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 : H225: Highly flammable liquid and vapour.
   Skin irritation, Category 2 : H315: Causes skin irritation.
   Eye irritation, Category 2 : H319: Causes serious eye irritation.
   Reproductive toxicity, Category 1B : H360D: May damage the unborn child.
   Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.
   Short-term (acute) aquatic hazard, Category 1 : H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1 : H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Danger
   Hazard statements : H225 Highly flammable liquid and vapour.
                      H315 Causes skin irritation.
H319  Causes serious eye irritation.
H360D May damage the unborn child.
H373  May cause damage to organs through prolonged or repeated exposure.
H410  Very toxic to aquatic life with long lasting effects.

Precautionary statements :  

**Prevention:**

P201  Obtain special instructions before use.
P210  Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P273  Avoid release to the environment.
P280  Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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

Hazardous components which must be listed on the label:

N,N-Dimethylacetamide

Moxidectin

**Additional Labelling**

Restricted to professional users.

### 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.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>204-826-4</td>
<td></td>
<td>Acute Tox. 4; H332</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4; H312</td>
<td></td>
</tr>
<tr>
<td>Substance</td>
<td>CAS Number</td>
<td>Eye Irrit.</td>
<td>Skin Irrit.</td>
<td>Acute Tox.</td>
<td>Aquatic Acute</td>
</tr>
<tr>
<td>-----------</td>
<td>------------</td>
<td>------------</td>
<td>-------------</td>
<td>------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>2; H319</td>
<td>2; H315</td>
<td>4; H302</td>
<td>1; H410</td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl), .alpha.- [(tetrahydro-2-furanyl)methyl]-omega-.hydroxy-</td>
<td>31692-85-0</td>
<td>2; H319</td>
<td></td>
<td>4; H301</td>
<td>1; H400</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td></td>
<td></td>
<td>3; H332</td>
<td>1; H400</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>2; H225</td>
<td>2; H319</td>
<td>3; H301</td>
<td></td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>2; H319</td>
<td>2; H319</td>
<td>3; H332</td>
<td>1; H400</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td></td>
<td></td>
<td></td>
<td>1; H400</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fluralaner / Moxidectin Liquid Formulation

Version 6.1
Revision Date: 21.04.2021
SDS Number: 657384-00013
Date of last issue: 15.10.2020
Date of first issue: 02.05.2016

H410
M-Factor (Acute aquatic toxicity): 1
M-Factor (Chronic aquatic toxicity): 1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

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

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

In case of skin contact: In case of contact, immediately flush skin with 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.

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
工程施工控制，适当的个人防护装备，适当的去污和去污染程序，工业卫生监测，医疗监视和使用行政控制。

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>TWA</td>
<td>10 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>35 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>20 ppm</td>
<td>2000/39/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>72 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>TWA</td>
<td>125 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>295 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further information: The EU has set an indicative limit value for this substance, Chemicals that can be absorbed through the skin.

Further information: Identifies the possibility of significant uptake through the skin, Indicative.

Further information: Identifies the possibility of significant uptake through the skin, Indicative.
Further information: The EU has set an indicative limit value for this substance

<table>
<thead>
<tr>
<th>Substance</th>
<th>Exposure route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td>TWA</td>
<td>500 ppm / 1.210 mg/m³</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
</tr>
</tbody>
</table>

Further information: Indicative

### 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></td>
<td></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 systemic 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></td>
<td></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>
<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>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>62 mg/kg bw/day</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>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Long-term systemic effects</td>
<td>0,5 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>0,86 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Dermal</td>
<td>Long-term systemic effects</td>
<td>0,25 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0,25 mg/kg bw/day</td>
</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>
</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>
</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.

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**

- **Material**: 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
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

Decomposition temperature: No data available

pH: No data available

Viscosity

Viscosity, kinematic: 7,5 mm²/s

Solubility(ies)

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

Fluralaner / Moxidectin Liquid Formulation

Version 6.1
Revision Date: 21.04.2021
SDS Number: 657384-00013
Date of last issue: 15.10.2020
Date of first issue: 02.05.2016

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

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
### Fluralaner / Moxidectin Liquid Formulation

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

#### 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
Fluralaner / Moxidectin Liquid Formulation

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
Result: negative

Fluralaner:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
### Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse Lymphoma</td>
<td>negative</td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Cell type</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micronucleus test</td>
<td>Mouse</td>
<td>Bone marrow</td>
<td>Oral</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>OECD Test Guideline 471</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Acetone:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
</tr>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>Mouse</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Moxidectin:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
</tr>
<tr>
<td>Chinese hamster ovary cells</td>
<td>negative</td>
</tr>
<tr>
<td>in vitro assay</td>
<td>negative</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chromosomal aberration</td>
<td>negative</td>
</tr>
</tbody>
</table>
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
Fluralaner / Moxidectin Liquid Formulation

Result: negative

Moxidectin:
Species: Mouse
Application Route: Oral
Exposure time: 2 Years
NOAEL: 4.5 mg/kg body weight
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 2 Years
NOAEL: 4.5 mg/kg body weight
Result: negative

Species: Dog
Application Route: Oral
Exposure time: 1 Year
NOAEL: 0.5 mg/kg body weight
Result: negative

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

Reproductive toxicity
May damage the unborn child.

