SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Fluralaner / Moxidectin Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
              20 Spartan Road
              1619 Spartan, South Africa

   Telephone : +27119239300
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Flammable liquids, Category 2 H225: Highly flammable liquid and vapour.
Skin irritation, Category 2 H315: Causes skin irritation.
Eye irritation, Category 2 H319: Causes serious eye irritation.
Reproductive toxicity, Category 1B H360D: May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 2 H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1 H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1 H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :

Signal word : Danger
Hazard statements : H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H360D May damage the unborn child.
H373 May cause damage to organs 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, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

**Response:**
P308 + P313 IF exposed or concerned: Get medical advice/attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:
N,N-Dimethylacetamide
Moxidectin

**Additional Labelling**
Restricted to professional users.

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

2.3 Other hazards
Vapours may form explosive mixture with air.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-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>204-826-4</td>
<td>616-011-00-4</td>
<td>Acute Tox. 4; H332 Acute Tox. 4; H312 Eye Irrit. 2; H319 Repr. 1B; H360D</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td></td>
<td></td>
<td>Repr. 2; H361d Aquatic Chronic 1; H410</td>
<td>&gt;= 25 - &lt; 30</td>
</tr>
</tbody>
</table>
# SECTION 4: First aid measures

## 4.1 Description of 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.

**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).

**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 explanation of abbreviations see section 16.
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.

4.2 Most important symptoms and effects, both acute and delayed

| Risks | Causes skin irritation. Causes serious eye irritation. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure. |

4.3 Indication of any immediate medical attention and special treatment needed

| Treatment | Treat symptomatically and supportively. |

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

| Unsuitable extinguishing media | High volume water jet |

5.2 Special hazards arising from the substance or mixture

| 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) |
5.3 Advice for firefighters

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

---

**SECTION 6: Accidental release measures**

6.1 Personal precautions, protective equipment and emergency procedures

- **Personal precautions**: Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

- **Environmental precautions**: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

- **Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.
SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSOanal PROTECTIONS section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

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.

7.2 Conditions for safe storage, including any incompatibilities

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

Advice on common storage : 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

7.3 Specific end use(s)
### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>TWA OEL-RL</td>
<td>10 ppm</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>36 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL</td>
<td>20 ppm</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>71 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>20 ppm</td>
<td>2000/39/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>72 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
<td>2000/39/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>36 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>TWA OEL-RL</td>
<td>750 ppm</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.780 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL</td>
<td>1.500 ppm</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3.560 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>500 ppm</td>
<td>2000/39/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.210 mg/m³</td>
<td></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>TWA OEL-RL</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Further information:**
- Absorption through the skin, Recommended Limit
- Wipe limit: 1000 µg/100 cm²

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>36 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>36 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>13.6 mg/kg</td>
</tr>
</tbody>
</table>
Effects

Consumers
Consumers
Consumers

Inhalation
Skin contact
Ingestion

Long-term local effects
Long-term systemic effects
Long-term systemic effects

Consumers
Consumers
Consumers

Inhalation
Skin contact
Ingestion

Acute local effects
Long-term systemic effects
Long-term systemic effects

Acetone
Workers
Workers

Inhalation
Inhalation

Long-term systemic effects
Long-term systemic effects

Workers
Workers

Inhalation

Long-term systemic effects

Acetone
Workers

Inhalation

Long-term systemic effects

Workers

Inhalation

Long-term systemic effects

Workers

Skin contact

Long-term systemic effects

Consumers
Consumers
Consumers
Consumers

Inhalation
Skin contact
Ingestion

Long-term systemic effects
Long-term systemic effects
Long-term systemic effects

Workers
Consumers
Consumers

Inhalation
Ingestion

Acute local effects
Long-term systemic effects

Expected No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Fresh water</td>
<td>0.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0966 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>485 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>2.27 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.15 mg/kg</td>
</tr>
<tr>
<td>Acetone</td>
<td>Fresh water</td>
<td>10.6 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>1.06 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>21 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>30.4 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>3.04 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>29.5 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>Fresh water</td>
<td>0.199 µg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.02 µg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.02 µg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>0.17 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.0996 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.00996 mg/kg</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

Engineering measures

Use explosion-proof electrical, ventilating and lighting equipment.
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

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.

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.

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.

