SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Very highly flammable liquids

GHS Classification
Flammable liquids : Category 2
Acute toxicity (Oral) : Category 5
Acute toxicity (Inhalation) : Category 5
Acute toxicity (Dermal) : Category 5
Skin corrosion/irritation : Category 2
Serious eye damage/eye irritation : Category 2A
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 2 (Central nervous system)
Aspiration hazard : Category 2
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. 
H303 + H313 + H333 May be harmful if swallowed, in contact with skin or if inhaled. 
H305 May be harmful if swallowed and enters airways. 
H315 Causes skin irritation. 
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, hot surfaces, sparks, open flames and other ignition sources. No smoking. 
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:
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor. 
P302 + P352 + P312 IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/doctor if you feel unwell. 
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. 
P304 + P312 IF INHALED: Call a POISON CENTER/ doctor if you feel unwell. 
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. 
P331 Do NOT induce vomiting. 
P332 + P313 If skin irritation occurs: Get medical advice/ attention. 
P337 + P313 If eye irritation persists: Get medical advice/ attention. 
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

**Storage:**
P405 Store locked up.

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

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 20 %

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

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>N,N-Dimethylacetamide</td>
</tr>
<tr>
<td></td>
<td>Fluralaner</td>
</tr>
<tr>
<td></td>
<td>Acetone</td>
</tr>
<tr>
<td></td>
<td>N,N-Diethyl-m-toluamide</td>
</tr>
<tr>
<td></td>
<td>Moxidectin</td>
</tr>
<tr>
<td></td>
<td>2,6-Di-tert-butyl-p-cresol</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 plenty of water for at least 15 minutes while removing 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:**
May be harmful if swallowed, in contact with skin or if inhaled.
Hand effects, both acute and delayed

May be harmful if swallowed and enters airways.
Causes skin irritation.
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 and personal protective equipment recommendations.

Environmental precautions:
Discharge into the environment must be avoided.
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

<table>
<thead>
<tr>
<th>Technical measures</th>
<th>See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local/Total ventilation</td>
<td>If sufficient ventilation is unavailable, use with local exhaust ventilation.</td>
</tr>
<tr>
<td></td>
<td>If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust ventilation.</td>
</tr>
<tr>
<td>Advice on safe handling</td>
<td>Do not get on skin or clothing.</td>
</tr>
<tr>
<td></td>
<td>Do not breathe vapours or spray mist.</td>
</tr>
<tr>
<td></td>
<td>Do not swallow.</td>
</tr>
<tr>
<td></td>
<td>Do not get in eyes.</td>
</tr>
<tr>
<td></td>
<td>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment</td>
</tr>
<tr>
<td></td>
<td>Non-sparking tools should be used.</td>
</tr>
<tr>
<td></td>
<td>Keep container tightly closed.</td>
</tr>
<tr>
<td></td>
<td>Keep away from heat and sources of ignition.</td>
</tr>
<tr>
<td></td>
<td>Take precautionary measures against static discharges.</td>
</tr>
<tr>
<td></td>
<td>Take care to prevent spills, waste and minimize release to the environment.</td>
</tr>
<tr>
<td>Conditions for safe storage</td>
<td>Keep in properly labelled containers.</td>
</tr>
<tr>
<td></td>
<td>Store locked up.</td>
</tr>
<tr>
<td></td>
<td>Keep tightly closed.</td>
</tr>
<tr>
<td></td>
<td>Keep in a cool, well-ventilated place.</td>
</tr>
<tr>
<td></td>
<td>Store in accordance with the particular national regulations.</td>
</tr>
<tr>
<td></td>
<td>Keep away from heat and sources of ignition.</td>
</tr>
<tr>
<td>Materials to avoid</td>
<td>Do not store with the following product types:</td>
</tr>
<tr>
<td></td>
<td>Self-reactive substances and mixtures</td>
</tr>
<tr>
<td></td>
<td>Organic peroxides</td>
</tr>
<tr>
<td></td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td></td>
<td>Flammable gases</td>
</tr>
<tr>
<td></td>
<td>Pyrophoric liquids</td>
</tr>
<tr>
<td></td>
<td>Pyrophoric solids</td>
</tr>
<tr>
<td></td>
<td>Self-heating substances and mixtures</td>
</tr>
<tr>
<td></td>
<td>Poisonous gases</td>
</tr>
<tr>
<td></td>
<td>Explosives</td>
</tr>
</tbody>
</table>
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>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>Acetone</td>
<td>67-64-1</td>
<td>TWA</td>
<td>750 ppm</td>
<td>ACGLH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGLH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2,375 mg/m³</td>
<td>IN OEL</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>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>TWA (Inhalable fraction and vapor)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information: Skin

