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
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00
Telefax : 908-735-1496

E-mail address of person responsible for the SDS : EHSDATASETWORKER@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 pro-
Long-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
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Hazard statements:
- H225  Highly flammable liquid and vapour.
- H315  Causes skin irritation.
- H319  Causes serious eye irritation.
- H360D May damage the unborn child.
- H373  May cause damage to organs through prolonged or repeated exposure.
- H410  Very toxic to aquatic life with long lasting effects.

Precautionary statements:
- Prevention:
  - P201  Obtain special instructions before use.
  - P210  Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
  - P273  Avoid release to the environment.
  - P280  Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:
  - P308 + P313  IF exposed or concerned: Get medical advice/attention.
  - P391  Collect spillage.

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

Additional Labelling:
Restricted to professional users.

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

2.3 Other hazards
Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

### 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>616-011-00-4</td>
<td>Acute Tox.4; H332</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>205-149-7</td>
<td>616-018-00-2</td>
<td></td>
<td>Acute Tox.4; H312</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit.2; H319 Repr.1B; H360D</td>
<td></td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td></td>
<td></td>
<td>Repr.2; H361d Aquatic Chronic1; H410</td>
<td>&gt;= 25 - &lt; 30</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>205-149-7</td>
<td>616-018-00-2</td>
<td>Acute Tox.4; H302 Skin Irrit.2; H315 Eye Irrit.2; H319</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>
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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.

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

In case of skin contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
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4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treatment:
- Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media:
- High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:
- Do not use a solid water stream as it may scatter and spread fire.
- Flash back possible over considerable distance.
- Vapours may form explosive mixtures with air.
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Chlorine compounds
- Fluorine compounds
- Nitrogen oxides (NOx)

5.3 Advice for firefighters

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

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Remove all sources of ignition.
- Ventilate the area.
Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

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

6.3 Methods and material for containment and cleaning up
Methods for cleaning up:
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapours/mists with a water spray jet.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation:
- Use with local exhaust ventilation.
- Use only in an area equipped with explosion-proof exhaust ventilation if advised by assessment of the local exposure potential.
Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe vapours or spray mist.
- Do not swallow.
- Do not get in eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Non-sparking tools should be used.
- Keep container tightly closed.
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Date of first issue: 02.05.2016

Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

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

Advice on common storage:
Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures, which in contact with water, emit flammable gases
Explosives
Gases

7.3 Specific end use(s)

Specific use(s):
No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<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 35 mg/m3</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>STEL</td>
<td>20 ppm 72 mg/m3</td>
<td>2000/39/EC</td>
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<tr>
<td>Further information</td>
<td></td>
<td>TWA</td>
<td>10 ppm 36 mg/m3</td>
<td>2000/39/EC</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Fluralaner / Moxidectin Liquid Formulation

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**Further information**

<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>Fluralaner</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>
<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>
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Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Fresh water</td>
<td>0,5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0,0966 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>485 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>2,27 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0,15 mg/kg</td>
</tr>
<tr>
<td>Acetone</td>
<td>Fresh water</td>
<td>10,6 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>1,06 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>21 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>30,4 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>3,04 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>29,5 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>Fresh water</td>
<td>0,199 µg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0,02 µg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0,02 µg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>0,17 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0,0996 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0,00996 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0,04769 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>8,33 mg/kg food</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves
Remarks: Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.
Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection: Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.
Filter type: Self-contained breathing apparatus

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>clear</td>
</tr>
<tr>
<td>Odour</td>
<td>No information available.</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>2 °C</td>
</tr>
<tr>
<td>Method</td>
<td>closed cup</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>1.06</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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**Decomposition temperature**: No data available

**Viscosity**
- **Viscosity, kinematic**: No data available

**Explosive properties**: Not explosive

**Oxidizing properties**: The substance or mixture is not classified as oxidizing.

### 9.2 Other information

- **Flammability (liquids)**: Not applicable
- **Particle size**: Not applicable

## SECTION 10: Stability and reactivity

### 10.1 Reactivity
Not classified as a reactivity hazard.

### 10.2 Chemical stability
Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

- **Hazardous reactions**: Highly flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

- **Conditions to avoid**: Heat, flames and sparks.

### 10.5 Incompatible materials

- **Materials to avoid**: Oxidizing agents

### 10.6 Hazardous decomposition products
No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

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

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Date of first issue: 02.05.2016

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

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

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

Components:

N,N-Dimethylacetamide:

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

Acute inhalation toxicity: LC50 (Rat): 2.2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

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

Fluralaner:

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

Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
Remarks: No significant adverse effects were reported

N,N-Diethyl-m-toluamide:

Acute oral toxicity: LD50 (Rat): 1.950 mg/kg

Acute inhalation toxicity: LC50 (Rat): 5.95 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rat): 5.000 mg/kg

Acetone:

Acute oral toxicity: LD50 (Rat): 5.800 mg/kg

Acute inhalation toxicity: LC50 (Rat): 76 mg/l
Exposure time: 4 h
Test atmosphere: vapour

Acute dermal toxicity: LD50 (Rabbit): 7.426 mg/kg
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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

