SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version: 5.2
Revision Date: 10/18/2018
SDS Number: 656884-00009
Date of last issue: 2018/04/12
Date of first issue: 2016/05/02

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier's details
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: 1-908-423-6000

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:

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.
P362 + P364 Take off contaminated clothing and wash it before reuse.
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
Important symptoms and outlines of the emergency assumed:
Vapours may form explosive mixture with air.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>35</td>
<td>2-723</td>
</tr>
<tr>
<td></td>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 25 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Acetone</td>
<td>67-64-1</td>
<td>&gt;= 10 - &lt; 20</td>
<td>2-542</td>
</tr>
<tr>
<td></td>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>&gt;= 10 - &lt; 20</td>
<td>3-1321</td>
</tr>
<tr>
<td></td>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
<td>3-540/9-1805</td>
</tr>
</tbody>
</table>

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
media
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

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. 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.

Avoidance of contact: Oxidizing agents

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.

Storage


Materials to avoid: Do not store with the following product types: Oxidizing solids Oxidizing liquids

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>
</table>

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**SAFETY DATA SHEET**

**Fluralaner / Moxidectin Liquid Formulation**

**Components**

<table>
<thead>
<tr>
<th>CAS-No.</th>
<th>Target substance</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>127-19-5</td>
<td>N,N-Dimethylacetamide</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>67-64-1</td>
<td>Acetone</td>
<td>Urine</td>
<td>Within 2 h prior to end of shift</td>
<td>40 mg/l</td>
<td>JSOH</td>
</tr>
<tr>
<td>113507-06-5</td>
<td>Moxidectin</td>
<td>TWA</td>
<td>10 µg/m3 (OEB 3)</td>
<td>Internal</td>
<td></td>
</tr>
</tbody>
</table>

**Target Substance**

- N,N-Dimethylacetamide
- Acetone
- Moxidectin

**Biological Specimen**

- Urine

**Sampling Time**

- End of shift at end of work-week
- Within 2 h prior to end of shift
- As soon as possible after exposure ceases

**Permissible Concentration**

- 30 mg/g Creatinine
- 40 mg/l
- 25 mg/l

**Basis**

- ACGIH
- JSOH
- BEI

**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:

Material: Chemical-resistant gloves

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

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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Colour: clear

Odour: No information available.

Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: 2 °C

Method: closed cup

Evaporation rate: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): Not applicable

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

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.
Particle size: Not applicable

10. STABILITY AND REACTIVITY
Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions
Highly flammable liquid and vapour.
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.
Conditions to avoid: Heat, flames and sparks.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

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

**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

**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

**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

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Route</th>
<th>LD50 (Rat)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td>Intraperitoneal</td>
<td>&gt; 2,000 mg/kg</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Acetone</td>
<td>Subcutaneous</td>
<td>&gt; 640 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

### Acute toxicity (other routes of administration)

<table>
<thead>
<tr>
<th>Component</th>
<th>Application Route</th>
<th>LD50 (Rat)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>Intraperitoneal</td>
<td>394 mg/kg</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>Intraperitoneal</td>
<td>&gt; 2,000 mg/kg</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>Subcutaneous</td>
<td>&gt; 640 mg/kg</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Route</th>
<th>LD50 (Rat)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>Subcutaneous</td>
<td>263 mg/kg</td>
</tr>
</tbody>
</table>

### Skin corrosion/irritation

Causes skin irritation.

### Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Acetone</td>
<td></td>
<td>Repeated exposure may cause skin dryness or cracking.</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>Rabbit</td>
<td>Skin irritation</td>
</tr>
<tr>
<td>Moxidectin</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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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

Acetone:
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

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

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:

Acetone:
- Test Type: Maximisation Test
- Exposure routes: Skin contact
- Species: Guinea pig
- Result: negative

Moxidectin:
- Test Type: Buehler Test
- Exposure routes: Dermal
- Species: Guinea pig
- Result: Not a skin sensitizer.

