SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340
Telephone : 908-740-4000
Emergency telephone : 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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Flammable liquids : Category 2
Acute toxicity (Oral) : Category 5
Acute toxicity (Inhalation) : Category 5
Acute toxicity (Dermal) : Category 5
Skin irritation : Category 2
Eye irritation : Category 2A
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Central nervous system)
Aspiration hazard : Category 2
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version: 5.1  Revision Date: 13.09.2019  SDS Number: 656874-00010  Date of last issue: 18.10.2018  Date of first issue: 02.05.2016

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms:
- Flammable liquid and vapor
- High risk of serious eye damage
- High risk of skin irritation
- May cause cancer

Signal Word: Danger

Hazard Statements:
- H225 Highly flammable liquid and vapor.
- 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.
- H372 Causes 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.
- P210 Keep away from heat/sparks/open flames/hot surfaces.
- No smoking.
- 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.
- P391 Collect spillage.

Additional Labeling

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

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>Flammable liquids, Category 4 Acute toxicity (Oral), Category 5 Acute toxicity (Inhalation), Category 4 Acute toxicity (Dermal), Category 4 Eye irritation,</td>
<td>&gt;= 30 &lt;= 50</td>
</tr>
<tr>
<td>Compound</td>
<td>SDS Number</td>
<td>Classification Details</td>
<td>Classification</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------</td>
<td>-----------------------------------------------------------------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>Reproductive toxicity, Category 2B, Long-term (chronic) aquatic hazard, Category 1</td>
<td>Category 2A</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>Acute toxicity (Oral), Category 4, Acute toxicity (Inhalation), Category 5, Acute toxicity (Dermal), Category 5, Skin irritation, Category 2, Eye irritation, Category 2A, Short-term (acute) aquatic hazard, Category 3, Long-term (chronic) aquatic hazard, Category 3</td>
<td>Category 2A</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>Flammable liquids, Category 2, Eye irritation, Category 2A, Specific target organ toxicity - single exposure, Category 3, Aspiration hazard, Category 2</td>
<td>Category 2A</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>Acute toxicity (Oral), Category 3, Acute toxicity (Inhalation), Category 4, Acute toxicity (Dermal), Category 5, Eye irritation, Category 2B, Reproductive toxicity, Category 2, Specific target organ toxicity - repeated exposure (Central nervous system), Category 1, Short-term (acute) aquatic hazard, Category 1</td>
<td>Category 2B</td>
</tr>
</tbody>
</table>
SECTION 4. FIRST AID MEASURES

General advice:  In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled:  If inhaled, remove to fresh air. Get medical attention.

In case of skin contact:  In case of contact, immediately flush skin with 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 center immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed:  May be harmful if swallowed, in contact with skin or if inhaled. May be harmful if swallowed and enters airways. Causes skin irritation. Causes serious eye irritation. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders:  First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician:  Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:  Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical
Unsuitable extinguishing media: High volume water jet
Specific hazards during fire fighting:
- Do not use a solid water stream as it may scatter and spread fire.
- Flash back possible over considerable distance.
- Vapors may form explosive mixtures with air.
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Chlorine compounds
- Fluorine compounds
- Nitrogen oxides (NOx)

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for fire-fighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Remove all sources of ignition.
- 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/vapors/mists with a water spray jet.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
SECTION 7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.
- If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe vapors or spray mist.
- Do not swallow.
- Do not get in eyes.
- 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 and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store locked up.
- Keep tightly closed.
- Keep in a cool, well-ventilated place.
- Store in accordance with the particular national regulations.
- Keep away from heat and sources of ignition.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Flammable solids
  - Pyrophoric liquids
  - Pyrophoric solids
  - Self-heating substances and mixtures
  - Substances and mixtures which in contact with water emit flammable gases
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters
SAFETY DATA SHEET
Fluralaner / Moxidectin Liquid Formulation

Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
---|---|---|---|---|
N,N-Dimethylacetamide | 127-19-5 | LT | 8 ppm, 28 mg/m³ | BR OEL |
Further information: Absorption through the skin, Degree of harmfulness: maximum
TWA | 10 ppm | ACGIH |
Fluralaner | 864731-61-3 | TWA | 100 µg/m³ (OEB 2) | Internal |
Further information: Skin
Wipe limit | 1000 µg/100 cm² | Internal |
Acetone | 67-64-1 | LT | 780 ppm, 1.870 mg/m³ | BR OEL |
Further information: Degree of harmfulness: minimum
TWA | 250 ppm | ACGIH |
STEL | 500 ppm | ACGIH |
Moxidectin | 113507-06-5 | TWA | 10 µg/m³ (OEB 3) | Internal |
Wipe limit | 100 µg/100 cm² | Internal |
2,6-Di-tert-butyl-p-cresol | 128-37-0 | TWA (Inhalable fraction and vapor) | 2 mg/m³ | ACGIH |