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid

Colour : Colorless to pale yellow

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 : No data available
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version 5.0  Revision Date: 15.10.2020  SDS Number: 656891-00011  Date of last issue: 13.09.2019
Date of first issue: 02.05.2016

Flash point: 2 °C
Method: closed cup
Evaporation rate: No data available
Flammability (solid, gas): 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: 1,08 g/cm³

Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature: No data available

Viscosity, kinematic: 7,5 mm²/s
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.

9.2 Other information
Flammability (liquids): Not applicable
Particle size: Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Highly flammable liquid and vapour.
Vapours may form explosive mixture with air.
10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

N,N-Dimethylacetamide:

Acute oral toxicity: LD50 (Rat): 4.800 mg/kg

Acute inhalation toxicity: LC50 (Rat): 2,2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: Acute toxicity estimate: 1.100 mg/kg
Method: Expert judgement
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

Fluralaner:

Acute oral toxicity: LD50 (Rat): > 2.000 mg/kg
Remarks: No mortality observed at this dose.
No significant adverse effects were reported
Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
Remarks: No significant adverse effects were reported

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

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 1.950 mg/kg</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): 5.95 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): 5.000 mg/kg</td>
</tr>
</tbody>
</table>

**Acetone:**

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 5.800 mg/kg</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): 76 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: vapour</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): 7.426 mg/kg</td>
</tr>
</tbody>
</table>

**Moxidectin:**

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 106 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 42 - 84 mg/kg</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): 3.28 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 5 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td></td>
<td>LC50 (Rat): 2.87 - 4.06 mg/l</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2.000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Remarks: No significant adverse effects were reported</td>
</tr>
<tr>
<td>Acute toxicity (other routes of administration)</td>
<td>LD50 (Rat): 394 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 84 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal</td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): &gt; 640 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Subcutaneous</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 263 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Subcutaneous</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 6.000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 401</td>
</tr>
</tbody>
</table>
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
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

N,N-Diethyl-m-toluamide:
- **Species**: Rabbit
- **Result**: Irritation to eyes, reversing within 21 days

Acetone:
- **Species**: Rabbit
- **Method**: OECD Test Guideline 405
- **Result**: Irritation to eyes, reversing within 21 days

Moxidectin:
- **Species**: Rabbit
- **Result**: Moderate eye irritation

2,6-Di-tert-butyl-p-cresol:
- **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
<table>
<thead>
<tr>
<th>Component</th>
<th>Genotoxicity in vitro</th>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: Rodent dominant lethal test (germ cell) (in vivo)</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Application Route: Inhalation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method: OECD Test Guideline 478</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: Micronucleus test</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cell type: Bone marrow</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

**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.

**Not a skin sensitizer.**
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Moxidectin:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Result: negative

Test Type: in vitro assay
Test system: Escherichia coli
Result: negative

Genotoxicity in vivo: Test Type: Chromosomal aberration
Species: Rat
Cell type: Bone marrow
Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
Species: Rat
Cell type: Liver cells
Result: negative

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

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

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

Carcinogenicity
Not classified based on available information.

Components:
N,N-Dimethylacetamide:
Species: Rat
### Application Route

- **Exposure time**: 18 months
- **Result**: negative

### Fluralaner:

- **Carcinogenicity - Assessment**: No data available

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

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

### Acetone:

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

### Moxidectin:

- **Species**: Mouse
  - **Application Route**: Oral
  - **Exposure time**: 2 Years
  - **NOAEL**: 4.5 mg/kg body weight
  - **Result**: negative
- **Species**: Rat
  - **Application Route**: Oral
  - **Exposure time**: 2 Years
  - **NOAEL**: 4.5 mg/kg body weight
  - **Result**: negative
- **Species**: Dog
  - **Application Route**: Oral
  - **Exposure time**: 1 Year
  - **NOAEL**: 0.5 mg/kg body weight
  - **Result**: negative

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

- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 22 Months
- **Result**: negative

### Reproductive toxicity

May damage the unborn child.