2,6-Di-tert-butyl-p-cresol:
- Test Type: Human repeat insult patch test (HRIPT)
- Exposure routes: Skin contact
- Species: Humans
- Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

N,N-Dimethylacetamide:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Genotoxicity in vivo:

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

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

N,N-Diethyl-m-toluamide:
Genotoxicity in vitro :
Test Type: Bacterial reverse mutation assay (AMES)
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

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

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

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

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

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

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

| Species | Rat          |
| Application Route | Ingestion    |
| Exposure time | 22 Months    |
| Result       | negative     |

### Reproductive toxicity

May damage the unborn child.

### Components:

#### N,N-Dimethylacetamide:

*Effects on fertility*  
Test Type: One-generation reproduction toxicity study  
Species: Rat  
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:

- **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

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

- **Effects on foetal development**:
  - **Test Type**: Embryo-foetal development
    - **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 (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)
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
NOAEL : 56 - 280 mg/kg
Application Route : Oral
Exposure time : 24 Weeks
Symptoms : Diarrhoea
Species : Rat
NOAEL : 400 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Liver, thymus
Species : Rat
NOAEL : 500 mg/kg
Application Route : Dermal
Exposure time : 90 Days
Target Organs : Liver
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.
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

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

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

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

Toxicity to algae:
- NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- NOEC (Daphnia magna (Water flea)): >= 79 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211
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Date of first issue: 2016/05/02

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:
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.

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

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

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

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

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

Hazardous to the ozone layer
Not applicable

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.

National Regulations
Refer to section 15 for specific national regulation.

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
SAFETY DATA SHEET

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Date of first issue: 2016/05/02

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and var-
iations in regional or country regulations.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Group 4, Type 1 petroleum, Water insoluble liquid, (200 litre)

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>114</td>
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<tr>
<td>2,6-Di-tert-butyl-4-methylphenol</td>
<td>64</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-dimethylacetamide</td>
<td>284</td>
</tr>
</tbody>
</table>

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information
on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information
on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>284</td>
<td>&gt;=30 - &lt;40</td>
</tr>
<tr>
<td>Acetone</td>
<td>17</td>
<td>&gt;=10 - &lt;20</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-4-cresol</td>
<td>262</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
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<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
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<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>284</td>
</tr>
<tr>
<td>acetone</td>
<td>17</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable
**SAFETY DATA SHEET**

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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
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<tr>
<td>5.2</td>
<td>10/18/2018</td>
<td>656884-00009</td>
<td>2018/04/12</td>
<td>2016/05/02</td>
</tr>
</tbody>
</table>

**Ordinance on Prevention of Organic Solvent Poisoning**
Organic Solvents Class 2

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**
Inflammable Substance

**Poisonous and Deleterious Substances Control Law**
Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

**Class I Designated Chemical Substances**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>213</td>
<td>35</td>
</tr>
</tbody>
</table>

**High Pressure Gas Safety Act**
Not applicable

**Explosive Control Law**
Not applicable

**Vessel Safety Law**
Flammable liquids (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

**Aviation Law**
Flammable liquid (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

**Marine Pollution and Sea Disaster Prevention etc Law**
Bulk transportation: Noxious liquid substance (Category Z)
Pack transportation: Classified as marine pollutant

**Narcotics and Psychotropics Control Act**
Narcotic or Psychotropic Raw Material
Not applicable

Specific Narcotic or Psychotropic Raw Material
Not applicable

**Waste Disposal and Public Cleansing Law**
Specially Controlled Industrial Waste

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

**16. OTHER INFORMATION**

Further information
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

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

Date format: yyyy/mm/dd

Full text of other abbreviations:
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
- JP OEL ISHL: Japan. Administrative Control Levels
- JSOH: Occupational exposure limits based on biological monitoring (JSOH).

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 Germany; 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 Standardisation; 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 Toxicology 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 mate-
rial 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 ap-
propriateness of the SDS material in the user’s end product, if applicable.

JP / EN