SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP
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
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 2 (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

GHS label elements

Signal Word: Danger

Hazard pictograms:
- Flammable
- Corrosive
- Harmful if swallowed
- May be harmful if inhaled
- Highly flammable liquid and vapor

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.
- 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 vapors.
- 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.
- 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.
- P312 Call a POISON CENTER/doctor if you feel unwell.
- 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.
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Fluralaner / Moxidectin Liquid Formulation

Version: 6.1
Revision Date: 13.09.2019
SDS Number: 657369-00010
Date of last issue: 18.10.2018
Date of first issue: 02.05.2016

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

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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</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.
SAFETY DATA SHEET

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May cause damage to organs through prolonged or repeated exposure.

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

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
- High volume water jet

Specific hazards during 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.

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</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>CMP</td>
<td>10 ppm</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Biological Exposure Index (BEI), Skin, Liver, reproduction</td>
<td></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>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>CMP</td>
<td>500 ppm</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: A4 - Not classifiable as a human carcinogen: Agents which cause concern that they could be carcinogenic for humans but which cannot be assessed conclusively because of a lack of data. In vitro or animal studies do not provide indications of carcinogenicity which are sufficient to classify the agent into one of the other categories., Biological Exposure Index (BEI), Irritation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP - CPT</td>
<td>750 ppm</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: A4 - Not classifiable as a human carcinogen: Agents which cause concern that they could be carcinogenic for humans but which cannot be assessed conclusively because of a lack of data. In vitro or animal studies do not provide indications of carcinogenicity which are sufficient to classify the agent into one of the other categories., Biological Exposure Index (BEI), Irritation</td>
<td></td>
<td></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>CMP (Vapour and aerosol, inhalable fraction)</td>
<td>2 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Vapour and aerosol, A4 - Not classifiable as a human carcinogen: Agents which cause concern that they could be carcinogenic for humans but which cannot be assessed conclusively because of a lack of data. In vitro or animal studies do not provide indications of carcinogenicity which are sufficient to classify the agent into one of the other categories., Irritation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction and vapor)</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></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### N,N-Dimethylacetamide

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Exposure</th>
<th>Limit</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>Urine</td>
<td>after the last shift of the last day of the work week</td>
<td>30 mg/g Creatinine</td>
</tr>
</tbody>
</table>

### N-Methylacetamide

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Exposure</th>
<th>Limit</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methylacetamide</td>
<td></td>
<td>Urine</td>
<td>End of shift at end of work week</td>
<td>30 mg/g Creatinine</td>
</tr>
</tbody>
</table>

### Acetone

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Exposure</th>
<th>Limit</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>Urine 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

#### 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.

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
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):
### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reac-</td>
<td>Highly flammable liquid and vapor. Vapors may form explosive mixture with air.</td>
</tr>
<tr>
<td>tions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Heat, flames and sparks.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition</td>
<td>No hazardous decomposition products are known.</td>
</tr>
<tr>
<td>products</td>
<td></td>
</tr>
</tbody>
</table>

### 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

- **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

**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
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Date of first issue: 02.05.2016

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:

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:**
- **Routes of exposure:** Skin contact  
- **Species:** Guinea pig  
- **Result:** negative

---

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## Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>SAFETY DATA SHEET</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SAFETY DATA SHEET</strong></td>
</tr>
<tr>
<td><strong>Fluralaner / Moxidectin Liquid Formulation</strong></td>
</tr>
<tr>
<td><strong>Version</strong></td>
</tr>
</tbody>
</table>

### Fluralaner:
- **Test Type:** Maximization Test
- **Routes of exposure:** Dermal
- **Species:** Guinea pig
- **Result:** Not a skin sensitizer.

### Acetone:
- **Test Type:** Maximization Test
- **Routes of exposure:** Skin contact
- **Species:** Guinea pig
- **Result:** negative

### Moxidectin:
- **Test Type:** Buehler Test
- **Routes of exposure:** Dermal
- **Species:** Guinea pig
- **Result:** Not a skin sensitizer.

