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

Fluralaner / Moxidectin Liquid Formulation

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 Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000
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
Skin irritation, Category 2
Eye irritation, Category 2
Reproductive toxicity, Category 1B
Specific target organ toxicity - repeated exposure, Category 2
Short-term (acute) aquatic hazard, Category 1
Long-term (chronic) aquatic hazard, Category 1

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.
H400: Very toxic to aquatic life.
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.

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<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>N,N-Dimethylacetamide</td>
<td>127-19-5 204-826-4</td>
<td>Acute Tox. 4; H332</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Substance</td>
<td>CAS Number</td>
<td>Hazard Class</td>
<td>Acute Toxicity Estimate</td>
</tr>
<tr>
<td>-----------</td>
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<td>-------------------------</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>Repr. 2; H361d</td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Chronic 1; H410</td>
<td>Acute toxicity estimate</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3 205-149-7 616-018-00-2</td>
<td>Acute Tox. 3; H301 Acute Tox. 4; H332 Eye Irrit. 2; H319 Skin Irrit. 2; H315 STOT SE 3; H336 STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>M-Factor (Acute aquatic toxicity): 10.000 M-Factor (Chronic aquatic toxicity):</td>
</tr>
<tr>
<td></td>
<td>31692-85-0</td>
<td>Eye Irrit. 2; H319</td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1 200-662-2 606-001-00-8</td>
<td>Flam. Liq. 2; H225 Eye Irrit. 2; H319</td>
<td></td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>Acute Tox. 4; H332 Eye Irrit. 2; H319 Repr. 2; H361d STOT SE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td></td>
</tr>
</tbody>
</table>
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 soap and plenty of water. Remove 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.

For explanation of abbreviations see section 16.
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/PERSONAL PROTECTION 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)

**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,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>TWA</td>
<td>10 ppm 35 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
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<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm 36 mg/m³</td>
<td>2000/39/EC</td>
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<tr>
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<td></td>
<td>STEL</td>
<td>20 ppm 72 mg/m³</td>
<td>2000/39/EC</td>
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<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
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</tbody>
</table>
Further information: Skin

<table>
<thead>
<tr>
<th>Substance</th>
<th>Wipe limit</th>
<th>Value</th>
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<tbody>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>TWA</td>
</tr>
<tr>
<td></td>
<td>1000 µg/100 cm²</td>
<td>125 ppm</td>
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<tr>
<td></td>
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<td>295 mg/m³</td>
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<tr>
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<td>500 ppm</td>
</tr>
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<td></td>
<td>1.210 mg/m³</td>
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<td></td>
<td></td>
<td>FOR-2011-12-06-1358</td>
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<td>2000/39/EC</td>
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<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>TWA</td>
</tr>
<tr>
<td></td>
<td>100 µg/m³ (OEB 3)</td>
<td>10 µg/m³</td>
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<td></td>
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<td>Internal</td>
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<td></td>
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<td>Internal</td>
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**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>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>36 mg/m³</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></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>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>7 mg/m³</td>
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<tr>
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</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>
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<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>1 mg/kg bw/day</td>
</tr>
<tr>
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<tr>
<td>Acetone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1210 mg/m³</td>
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<tr>
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<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>2420 mg/m³</td>
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<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>186 mg/kg bw/day</td>
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<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>200 mg/m³</td>
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</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>62 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>62 mg/kg bw/day</td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p- cresol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>3.5 mg/m³</td>
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</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Dermal</td>
<td>Long-term systemic effects</td>
<td>0.5 mg/kg bw/day</td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
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<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>0.86 mg/m³</td>
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</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Dermal</td>
<td>Long-term systemic effects</td>
<td>0.25 mg/kg bw/day</td>
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<tr>
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<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0.25 mg/kg bw/day</td>
</tr>
<tr>
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</tr>
</tbody>
</table>

**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>
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</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>
</tbody>
</table>
Intermittent use/release | 5 mg/l
---|---
Sewage treatment plant | 485 mg/l
Fresh water sediment | 2,27 mg/kg
Soil | 0,15 mg/kg
Acetone
Fresh water | 10,6 mg/l
Marine water | 1,06 mg/l
Intermittent use/release | 21 mg/l
Sewage treatment plant | 100 mg/l
Fresh water sediment | 30,4 mg/kg dry weight (d.w.)
Marine sediment | 3,04 mg/kg dry weight (d.w.)
Soil | 29,5 mg/kg dry weight (d.w.)
2,6-Di-tert-butyl-p-cresol
Fresh water | 0,199 µg/l
Intermittent use/release | 0,02 µg/l
Marine water | 0,02 µg/l
Sewage treatment plant | 0,17 mg/l
Fresh water sediment | 0,0996 mg/kg dry weight (d.w.)
Marine sediment | 0,00996 mg/kg dry weight (d.w.)
Soil | 0,04769 mg/kg dry weight (d.w.)
Oral (Secondary Poisoning) | 8,33 mg/kg food

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.
Use explosion-proof electrical, ventilating and lighting equipment.

