SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version: 3.2  
Revision Date: 10/18/2018  
SDS Number: 656889-00009  
Date of last issue: 12.04.2018  
Date of first issue: 02.05.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 50 Tuas West Drive  
Singapore - Singapore 638408
Telephone: 908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification
Flammable liquids: Category 2
Skin corrosion/irritation: Category 2
Serious eye damage/eye irritation: Category 2
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 2 (Central nervous system)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms: ![Danger], ![Flammable], ![Eye], ![Plant]
Signal word: Danger
Hazard statements: H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H360D May damage the unborn child.
H373 May cause damage to organs (Central nervous system) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ventilating/lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response:
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/attention.
P332 + P313 If skin irritation occurs: Get medical advice/attention.
P337 + P313 If eye irritation persists: Get medical advice/attention.
P391 Collect spillage.

Storage:
P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

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

Other hazards which do not result in classification:
Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS
4. 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.

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.

Most important symptoms and effects, both acute and delayed: Causes skin irritation. Causes serious eye irritation. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

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.

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: High volume water jet

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)

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.

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

6. ACCIDENTAL RELEASE MEASURES

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

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.

Methods and materials for containment and 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.

7. HANDLING AND STORAGE

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.
- 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.

Conditions for safe storage:
- 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.

Materials to avoid:
- Do not store with the following product types:
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Oxidizing agents
  - Flammable gases
  - Pyrophoric liquids
  - Pyrophoric solids
  - Self-heating substances and mixtures
  - Poisonous gases
  - Explosives

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>PEL (long term)</td>
<td>10 ppm 36 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

- Wipe limit 1000 µg/100 cm² Internal

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>PEL (long term)</td>
<td>750 ppm 1,780 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (short term)</td>
<td>1,000 ppm 2,380 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>250 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>500 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>N-Methylacetamide</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>30 mg/g Creatinine</td>
<td>ACGIH BEI</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>Acetone</td>
<td>Urine</td>
<td>End of shift (As soon as possible after exposure ceases)</td>
<td>25 mg/l</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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

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

Hand protection: Chemical-resistant gloves

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

Skin and body protection: Work uniform or laboratory coat.
**SAFETY DATA SHEET**

**Fluralaner / Moxidectin Liquid Formulation**

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<tr>
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<th>Date of last issue:</th>
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</thead>
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<tr>
<td>3.2</td>
<td>10/18/2018</td>
<td>656889-00009</td>
<td>12.04.2018</td>
<td>02.05.2016</td>
</tr>
</tbody>
</table>

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.

**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.

### 9. 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><strong>pH</strong></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><strong>Flash point</strong></td>
<td>2 °C</td>
</tr>
<tr>
<td></td>
<td>Method: 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>Flammability (liquids)</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>
</tbody>
</table>
### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Highly flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Heat, flames and sparks.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### 11. TOXICOLOGICAL INFORMATION

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

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

**Product:**

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

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

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

**Components:**

**N,N-Dimethylacetamide:**
- Acute oral toxicity: LD50 (Rat): 4,800 mg/kg
Acute inhalation toxicity: LC50 (Rat): 2.2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: Acute toxicity estimate: 1,100 mg/kg
Method: Expert judgement
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

**Fluralaner:**

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

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Remarks: No significant adverse effects were reported

**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): LD50 (Rat): 394 mg/kg
application)

**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
- Result: Skin irritation

**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
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Moxidectin:
Species: Rabbit
Result: Moderate eye irritation

2,6-Di-tert-butyl-p-cresol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
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
- **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

**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 
Application Route: Ingestion 
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

**N,N-Dimethylacetamide:**
Species: Rat
Application Route: Inhalation (vapour)
Exposure time: 18 month(s)
Result: negative

**Fluralaner:**
Carcinogenicity - Assessment: No data available

**N,N-Diethyl-m-toluamide:**
Species: Rat
Application Route: Ingestion
Exposure time: 104 weeks
Result: negative

**Acetone:**
Species: Mouse
Application Route: Skin contact
Exposure time: 424 days
Result: negative

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

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

Species: Dog
Application Route: Oral
Exposure time: 1 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
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 (Central nervous system) 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)
### 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  
**NOAEL:** 500 mg/kg  
**Application Route:** Dermal  
**Exposure time:** 90 Days  
**Target Organs:** Liver, thymus  
**Remarks:** No significant adverse effects were reported