<table>
<thead>
<tr>
<th>Components</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Wipe limit</td>
<td>1000 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 workweek</td>
<td>30 mg/g Creatinine</td>
<td>ACGIH BEI</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>Acetone</td>
<td>Urine</td>
<td>End of shift (As soon as possible after exposure ceases)</td>
<td>25 mg/l</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.
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, 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

Appearance: liquid

Colour: clear

Odour: No data available

Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: 2 °C
Method: closed cup

Evaporation rate: No data available
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Flammability (solid, gas) : Not applicable
Flammability (liquids) : Not applicable
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : 1.06
Density : No data available
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 : No data available
 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 : Inhalation
exposure
Skin contact
Ingestion
Eye contact

**Acute toxicity**
May be harmful if swallowed, in contact with skin or if inhaled.

**Product:**

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

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

- **Acute dermal toxicity**
  - Acute toxicity estimate: 2,827 mg/kg
  - Method: Calculation method

**Components:**

**N,N-Dimethylacetamide:**

- **Acute oral toxicity**
  - LD50 (Rat): 4,800 mg/kg

- **Acute inhalation toxicity**
  - LC50 (Rat): 2.2 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist

- **Acute dermal toxicity**
  - Acute toxicity estimate: 1,100 mg/kg
  - Method: Expert 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

**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

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

- **Acute oral toxicity**
  - LD50 (Rat): 1,950 mg/kg
<table>
<thead>
<tr>
<th>Component</th>
<th>Acute oral toxicity</th>
<th>Acute dermal toxicity</th>
<th>Acute inhalation toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fluralaner</strong></td>
<td>LD50 (Rat): 106 mg/kg</td>
<td></td>
<td>LC50 (Rat): 5.95 mg/l</td>
</tr>
<tr>
<td><strong>Moxidectin</strong></td>
<td>LD50 (Mouse): 42 - 84 mg/kg</td>
<td></td>
<td>LC50 (Rat): 3.28 mg/l</td>
</tr>
<tr>
<td><strong>2,6-Di-tert-butyl-p-cresol</strong></td>
<td>LD50 (Rat): &gt; 6,000 mg/kg</td>
<td></td>
<td>LC50 (Rat): 2.87 - 4.06 mg/l</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**

Causes skin irritation.

**Components:**

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

- **Fluralaner:**
  - LC50 (Rat): 5.95 mg/l
    - Exposure time: 4 h
    - Test atmosphere: dust/mist
  - LD50 (Rat): 5,000 mg/kg

- **Moxidectin:**
  - LD50 (Rat): 106 mg/kg
  - LD50 (Mouse): 42 - 84 mg/kg
  - 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
  - LD50 (Rat): > 2,000 mg/kg
    - Remarks: No significant adverse effects were reported
  - LD50 (Rat): > 640 mg/kg
    - Application Route: Intraperitoneal
  - LD50 (Mouse): 263 mg/kg
    - Application Route: Subcutaneous

- **2,6-Di-tert-butyl-p-cresol:**
  - LD50 (Rat): > 6,000 mg/kg
    - Method: OECD Test Guideline 401
  - LD50 (Rat): > 2,000 mg/kg
    - Method: OECD Test Guideline 402
    - Assessment: The substance or mixture has no acute dermal toxicity
### Species: Rabbit

<table>
<thead>
<tr>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

### Acetone:

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

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

**Species:** Rabbit

<table>
<thead>
<tr>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin irritation</td>
</tr>
</tbody>
</table>

### Moxidectin:

**Species:** Rabbit

<table>
<thead>
<tr>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild skin irritation</td>
</tr>
</tbody>
</table>

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

**Species:** Rabbit

<table>
<thead>
<tr>
<th>Method</th>
<th>OECD Test Guideline 404</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Serious eye damage/eye irritation

Causes serious eye irritation.