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
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. Equipment should conform to NS EN 137

Filter type: Self-contained breathing apparatus

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Physical state: liquid
- Colour: Colorless to pale yellow
- Odour: No data available
- Odour Threshold: No data available
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: No data available
- Flammability (solid, gas): Not applicable
- Flammability (liquids): Not applicable
- Upper explosion limit / Upper flammability limit: No data available
- Lower explosion limit / Lower flammability limit: No data available
- Flash point: 2 °C
  Method: closed cup
- Auto-ignition temperature: No data available
- Decomposition temperature: No data available
- pH: No data available
- Viscosity: 7,5 mm²/s
- Solubility(ies): No data available
- Water solubility: No data available
- Partition coefficient: n-octanol/water: Not applicable
- Vapour pressure: No data available
- Relative density: 1,06
Density : 1,08 g/cm³
Relative vapour density : No data available
Particle characteristics
  Particle size : Not applicable

9.2 Other information
  Explosives : Not explosive
  Oxidizing properties : The substance or mixture is not classified as oxidizing.
  Evaporation rate : No data available

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 hazard classes as defined in Regulation (EC) No 1272/2008
  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 toxicity estimate: 2.2 mg/l
Test atmosphere: dust/mist
Method: Calculation method

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

**Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**
Acute oral toxicity: LD50 (Rat, female): > 2.000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

**N,N-Diethyl-m-toluamide:**
Acute oral toxicity: LD50 (Rat): 1.950 mg/kg

Acute toxicity estimate: 1.892 mg/kg
Method: Expert judgement
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

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:
Species: Rabbit
Result: No skin irritation

Fluralaner:
Species: Rabbit
Result: No skin irritation

Poly(oxy-1,2-ethanediyl), alpha-[(tetrahydro-2-furanyl)methyl]-omega-hydroxy-:
Species: reconstructed human epidermis (RhE)
Method: OECD Test Guideline 439
Remarks: Based on data from similar materials
Result: No skin irritation

N,N-Diethyl-m-toluamide:
Species: Rabbit
Result: Skin irritation
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

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
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Poly(oxy-1,2-ethanediyl), .alpha.-[tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:
Species: Tissue Culture
Method: OECD Test Guideline 492
Remarks: Based on data from similar materials

Species: Bovine cornea
Method: OECD Test Guideline 437
Remarks: Based on data from similar materials

Result: Irritation to eyes, reversing within 21 days

N,N-Diethyl-m-toluamide:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

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.

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Test Type: KeratinoSens assay  
Method: OECD Test Guideline 442D  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Direct Peptide Reactivity Assay (DPRA)  
Method: OECD Test Guideline 442C  
Result: positive  
Remarks: Based on data from similar materials

Test Type: Dendritic cell activation test  
Method: OECD Test Guideline 442E  
Result: negative  
Remarks: Based on data from similar materials

Acetone:

Test Type: Maximisation Test  
Exposure routes: Skin contact  
Species: Guinea pig  
Result: negative

Moxidectin:

Test Type: Buehler Test  
Exposure routes: Dermal  
Species: Guinea pig  
Result: Not a skin sensitizer.

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

Test Type: Human repeat insult patch test (HRIPT)  
Exposure routes: Skin contact  
Species: Humans  
Result: negative

Germ cell mutagenicity

Not classified based on available information.

Components:

N,N-Dimethylacetamide:

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

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

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanylmethyl].omega.-hydroxy-.:  
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

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

Acetone:  
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test  
Result: negative
Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative
Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

Moxidectin:  
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative
Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells
Result: negative

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

Genotoxicity in vivo:

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

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

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

Genotoxicity in vitro:

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo:

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

Carcinogenicity
Not classified based on available information.

Components:

N,N-Dimethylacetamide:

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

Fluralaner:

Carcinogenicity - Assessment: No data available

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 Years
NOAEL: 0.5 mg/kg body weight
Result: negative

**2,6-Di-tert-butyl-p-cresol:**
Species: Rat
Application Route: Ingestion
Exposure time: 22 Months
Result: negative

**Reproductive toxicity**
May damage the unborn child.

**Components:**

**N,N-Dimethylacetamide:**

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

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Inhalation
Result: positive

Reproductive toxicity - As-
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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

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: Dermal
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: Skeletal malformations
Remarks: Maternal toxicity observed.

Reproductive toxicity - Assessment
Suspected of damaging the unborn child.

N,N-Diethyl-m-toluamide:

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

Acetone:

Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
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: Ingestion
General Toxicity Maternal: LOAEL: 10 mg/kg body weight
Embryo-foetal toxicity: LOAEL: 10 mg/kg body weight
Result: Skeletal malformations
Remarks: The effects were seen only at maternally toxic doses.