### Acetone:

**Species:** Rat  
**NOAEL:** 900 mg/kg  
**LOAEL:** 1,700 mg/kg  
**Application Route:** Ingestion  
**Exposure time:** 90 Days

**Species:** Rat  
**NOAEL:** 45 mg/l  
**Application Route:** inhalation (vapour)  
**Exposure time:** 8 Weeks

### Moxidectin:

**Species:** Mouse  
**NOAEL:** 3.9 mg/kg  
**LOAEL:** 15.4 mg/kg  
**Application Route:** Oral  
**Exposure time:** 4 Weeks  
**Symptoms:** Tremors

**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  

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.
12. ECOLOGICAL INFORMATION

Ecotoxicity

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
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 : 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 (Zebrafish): >= 0.049 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 204
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.000047 mg/l
Exposure time: 21 d
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**
- NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l
- Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- NOEC (Daphnia magna (Water flea)): >= 79 mg/l
- Exposure time: 21 d
- Method: OECD Test Guideline 211

**Toxicity to microorganisms**
- EC50: 61,150 mg/l
- Exposure time: 30 min
- Method: ISO 8192

### 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)): 0.00003 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 fish (Chronic toxicity)**
- NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l
- Exposure time: 30 d
- Method: OECD Test Guideline 210

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- NOEC (Daphnia magna (Water flea)): 0.316 mg/l
- Exposure time: 21 d

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

**Toxicity to microorganisms**
- EC₅₀: > 10,000 mg/l
- Exposure time: 3 h
- Method: OECD Test Guideline 209

### 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
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

Mobility in soil

**Components:**

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

Other adverse effects

**Components:**

**Fluralaner:**
- Results of PBT and vPvB assessment: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

13. DISPOSAL CONSIDERATIONS

Disposal methods

- **Waste from residues:** Dispose of in accordance with local regulations.
- **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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 1090
Proper shipping name : ACETONE SOLUTION
Class : 3
Packing group : II
Labels : 3

IATA-DGR
UN/ID No. : UN 1090
Proper shipping name : Acetone solution
Class : 3
Packing group : II
Labels : Flammable Liquids
Packing instruction (cargo aircraft) : 364
Packing instruction (passenger aircraft) : 353

IMDG-Code
UN number : UN 1090
Proper shipping name : ACETONE SOLUTION
(Moxidectin, 2,6-Di-tert-butyl-p-cresol)
Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.
Environmental Protection and Management Act and : Not applicable
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Acetone

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

16. OTHER INFORMATION

**Further information**

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


Date format: dd.mm.yyyy

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **ACGIH BEI**: ACGIH - Biological Exposure Indices (BEI)
- **SG OEL**: Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances
- **ACGIH / TWA**: 8-hour, time-weighted average
- **ACGIH / STEL**: Short-term exposure limit
- **SG OEL / PEL (long term)**: Permissible Exposure Level (PEL) Long Term
- **SG OEL / PEL (short term)**: Permissible Exposure Level (PEL) Short Term

**Abbreviations**

- **AICS** - Australian Inventory of Chemical Substances
- **ANTT** - National Agency for Transport by Land of Brazil
- **ASTM** - American Society for the Testing of Materials
- **bw** - Body weight
- **CMR** - Carcinogen, Mutagen or Reproductive Toxicant
- **CPR** - Controlled Products Regulations
- **DIN** - Standard of the German Institute for Standardisation
- **DSL** - Domestic Substances List (Canada)
- **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
- **ERG** - Emergency Response Guide
- **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
- **Nch** - Chilean Norm
- **NO(A)EC** - No Observed (Adverse) Effect Concentration
- **NO(A)EL** - No Observed (Adverse) Effect Level
- **NOELR** - No Observable Effect Loading Rate
- **NOM** - Official Mexican Norm
- **NTP** - National Tox-
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

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icology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

SG / EN