### Components:

- **N,N-Dimethylacetamide:**
18 / 30

<table>
<thead>
<tr>
<th>Effect Type</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>One-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Inhalation</td>
<td>negative</td>
</tr>
<tr>
<td>Effects on foetal development</td>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Inhalation</td>
<td>positive</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Clear evidence of adverse effects on development, based on animal experiments.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Fluralaner:**

<table>
<thead>
<tr>
<th>Effect Type</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Two-generation study</td>
<td>Rat</td>
<td>Oral</td>
<td>No effects on fertility, Postimplantation loss., Adverse neonatal effects.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dog</td>
<td>Oral</td>
<td>No effects on fertility and early embryonic development were detected. Remarks: No significant adverse effects were reported</td>
</tr>
<tr>
<td>Effects on foetal development</td>
<td>Development</td>
<td>Rat</td>
<td>Oral</td>
<td>Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rabbit</td>
<td>Oral, Dermal</td>
<td>Skeletal malformations, Visceral malformations Remarks: Maternal toxicity observed.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Effect Type</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive toxicity</td>
<td>Suspected of damaging the unborn child.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type</td>
<td>Species</td>
<td>Application Route</td>
<td>LOAEL</td>
<td>Symptoms</td>
</tr>
<tr>
<td>-----------</td>
<td>---------</td>
<td>-------------------</td>
<td>-------</td>
<td>----------</td>
</tr>
<tr>
<td>Effects on foetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>0,8 mg/kg body weight</td>
<td>Reduced foetal weight, foetal mortality</td>
</tr>
<tr>
<td>Effects on fertility</td>
<td>Rat</td>
<td>Ingestion</td>
<td>0,8 mg/kg body weight</td>
<td>Reduced foetal weight, foetal mortality</td>
</tr>
<tr>
<td>Effects on foetal development</td>
<td>Rat</td>
<td>inhalation (vapour)</td>
<td>0,8 mg/kg body weight</td>
<td>Reduced foetal weight, foetal mortality</td>
</tr>
</tbody>
</table>

**Acetone:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>LOAEL</th>
<th>Symptoms</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Rat</td>
<td>Ingestion</td>
<td>0,8 mg/kg body weight</td>
<td>Reduced foetal weight, foetal mortality</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Moxidectin:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>LOAEL</th>
<th>Symptoms</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Rat</td>
<td>Oral</td>
<td>0,8 mg/kg body weight</td>
<td>Reduced foetal weight, foetal mortality</td>
<td>negative</td>
</tr>
<tr>
<td>Effects on foetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>0,8 mg/kg body weight</td>
<td>Reduced foetal weight, foetal mortality</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>LOAEL</th>
<th>Symptoms</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Rat</td>
<td>Oral</td>
<td>0,8 mg/kg body weight</td>
<td>Reduced foetal weight, foetal mortality</td>
<td>negative</td>
</tr>
<tr>
<td>Effects on foetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>0,8 mg/kg body weight</td>
<td>Reduced foetal weight, foetal mortality</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Reproductive toxicity - Assessment**

- Some evidence of adverse effects on development, based on animal experiments.

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

- 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

- 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

- 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

- 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

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

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

**STOT - single exposure**
Not classified based on available information.

**Components:**

- **Acetone:**
  - Assessment: May cause drowsiness or dizziness.

**STOT - repeated exposure**
May cause damage to organs 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
Remarks: No significant adverse effects were reported

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

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

Moxidectin:
Species: Mouse
NOAEL: 3,9 mg/kg
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
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>0.3 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.87 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>52 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Tremors, Lachrymation</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>25 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>22 Months</td>
</tr>
</tbody>
</table>

Aspiration toxicity
Not classified based on available information.

Components:

Fluralaner:
Not applicable

Acetone:
The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

Experience with human exposure

Components:

Fluralaner:

<table>
<thead>
<tr>
<th>Skin contact</th>
<th>Remarks: May irritate skin.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye contact</td>
<td>Remarks: May cause eye irritation.</td>
</tr>
</tbody>
</table>

Moxidectin:

<table>
<thead>
<tr>
<th>Inhalation</th>
<th>Remarks: No human information is available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td>Remarks: No human information is available.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Remarks: No human information is available.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Remarks: No human information is available.</td>
</tr>
</tbody>
</table>

SECTION 12: Ecological information

12.1 Toxicity

Components:

N,N-Dimethylacetamide:

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Leuciscus idus (Golden orfe)): &gt; 500 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 500 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
</tbody>
</table>
### SAFETY DATA SHEET

**Fluralaner / Moxidectin Liquid Formulation**

**Version**: 5.0  
**Revision Date**: 15.10.2020  
**SDS Number**: 656891-00011  
**Date of last issue**: 13.09.2019  
**Date of first issue**: 02.05.2016