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

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

2,6-Di-tert-butyl-p-cresol:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

Version 6.1
Revision Date: 27.08.2021
SDS Number: 657384-00014
Date of last issue: 21.04.2021
Date of first issue: 02.05.2016

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
<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Symptoms</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fluralaner</strong></td>
<td>Rat</td>
<td>500 mg/kg</td>
<td></td>
<td>Dermal</td>
<td>90 Days</td>
<td>Liver</td>
<td>Liver, thymus gland</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td><strong>Acetone</strong></td>
<td>Rat</td>
<td>900 mg/kg</td>
<td>1.700 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Moxidectin</strong></td>
<td>Mouse</td>
<td>3.9 mg/kg</td>
<td>15.4 mg/kg</td>
<td>Oral</td>
<td>4 Weeks</td>
<td>Tremors</td>
<td>Central nervous system</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>3.9 mg/kg</td>
<td>7.9 mg/kg</td>
<td>Oral</td>
<td>13 Weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>0.3 mg/kg</td>
<td>0.9 mg/kg</td>
<td>Oral</td>
<td>90 Days</td>
<td>Tremors, Salivation</td>
<td>Central nervous system</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>0.3 mg/kg</td>
<td>0.87 mg/kg</td>
<td>Oral</td>
<td>52 Weeks</td>
<td>Tremors, Lachrymation, Salivation</td>
<td>Central nervous system</td>
<td></td>
</tr>
</tbody>
</table>
### 2,6-Di-tert-butyl-p-cresol:

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>NOAEL (mg/kg)</td>
<td>25</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.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

**Product:**

**Assessment:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 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

**Components:**

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

Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h
EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h

Toxicity to microorganisms: EC10: > 1.995 mg/l
Exposure time: 30 min

Fluralaner:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 0,0488 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 0,015 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0,08 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity): NOEC: >= 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

**Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 97 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 75 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Selenastrum capricornutum (green algae)): 41 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Selenastrum capricornutum (green algae)): 7.6 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 3.7 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

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
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Method: OECD Test Guideline 203
LC50 (Onchorhynchus 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 daphnia and other aquatic invertebrates:
LC50 (Danio rerio (zebra fish)): > 0,57 mg/l
Exposure time: 96 h

Toxicity to algae/aquatic plants:
EC50 (Daphnia magna (Water flea)): 0,48 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

M-Factor (Acute aquatic toxicity): 1

Toxicity to microorganisms:
EC50: > 10.000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity):
NOEC: 0,053 mg/l
Exposure time: 30 d
Species: Oryzias latipes (Japanese medaka)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: 0,316 mg/l
Exposure time: 21 d
ic toxicity) 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.

**Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**
Biodegradability: Result: Not readily biodegradable.
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

**N,N-Diethyl-m-toluamide:**
Biodegradability: Result: Readily biodegradable.
Biodegradation: 83,8 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

**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-octanol/water: \( \log \text{Pow: 4,5} \)

**Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**
Partition coefficient: n-octanol/water: \( \log \text{Pow: < 4} \)
Remarks: Calculation
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

Bioaccumulation
: 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

Product:
Assessment
: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Components:

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

12.6 Endocrine disrupting properties

Product:
Assessment
: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects
No data available
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according to Regulation (EC) No. 1907/2006

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

<table>
<thead>
<tr>
<th>Product</th>
<th>Contaminated packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispose of in accordance with local regulations.</td>
<td>Empty containers should be taken to an approved waste handling site for recycling or disposal.</td>
</tr>
<tr>
<td>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.</td>
<td>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.</td>
</tr>
</tbody>
</table>

SECTION 14: Transport information

14.1 UN number or ID number

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

14.2 UN proper shipping name

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

<table>
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<th>ADN</th>
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<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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<tr>
<td>3</td>
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14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
</tr>
</tbody>
</table>
Fluralaner / Moxidectin Liquid Formulation

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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fluralaner / Moxidectin Liquid Formulation

SECTION 15: Regulatory information

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

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 N,N-Dimethylacetamide (Number on list 72, 30)

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 (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors

This product is regulated by Regulation (EU) 2019/1148: all suspicious transactions, and significant disappearances and thefts should be reported to the relevant national contact point. Please see https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-we-do/policies/crisis-and-terrorism/explosives/explosives-precursors/docs/list_of_competent_authorities_and_national_contact_points_en.pdf


---

Acetone (ANNEX II)

<table>
<thead>
<tr>
<th>P5c</th>
<th>FLAMMABLE LIQUIDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>5.000 t</td>
<td>50.000 t</td>
</tr>
</tbody>
</table>

| E1  | ENVIRONMENTAL HAZARDS | 100 t | 200 t |

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

Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

AICS : not determined

DSL : not determined

IECSC : not determined
SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Fluralaner / Moxidectin Liquid Formulation

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 lines.

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.
EUH066 : Repeated exposure may cause skin dryness or cracking.

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
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
2000/39/EC / TWA : Limit Value - eight hours
2000/39/EC / STEL : Short term exposure limit
FOR-2011-12-06-1358 / TWA : Long term exposure limit
2000/39/EC : Limit Value - eight hours

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 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; TECI - Thailand Existing Chemicals Inventory; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:
<table>
<thead>
<tr>
<th>Category</th>
<th>Classification</th>
</tr>
</thead>
<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>

Classification procedure:
- Based on product data or assessment
- Calculation method

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.