SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Fluralaner / Moxidectin Liquid Formulation

Version 4.0 Revision Date: 10/18/2018 SDS Number: 657379-00009 Date of last issue: 12.04.2018

Date of first issue: 02.05.2016

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
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

Telephone: 908-740-4000
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.

Additional Labeling:
- 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>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5 204-826-4 616-011-00-4</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></td>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>Repr. 2; H361d Aquatic Chronic 1; H410</td>
<td>&gt;= 25 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3 205-149-7 616-018-00-2</td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319</td>
<td>&gt;= 10 - &lt; 20</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.

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. Get medical attention. Rinse mouth thoroughly with water.
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 and personal protective equipment recommendations.

6.2 Environmental precautions

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.

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/PERSONAL PROTECTION section.

Local/Total ventilation: Use with local exhaust ventilation. Use only in an area equipped with explosion-proof exhaust ventilation if advised by assessment of the local exposure potential.

Advice on safe handling: Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Do not get in eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Non-sparking tools should be used. Keep container tightly closed.
Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: Ensure that eye flushing systems and safety showers are located 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)
Specific use(s): No data available

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>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>Further information</td>
<td></td>
<td></td>
<td></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>Further information</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>20 ppm</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>72 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Can be absorbed through skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.</td>
<td></td>
</tr>
</tbody>
</table>
Further information: Can be absorbed through skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.

<table>
<thead>
<tr>
<th>Substance name</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Sampling time</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>TWA</td>
<td>500 ppm 1,210 mg/m3</td>
<td>GB EH40</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>TWA</td>
<td>10 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure should be used.

**Biological occupational exposure limits**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Control parameters</th>
<th>Sampling time</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>N-methylacetamide: 100 Millimoles per mole Creatinine (Urine)</td>
<td>After shift</td>
</tr>
</tbody>
</table>

**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 bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>7 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2.7 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>1 mg/kg bw/day</td>
</tr>
<tr>
<td>Acetone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1210 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>2420 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>186 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>200 mg/m3</td>
</tr>
</tbody>
</table>
Fluralaner / Moxidectin Liquid Formulation

Predicted 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 (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>3.04 mg/kg (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>29.5 mg/kg (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 (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.00996 mg/kg (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.04769 mg/kg (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>8.33 mg/kg food</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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**

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: Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

Filter type: Self-contained breathing apparatus

**SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

- **Appearance**: liquid
- **Colour**: clear
- **Odour**: No information available.
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: 2 °C
  - Method: closed cup
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
### Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>1.06</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

#### 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. Can react with strong oxidizing agents.

#### 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:
- Acute oral toxicity: LD50 (Rat): 1,950 mg/kg
- Acute inhalation toxicity: LC50 (Rat): 5.95 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rat): 5,000 mg/kg

Acetone:
- Acute oral toxicity: LD50 (Rat): 5,800 mg/kg
- Acute inhalation toxicity: LC50 (Rat): 76 mg/l
  Exposure time: 4 h
  Test atmosphere: vapour
- Acute dermal toxicity: LD50 (Rabbit): 7,426 mg/kg

Moxidectin:
- Acute oral toxicity: LD50 (Rat): 106 mg/kg
  LD50 (Mouse): 42 - 84 mg/kg
- Acute inhalation toxicity: LC50 (Rat): 3.28 mg/l
  Exposure time: 5 h
  Test atmosphere: dust/mist
  LC50 (Rat): 2.87 - 4.06 mg/l
  Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
  Remarks: No significant adverse effects were reported

- Acute toxicity (other routes of administration):
  LD50 (Rat): 394 mg/kg
  Application Route: Intraperitoneal
  LD50 (Mouse): 84 mg/kg
  Application Route: Intraperitoneal
  LD50 (Rat): > 640 mg/kg
  Application Route: Subcutaneous
  LD50 (Mouse): 263 mg/kg
  Application Route: Subcutaneous

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

Skin corrosion/irritation
Causes skin irritation.
Components:

N,N-Dimethylacetamide:

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

Fluralaner:

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

N,N-Diethyl-m-toluamide:

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

Acetone:

| Assessment  |Repeated exposure may cause skin dryness or cracking. |

Moxidectin:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Mild skin irritant</td>
</tr>
</tbody>
</table>

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

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

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

N,N-Dimethylacetamide:

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

Fluralaner:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Mild eye irritant</td>
</tr>
</tbody>
</table>

N,N-Diethyl-m-toluamide:

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

Acetone:

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

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

N,N-Dimethylacetamide:

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Fluralaner:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

Acetone:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Moxidectin:

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

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Human repeat insult patch test (HRIPT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Humans</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>
Germ cell mutagenicity
Not classified based on available information.

Components:

N,N-Dimethylacetamide:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Rat
Application Route: Inhalation
Method: OECD Test Guideline 478
Result: negative

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

Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

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

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

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

Carcinogenicity
Not classified based on available information.

Components:

N,N-Dimethylacetamide:
Species: Rat
Application Route: Inhalation (vapour)
Exposure time: 18 month(s)
Result: negative

Fluralaner:
## Carcinogenicity - Assessment

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>104 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Acetone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Exposure time</td>
<td>424 days</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Moxidectin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>4.5 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>4.5 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>0.5 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</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>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>22 Months</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Reproductive toxicity

May damage the unborn child.

### Components:

**N,N-Dimethylacetamide:**

**Effects on fertility**

- Test Type: One-generation reproduction toxicity study
- Species: Rat
- Application Route: Inhalation
- Result: negative

**Effects on foetal development**

- Test Type: Embryo-foetal development
Reproductive toxicity - Assessment:

Species: Rat
Application Route: Inhalation
Result: positive

Clear evidence of adverse effects on development, based on animal experiments.

Fluralaner:

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

Test Type: One-generation reproduction toxicity study
Species: Dog
Application Route: Oral
Fertility: NOAEL: 75 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.
Remarks: No significant adverse effects were reported.

Effects on foetal development:
Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects

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

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

Reproductive toxicity - Assessment:

Suspected of damaging the unborn child.

N,N-Diethyl-m-toluamide:

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

Acetone:

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

**Effects on foetal development**: Test Type: Embryo-foetal development
Species: Rat
Application Route: inhalation (vapour)
Result: negative

Moxidectin:

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

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

### 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
### Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>400 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver, thymus</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>500 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Dermal</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

#### Acetone:

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>45 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (vapour)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>8 Weeks</td>
</tr>
</tbody>
</table>

#### Moxidectin:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>3.9 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>15.4 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>4 Weeks</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Tremors</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>3.9 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>7.9 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Tremors, Salivation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.3 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.9 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Tremors, Lachrymation, Salivation</td>
</tr>
</tbody>
</table>

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

2,6-Di-tert-butyl-p-cresol:
Species : Rat
NOAEL : 25 mg/kg
Application Route : Ingestion
Exposure time : 22 Months

Aspiration toxicity
Not classified based on available information.

Components:
Fluralaner:
Not applicable

Experience with human exposure
Components:
Fluralaner:
Skin contact : Remarks: May irritate skin.
Eye contact : Remarks: May cause eye irritation.

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

SECTION 12: Ecological information

12.1 Toxicity

Product:
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 : EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h
EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Fluralaner / Moxidectin Liquid Formulation

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: NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity): NOEC: >= 0.049 mg/l
Exposure time: 21 d
Species: Zebrafish
Method: OECD Test Guideline 204
Remarks: No toxicity at the limit of solubility

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

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

**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: 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 (Lepeomis 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
- **EC50 (Pseudokirchneriella subcapitata (green algae))**: 0.087 mg/l
  - **Exposure time**: 72 h
  - **Method**: OECD Test Guideline 201

#### M-Factor (Acute aquatic toxicity)
- **M-Factor**: 10,000

#### M-Factor (Chronic aquatic toxicity)
- **M-Factor**: 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
- **ErC50 (Pseudokirchneriella subcapitata (green algae))**: > 0.24 mg/l
  - **Exposure time**: 72 h
  - **Method**: OECD Test Guideline 201

