SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version 4.0 Revision Date: 10/18/2018 SDS Number: 656875-00009 Date of last issue: 04/12/2018 Date of first issue: 05/02/2016

SECTION 1. IDENTIFICATION

Product name: Fluralaner / Moxidectin Liquid Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Flammable liquids: Category 2
Skin irritation: Category 2
Eye irritation: Category 2A
Reproductive toxicity: Category 1B
Specific target organ systemic toxicity - repeated exposure: Category 1 (Central nervous system)

GHS label elements
Hazard pictograms:
Signal Word: Danger
Hazard Statements: H225 Highly flammable liquid and vapor. 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:
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
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.

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>Mixture</th>
</tr>
</thead>
</table>

**Components**

<table>
<thead>
<tr>
<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 - &lt; 60</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration or concentration range is withheld as a trade secret

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.
- Get medical attention.
- Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
- Causes skin irritation.
- Causes serious eye irritation.
- May damage the unborn child.
- 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.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, or other protective measures:
- Remove all sources of ignition.
tive equipment and emergency procedures

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/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 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.

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>TWA</td>
<td>10 ppm / 36 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm / 36 mg/m³</td>
<td>CA QC OEL</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>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>TWA</td>
<td>500 ppm / 1,200 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>750 ppm / 1,800 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>250 ppm</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>500 ppm</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>500 ppm / 1,900 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV</td>
<td>1,000 ppm / 2,380 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>250 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>500 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</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-</td>
<td>Urine</td>
<td>End of</td>
<td>30 mg/g</td>
<td>ACGIH</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

**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,
SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Color: clear
Odor: No information 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
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
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
Not classified based on available information.

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
<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Acute oral toxicity</th>
<th>Acute dermal toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Acute dermal toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td>LC50 (Rat): 3.28 mg/l</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Remarks: No mortality observed at this dose. No significant adverse effects were reported</td>
<td></td>
<td>Exposure time: 5 h</td>
<td>Remarks: No significant adverse effects were reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Test atmosphere: dust/mist</td>
<td></td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>LD50 (Rat): 1.950 mg/kg</td>
<td></td>
<td>LC50 (Rat): 76 mg/l</td>
<td>LD50 (Rabbit): 7,426 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Exposure time: 4 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Test atmosphere: vapor</td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>LD50 (Rat): 5,800 mg/kg</td>
<td></td>
<td>LC50 (Rat): 2.87 - 4.06 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Test atmosphere: dust/mist</td>
<td></td>
</tr>
<tr>
<td>Moxidectin</td>
<td>LD50 (Rat): 106 mg/kg</td>
<td></td>
<td>LC50 (Rat): 2.87 - 4.06 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 42 - 84 mg/kg</td>
<td></td>
<td>Test atmosphere: dust/mist</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): &gt; 640 mg/kg</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Application Route: Subcutaneous</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 263 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Subcutaneous</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Skin corrosion/irritation
Causes skin irritation.

Components:

N,N-Dimethylacetamide:
Species: Rabbit
Result: No skin irritation

Fluralaner:
Species: Rabbit
Result: No skin irritation

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

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

Moxidectin:
Species: Rabbit
Result: Mild skin irritant

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

N,N-Dimethylacetamide:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days

Fluralaner:
Species: Rabbit
Result: Mild eye irritant

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

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

Moxidectin:
Species: Rabbit
Result: Moderate eye irritation
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
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Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Result: negative

**Genotoxicity in vivo**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micronucleus test</td>
<td>negative</td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
</tr>
<tr>
<td>Cell type: Bone marrow</td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Acetone:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>negative</td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
</tr>
</tbody>
</table>

**Moxidectin:**

**Genotoxicity in vitro**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chromosomal aberration</td>
<td>negative</td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Cell type: Bone marrow</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo</td>
<td>negative</td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
</tbody>
</table>
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:**
- **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

