mg/l}$
    - Exposure time: 72 h
    - Method: OECD Test Guideline 201

  - NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l
    - Exposure time: 72 h
    - Method: OECD Test Guideline 201

- **M-Factor (Acute aquatic toxicity):**
  - 1

- **Toxicity to fish (Chronic toxicity):**
  - NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l
    - Exposure time: 30 d
    - Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): 0.316 mg/l
- Exposure time: 21 d

M-Factor (Chronic aquatic toxicity):
- 1

Toxicity to microorganisms:
- EC50: > 10,000 mg/l
- Exposure time: 3 h
- Method: OECD Test Guideline 209

Persistence and degradability

Components:

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

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

2,6-Di-tert-butyl-p-cresol:
- Biodegradability: Result: Not readily biodegradable.
  - Biodegradation: 4.5 %
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301C

Bioaccumulative potential

Components:

Fluralaner:
- Bioaccumulation: Species: Zebrafish
  - Bioconcentration factor (BCF): 79.4
  - Method: OECD Test Guideline 305
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Partition coefficient: n-octanol/water

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl].omega.-hydroxy-:
Partition coefficient: n-octanol/water

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

Acetone:
Partition coefficient: n-octanol/water

Moxidectin:
Partition coefficient: n-octanol/water

2,6-Di-tert-butyl-p-cresol:
Bioaccumulation:
Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 330 - 1,800

Mobility in soil

Components:

Fluralaner:
Distribution among environmental compartments

Other adverse effects

Components:

Fluralaner:
Results of PBT and vPvB assessment

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues
Contaminated packaging

Dispose of in accordance with local regulations.
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.
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.

**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.

15. REGULATORY INFORMATION

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

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**
Hazardous substances that must be registered : Not applicable
Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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

16. OTHER INFORMATION

Further information
Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
ID OEL : Indonesia. Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
ID OEL / NAB : Long term exposure limit
ID OEL / PSD : Short term exposure limit

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International
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.