N,N-Diethyl-m-toluamide:
Species: Rabbit
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<table>
<thead>
<tr>
<th>Result</th>
<th>Skin irritation</th>
</tr>
</thead>
</table>

**Acetone:**
- **Assessment:** Repeated exposure may cause skin dryness or cracking.

**Moxidectin:**
- **Species:** Rabbit
- **Result:** Mild skin irritant

**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 irritant

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

**Acetone:**
- **Species:** Rabbit
- **Method:** OECD Test Guideline 405
- **Result:** Irritation to eyes, reversing within 21 days
- **Remarks:** Based on data from similar materials

**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:

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

Fluralaner:

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

Acetone:

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

Moxidectin:

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

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human repeat insult patch test (HRIPT)</td>
<td>Skin contact</td>
<td>Humans</td>
<td>negative</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

N,N-Dimethylacetamide:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Rodent dominant lethal test (germ cell) (in vivo)</td>
<td>Species: Rat Application Route: Inhalation</td>
</tr>
</tbody>
</table>
Method: OECD Test Guideline 478
Result: negative

**Fluralaner:**

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

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

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

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

**Acetone:**

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

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

**Moxidectin:**

**Genotoxicity in vitro:**
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Test Type: In vitro mammalian cell gene mutation test
  Test system: Chinese hamster ovary cells
  Result: negative
  Test Type: in vitro assay
  Test system: Escherichia coli
  Result: negative
Fluralaner / Moxidectin Liquid Formulation

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

Fluralaner / Moxidectin Liquid Formulation

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:
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

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

Species: Rabbit
Application Route: Ingestion (vapour)
Result: negative

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

N,N-Diethyl-m-toluamide:
Species: Rat
Application Route: Ingestion
Result: negative

Acetone:
Species: Rat
Application Route: Ingestion
Result: negative
Moxidectin:

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

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

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

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

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

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

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

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

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

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

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

**Components:**

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

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

**Repeated dose toxicity**

**Components:**

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

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

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

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

- Species: Rat
  - NOAEL: 500 mg/kg
<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>
Application Route: Ingestion
Exposure time: 22 Months

Aspiration toxicity
Not classified based on available information.

Components:
Fluralaner:
Not applicable

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

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

SECTION 12: Ecological information

12.1 Toxicity

Product:
Components:

N,N-Dimethylacetamide:
Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h

Toxicity to algae: EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h
EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l
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
### Toxicity to daphnia and other aquatic invertebrates

**Method:** OECD Test Guideline 203  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>EC50 (mg/l)</th>
<th>Exposition time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Daphnia magna</em> (Water flea)</td>
<td>OECD Test Guideline 202</td>
<td>&gt; 0.015</td>
<td>48 h</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### Toxicity to algae

**Method:** OECD Test Guideline 202  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>NOEC (mg/l)</th>
<th>Exposition time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Pseudokirchneriella subcapitata</em> (green algae)</td>
<td>OECD Test Guideline 201</td>
<td>&gt;= 0.08</td>
<td>72 h</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### Toxicity to fish (Chronic toxicity)

**Method:** OECD Test Guideline 204  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>NOEC (mg/l)</th>
<th>Exposition time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Zebrafish</em></td>
<td>OECD Test Guideline 201</td>
<td>&gt;= 0.049</td>
<td>21 d</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

**Method:** OECD Test Guideline 204  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>NOEC (mg/l)</th>
<th>Exposition time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Daphnia magna</em> (Water flea)</td>
<td>OECD Test Guideline 204</td>
<td>0.000047</td>
<td>21 d</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### M-Factor (Chronic aquatic toxicity)

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 8192</td>
<td></td>
</tr>
<tr>
<td>OECD Test Guideline 211</td>
<td></td>
</tr>
</tbody>
</table>

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

### Toxicity to fish

**Method:** OECD Test Guideline 201  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>LC50 (mg/l)</th>
<th>Exposition time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Pimephales promelas</em> (fathead minnow)</td>
<td>OECD Test Guideline 201</td>
<td>110</td>
<td>96 h</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates

**Method:** OECD Test Guideline 203  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>EC50 (mg/l)</th>
<th>Exposition time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Daphnia magna</em> (Water flea)</td>
<td>OECD Test Guideline 202</td>
<td>75</td>
<td>48 h</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### Acetone:

### Toxicity to fish

**Method:** OECD Test Guideline 201  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>LC50 (mg/l)</th>
<th>Exposition time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Oncorhynchus mykiss</em> (rainbow trout)</td>
<td>OECD Test Guideline 201</td>
<td>5.540</td>
<td>96 h</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates

**Method:** OECD Test Guideline 203  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>EC50 (mg/l)</th>
<th>Exposition time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Daphnia pulex</em> (Water flea)</td>
<td>OECD Test Guideline 202</td>
<td>8.800</td>
<td>48 h</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### Toxicity to algae

**Method:** OECD Test Guideline 202  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>NOEC (mg/l)</th>
<th>Exposition time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Pseudokirchneriella subcapitata</em> (green algae)</td>
<td>OECD Test Guideline 201</td>
<td>7.000</td>
<td>96 h</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

