SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version: 6.1  Revision Date: 13.09.2019  SDS Number: 656886-00010  Date of last issue: 18.10.2018
Date of first issue: 02.05.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Flammable liquids: Category 2
Acute toxicity (Oral): Category 5
Acute toxicity (Inhalation): Category 5
Acute toxicity (Dermal): Category 5
Skin irritation: Category 2
Eye irritation: Category 2A
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Central nervous system)

Aspiration hazard: Category 2

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements:
H225 Highly flammable liquid and vapor.
H303 + H313 + H333 May be harmful if swallowed, in contact with skin or if inhaled.
H305 May be harmful if swallowed and enters airways.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H360D May damage the unborn child.
H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

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 vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.
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 or doctor/ physician 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 or doctor/ physician if you feel unwell.
P331 Do NOT induce vomiting.
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.

Storage:
P405 Store locked up.

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

Other hazards:
Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>CAS-No.</td>
</tr>
<tr>
<td></td>
<td>127-19-5</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
</tr>
</tbody>
</table>
SECTION 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 center immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: May be harmful if swallowed, in contact with skin or if inhaled. May be harmful if swallowed and enters airways. Causes skin irritation. Causes serious eye irritation. May damage the unborn child. Causes 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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: High volume water jet

Specific hazards during fire fighting: Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-
SECTION 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/vapors/mists with a water spray jet.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSOANAL PROTECTION section.

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.
- If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust ventila-
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

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

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage:
- Keep in properly labeled 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:
  - Strong oxidizing agents
  - Organic peroxides
  - Flammable solids
  - Pyrophoric liquids
  - Pyrophoric solids
  - Self-heating substances and mixtures
  - Substances and mixtures which in contact with water emit flammable gases
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>VLE-PPT</td>
<td>10 ppm</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
### Further information: Skin

<table>
<thead>
<tr>
<th>Component</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>Acetone</td>
<td>67-64-1</td>
<td>VLE-PPT</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>500 ppm</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VLE-CT</td>
<td></td>
<td></td>
<td>750 ppm</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td></td>
<td></td>
<td>250 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td></td>
<td></td>
<td>500 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>TWA</td>
<td></td>
<td>10 µg/m³ (OEB 3)</td>
<td></td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td></td>
<td>100 µg/100 cm²</td>
<td></td>
<td>Internal</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>MX BEI</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>Acetone</td>
<td>Urine</td>
<td>End of shift</td>
<td>50 mg/l</td>
<td>MX BEI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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

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:
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Color: clear
Odor: No data available
Odor 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
Vapor pressure: No data available
Relative vapor 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
Autoignition 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

SECTION 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 vapor.
  Vapors 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.

SECTION 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 judgment
  - 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: vapor
- **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

**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

**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

Respiratory or skin sensitization

**Skin sensitization**
- Not classified based on available information.

**Respiratory sensitization**
- Not classified based on available information.

Components:

**N,N-Dimethylacetamide:**
- Routes of exposure: Skin contact
- Species: Guinea pig
- Result: negative

**Fluralaner:**
- Test Type: Maximization Test
- Routes of exposure: Dermal
- Species: Guinea pig
- Result: Not a skin sensitizer.

**Acetone:**
- Test Type: Maximization Test
- Routes of exposure: Skin contact
- Species: Guinea pig
- Result: negative
**Moxidectin:**
- **Test Type:** Buehler Test
- **Routes of exposure:** Dermal
- **Species:** Guinea pig
- **Result:** Not a skin sensitizer.

**Germ cell mutagenicity**
- Not classified based on available information.

**Components:**

**N,N-Dimethylacetamide:**
- **Genotoxicity in vitro:**
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- **Genotoxicity in vivo:**
  - Test Type: Rodent dominant lethal test (germ cell) (in vivo)
  - Species: Rat
  - Application Route: Inhalation
  - Method: OECD Test Guideline 478
  - Result: negative

**Fluralaner:**
- **Genotoxicity in vitro:**
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: Mouse Lymphoma
  - Result: negative
  - Test Type: Chromosomal aberration
  - Result: negative
- **Genotoxicity in vivo:**
  - Test Type: Micronucleus test
  - Species: Mouse
  - Cell type: Bone marrow
  - Application Route: Oral
  - Result: negative

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

**Acetone:**
- **Genotoxicity in vitro:**
  - Test Type: In vitro mammalian cell gene mutation test
  - Result: negative
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: Chromosome aberration test in vitro
  - Result: negative
- **Genotoxicity in vivo:**
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo
## 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 test
  - 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

## Carcinogenicity
- Not classified based on available information.

### Components:

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

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

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

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

**Moxidectin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</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>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>

**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 fetal development**

Test Type: Embryo-fetal 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
Effects on fetal development:

- **Test Type:** Development
- **Species:** Rat
- **Application Route:** Oral
- **Developmental Toxicity:** 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 fetal development:

- **Test Type:** Development
- **Species:** Rabbit
- **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:** Dermal
- **Developmental Toxicity:** NOAEL: 100 mg/kg body weight
- **Result:** Skeletal malformations. Remarks: Maternal toxicity observed.

