SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version: 5.1  Revision Date: 27.08.2021  SDS Number: 656889-00014  Date of last issue: 21.04.2021
Date of first issue: 02.05.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier's details
Company: MSD
Address: 50 Tuas West Drive
         Singapore - Singapore 638408
Telephone: +1-908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
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 2
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.
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

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; 50</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;= 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>
</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>PEL (long term)</td>
<td>10 ppm 36 mg/m³</td>
<td>SG 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>1000 µg/100 cm²</td>
<td>Internal</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>PEL (long term)</td>
<td>750 ppm 1.780 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (short term)</td>
<td>1,000 ppm 2,380 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>250 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>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>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhal-)</td>
<td>2 mg/m³</td>
<td>ACGIH</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-Methyla-cetamide</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

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

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, dis-
posable 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: 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>
</tbody>
</table>
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
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.

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
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 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)
Remarks: OECD Test Guideline 442C
Remarks: positive
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

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), alpha-[(tetrahydro-2-furanyl)methyl]-omega-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 Year
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.
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)
<table>
<thead>
<tr>
<th></th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td>Dog</td>
<td>1 mg/kg</td>
<td>Oral</td>
<td>52 Weeks</td>
<td>Liver</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td></td>
<td>Juvenile dog</td>
<td>56 - 280 mg/kg</td>
<td>Oral</td>
<td>24 Weeks</td>
<td>Liver, thymus gland</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>400 mg/kg</td>
<td>Oral</td>
<td>90 Days</td>
<td>Liver, thymus gland</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>500 mg/kg</td>
<td>Dermal</td>
<td>90 Days</td>
<td>Liver</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Acetone</td>
<td>Rat</td>
<td>900 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>1,700 mg/kg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moxidectin</td>
<td>Mouse</td>
<td>3.9 mg/kg</td>
<td>Oral</td>
<td>4 Weeks</td>
<td>Tremors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>3.9 mg/kg</td>
<td>Oral</td>
<td>4 Weeks</td>
<td>Tremors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>7.9 mg/kg</td>
<td>Oral</td>
<td></td>
<td>Tremors</td>
<td></td>
</tr>
</tbody>
</table>
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: LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
   Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 500 mg/l
   Exposure time: 48 h
Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
   Exposure time: 72 h
   EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l
   Exposure time: 72 h
Toxicity to microorganisms: EC10: > 1,995 mg/l
   Exposure time: 30 min

Fluralaner:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.0488 mg/l
   Exposure time: 96 h
   Method: OECD Test Guideline 203
   Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 0.015 mg/l
   Exposure time: 48 h
   Method: OECD Test Guideline 202
   Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l
   Exposure time: 72 h
   Method: OECD Test Guideline 201
   Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity): NOEC (Zebrafish): >= 0.049 mg/l
   Exposure time: 21 d
   Method: OECD Test Guideline 204
   Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.000047 mg/l
   Exposure time: 21 d
   Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity): 1,000
Poly(oxy-1,2-ethanediyl), alpha-[(tetrahydro-2-furanyl)methyl]-omega-hydroxy-:
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
<table>
<thead>
<tr>
<th>Aquatic Invertebrates</th>
<th>Exposure time: 48 h</th>
<th>Method: OECD Test Guideline 202</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to Algae/Aquatic Plants</strong></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l</td>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>EC10 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l</td>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td><strong>N,N-Diethyl-m-toluamide:</strong></td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): 97 mg/l</td>
<td>Exposure time: 96 h</td>
<td>Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td><strong>Toxicity to Fish</strong></td>
<td>EC50 (Daphnia magna (Water flea)): 75 mg/l</td>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to Daphnia and Other Aquatic Invertebrates</strong></td>
<td>ErC50 (Selenastrum capricornutum (green algae)): 41 mg/l</td>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td><strong>Toxicity to Algae/Aquatic Plants</strong></td>
<td>NOEC (Selenastrum capricornutum (green algae)): 7.6 mg/l</td>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td><strong>Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)</strong></td>
<td>NOEC (Daphnia magna (Water flea)): 3.7 mg/l</td>
<td>Exposure time: 21 d</td>
<td></td>
</tr>
<tr>
<td><strong>Acetone:</strong></td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg/l</td>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to Fish</strong></td>
<td>EC50 (Daphnia pulex (Water flea)): 8,800 mg/l</td>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to Daphnia and Other Aquatic Invertebrates</strong></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l</td>
<td>Exposure time: 96 h</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to Algae/Aquatic Plants</strong></td>
<td>NOEC (Daphnia magna (Water flea)): &gt;= 79 mg/l</td>
<td>Exposure time: 21 d</td>
<td>Method: OECD Test Guideline 211</td>
</tr>
<tr>
<td><strong>Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)</strong></td>
<td>EC50: 61,150 mg/l</td>
<td>Exposure time: 30 min</td>
<td>Method: ISO 8192</td>
</tr>
</tbody>
</table>
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 mg/l
Exposure time: 96 h

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

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1
Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l
Exposure time: 30 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.316 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 201

M-Factor (Chronic aquatic toxicity) : 1
Toxicity to microorganisms : EC50: > 10,000 mg/l
Exposure time: 3 h
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

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

**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

This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

### 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.

### 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
UN number: UN 1090
Proper shipping name: ACETONE SOLUTION
Class: 3
Packing group: II
15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations: Acetone

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**

Sources of key data used to compile the Safety Data Sheet:

**Full text of other abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>ACGIH / STEL</td>
<td>Short-term exposure limit</td>
</tr>
<tr>
<td>SG OEL / PEL (long term)</td>
<td>Permissible Exposure Level (PEL) Long Term</td>
</tr>
<tr>
<td>SG OEL / PEL (short term)</td>
<td>Permissible Exposure Level (PEL) Short Term</td>
</tr>
</tbody>
</table>

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 mate-
rial 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 ap-
propriateness of the SDS material in the user’s end product, if applicable.

SG / EN