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

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.
                      H400 Very toxic to aquatic life.
                      H410 Very toxic to aquatic life with long lasting effects.
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-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>Acute Tox. 4; H332</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>204-826-4</td>
<td>Acute Tox. 4; H312</td>
<td></td>
</tr>
</tbody>
</table>
## Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>Compound</th>
<th>CAS Number</th>
<th>Eye Irrit.</th>
<th>Skin Irrit.</th>
<th>Acute Tox.</th>
<th>Aquatic Acute</th>
<th>Aquatic Chronic</th>
<th>M-Factor (Acute aquatic toxicity)</th>
<th>M-Factor (Chronic aquatic toxicity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>2; H332</td>
<td>2; H319</td>
<td>4; H301</td>
<td>1; H400</td>
<td>1; H410</td>
<td>&gt;= 25 - &lt; 30</td>
<td>&gt;= 20 - &lt; 30</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>4; H332</td>
<td>1; H400</td>
<td>1; H410</td>
<td>1,892 mg/kg</td>
<td>10,000</td>
<td>1 - &lt; 2.5</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3 205-149-7 616-018-00-2</td>
<td>4; H302</td>
<td>2; H315</td>
<td>3; H301</td>
<td>1; H400</td>
<td>1; H410</td>
<td>&gt;= 10 - &lt; 20</td>
<td>1 - &lt; 2.5</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1 200-662-2 606-001-00-8</td>
<td>Flam. Liq. 2; H225</td>
<td>2; H319</td>
<td>3; H301</td>
<td>1; H400</td>
<td>1; H410</td>
<td>&gt;= 10 - &lt; 20</td>
<td>1 - &lt; 2.5</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>Acute Tox. 3; H301</td>
<td>Acute Tox. 4; H332</td>
<td>Eye Irrit. 2; H332</td>
<td>Repr. 2; H361d</td>
<td>STOT RE 1; H372 (Central nervous system)</td>
<td>Aquatic Acute 1; H400</td>
<td>Aquatic Chronic 1; H410</td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of first aid measures

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

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

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

**In case of skin contact**: In case of contact, immediately flush skin with 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 diking 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.
Hygiene measures: Take care to prevent spills, waste and minimize release to the environment.

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

<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 36 mg/m³</td>
<td>2000/39/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>20 ppm 72 mg/m³</td>
<td>2000/39/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 ppm 36 mg/m³</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

Further information: Identifies the possibility of significant uptake through the skin, 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>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>36 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>13.6 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>7 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2.7 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>1 mg/kg bw/day</td>
</tr>
<tr>
<td>Acetone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1210 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>2420 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>186 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>200 mg/m3</td>
</tr>
<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>Workers</td>
<td>Dermal</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>
</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

: Work uniform or laboratory coat.
: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
: Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection

: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
: Equipment should conform to I.S. 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
Viscosity, kinematic : 7.5 mm2/s
Fluralaner / Moxidectin Liquid Formulation

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 : Inhalation
exposure
Skin contact
Ingestion
Eye contact

**Acute toxicity**
Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Acute toxicity estimate: &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Acute toxicity estimate: &gt; 5 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>4 h</td>
</tr>
<tr>
<td>Test atmosphere:</td>
<td>dust/mist</td>
</tr>
<tr>
<td>Method</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Acute toxicity estimate: &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

**Components:**

**N,N-Dimethylacetamide:**

<table>
<thead>
<tr>
<th>Exposure</th>
<th>LD50 (Rat): 4,800 mg/kg</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Exposure</th>
<th>LC50 (Rat): 2.2 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>4 h</td>
</tr>
<tr>
<td>Test atmosphere:</td>
<td>dust/mist</td>
</tr>
<tr>
<td>Method</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposure</th>
<th>LD50 (Rat): 1,100 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>Expert judgement</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on harmonised classification in EU regulation 1272/2008, Annex VI</td>
</tr>
</tbody>
</table>

**Fluralaner:**

<table>
<thead>
<tr>
<th>Exposure</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>No mortality observed at this dose. No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposure</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Exposure</th>
<th>LD50 (Rat, female): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 423</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Exposure</th>
<th>LD50 (Rat): 1,950 mg/kg</th>
</tr>
</thead>
</table>
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according to Regulation (EC) No. 1907/2006

Fluralaner / Moxidectin Liquid Formulation

Version 6.1
Revision Date: 27.08.2021
SDS Number: 657380-00014
Date of last issue: 21.04.2021
Date of first issue: 02.05.2016

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

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 Result: negative

Fluralaner:

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

  - Test Type: Mouse Lymphoma Result: negative

  - Test Type: Chromosomal aberration Result: negative

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

Poly(oxy-1,2-ethanediyl), \(\alpha\)-[(tetrahydro-2-furanyl)methyl]-\(\omega\)-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
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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fluralaner / Moxidectin Liquid Formulation

Application Route: Inhalation
Result: negative

Effects on foetal development:
Test Type: Embryo-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
General Toxicity F1: LOAEL: 100 mg/kg body weight
Result: No effects on fertility, Postimplantation loss, Adverse neonatal effects.

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

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

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

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

Reproductive toxicity - Assessment:
Suspected of damaging the unborn child.

N,N-Diethyl-m-toluamide:

Effects on foetal development:
Test Type: Embryo-foetal development
ment

Species: Rat
Application Route: Ingestion
Result: negative

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

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

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

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

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

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

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

2,6-Di-tert-butyl-p-cresol:
Fluralaner / Moxidectin Liquid Formulation

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

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

STOT - single exposure
Not classified based on available information.