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
    - 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 fetal 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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Effects on fetal development</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Symptoms</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N,N-Diethyl-m-toluamide:</strong></td>
<td></td>
<td>Test Type: Embryo-fetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Reduced fetal weight, Fetal mortality</td>
<td>The effects were seen only at maternally toxic doses.</td>
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<tr>
<td></td>
<td></td>
<td>Species: Rat</td>
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<td>Application Route: Ingestion</td>
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<td></td>
<td></td>
<td>Result: negative</td>
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<tr>
<td><strong>Acetone:</strong></td>
<td></td>
<td>Test Type: One-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Reduced fetal weight, Fetal mortality</td>
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<td></td>
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<td>Species: Rat</td>
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<td>Application Route: Ingestion</td>
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<td>Result: negative</td>
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<td></td>
<td></td>
<td>Test Type: Embryo-fetal development</td>
<td>Rat</td>
<td>Inhalation (vapor)</td>
<td>negative</td>
<td>Reduced fetal weight, Fetal mortality</td>
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<tr>
<td></td>
<td></td>
<td>Species: Rat</td>
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<td></td>
<td></td>
<td>Application Route: inhalation (vapor)</td>
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<td>Result: negative</td>
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<tr>
<td><strong>Moxidectin:</strong></td>
<td></td>
<td>Test Type: Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Oral</td>
<td></td>
<td>No effects on fertility, Some evidence of adverse effects on development, based on animal experiments.</td>
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<tr>
<td></td>
<td></td>
<td>Species: Rat</td>
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<td></td>
<td></td>
<td>Application Route: Oral</td>
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<td></td>
<td></td>
<td>General Toxicity F1: LOAEL: 0.8 mg/kg body weight</td>
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<td></td>
<td></td>
<td>Symptoms: Reduced fetal weight, Fetal mortality</td>
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<tr>
<td></td>
<td></td>
<td>Result: No effects on fertility, Some evidence of adverse effects on development, based on animal experiments.</td>
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<tr>
<td></td>
<td></td>
<td>Test Type: Three-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Oral</td>
<td></td>
<td>No effects on fertility, Some evidence of adverse effects on development, based on animal experiments.</td>
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<td></td>
<td></td>
<td>Species: Rat</td>
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<td></td>
<td></td>
<td>Application Route: Oral</td>
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<td></td>
<td></td>
<td>General Toxicity F1: LOAEL: 0.8 mg/kg body weight</td>
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<td>Symptoms: Reduced fetal weight, Fetal mortality</td>
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<td></td>
<td></td>
<td>Result: No effects on fertility, Some evidence of adverse effects on development, based on animal experiments.</td>
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<td></td>
<td></td>
<td>Test Type: Embryo-fetal development</td>
<td>Rat</td>
<td>Oral</td>
<td></td>
<td>Skeletal malformations</td>
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<tr>
<td></td>
<td></td>
<td>Species: Rat</td>
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<td></td>
<td></td>
<td>Application Route: Oral</td>
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<td></td>
<td></td>
<td>General Toxicity Maternal: LOAEL: 10 mg/kg body weight</td>
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<td></td>
<td></td>
<td>Embryo-fetal toxicity: LOAEL: 10 mg/kg body weight</td>
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<td></td>
<td></td>
<td>Result: Some evidence of adverse effects on development, based on</td>
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<td></td>
<td></td>
<td>Remarks: The effects were seen only at maternally toxic doses.</td>
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<td></td>
<td></td>
<td>Test Type: Embryo-fetal development</td>
<td>Rabbit</td>
<td>Oral</td>
<td></td>
<td>No teratogenic effects, No embryotoxic effects.</td>
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<tr>
<td></td>
<td></td>
<td>Species: Rabbit</td>
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<td></td>
<td></td>
<td>Application Route: Oral</td>
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<td></td>
<td></td>
<td>General Toxicity Maternal: LOAEL: 5 mg/kg body weight</td>
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<td></td>
<td></td>
<td>Developmental Toxicity: NOAEL: 10 mg/kg body weight</td>
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</tr>
</tbody>
</table>
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

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: Central nervous system
Assessment: 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

Species: Rat
NOAEL: 500 mg/kg
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

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
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
Not classified based on available information.
## Components:

### Fluralaner:
- Not applicable

### Experience with human exposure

#### Fluralaner:
- **Skin contact**: Remarks: May irritate skin.
- **Eye contact**: Remarks: May cause eye irritation.

#### Moxidectin:
- **Inhalation**: Remarks: No human information is available.

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide:</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 500 mg/l Exposure time: 96 h</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to algae</strong></td>
<td>EC50 (Desmodesmus subspicatus (green algae)): &gt; 500 mg/l Exposure time: 72 h</td>
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<td></td>
<td></td>
<td>EC10 (Desmodesmus subspicatus (green algae)): &gt; 500 mg/l Exposure time: 72 h</td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>EC10: &gt; 1,995 mg/l Exposure time: 30 min</td>
<td></td>
</tr>
</tbody>
</table>

### SECTION 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 algae**: EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l Exposure time: 72 h
- **Toxicity to microorganisms**: EC10: > 1,995 mg/l Exposure time: 30 min

#### Fluralaner:
- **Toxicity to fish**: LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.0488 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility.
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 0.015 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility.
- **Toxicity to algae**: NOEC (Pseudokirchneriella subcapitata (green algae)): >=
Toxicity to fish (Chronic toxicity):

0.08 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC (Zebrfish): >= 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:
NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l
Exposure time: 96 h

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

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

Moxidectin:

Toxicity to fish:
LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0006 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 0.0002 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 0.00003 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Toxicity to algae:
EC50 (Pseudokirchneriella subcapitata (green algae)): 0.087 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

TDG
UN number: UN 1090
Proper shipping name: ACETONE SOLUTION
Class: 3
Packing group: II
Labels: 3
ERG Code: 127
Marine pollutant: yes (Moxidectin, 2,6-Di-tert-butyl-p-cresol)

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

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)
CA BC OEL: Canada. British Columbia OEL
CA QC OEL: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
CA AB OEL / TWA: 8-hour Occupational exposure limit
CA AB OEL / STEL: 15-minute occupational exposure limit
CA BC OEL / TWA: 8-hour time weighted average
CA BC OEL / STEL: short-term exposure limit
CA QC OEL / TWA: Time-weighted average exposure value
CA QC OEL / STEV: Short-term exposure 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; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan);
SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System


Revision Date: 10/18/2018

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

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.

CA / Z8