Biological occupational exposure limits

| Components | CAS-No. | Control parameters | Biological specimen | Sampling time | Permissible concentration | Basis |
---|---|---|---|---|---|---|
N,N-Dimethylacetamide | 127-19-5 | N-Methylacetamide | Urine | End of shift at end of work-week | 30 mg/g Creatinine | ACGIH BEI |
Acetone | 67-64-1 | Acetone | Urine | End of shift (As soon as possible after exposure ceases) | 25 mg/l | ACGIH BEI |

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

Fluralaner / Moxidectin Liquid Formulation

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Color: clear

Odor: No data available

Odor Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: 2 °C

Method: closed cup

Evaporation rate: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): Not applicable

Upper explosion limit / Upper flammability limit: No data available
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: No data available

Relative vapor density: No data available

Relative density: 1.06

Density: No data available

Solubility(ies)
  Water solubility: No data available

Partition coefficient: n-octanol/water: Not applicable

Autoignition temperature: No data available

Decomposition temperature: No data available

Viscosity
  Viscosity, kinematic: No data available

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Particle size: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

Possibility of hazardous reactions:
  Highly flammable liquid and vapor.
  Vapors may form explosive mixture with air.
  Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
  Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
  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

<table>
<thead>
<tr>
<th>Component</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Acute dermal toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N,N-Dimethylacetamide</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 4.800 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): 2.2 mg/l</td>
<td>Exposure time: 4 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>Acute toxicity estimate: 1.100 mg/kg Method: Expert judgment Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **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 |

| **N,N-Diethyl-m-toluamide**|                     |                           |                       |
| Acute oral toxicity        | LD50 (Rat): 1.950 mg/kg |                           |                       |
| Acute inhalation toxicity  | LC50 (Rat): 5.95 mg/l  | Exposure time: 4 h        |                       |
|                            | Test atmosphere: dust/mist |                       |                       |
| Acute dermal toxicity      | LD50 (Rat): 5.000 mg/kg |                           |                       |

| **Acetone**                |                     |                           |                       |
| Acute oral toxicity        | LD50 (Rat): 5.800 mg/kg |                           |                       |
| Acute inhalation toxicity  | LC50 (Rat): 76 mg/l   | Exposure time: 4 h        |                       |
|                            | Test atmosphere: vapor |                       |                       |
| Acute dermal toxicity      | LD50 (Rabbit): 7.426 mg/kg |                           |                       |

| **Moxidectin**             |                     |                           |                       |
Acute oral toxicity: LD50 (Rat): 106 mg/kg

LD50 (Mouse): 42 - 84 mg/kg

Acute inhalation toxicity: LC50 (Rat): 3.28 mg/l
Exposure time: 5 h
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
Causes skin irritation.

Components:

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

Fluralaner:
Species: Rabbit
Result: No skin irritation

N,N-Diethyl-m-toluamide:
Species: Rabbit
Result: Skin irritation
Acetone:
 tentative
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

N,N-Diethyl-m-toluamide:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

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 sensitization

Skin sensitization

Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Components:

N,N-Dimethylacetamide:

<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
</tr>
</tbody>
</table>

Fluralaner:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximization Test</td>
<td>Dermal</td>
<td>Guinea pig</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

Acetone:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximization Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
</tr>
</tbody>
</table>

Moxidectin:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buehler Test</td>
<td>Dermal</td>
<td>Guinea pig</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human repeat insult patch test (HRIPT)</td>
<td>Skin contact</td>
<td>Humans</td>
<td>negative</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

N,N-Dimethylacetamide:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Rodent dominant lethal test (germ cell) (in vivo)</td>
<td>Species: Rat Application Route: Inhalation Method: OECD Test Guideline 478 Result: negative</td>
</tr>
</tbody>
</table>

Fluralaner:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Genotoxicity in vivo</td>
</tr>
<tr>
<td>---------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td><strong>Fluralaner / Moxidectin Liquid Formulation</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Result:</strong></td>
<td>negative</td>
</tr>
<tr>
<td><strong>Test Type:</strong></td>
<td>Mouse Lymphoma</td>
</tr>
<tr>
<td><strong>Species:</strong></td>
<td>Mouse</td>
</tr>
<tr>
<td><strong>Cell type:</strong></td>
<td>Bone marrow</td>
</tr>
<tr>
<td><strong>Application Route:</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Result:</strong></td>
<td>negative</td>
</tr>
<tr>
<td><strong>Test Type:</strong></td>
<td>Micronucleus test</td>
</tr>
<tr>
<td><strong>Species:</strong></td>
<td>Mouse</td>
</tr>
<tr>
<td><strong>Cell type:</strong></td>
<td>Bone marrow</td>
</tr>
<tr>
<td><strong>Application Route:</strong></td>
<td>Ingestion</td>
</tr>
<tr>
<td><strong>Result:</strong></td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>N,N-Diethyl-m-toluamide:</strong></th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Genotoxicity in vivo</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acetone:</strong></td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td>Result: negative</td>
</tr>
<tr>
<td><strong>Genotoxicity in vivo</strong></td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Result: negative</td>
</tr>
<tr>
<td><strong>Genotoxicity in vivo</strong></td>
<td>Test Type: Chromosomal aberration test in vitro</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

