SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier’s details
Company : MSD
Address : JL Raya Pandaan KM. 48
           Pandaan, Jawa Timur - Indonesia
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
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 2A
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
Vapours may form explosive mixture with air.
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Fluralaner / Moxidectin Liquid Formulation

Version: 5.0
Revision Date: 2020/10/15
SDS Number: 656881-00012
Date of last issue: 2020/03/23
Date of first issue: 2016/05/02

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>&gt;= 30</td>
<td>&lt; 60</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 25</td>
<td>&lt; 30</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>&gt;= 10</td>
<td>&lt; 25</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>&gt;= 10</td>
<td>&lt; 20</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>&gt;= 1</td>
<td>&lt; 2.5</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>&gt;= 0.025</td>
<td>&lt; 0.25</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.
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.

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 (see section 8).

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: 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 (see section 7) and personal protective equipment recommendations (see section 8).

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

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: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling: Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
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>NAB</td>
<td>10 ppm</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>36 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Further information: Adopted in Year 1996, Liver damage, Embryo/fetal damage, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals, Identifies chemicals that need a BEI (= Biological Exposure Indices)</td>
<td>TWA</td>
<td>10 ppm</td>
<td>ACGIH</td>
<td></td>
</tr>
</tbody>
</table>
## Biological occupational exposure limits

<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 explosion-proof electrical, ventilating and lighting equip-
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.

**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

**Hand protection**: 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.

**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.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: liquid

**Colour**: Colorless to pale yellow

**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 : 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 : 1.08 g/cm³
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 : 7.5 mm²/s
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : Not applicable
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
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
   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:**
- **Species:** Rabbit
- **Result:** Irritation to eyes, reversing within 21 days

**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
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:

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

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
- Test Type: Mammalian erythrocyte micronucleus test (in vivo
- Result: negative

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

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

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

- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 104 weeks
- **Result**: negative

### Acetone:

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

### Moxidectin:

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

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

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

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

- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 22 Months
- **Result**: negative

#### Reproductive toxicity

May damage the unborn child.

### Components:

#### N,N-Dimethylacetamide:

- **Effects on fertility**: Test Type: One-generation reproduction toxicity study
  - **Species**: Rat
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Fluralaner / Moxidectin Liquid Formulation

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>negative</td>
</tr>
</tbody>
</table>

### 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
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
### 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  
  - **LOAEL:** 56 - 280 mg/kg  
  - **Application Route:** Oral  
  - **Exposure time:** 24 Weeks
## Symptoms

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>400 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver, thymus gland</td>
</tr>
</tbody>
</table>

**Remarks:** No significant adverse effects were reported

### Acetone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>900 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>1,700 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

### Moxidectin:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>3.9 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>15.4 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>4 Weeks</td>
</tr>
</tbody>
</table>

**Symptoms:** Tremors

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

### Species:

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.3 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.87 mg/kg</td>
</tr>
</tbody>
</table>
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.
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

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
<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC10 (Desmodesmus subspicatus (green algae)): &gt; 500 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>EC10: &gt; 1,995 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 30 min</td>
</tr>
</tbody>
</table>

**Fluralaner:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 0.0488 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 0.015 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>NOEC (Zebrafish): &gt;= 0.049 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 204</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC (Daphnia magna (Water flea)): 0.000047 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 110 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 75 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
</tbody>
</table>

**Acetone:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia pulex (Water flea)): 8,800 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
</tbody>
</table>
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/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 0.087 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 10,000
M-Factor (Chronic aquatic toxicity): 10,000

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

Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 0.57 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.48 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 1

Toxicity to 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
24/27

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
15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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

Fluralaner / Moxidectin Liquid Formulation

Version 5.0  Revision Date: 2020/10/15  SDS Number: 656881-00012  Date of last issue: 2020/03/23
Date of first issue: 2016/05/02

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:

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

Date format  :  yyyy/mm/dd

Full text of other abbreviations

ACGIH  :  USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI  :  ACGIH - Biological Exposure Indices (BEI)
ID OEL  :  Indonesia. Occupational Exposure Limits

ACGIH / TWA  :  8-hour, time-weighted average
ACGIH / STEL  :  Short-term exposure limit
ID OEL / NAB  :  Long term exposure limit
ID OEL / PSD  :  Short term exposure limit

AICS - Australian Inventory of Industrial Chemicals; 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; 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 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 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 - Trans-
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.