Components:

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

Effects on foetal development:
Species: Rat
Application Route: Inhalation
Result: positive

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

Fluralaner:
Effects on fertility: Test Type: Two-generation study
Species: Rat
Application Route: Oral
General Toxicity - Parent: NOAEL: 50 mg/kg body weight
Fluralaner / Moxidectin Liquid Formulation

---

### 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

**Species**: Dog  
**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**: Rat  
**Application Route**: Oral  
**Developmental Toxicity**: NOAEL: 100 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

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

**Effects on foetal development**  
**Species**: Rat  
**Application Route**: Ingestion  
**Result**: negative

**Acetone**

**Effects on fertility**  
**Species**: Rat  
**Application Route**: Ingestion  
**Result**: negative

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

---
Fluralaner / Moxidectin Liquid Formulation

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.

Effects on foetal development:
- 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.

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: Embryofetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative

STOT - single exposure
Not classified based on available information.
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Fluralaner / Moxidectin Liquid Formulation

Components:
Acetone:
Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

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

2,6-Di-tert-butyl-p-cresol:
Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:
N,N-Dimethylacetamide:
Species: Rat
NOAEL: 90 mg/m3
LOAEL: 360 mg/m3
Application Route: Inhalation (vapour)
Exposure time: 24 Months

Fluralaner:
Species: Dog
NOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 52 Weeks
Target Organs: Liver
Remarks: No significant adverse effects were reported

Species: Juvenile dog
LOAEL: 56 - 280 mg/kg
Application Route: Oral
Exposure time: 24 Weeks
Symptoms: Diarrhoea

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

Species: Rat
NOAEL: 500 mg/kg
**Fluralaner / Moxidectin Liquid Formulation**

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Dermal</th>
</tr>
</thead>
<tbody>
<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>

### 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>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>52 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Tremors, Lachrymation</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>25 mg/kg</td>
</tr>
</tbody>
</table>
Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<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
Fluralaner / Moxidectin Liquid Formulation


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
Fluralaner / Moxidectin Liquid Formulation

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
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 0.0002 mg/l
Fluralaner / Moxidectin Liquid Formulation

Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 0.00003 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): 0.087 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity):
- 10.000

M-Factor (Chronic aquatic toxicity):
- 10.000

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

Toxicity to fish:
- LC50 (Danio rerio (zebra fish)): > 0.57 mg/l
- Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 0.48 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
- ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

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

M-Factor (Acute aquatic toxicity):
- 1

Toxicity to 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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Biodegradability</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide:</td>
<td>Biodegradable.</td>
<td>Remarks: The 10 day time window criterion is not fulfilled.</td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:</td>
<td>Biodegradable.</td>
<td>Method: OECD Test Guideline 301F; Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide:</td>
<td>Readable.</td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>Readable.</td>
<td></td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol:</td>
<td>Not readily biodegradable.</td>
<td></td>
</tr>
</tbody>
</table>

12.3 Bioaccumulative potential

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Bioaccumulation</th>
<th>Partition coefficient: n-octanol/water</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner:</td>
<td>Species: Zebrafish</td>
<td>log Pow: 4,5</td>
<td></td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>log Pow: &lt; 4</td>
<td></td>
<td>Remarks: Calculation</td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 15.10.2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1</td>
<td>21.04.2021</td>
<td>657384-00013</td>
<td>Date of first issue: 02.05.2016</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Partition coefficient: n-octanol/water</th>
<th>log Pow: 2,02</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acetone:</strong> Partition coefficient: n-octanol/water</td>
<td>log Pow: -0,27 - -0,23</td>
</tr>
<tr>
<td><strong>Moxidectin:</strong> Partition coefficient: n-octanol/water</td>
<td>log Pow: 4,7</td>
</tr>
<tr>
<td><strong>2,6-Di-tert-butyl-p-cresol:</strong> Bioaccumulation Species: Cyprinus carpio (Carp) Bioconcentration factor (BCF): 330 - 1.800</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

#### 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 Other adverse effects

#### Product:

| Endocrine disrupting potential | 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. |

### 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 or ID number

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</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>
</tr>
</thead>
<tbody>
<tr>
<td>ACETONE, SOLUTION</td>
<td>ACETONE, SOLUTION</td>
<td>ACETONE, SOLUTION</td>
<td>ACETONE, SOLUTION</td>
<td>Acetone, solution</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

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

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group: II</td>
<td>Packing group: II</td>
</tr>
<tr>
<td>Classification Code: F1</td>
<td>Classification Code: F1</td>
</tr>
<tr>
<td>Hazard Identification Number: 33</td>
<td></td>
</tr>
<tr>
<td>Labels: 3</td>
<td></td>
</tr>
</tbody>
</table>

Date of last issue: 15.10.2020
Date of first issue: 02.05.2016
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fluralaner / Moxidectin Liquid Formulation

Hazard Identification Number : 33
Labels : 3
Tunnel restriction code : (D/E)

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

IMDG
Packing group : II
Labels : 3
EmS Code : F-E, S-D

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 Maritime transport in bulk according to IMO instruments
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 - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, : Conditions of restriction for the following entries should be considered:
preparations and articles (Annex XVII)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).
REACH - List of substances subject to authorisation (Annex XIV)
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

REACH - List of substances subject to authorisation (Annex XIV)
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

This product is regulated by Regulation (EU) 2019/1148: Acetone (ANNEX II)


<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
<tr>
<td>P5c</td>
<td>FLAMMABLE LIQUIDS</td>
<td>5.000 t</td>
<td>50.000 t</td>
</tr>
</tbody>
</table>

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

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.
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

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organiza-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fluralaner / Moxidectin Liquid Formulation

Version 6.1  Revision Date: 21.04.2021  SDS Number: 657384-00013  Date of last issue: 15.10.2020

Revision Date: 21.04.2021  SDS Number: 657384-00013  Date of last issue: 15.10.2020

Date of first issue: 02.05.2016

Further information:
Sources of key data used to compile the Safety Data Sheet:

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

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.

NO / EN