#### 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: >= 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

### 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 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

**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
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version 5.0
Revision Date: 15.10.2020
SDS Number: 656891-00011
Date of last issue: 13.09.2019
Date of first issue: 02.05.2016

12.2 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

12.3 Bioaccumulative potential

Components:

Fluralaner:
Bioaccumulation: Species: Zebrafish
Bioconcentration factor (BCF): 79,4
Method: OECD Test Guideline 305
**SAFETY DATA SHEET**

**Fluralaner / Moxidectin Liquid Formulation**

**Partition coefficient: n-octanol/water**
- **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

**12.4 Mobility in soil**

**Components:**
- **Fluralaner**
  - **Distribution among environmental compartments**
  - **log Koc**: 3,4

**12.5 Results of PBT and vPvB assessment**

**Components:**
- **Fluralaner**
  - **Assessment**
  - This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

**12.6 Other adverse effects**

No data available

**SECTION 13: Disposal considerations**

**13.1 Waste treatment methods**
- **Product**
  - Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

- **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

14.1 UN number

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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<td>UN 1090</td>
<td>UN 1090</td>
<td>UN 1090</td>
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</table>

14.2 UN proper shipping name

<table>
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<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETONE, SOLUTION</td>
<td>ACETONE, SOLUTION</td>
<td>ACETONE, SOLUTION</td>
<td>ACETONE, SOLUTION (Fluralaner, Moxidectin)</td>
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</tbody>
</table>

14.3 Transport hazard class(es)

<table>
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<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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</thead>
<tbody>
<tr>
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<td>3</td>
</tr>
</tbody>
</table>

14.4 Packing group

ADN
- Packing group: II
- Classification Code: F1
- Hazard Identification Number: 33
- Labels: 3

ADR
- Packing group: II
- Classification Code: F1
- Hazard Identification Number: 33
- Labels: 3
- Tunnel restriction code: (D/E)

RID
- Packing group: II
- Classification Code: F1
- Hazard Identification Number: 33
- Labels: 3

IMDG
- Packing group: II
- Labels: 3
- EmS Code: F-E, S-D
SAFETY DATA SHEET
Fluralaner / Moxidectin Liquid Formulation

Version 5.0
Revision Date: 15.10.2020
SDS Number: 656891-00011
Date of last issue: 13.09.2019
Date of first issue: 02.05.2016

IATA (Cargo)
Packing instruction (cargo aircraft): 364
Packing instruction (LQ): Y341
Packing group: II
Labels: Flammable Liquids

IATA (Passenger)
Packing instruction (passenger aircraft): 353
Packing instruction (LQ): Y341
Packing group: II
Labels: Flammable Liquids

14.5 Environmental hazards

ADN
Environmentally hazardous: yes

ADR
Environmentally hazardous: yes

RID
Environmentally hazardous: yes

IMDG
Marine pollutant: yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical
Full text of H-statements

H225 : Highly flammable liquid and vapour.
H301 : Toxic if swallowed.
H302 : Harmful if swallowed.
H312 : Harmful in contact with skin.
H315 : Causes skin irritation.
H319 : Causes serious eye irritation.
H322 : Harmful if inhaled.
H336 : May cause drowsiness or dizziness.
H360D : Causes damage to organs through prolonged or repeated exposure.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Repr. : Reproductive toxicity
Skin Irrit. : Skin irritation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
ZA BEI : South Africa. Hazardous Chemical Substances Regulations, Biological Exposure Indices.
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
2000/39/EC / TWA : Limit Value - eight hours
2000/39/EC / STEL : Short term exposure limit
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Maritime Organiza-
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version 5.0  Revision Date: 15.10.2020  SDS Number: 656891-00011  Date of last issue: 13.09.2019  Date of first issue: 02.05.2016

Further information

Classification of the mixture: Classification procedure:
- Flam. Liq. 2 H225 Based on product data or assessment
- Skin Irrit. 2 H315 Calculation method
- Eye Irrit. 2 H319 Calculation method
- Repr. 1B H360D Calculation method
- STOT RE 2 H373 Calculation method
- Aquatic Acute 1 H400 Calculation method
- Aquatic Chronic 1 H410 Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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.

ZA / EN