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 : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Flammable liquids, Category 2 H225: Highly flammable liquid and vapour.
   Skin irritation, Category 2 H315: Causes skin irritation.
   Eye irritation, Category 2 H319: Causes serious eye irritation.
   Reproductive toxicity, Category 1B H360D: May damage the unborn child.
   Specific target organ toxicity - repeated exposure, Category 2 H373: May cause damage to organs through pro-
   longed or repeated exposure.
   Short-term (acute) aquatic hazard, Category 1 H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1 H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : ![Safety Data Sheet Pictograms]
   Signal word : Danger
Fluralaner / Moxidectin Liquid Formulation

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

<table>
<thead>
<tr>
<th>Components</th>
<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></td>
<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>
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<tr>
<td></td>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td></td>
<td></td>
<td>Repr. 2; H361d Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity):</td>
<td>&gt;= 25 - &lt; 30</td>
</tr>
</tbody>
</table>
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Fluralaner / Moxidectin Liquid Formulation

Version 4.2  Revision Date: 13.09.2019  SDS Number: 657380-00010  Date of last issue: 18.10.2018
Date of first issue: 02.05.2016

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Acute Tox.</th>
<th>H302</th>
<th>Skin Irr.</th>
<th>H315</th>
<th>Eye Irrit.</th>
<th>H319</th>
<th>Aquatic Chronic 3; H412</th>
<th>&gt;= 10 - &lt; 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3 205-149-7 616-018-00-2</td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Aquatic Chronic 3; H412</td>
<td>&gt;= 10 - &lt; 20</td>
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</tr>
<tr>
<td>Acetone</td>
<td>67-64-1 200-662-2 606-001-00-8</td>
<td>Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336</td>
<td>&gt;= 10 - &lt; 20</td>
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</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>Acute Tox. 3; H301 Acute Tox. 4; H332 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 1 - &lt; 2.5</td>
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<td></td>
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<tr>
<td>M-Factor (Acute aquatic toxicity):</td>
<td>10,000</td>
<td>M-Factor (Chronic aquatic toxicity): 10,000</td>
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</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0 204-881-4</td>
<td>Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
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<td></td>
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<tr>
<td>M-Factor (Acute aquatic toxicity):</td>
<td>1</td>
<td>M-Factor (Chronic aquatic toxicity): 1</td>
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<td></td>
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</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

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

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

In case of skin contact: In case of contact, immediately flush skin with 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.
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)
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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: If sufficient ventilation is unavailable, use with local exhaust ventilation. If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust ventilation.

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

Hygiene measures: 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)
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Specific use(s) : No data available  

SECTION 8: Exposure controls/personal protection  

8.1 Control parameters  

**Occupational Exposure Limits**  

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
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<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>STEL</td>
<td>20 ppm</td>
<td>72 mg/m³</td>
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<td></td>
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<tr>
<td>Further information</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
<td>36 mg/m³</td>
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<td></td>
<td></td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 ppm</td>
<td>36 mg/m³</td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td>OELV - 15 min (STEL)</td>
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<td>72 mg/m³</td>
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<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
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<td>Acetone</td>
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<td>Moxidectin</td>
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<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
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<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>OELV - 8 hrs (TWA)</td>
<td>2 mg/m³</td>
<td>IE OEL</td>
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</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:  

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>36 mg/m³</td>
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<tr>
<td>Substance name</td>
<td>Environmental Compartment</td>
<td>Value</td>
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<td>--------------------------------</td>
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<td>------------------------</td>
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<tr>
<td>N,N-Dimethylacetamide</td>
<td>Fresh water</td>
<td>0.5 mg/l</td>
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<td>Marine water</td>
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<td></td>
<td>Intermittent use/release</td>
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<td>Sewage treatment plant</td>
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<tr>
<td></td>
<td>Fresh water sediment</td>
<td>2.27 mg/kg</td>
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<tr>
<td></td>
<td>Soil</td>
<td>0.15 mg/kg</td>
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<tr>
<td>Acetone</td>
<td>Fresh water</td>
<td>10.6 mg/l</td>
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<td></td>
<td>Marine water</td>
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<td>Intermittent use/release</td>
<td>21 mg/l</td>
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<td>Sewage treatment plant</td>
<td>100 mg/l</td>
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<tr>
<td></td>
<td>Fresh water sediment</td>
<td>30.4 mg/kg dry weight (d.w.)</td>
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<td>Marine sediment</td>
<td>3.04 mg/kg dry weight (d.w.)</td>
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<td>Soil</td>
<td>29.5 mg/kg dry weight (d.w.)</td>
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<td>2,6-Di-tert-butyl-p-cresol</td>
<td>Fresh water</td>
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<tr>
<td></td>
<td>Intermittent use/release</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.02 µg/l</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8.2 Exposure controls

