1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier's details
- Company: MSD
- Address: Briahnager - Off Pune Nagar Road
  Wagholi - Pune - India 412 207
- 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

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
- Very highly flammable liquids

GHS Classification
- Flammable liquids: Category 2
- Acute toxicity (Oral): Category 5
- Acute toxicity (Inhalation): Category 5
- Acute toxicity (Dermal): Category 5
- 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
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version: 4.0  Revision Date: 10/18/2018  SDS Number: 657381-00009  Date of last issue: 12.04.2018  Date of first issue: 02.05.2016

GHS label elements

Hazard pictograms

Signal word: Danger

Hazard statements:
- H225 Highly flammable liquid and vapour.
- H303 + H313 + H333 May be harmful if swallowed, in contact with skin or if inhaled.
- 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, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- 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:
- P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
- P302 + P352 + P312 IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/doctor if you feel unwell.
- P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
- P304 + P312 IF INHALED: Call a POISON CENTER/ doctor if you feel unwell.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P312 Call a POISON CENTER/doctor if you feel unwell.
- 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:
- 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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>N,N-Dimethylacetamide</td>
</tr>
<tr>
<td></td>
<td>Fluralaner</td>
</tr>
<tr>
<td></td>
<td>Acetone</td>
</tr>
<tr>
<td></td>
<td>N,N-Diethyl-m-toluamide</td>
</tr>
<tr>
<td></td>
<td>Moxidectin</td>
</tr>
<tr>
<td></td>
<td>2,6-Di-tert-butyl-p-cresol</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 : May be harmful if swallowed, in contact with skin or if inhaled. 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

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

**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.

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>
</table>

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SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version 4.0  Revision Date: 10/18/2018  SDS Number: 657381-00009  Date of last issue: 12.04.2018

Date of first issue: 02.05.2016

<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., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

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
Fluralaner / Moxidectin Liquid Formulation

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: 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>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>2 °C</td>
</tr>
<tr>
<td>Method</td>
<td>closed cup</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>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>
</tbody>
</table>
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**
May be harmful if swallowed, in contact with skin or if inhaled.

**Product:**
- **Acute oral toxicity**: Acute toxicity estimate: 3,548 mg/kg
  Method: Calculation method
- **Acute inhalation toxicity**: Acute toxicity estimate: 5.3 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method
Acute dermal toxicity: Acute toxicity estimate: 2,827 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: 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

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

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

N,N-Diethyl-m-toluamide:
Species: Rabbit
Result: Skin irritation

Moxidectin:
### Species: Rabbit

#### 2,6-Di-tert-butyl-p-cresol:
- **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
- **Method**: OECD Test Guideline 405
- **Result**: Irritation to eyes, reversing within 21 days

#### 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
- **Method**: OECD Test Guideline 405
- **Result**: No eye irritation
- **Remarks**: Based on data from similar materials

### Respiratory or skin sensitisation

#### Skin sensitisation
Not classified based on available information.

#### Respiratory sensitisation
Not classified based on available information.
Components:

N,N-Dimethylacetamide:
- Exposure routes: Skin contact
- Species: Guinea pig
- Result: negative

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

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

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

- Genotoxicity in vivo:

  Test Type: Rodent dominant lethal test (germ cell) (in vivo)
  Species: Rat
  Application Route: Inhalation
  Method: OECD Test Guideline 478
  Result: negative

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

  Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Result: negative

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>4.5 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>0.5 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>22 Months</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Reproductive toxicity**

May damage the unborn child.

**Components:**

**N,N-Dimethylacetamide:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Inhalation Result: negative</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development Species: Rat Application Route: Inhalation Result: positive</th>
</tr>
</thead>
</table>

**Reproductive toxicity - Assessment**

Clear evidence of adverse effects on development, based on animal experiments.

**Fluralaner:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>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</th>
</tr>
</thead>
</table>

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.

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
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.

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 Assessment: Central nervous system
- Causes damage to organs through prolonged or repeated exposure.
2,6-Di-tert-butyl-p-cresol:
Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

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

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

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

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

Species: Rat
NOAEL: 500 mg/kg
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: Inhalation
Exposure time: 90 Days

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

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

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.3 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.87 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>52 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Tremors, Lachrymation, Salivation</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>25 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>22 Months</td>
</tr>
</tbody>
</table>

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:**

<table>
<thead>
<tr>
<th>Toxicty to fish</th>
<th>LC50 (Leuciscus idus (Golden orfe)): &gt; 500 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicty to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 500 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicty to algae</th>
<th>EC50 (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 (Desmodesmus subspicatus (green algae)): &gt; 500 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicty to microorganisms</th>
<th>EC10: &gt; 1,995 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 30 min</td>
</tr>
</tbody>
</table>

**Fluralaner:**

<table>
<thead>
<tr>
<th>Toxicty 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>Toxicty 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>Toxicty to algae</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>Toxicty to fish (Chronic toxicity)</th>
<th>NOEC: &gt;= 0.049 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td>Species: Zebrafish</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>
### Acetone:

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Description</th>
<th>Toxicity</th>
<th>Exposure Time</th>
<th>Species</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC: 0.000047 mg/l Exposure time: 21 d</td>
<td>Daphnia magna (Water flea) Method: OECD Test Guideline 211</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>1,000</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Description</th>
<th>Toxicity</th>
<th>Exposure Time</th>
<th>Species</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 110 mg/l Exposure time: 96 h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): 75 mg/l Exposure time: 48 h</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Moxidectin:

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Description</th>
<th>Toxicity</th>
<th>Exposure Time</th>
<th>Species</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0006 mg/l Exposure time: 96 h Method: OECD Test Guideline 203</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): 0.0002 mg/l Exposure time: 96 h Method: OECD Test Guideline 203</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): 0.00003 mg/l Exposure time: 48 h Method: OECD Test Guideline 202</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 0.087 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

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 : ER50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

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

Toxicity to fish (Chronic toxicity) : NOEC: 0.053 mg/l
Exposure time: 30 d
Species: Oryzias latipes (Japanese medaka)
Method: OECD Test Guideline 210

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

M-Factor (Chronic aquatic toxicity) : 1

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

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 IMO instruments
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

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:

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

Date format: dd.mm yyyy

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
- IN OEL: India. Permissible levels of certain chemical substances in work environment.

- ACGIH / TWA: 8-hour, time-weighted average
- ACGIH / STEL: Short-term exposure limit
- IN OEL / TWA: Time-Weighted Average Concentration (TWA) (8 hrs.)
- IN OEL / STEL: Short-term exposure Limit STEL (15 min)

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 -
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version 4.0  Revision Date: 10/18/2018  SDS Number: 657381-00009  Date of last issue: 12.04.2018  Date of first issue: 02.05.2016

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.

IN / EN