| **Moxidectin:**                | Test Type: Bacterial reverse mutation assay (AMES) | Result: negative |
| **Genotoxicity in vivo**       | Test Type: Chromosomal aberration                |                 |
| **Genotoxicity in vivo**       | 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:  
Application Route:  
Exposure time:  
Result:  
Rat  
inhalation (vapor)  
18 month(s)  
negative

Fluralaner:

Carcinogenicity - Assessment:  
No data available

N,N-Diethyl-m-toluamide:

Species:  
Application Route:  
Exposure time:  
Result:  
Rat  
Ingestion  
104 weeks  
negative

Acetone:

Species:  
Application Route:  
Exposure time:  
Result:  
Mouse  
Skin contact  
424 days  
negative

Moxidectin:

Species:  
Application Route:  
Exposure time:  
Mouse  
Oral  
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 fetal development:
Test Type: Embryo-fetal development
Species: Rat
Application Route: Inhalation
Result: positive

Reproductive toxicity - Assessment:
Clear evidence of adverse effects on development, based on animal experiments.

Fluralaner:

Effects on fertility:
Test Type: Two-generation study
Species: Rat
Application Route: Oral
General Toxicity Parent: NOAEL: 50 mg/kg body weight
General Toxicity F1: LOAEL: 100 mg/kg body weight
Result: No effects on fertility., Postimplantation loss., Adverse neonatal effects.

Test Type: One-generation reproduction toxicity study
Species: Dog
Application Route: Oral
Fertility: NOAEL: 75 mg/kg body weight
Effects on fetal development:
- Test Type: Development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: NOAEL: 100 mg/kg body weight
  - Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects.

- Test Type: Development
  - Species: Rabbit
  - Application Route: Oral
  - Developmental Toxicity: NOAEL: 10 mg/kg body weight
  - Result: Skeletal malformations., Visceral malformations.
  - Remarks: Maternal toxicity observed.

- Test Type: Development
  - Species: Rabbit
  - Application Route: Dermal
  - Developmental Toxicity: NOAEL: 100 mg/kg body weight
  - Result: Skeletal malformations.

Reproductive toxicity - Assessment:
- Suspected of damaging the unborn child.

N,N-Diethyl-m-toluamide:
- Effects on fetal development:
  - Test Type: Embryo-fetal development
    - Species: Rat
    - Application Route: Ingestion
    - Result: negative

Acetone:
- Effects on fertility:
  - Test Type: One-generation reproduction toxicity study
    - Species: Rat
    - Application Route: Ingestion
    - Result: negative

- Effects on fetal development:
  - Test Type: Embryo-fetal development
    - Species: Rat
    - Application Route: inhalation (vapor)
    - Result: negative

Moxidectin:
- Effects on fertility:
  - Test Type: Two-generation reproduction toxicity study
    - Species: Rat
    - Application Route: Oral
    - General Toxicity F1: LOAEL: 0.8 mg/kg body weight
    - Symptoms: Reduced fetal weight., Fetal mortality.
    - Result: No effects on fertility., Some evidence of adverse effects on development, based on animal experiments.
Test Type: Three-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
General Toxicity F1: LOAEL: 0.8 mg/kg body weight  
Symptoms: Reduced fetal weight, Fetal mortality.  
Result: No effects on fertility, Some evidence of adverse effects on development, based on animal experiments.

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

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
General Toxicity Maternal: LOAEL: 5 mg/kg body weight  
Developmental Toxicity: NOAEL: 10 mg/kg body weight  
Result: No teratogenic effects, No embryotoxic effects.