Reproductive toxicity - Assessment:

- Suspected of damaging the unborn child.

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

Effects on fetal development:

- **Test Type:** Embryo-fetal development
- **Species:** Rat
- **Application Route:** Ingestion
- **Result:** Negative

**Acetone:**

Effects on fertility:

- **Test Type:** One-generation reproduction toxicity study
- **Species:** Rat
- **Application Route:** Ingestion
- **Result:** Negative

Effects on fetal development:

- **Test Type:** Embryo-fetal development
- **Species:** Rat
- **Application Route:** Inhalation (vapor)
- **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 fetal weight., Fetal 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 fetal weight., Fetal mortality.  
Result: No effects on fertility., Some evidence of adverse effects on development, based on animal experiments.

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

Test Type: Embryo-fetal 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.

STOT-single exposure  
Not classified based on available information.

Components:

Acetone:
Assessment: May cause drowsiness or dizziness.

STOT-repeated exposure  
Causes 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.

Repeated dose toxicity

Components:

N,N-Dimethylacetamide:
Species: Rat  
NOAEL: 90 mg/m³  
LOAEL: 360 mg/m³
Application Route: inhalation (vapor)
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: Diarrhea

Species: Rat
LOAEL: 400 mg/kg
Application Route: Oral
Exposure time: 90 Days
Target Organs: Liver, thymus gland
Remarks: No significant adverse effects were reported

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 (vapor)
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
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

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

Aspiration toxicity
May be harmful if swallowed and enters airways.

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.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

N,N-Dimethylacetamide:
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Toxicity to fish
- LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates
- EC50 (Daphnia magna (Water flea)): > 500 mg/l
  Exposure time: 48 h

Toxicity to algae/aquatic plants
- EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
  Exposure time: 72 h
- EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l
  Exposure time: 72 h

Toxicity to microorganisms
- EC10: > 1,995 mg/l
  Exposure time: 30 min

Fluralaner:

Toxicity to fish
- LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.0488 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203
  Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates
- EC50 (Daphnia magna (Water flea)): > 0.015 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202
  Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants
- NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity)
- NOEC (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

N,N-Diethyl-m-toluamide:

Toxicity to fish
- LC50 (Pimephales promelas (fathead minnow)): 110 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates
- EC50 (Daphnia magna (Water flea)): 75 mg/l
  Exposure time: 48 h

Acetone:

Toxicity to fish
- LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg/l
  Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia pulex (Water flea)): 8,800 mg/l
Exposure time: 48 h

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

Toxicity to 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

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
Bioaccumulative potential

Components:

Fluralaner:

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

Partition coefficient: n-octanol/water: log Pow: 4.5

N,N-Diethyl-m-toluamide:

Partition coefficient: n-octanol/water: log Pow: 2.02

Acetone:

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

Moxidectin:

Partition coefficient: n-octanol/water: log Pow: 4.7

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).

SECTION 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.
SECTION 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.

**Domestic regulation**

**NOM-002-SCT**

*UN number:* UN 1090

*Proper shipping name:* ACETONE, SOLUTION

*Class:* 3

*Packing group:* II

*Labels:* 3

**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.

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for Acetone
producing capsules, tablets and pills.

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

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

**SECTION 16. OTHER INFORMATION**

**Full text of other abbreviations**

- **ACGIH**: USA, ACGIH Threshold Limit Values (TLV)
- **ACGIH BEI**: ACGIH - Biological Exposure Indices (BEI)
- **MX BEI**: Official Mexican Norm NOM-047-SSA1-2011, Environmental Health - Biological exposure indices for workers occupation-ally exposed to chemical agents
- **NOM-010-STPS-2014**: Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
- **ACGIH / TWA**: 8-hour, time-weighted average
- **ACGIH / STEL**: Short-term exposure limit
- **NOM-010-STPS-2014 / VLE- PPT**: Time weighted average limit value
- **NOM-010-STPS-2014 / VLE- CT**: Short term exposure limit value

**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; **DIN** - Standard of the German Institute for Standardisation; **DSL** - Domestic Substances List (Canada); **ECx** - Concentration associated with x% response; **ELx** - Loading rate associated with x% response; **EmS** - Emergency Schedule; **ENCS** - Existing and New Chemical Substances (Japan); **ErCx** - Concentration associated with x% growth rate response; **ERG** - Emergency Response Guide; **GHS** - Globally Harmonized System; **GLP** - Good Laboratory Practice; **IARC** - International Agency for Research on Cancer; **IATA** - International Air Transport Association; **IBC** - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; **IC50** - Half maximal inhibitory concentration; **ICAO** - International Civil Aviation Organization; **IECSC** - Inventory of Existing Chemical Substances in China; **IMDG** - International Maritime Dangerous Goods; **IMO** - International Maritime Organization; **ISHL** - Industrial Safety and Health Law (Japan); **ISO** - International Organisation for 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 Tempera-

Revision Date: 13.09.2019

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8