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

Personal protective equipment

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

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

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

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Self-contained breathing apparatus

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: liquid
Colour: clear
Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/freezing point: No data available

Initial boiling point and boiling range:
Flash point:
  Method: closed cup
  Value: 2 °C

Evaporation rate: No data available

Flammability (solid, gas): Not applicable

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: No data available

Relative vapour density: No data available

Relative density: 1.06

Density: No data available

Solubility(ies)
  Water solubility: No data available

Partition coefficient: n-octanol/water: Not applicable

Auto-ignition temperature: No data available

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.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method

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

Acute dermal toxicity: Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method

Components:
N,N-Dimethylacetamide:
Acute oral toxicity: LD50 (Rat): 4,800 mg/kg
Acute inhalation toxicity: LC50 (Rat): 2.2 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity: Acute toxicity estimate: 1,100 mg/kg Method: Expert judgement Remarks: Based on harmonised classification in EU regulation
Fluralaner / Moxidectin Liquid Formulation

1272/2008, Annex VI

**Fluralaner:**
- **Acute oral toxicity**
  - LD50 (Rat): > 2,000 mg/kg
  - Remarks: No mortality observed at this dose.
  - No significant adverse effects were reported
- **Acute dermal toxicity**
  - LD50 (Rat): > 2,000 mg/kg
  - Remarks: No significant adverse effects were reported

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

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

**Moxidectin:**
- **Acute oral toxicity**
  - LD50 (Rat): 106 mg/kg
  - LD50 (Mouse): 42 - 84 mg/kg
- **Acute inhalation toxicity**
  - LC50 (Rat): 3.28 mg/l
  - Exposure time: 5 h
  - Test atmosphere: dust/mist
  - LC50 (Rat): 2.87 - 4.06 mg/l
  - Test atmosphere: dust/mist
- **Acute dermal toxicity**
  - LD50 (Rat): > 2,000 mg/kg
  - Remarks: No significant adverse effects were reported
- **Acute toxicity (other routes of administration)**
  - LD50 (Rat): 394 mg/kg
  - Application Route: Intraperitoneal
  - LD50 (Mouse): 84 mg/kg
  - Application Route: Intraperitoneal
  - LD50 (Rat): > 640 mg/kg
  - Application Route: Subcutaneous
SAFETY DATA SHEET
generated by Regulation (EC) No. 1907/2006

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Version: 4.2
Revision Date: 13.09.2019
SDS Number: 657380-00010
Date of last issue: 18.10.2018
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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
Result: Skin irritation

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:
### Fluralaner / Moxidectin Liquid Formulation

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

#### Fluralaner:
- **Species:** Rabbit
- **Result:** Mild eye irritation

#### 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

#### 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.

#### Acetone:
- **Test Type:** Maximisation Test

---

**MSD Public**

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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

N,N-Diethyl-m-toluamide:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Acetone:
Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
                      Result: negative

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

                      Test Type: Chromosome aberration test in vitro
                      Result: negative

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

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

                      Test Type: In vitro mammalian cell gene mutation test
                      Test system: Chinese hamster ovary cells
                      Result: negative

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

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

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

2,6-Di-tert-butyl-p-cresol:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
                      Result: negative

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

                      Test Type: Chromosome aberration test in vitro
                      Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
                      Species: Rat
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
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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
General Toxicity - Parent: NOAEL: 50 mg/kg body weight
General Toxicity F1: LOAEL: 100 mg/kg body weight
Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects.