### Components:

### N,N-Dimethylacetamide:

**Species:** Rabbit

<table>
<thead>
<tr>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
</tbody>
</table>

### Fluralaner:

**Species:** Rabbit

<table>
<thead>
<tr>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

### Acetone:

**Species:** Rabbit

<table>
<thead>
<tr>
<th>Method</th>
<th>OECD Test Guideline 405</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
</tbody>
</table>

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

**Species:** Rabbit

<table>
<thead>
<tr>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
</tbody>
</table>

### Moxidectin:

**Species:** Rabbit

<table>
<thead>
<tr>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate eye irritation</td>
</tr>
</tbody>
</table>

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

None of the components listed cause serious eye damage/eye irritation.
Species: Rabbit
Method: OECD Test Guideline 405
Result: No eye irritation
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.

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

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

N,N-Diethyl-m-toluamide:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
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

Acetone:

- Species: Mouse  
- Application Route: Skin contact  
- Exposure time: 424 days  
- Result: negative
N,N-Diethyl-m-toluamide:
Species: Rat
Application Route: Ingestion
Exposure time: 104 weeks
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: Suspected of damaging the unborn child.

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: Ingestion (vapour)
Result: negative

N,N-Diethyl-m-toluamide:
Effects on foetal development:
Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Fluralaner / Moxidectin Liquid Formulation

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.
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

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
<table>
<thead>
<tr>
<th>Exposure time</th>
<th>90 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Acetone:**

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

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

**Moxidectin:**

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

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

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

| Species | Dog |
| NOAEL   | 0.3 mg/kg |
| LOAEL   | 0.87 mg/kg |
| Application Route | Oral |
| Exposure time | 52 Weeks |
| Target Organs | Central nervous system |
| Symptoms | Tremors, Lachrymation |

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

| Species | Rat |
| NOAEL   | 25 mg/kg |
| Application Route | Ingestion |
| Exposure time | 22 Months |
Aspiration toxicity
May be harmful if swallowed and enters airways.

Components:
Fluralaner:
Not applicable

Acetone:
The substance or mixture causes concern owing to the assumption that it causes a human asp-iration 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 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
SAFETY DATA SHEET
Fluralaner / Moxidectin Liquid Formulation

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: >= 0.049 mg/l
Exposure time: 21 d
Species: Zebrafish
Method: OECD Test Guideline 204
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: 0.000047 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

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

Acetone:

Toxicity to fish:
LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia pulex (Water flea)): 8,800 mg/l
Exposure time: 48 h

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

Toxicity to microorganisms:
EC50: 61,150 mg/l
Exposure time: 30 min
Method: ISO 8192

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: >= 79 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

N,N-Diethyl-m-toluamide:

Toxicity to fish:
LC50 (Pimephales promelas (fathead minnow)): 110 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 75 mg/l
Exposure time: 48 h
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 microorganisms**
- EC50: > 10,000 mg/l
  - Exposure time: 3 h
  - Method: OECD Test Guideline 209

**Toxicity to fish (Chronic toxicity)**
- NOEC: 0.053 mg/l
  - Exposure time: 30 d
  - Species: Oryzias latipes (Japanese medaka)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC: 0.316 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity):

1

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.

Acetone:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 91 %
Exposure time: 28 d

N,N-Diethyl-m-toluamide:

Biodegradability: Result: Not readily biodegradable.

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

Acetone:

Partition coefficient: n-octanol/water: log Pow: -0.27 - -0.23

N,N-Diethyl-m-toluamide:

Partition coefficient: n-octanol/water: log Pow: 2.02
Fluralaner / Moxidectin Liquid Formulation

Moxidectin:
Partition coefficient: n-octanol/water: \( \log \text{Pow} \): 4.7

2,6-Di-tert-butyl-p-cresol:
Bioaccumulation: Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 330 - 1,800
Partition coefficient: n-octanol/water: \( \log \text{Pow} \): 5.1

Mobility in soil

Components:

Fluralaner:
Distribution among environmental compartments: \( \log \text{Koc} \): 3.4

Other adverse effects

Components:

Fluralaner:
Results of PBT and vPvB assessment: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

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
Labels: 3
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

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
(Moxidectin, 2,6-Di-tert-butyl-p-cresol)
Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : yes

Transport in bulk according to IMO instruments
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

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 : dd.mm.yyyy

Full text of other abbreviations
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.

IN / EN