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

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 fetal development : Test Type: Embryo-fetal 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

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

Components:

Moxidectin:

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>90 mg/m³</td>
</tr>
<tr>
<td>LOAEL</td>
<td>360 mg/m³</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (vapor)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>24 Months</td>
</tr>
</tbody>
</table>

**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       | Diarrhea |

**Species** : Rat

| LOAEL         | 400 mg/kg |
| Application Route | Oral |
| Exposure time  | 90 Days |
| Target Organs  | Liver, thymus gland |

**Species** : Rat

| LOAEL         | 500 mg/kg |
| Application Route | Dermal |
| Exposure time  | 90 Days |
| Target Organs  | Liver |

**Remarks:** No significant adverse effects were reported

### Acetone:

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

| Species | Rat |

**Version** | Revision Date: | SDS Number: | Date of last issue: | Date of first issue: |
|-----------|----------------|--------------|---------------------|----------------------|
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

NOAEL : 45 mg/l
Application Route : inhalation (vapor)
Exposure time : 8 Weeks

**Moxidectin:**

Species : Mouse
NOAEL : 3,9 mg/kg
LOAEL : 15,4 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Symptoms : Tremors

Species : Rat
NOAEL : 3,9 mg/kg
LOAEL : 7,9 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Central nervous system
Symptoms : Tremors, Salivation

Species : Dog
NOAEL : 0,3 mg/kg
LOAEL : 0,9 mg/kg
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 aspiration toxicity hazard.

**Experience with human exposure**

**Components:**

**Fluralaner:**

- **Skin contact**: Remarks: May irritate skin.
- **Eye contact**: Remarks: May cause eye irritation.

**Moxidectin:**

- **Inhalation**: Remarks: No human information is available.
- **Skin contact**: Remarks: No human information is available.
- **Eye contact**: Remarks: No human information is available.
- **Ingestion**: Remarks: No human information is available.

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**N,N-Dimethylacetamide:**

- **Toxicity to fish**: LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 500 mg/l
  Exposure time: 48 h
- **Toxicity to algae/aquatic plants**: EC50 (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 (Zebrasfish): >= 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

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

Acetone:

Toxicity to fish
LC50 (Oncorhynchus mykiss (rainbow trout)): 5.540 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates
EC50 (Daphnia pulex (Water flea)): 8.800 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants
NOEC (Pseudokirchneriella subcapitata (green algae)): 7.000 mg/l
Exposure time: 96 h

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

Toxicity to microorganisms
EC50: 61.150 mg/l
Exposure time: 30 min
Method: ISO 8192

Moxidectin:

Toxicity to fish
LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,0006 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 0,0002 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates
EC50 (Daphnia magna (Water flea)): 0,00003 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): 0.087 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

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

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.
N,N-Diethyl-m-toluamide:
- Biodegradability: Result: Not readily biodegradable.

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: $\log Pow: 4,5$

N,N-Diethyl-m-toluamide:
- Partition coefficient: n-octanol/water: $\log Pow: 2,02$

Acetone:
- Partition coefficient: n-octanol/water: $\log Pow: -0,27 - -0,23$

Moxidectin:
- Partition coefficient: n-octanol/water: $\log Pow: 4,7$

2,6-Di-tert-butyl-p-cresol:
- Bioaccumulation: Species: Cyprinus carpio (Carp)
  - Bioconcentration factor (BCF): 330 - 1.800
- Partition coefficient: n-octanol/water: $\log Pow: 5,1$

Mobility in soil

Components:

Fluralaner:
- Distribution among environmental compartments: $\log Koc: 3,4$
### Other adverse effects

**Components:**

**Fluralaner:**

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

---

### SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

- Waste from residues: Dispose of in accordance with local regulations.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

### SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**

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<th>Value</th>
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<td>Proper shipping name</td>
<td>ACETONE SOLUTION</td>
</tr>
<tr>
<td>Class</td>
<td>3</td>
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<tr>
<td>Packing group</td>
<td>II</td>
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<tr>
<td>Labels</td>
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**IATA-DGR**

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<td>UN 1090</td>
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<td>Acetone solution</td>
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<td>Class</td>
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<tr>
<td>Packing group</td>
<td>II</td>
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<tr>
<td>Labels</td>
<td>Flammable Liquids</td>
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<tr>
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<tr>
<td>Packing instruction (passenger aircraft)</td>
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**IMDG-Code**

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<td>ACETONE SOLUTION</td>
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<td>(Moxidectin, 2,6-Di-tert-butyl-p-cresol)</td>
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<td>Class</td>
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<td>Packing group</td>
<td>II</td>
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<td>Labels</td>
<td>3</td>
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<td>EmS Code</td>
<td>F-E, S-D</td>
</tr>
<tr>
<td>Marine pollutant</td>
<td>yes</td>
</tr>
</tbody>
</table>

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Domestic regulation

ANTT
UN number : UN 1090
Proper shipping name : ACETONE, SOLUTION
Class : 3
Packing group : II
Labels : 3
Hazard Identification Number : 33

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. Ordinance No. 1274 on the control and monitoring of chemicals. : Acetone

International Regulations

The ingredients of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
BR OEL : Brazil. NR 15 - Unhealthy activities and operations
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
BR OEL / LT : Up to 48 hours /week
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.