- **NOEC (Pseudokirchneriella subcapitata (green algae))**: 0.24 mg/l
  - **Exposure time**: 72 h
  - **Method**: OECD Test Guideline 201

#### M-Factor (Acute aquatic toxicity)
- **M-Factor**: 1
SAFETY DATA SHEET
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Toxicity to microorganisms: EC50: > 10,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

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

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

M-Factor (Chronic aquatic toxicity): 1

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
Partition coefficient: n- log Pow: 4.5
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<thead>
<tr>
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</tr>
</tbody>
</table>

**2-octanol/water**

**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:**

<table>
<thead>
<tr>
<th>Bioaccumulation</th>
<th>Species: Cyprinus carpio (Carp)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bioconcentration factor (BCF): 330 - 1,800</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>log Pow: 5.1</td>
</tr>
</tbody>
</table>

**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>UN 1090</th>
</tr>
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<tbody>
<tr>
<td>ADR</td>
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<tr>
<td>RID</td>
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<tr>
<td>IMDG</td>
<td>UN 1090</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 1090</td>
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</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>ACETONE, SOLUTION</th>
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</thead>
<tbody>
<tr>
<td>ADR</td>
<td>ACETONE, SOLUTION</td>
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<tr>
<td>RID</td>
<td>ACETONE, SOLUTION</td>
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<td>ACETONE, SOLUTION</td>
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<tr>
<td>IATA</td>
<td>Acetone, solution</td>
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14.3 Transport hazard class(es)

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<tbody>
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<td>RID</td>
<td>3</td>
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<tr>
<td>IMDG</td>
<td>3</td>
</tr>
<tr>
<td>IATA</td>
<td>3</td>
</tr>
</tbody>
</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
<th>II</th>
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<tbody>
<tr>
<td>Packing group</td>
<td>II</td>
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<tr>
<td>Classification Code</td>
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<tr>
<td>Hazard Identification Number</td>
<td>33</td>
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<tr>
<td>Labels</td>
<td>3</td>
</tr>
<tr>
<td>ADR</td>
<td>II</td>
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<tr>
<td>Packing group</td>
<td>II</td>
</tr>
<tr>
<td>Classification Code</td>
<td>F1</td>
</tr>
<tr>
<td>Hazard Identification Number</td>
<td>33</td>
</tr>
<tr>
<td>Labels</td>
<td>3</td>
</tr>
<tr>
<td>Tunnel restriction code</td>
<td>(D/E)</td>
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<tr>
<td>RID</td>
<td>II</td>
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<tr>
<td>Packing group</td>
<td>II</td>
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<tr>
<td>Classification Code</td>
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<tr>
<td>Hazard Identification Number</td>
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<td>Labels</td>
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<td>IMDG</td>
<td>II</td>
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<td>Labels</td>
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Date of first issue: 02.05.2016

EmS Code : F-E, S-D

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : N,N-Dimethylacetamide
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3
Fluralaner / Moxidectin Liquid Formulation

N,N-Dimethylacetamide (Number on list 30)


P5c FLAMMABLE LIQUIDS

E1 ENVIRONMENTAL HAZARDS

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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.

H332 : Harmful if inhaled.

H336 : May cause drowsiness or dizziness.

H360D : May damage the unborn child.

H361d : Suspected of damaging the unborn child.

H372 : 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
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</tbody>
</table>

**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  

**GB EH40** : UK. EH40 WEL - Workplace Exposure Limits  
**GB EH40 BAT** : UK. Biological monitoring guidance values  
**2000/39/EC / TWA** : Limit Value - eight hours  
**2000/39/EC / STEL** : Short term exposure limit  
**GB EH40 / TWA** : Long-term exposure limit (8-hour TWA reference period)  
**GB EH40 / STEL** : Short-term exposure limit (15-minute reference period)

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; AICS - Australian Inventory of Chemical Substances; 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; ICS0 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSNC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

**Further information**
# Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
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<th>Classification of the mixture</th>
<th>Classification procedure</th>
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<tbody>
<tr>
<td>Flam. Liq. 2</td>
<td>H225</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>H315</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

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.

GB / EN