Components:

Acetone:
- Assessment: May cause drowsiness or dizziness.

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

Components:

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

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

Repeated dose toxicity

Components:

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

Fluralaner:
- Species: Dog
- NOAEL: 1 mg/kg
- Application Route: Oral
- Exposure time: 52 Weeks
- Target Organs: Liver
- Remarks: No significant adverse effects were reported
- Species: Juvenile dog
### Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>500 mg/kg</td>
<td>400 mg/kg</td>
<td>Oral</td>
<td>24 Weeks</td>
<td>Liver, thymus gland</td>
<td>Diarrhoea</td>
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<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
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<th>Target Organs</th>
<th>Symptoms</th>
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<tr>
<td>Rat</td>
<td>45 mg/l</td>
<td>1,700 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Liver</td>
<td></td>
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<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
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<tbody>
<tr>
<td>Rat</td>
<td>3.9 mg/kg</td>
<td>15.4 mg/kg</td>
<td>Oral</td>
<td>4 Weeks</td>
<td>Central nervous system</td>
<td>Tremors</td>
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</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>0.3 mg/kg</td>
<td>0.9 mg/kg</td>
<td>Oral</td>
<td>90 Days</td>
<td>Central nervous system</td>
<td>Tremors, Lachrymation, Salivation</td>
</tr>
</tbody>
</table>
Species: Dog
NOAEL: 0.3 mg/kg
LOAEL: 0.87 mg/kg
Application Route: Oral
Exposure time: 52 Weeks
Target Organs: Central nervous system
Symptoms: Tremors, Lachrymation

Species: Rat
NOAEL: 25 mg/kg
Application Route: Ingestion
Exposure time: 22 Months

Aspiration toxicity
Not classified based on available information.

Components:

Fluralaner:
Not applicable

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
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

**Moxidectin:**

Toxicity to fish: LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0006 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 0.0002 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to 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:

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:
Fluralaner / Moxidectin Liquid Formulation

Bioaccumulation:
- **Species:** Zebrafish
- **Bioconcentration factor (BCF):** 79.4
- **Method:** OECD Test Guideline 305

Partition coefficient: n-octanol/water
- **Log Pow:** 4.5

**Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**
- **Partition coefficient: n-octanol/water**
  - **Log 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
- **Partition coefficient: n-octanol/water**
  - **Log Pow:** 5.1

12.4 Mobility in soil

**Components:**

**Fluralaner:**
- **Distribution among environmental compartments**
  - **Log Koc:** 3.4

12.5 Results of PBT and vPvB assessment

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

Fluralaner / Moxidectin Liquid Formulation

Version 6.1
Revision Date: 27.08.2021
SDS Number: 657380-00014
Date of last issue: 21.04.2021
Date of first issue: 02.05.2016

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

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

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<thead>
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<tr>
<td><strong>ADN</strong></td>
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<td><strong>ADR</strong></td>
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<td><strong>RID</strong></td>
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<td><strong>IMDG</strong></td>
<td>UN 1090</td>
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<td><strong>IATA</strong></td>
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14.2 UN proper shipping name

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

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<tr>
<td><strong>ADN</strong></td>
<td>3</td>
</tr>
</tbody>
</table>
Fluralaner / Moxidectin Liquid Formulation

14.4 Packing group

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

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

IMDG
Packing group : II
Labels : 3

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

14.5 Environmental hazards

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Environmentally hazardous : yes
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

<table>
<thead>
<tr>
<th>REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)</th>
<th>Conditions of restriction for the following entries should be considered: Number on list 3 N,N-Dimethylacetamide (Number on list 72, 30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). Regulation (EC) No 1005/2009 on substances that deplete the ozone layer</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EU) 2019/1021 on persistent organic pollutants (recast)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals</td>
<td>Not applicable</td>
</tr>
<tr>
<td>REACH - List of substances subject to authorisation (Annex XIV)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

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_competentAuthorities_and_national_contact_points_en.pdf


<table>
<thead>
<tr>
<th>P5c</th>
<th>FLAMMABLE LIQUIDS</th>
<th>Quantity 1</th>
<th>5,000 t</th>
<th>Quantity 2</th>
<th>50,000 t</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1</td>
<td>ENVIRONMENTAL HAZARDS</td>
<td>100 t</td>
<td>200 t</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Fluralaner / Moxidectin Liquid Formulation

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECS : not determined

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

SECTION 16: 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.
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
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
2000/39/EC / TWA : Limit Value - eight hours
### Fluralaner / Moxidectin Liquid Formulation

**SAFETY DATA SHEET**

**according to Regulation (EC) No. 1907/2006**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date: 27.08.2021</th>
<th>SDS Number: 657380-00014</th>
<th>Date of last issue: 21.04.2021</th>
<th>Date of first issue: 02.05.2016</th>
</tr>
</thead>
</table>

2000/39/EC / STEL : Short term exposure limit  
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)  
IE OEL / OELV - 15 min (STEL) : Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIR - 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; IMDG - International Maritime Dangerous Goods; ILO - International Labour Organization; ILO - International Labour Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

**Further information**


**Classification of the mixture:**

| Flam. Liq. 2 | H225 |
| Skin Irrit. 2 | H315 |
| Eye Irrit. 2 | H319 |
| Repr. 1B | H360D |
| STOT RE 2 | H373 |
| Aquatic Acute 1 | H400 |
| Aquatic Chronic 1 | H410 |

**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.