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

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

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

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

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

N,N-Diethyl-m-toluamide:
Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

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

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

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

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

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

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

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

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

Effects on foetal development: 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
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**Date of first issue**: 02.05.2016

<table>
<thead>
<tr>
<th>Fluralaner:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species</strong></td>
<td>Dog</td>
</tr>
<tr>
<td><strong>NOAEL</strong></td>
<td>1 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>52 Weeks</td>
</tr>
<tr>
<td><strong>Target Organs</strong></td>
<td>Liver</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

| Species | Juvenile dog |
| Application Route | Oral |
| Exposure time | 24 Weeks |
| Symptoms | Diarrhoea |

| Species | Rat |
| Application Route | Oral |
| Exposure time | 90 Days |
| Target Organs | Liver, thymus gland |
| Remarks | No significant adverse effects were reported |

| Species | Rat |
| Application Route | Dermal |
| Exposure time | 90 Days |
| Target Organs | Liver |

| Species | Rat |
| Application Route | Inhalation (vapour) |
| Exposure time | 8 Weeks |

| Species | Mouse |
| Application Route | Oral |
| Exposure time | 4 Weeks |
| Symptoms | Tremors |
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Species: Rat
NOAEL: 3.9 mg/kg
LOAEL: 7.9 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Central nervous system
Symptoms: Tremors, Salivation

Species: Dog
NOAEL: 0.3 mg/kg
LOAEL: 0.9 mg/kg
Application Route: Oral
Exposure time: 90 Days
Target Organs: Central nervous system
Symptoms: Tremors, Lachrymation, Salivation

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

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

Aspiration toxicity
Not classified based on available information.

Components:
Fluralaner:
Not applicable

Acetone:
The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

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.
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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)
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Method: OECD Test Guideline 211

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

N,N-Diethyl-m-toluamide:
Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 110 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 75 mg/l Exposure time: 48 h

Acetone:
Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia pulex (Water flea)): 8,800 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l Exposure time: 96 h
Toxicity to microorganisms : EC50 : 61,150 mg/l Exposure time: 30 min Method: ISO 8192
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: >= 79 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

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

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):

- Toxicity to microorganisms: EC50: > 10,000 mg/l
  - Exposure time: 3 h
  - Method: OECD Test Guideline 209
- Toxicity to fish (Chronic toxicity): NOEC: 0.053 mg/l
  - Exposure time: 30 d
  - Species: Oryzias latipes (Japanese medaka)
  - Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 0.316 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)

**M-Factor (Chronic aquatic toxicity):** 1

### 12.2 Persistence and degradability

**Components:**

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

**N,N-Diethyl-m-toluamide:**
- Biodegradability: Result: Not readily biodegradable.
Acetone:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 91 %
Exposure time: 28 d

2,6-Di-tert-butyl-p-cresol:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 4.5 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

12.3 Bioaccumulative potential

Components:

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

Partition coefficient: n-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 : 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

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
IMDG : UN 1090
IATA : UN 1090

14.2 UN proper shipping name
ADN : ACETONE, SOLUTION
ADR : ACETONE, SOLUTION
RID : ACETONE, SOLUTION
IMDG : ACETONE, SOLUTION
        (Moxidectin, 2,6-Di-tert-butyl-p-cresol)
IATA : Acetone, solution

14.3 Transport hazard class(es)
ADN : 3
ADR : 3
RID : 3
IMDG : 3
14.4 Packing group

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

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

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

**IMDG**
Packing group: II
Labels: 3

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

**IATA (Passenger)**
Packing instruction (passenger aircraft): 353
Packing instruction (LQ): Y341
Packing group: II
Labels: Flammable Liquids

14.5 Environmental hazards

**ADN**
Environmentally hazardous: yes

**ADR**
Environmentally hazardous: yes

**RID**
Environmentally hazardous: yes

**IMDG**
Marine pollutant: yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet.
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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 72, 30)


| E1 | ENVIRONMENTAL HAZARDS | Quantity 1: 100 t | Quantity 2: 200 t |
| P5c | FLAMMABLE LIQUIDS | Quantity 1: 5,000 t | Quantity 2: 50,000 t |

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

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

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

SECTION 16: Other information

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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
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
2000/39/EC / TWA: Limit Value - eight hours
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; 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 Equip-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fluralaner / Moxidectin Liquid Formulation

Version 4.2  Revision Date: 13.09.2019  SDS Number: 657380-00010  Date of last issue: 18.10.2018

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Property</th>
<th>Classification</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flam. Liq. 2</td>
<td>H225</td>
<td>Based on product data or assessment</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>H315</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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IE / EN