**Method:** OECD Test Guideline 202  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>EC50 (mg/l)</th>
<th>Exposition time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Pseudokirchneriella subcapitata</em> (green algae)</td>
<td>OECD Test Guideline 201</td>
<td>61.150</td>
<td>30 min</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

**Method:** OECD Test Guideline 204  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>NOEC (mg/l)</th>
<th>Exposition time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Daphnia magna</em> (Water flea)</td>
<td>OECD Test Guideline 204</td>
<td>0.000047</td>
<td>21 d</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>
### Moxidectin:

**Toxicity to fish:**
- LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0006 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
- LC50 (Oncorhynchus mykiss (rainbow trout)): 0.0002 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates:**
- EC50 (Daphnia magna (Water flea)): 0.0003 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

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

**M-Factor (Acute aquatic toxicity):**
- 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:**
- 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)
**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**

- **NOEC:** 0.316 mg/l
- **Exposure time:** 21 d
- **Species:** Daphnia magna (Water flea)
- **M-Factor (Chronic aquatic toxicity):** 1

**12.2 Persistence and degradability**

**Components:**

- **N,N-Dimethylacetamide:**
  - **Biodegradability:** Result: Not readily biodegradable.
  - **Biodegradation:** 70 %
  - **Exposure time:** 28 d
  - **Remarks:** The 10 day time window criterion is not fulfilled.

- **N,N-Diethyl-m-toluamide:**
  - **Biodegradability:** Result: Not readily biodegradable.

- **Acetone:**
  - **Biodegradability:** Result: Readily biodegradable.
  - **Biodegradation:** 91 %
  - **Exposure time:** 28 d

- **2,6-Di-tert-butyl-p-cresol:**
  - **Biodegradability:** Result: Not readily biodegradable.
  - **Biodegradation:** 4,5 %
  - **Exposure time:** 28 d
  - **Method:** OECD Test Guideline 301C

**12.3 Bioaccumulative potential**

**Components:**

- **Fluralaner:**
  - **Bioaccumulation:** Species: Zebrafish
    - **Bioconcentration factor (BCF):** 79.4
    - **Method:** OECD Test Guideline 305
  - **Partition coefficient: n-octanol/water:** log Pow: 4.5

- **N,N-Diethyl-m-toluamide:**
  - **Partition coefficient: n-octanol/water:** log Pow: 2.02

- **Acetone:**
  - **Partition coefficient: n-octanol/water:** log Pow: -0.27 - -0.23
Moxidectin:

Partition coefficient: n-octanol/water

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

Bioaccumulation

Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n-octanol/water

12.4 Mobility in soil

Components:

Fluralaner:

Distribution among environmental compartments

log Koc: 3.4

12.5 Results of PBT and vPvB assessment

Components:

Fluralaner:

Assessment

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

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

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

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal.
Empty containers retain residue and can be dangerous.
Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.
If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN: UN 1090
ADR: UN 1090
RID: UN 1090
<table>
<thead>
<tr>
<th>IMDG</th>
<th>: UN 1090</th>
</tr>
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<tr>
<td>IATA</td>
<td>: UN 1090</td>
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### 14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>: ACETONE, SOLUTION</th>
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<tbody>
<tr>
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</tr>
<tr>
<td>RID</td>
<td>: ACETONE, SOLUTION</td>
</tr>
</tbody>
</table>
| IMDG         | : ACETONE, SOLUTION  
  (Moxidectin, 2,6-Di-tert-butyl-p-cresol) |
| IATA         | : Acetone, solution |

### 14.3 Transport hazard class(es)

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<tr>
<td>IMDG</td>
<td>: 3</td>
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<tr>
<td>IATA</td>
<td>: 3</td>
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### 14.4 Packing group

#### ADN

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#### ADR

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<td>Tunnel restriction code</td>
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#### RID

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#### IMDG

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<td>EmS Code</td>
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#### IATA (Cargo)

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SAFETY DATA SHEET
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SDS Number: 657384-00009
Date of last issue: 12.04.2018
Date of first issue: 02.05.2016

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : N,N-Dimethylacetamide
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3 N,N-Dimethylacetamide (Number on list 30)

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Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

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

SECTION 16: Other information

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

Full text of H-Statements
H225 : Highly flammable liquid and vapour.
H301 : Toxic if swallowed.
H302 : Harmful if swallowed.
H312 : Harmful in contact with skin.
H315 : Causes skin irritation.
H319 : Causes serious eye irritation.
H332 : Harmful if inhaled.
H336 : May cause drowsiness or dizziness.
H360D : May damage the unborn child.
H361d : Suspected of damaging the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
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
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Date of first issue: 02.05.2016

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; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Property</th>
<th>Classification / Labelling / Packaging Regs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flam. Liq. 2</td>
<td>H225</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>H315</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
</tr>
</tbody>
</table>

Classification procedure:
Based on product data or assessment
Calculation method
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STOT RE 2   H373   Calculation method
Aquatic Acute 1   H400   Calculation method
Aquatic Chronic 1   H410   Calculation method

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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