### 2,6-Di-tert-butyl-p-cresol:
- **Test Type:** Human repeat insult patch test (HRIPT)
- **Routes of exposure:** 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
### 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 test  
  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
## Genotoxicity in vivo

Test Type: Mutagenicity (in vivo mammalian bone-marrows cytogenetic test, chromosom analysis)
Species: Rat
Application Route: Ingestion
Result: negative

## Genotoxicity in vitro

Result: negative
Test Type: Chromosome aberration test in vitro

## Carcinogenicity

Not classified based on available information.

### Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Rat</td>
<td>Inhalation (vapor)</td>
<td>18 month(s)</td>
<td>negative</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>Rat</td>
<td>Ingestion</td>
<td>104 weeks</td>
<td>negative</td>
</tr>
<tr>
<td>Acetone</td>
<td>Mouse</td>
<td>Skin contact</td>
<td>424 days</td>
<td>negative</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>Mouse</td>
<td>Oral</td>
<td>2 Years</td>
<td>NOAEL: 4,5 mg/kg body weight, negative</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Oral</td>
<td>2 Years</td>
<td>NOAEL: 4,5 mg/kg body weight, negative</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Application Route: Oral
Exposure time: 1 Years
Result: NOAEL: 0,5 mg/kg body weight

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
Result: No effects on fertility and early embryonic development were detected.
Remarks: No significant adverse effects were reported

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
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
</table>

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

Components:

Moxidectin:

Target Organs Assessment: Central nervous system
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 (vapor)
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: Diarrhea

Species: Rat
LOAEL: 400 mg/kg
Application Route: Oral
Exposure time: 90 Days
Target Organs: Liver, thymus gland
Remarks: No significant adverse effects were reported

Acetone:
Species: Rat
NOAEL: 900 mg/kg
LOAEL: 1.700 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

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

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

Fluralaner / Moxidectin Liquid Formulation

Version 6.1  Revision Date: 13.09.2019  SDS Number: 657369-00010  Date of last issue: 18.10.2018
Date of first issue: 02.05.2016

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.
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Eye contact: Remarks: May cause eye irritation.

**Moxidectin:**

| Ingestion | Remarks: No human information is available. |
| Exposure time: 96 h |
| 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. |
| NOEC (Daphnia magna (Water flea)): 0,000047 mg/l |

**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 |
| 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 | NOEC (Daphnia magna (Water flea)): 0,000047 mg/l |
### N,N-Diethyl-m-toluamide:

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 110 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 75 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
</tbody>
</table>

### Acetone:

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): 5.540 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia pulex (Water flea)): 8.800 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)): 7.000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC50: 61.150 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>30 min</td>
</tr>
<tr>
<td>Method</td>
<td>ISO 8192</td>
</tr>
</tbody>
</table>

### Moxidectin:

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0006 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 0.00003 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 0.087 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>M-Factor (Acute aquatic toxicity)</th>
<th>10.000</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>10.000</td>
</tr>
</tbody>
</table>
## 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

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

Results of PBT and vPvB assessment: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).
SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 1090
Proper shipping name: ACETONE SOLUTION
Class: 3
Packing group: II
Labels: 3

IATA-DGR
UN/ID No.: UN 1090
Proper shipping name: Acetone solution
Class: 3
Packing group: II
Labels: Flammable Liquids
Packing instruction (cargo aircraft): 364
Packing instruction (passenger aircraft): 353

IMDG-Code
UN number: UN 1090
Proper shipping name: ACETONE SOLUTION (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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.
SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents: Not applicable

Control of precursors and essential chemicals for the preparation of drugs:

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)

AR BEI: Argentina. Biological Exposure Indices

AR OEL: Argentina. Occupational Exposure Limits

ACGIH / TWA: 8-hour, time-weighted average

ACGIH / STEL: Short-term exposure limit

AR OEL / CMP: TLV (Threshold Limit Value)

AR OEL / CMP - CPT: STEL (Short Term Limit Value)

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

AR / Z8