SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Fluralaner / Diethyltoluamide Liquid Formulation

Version 8.0  Revision Date: 2021/09/21  SDS Number: 412178-00016  Date of last issue: 2020/12/07
Date of first issue: 2016/01/15

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner / Diethyltoluamide Liquid Formulation

Manufacturer or supplier's details
Company: MSD
Address: No. 485 Jing Tai Road
          Pu Tuo District - Shanghai - China 200331
Telephone: +1-908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

| Appearance | liquid |
| Colour     | yellow |
| Odour      | No data available |

Highly flammable liquid and vapour. May be harmful if swallowed and enters airways. May be harmful if inhaled. May damage the unborn child. Very toxic to aquatic life with long lasting effects.

GHS Classification

| Flammable liquids: Category 2 |
| Acute toxicity (Inhalation): Category 5 |
| Reproductive toxicity: Category 1B |
| Aspiration hazard: Category 2 |
| Long-term (chronic) aquatic hazard: Category 1 |

GHS label elements

| Hazard pictograms |
| Signal word: Danger |

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Hazard statements:
- H225 Highly flammable liquid and vapour.
- H305 May be harmful if swallowed and enters airways.
- H333 May be harmful if inhaled.
- H360D May damage the unborn child.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
**Prevention:**
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
- P233 Keep container tightly closed.
- P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
- P242 Use only non-sparking tools.
- P243 Take precautionary measures against static discharge.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
- P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
- P304 + P312 IF INHALED: Call a POISON CENTER/ doctor if you feel unwell.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P331 Do NOT induce vomiting.
- P391 Collect spillage.

**Storage:**
- P403 + P235 Store in a well-ventilated place. Keep cool.
- P405 Store locked up.

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

**Physical and chemical hazards**
Highly flammable liquid and vapour.

**Health hazards**
May be harmful if inhaled. May damage the unborn child. May be harmful if swallowed and enters airways.

**Environmental hazards**
Very toxic to aquatic life with long lasting effects.
Other hazards which do not result in classification
Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

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; 50</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 25 - &lt; 30</td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl).alpha.-[(tetrahydro-2-fluranyl)methyl].omega.-hydroxy-</td>
<td>31692-85-0</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>&gt;= 10 - &lt; 20</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 soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.0</td>
<td>2021/09/21</td>
<td>412178-00016</td>
<td>2020/12/07</td>
<td>2016/01/15</td>
</tr>
</tbody>
</table>

### 4. SUITABLE EXTINGUISHING MEDIA AND FIRE-FIGHTING GUIDELINES

**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.
- Vapours may form explosive mixtures with air.
- Exposure to combustion products may be a hazard to health.

### 5. HAZARDOUS COMBUSTION PRODUCTS

**Hazardous combustion products:**
- Carbon oxides
- Chlorine compounds
- Fluorine compounds
- Nitrogen oxides (NOx)

### 6. SPECIFIC EXTINGUISHING METHODS

**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.

### 7. SPECIAL PROTECTIVE EQUIPMENT FOR FIREFIGHTERS

**Special protective equipment for firefighters:**
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal precautions, protective equipment and emergency procedures

- Remove all sources of ignition.
- Ventilate the area.
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### Environmental precautions

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

#### Methods and materials for containment and cleaning up

- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapours/mists with a water spray jet.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
7. HANDLING AND STORAGE

Handling
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation. Use explosion-proof electrical, ventilating and lighting equipment.
Advice on safe handling: Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Avoid contact with 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, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact: Oxidizing agents

Storage
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

Packaging material: Unsuitable material: None known.

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)</th>
<th>Control parameters / Permissible</th>
<th>Basis</th>
</tr>
</thead>
</table>
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<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 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 last shift of the week</td>
<td>20 mg/g Creatinine CN BEI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>N-Methylacetamide</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>30 mg/g Creatinine ACGIH 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 CN BEI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acetone</td>
<td>Urine</td>
<td>End of shift (As soon as possible after exposure ceases)</td>
<td>25 mg/l ACGIH BEI</td>
</tr>
</tbody>
</table>

**Engineering measures**: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment. Use explosion-proof electrical, ventilating and lighting equipment.

**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
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Eye/face 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.

Hand protection:
- Material: Chemical-resistant gloves
- Remarks: Take note that the product is flammable, which may impact the selection of hand protection.
- Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance: liquid
- Colour: yellow
- Odour: No data available
- Odour Threshold: No data available
- pH: No data available
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: 103 °C
- Flash point: 7 °C
- Evaporation rate: No data available
- Flammability (solid, gas): Not applicable
- Flammability (liquids): Not applicable
- Upper explosion limit / Upper flammability limit: No data available
### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Highly flammable liquid and vapour.</td>
</tr>
<tr>
<td></td>
<td>Vapours may form explosive mixture with air. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Heat, flames and sparks.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inhalation</td>
</tr>
<tr>
<td></td>
<td>Skin contact</td>
</tr>
<tr>
<td></td>
<td>Ingestion</td>
</tr>
<tr>
<td></td>
<td>Eye contact</td>
</tr>
</tbody>
</table>
### Acute toxicity
May be harmful if inhaled.

**Product:**

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Remarks: No mortality observed at this dose.</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>Acute toxicity estimate: 5.95 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td></td>
<td>Method: Calculation method</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Symptoms: Erythema</td>
</tr>
</tbody>
</table>

**Components:**

#### N,N-Dimethylacetamide:

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 4,800 mg/kg</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): 2.2 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>Acute toxicity estimate: 1,100 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: Expert judgement</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI</td>
</tr>
</tbody>
</table>

#### Fluralaner:

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</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>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Remarks: No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

#### Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat, female): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 423</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 1,950 mg/kg</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): 5.95 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): 5,000 mg/kg</td>
</tr>
</tbody>
</table>
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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

Skin corrosion/irritation
Not classified based on available information.

Product:
Species: Rabbit
Result: No skin irritation

Components:

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

Fluralaner:
Species: Rabbit
Result: No skin irritation

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:
Species: reconstructed human epidermis (RhE)
Method: OECD Test Guideline 439
Remarks: Based on data from similar materials
Result: No skin irritation

N,N-Diethyl-m-toluamide:
Species: Rabbit
Result: No skin irritation

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

Serious eye damage/eye irritation
Not classified based on available information.

Product:
Species: Rabbit
Result: Mild eye irritation
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Components:

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

Fluralaner:
Species: Rabbit
Result: Mild eye irritation

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:
Species: Tissue Culture
Method: OECD Test Guideline 492
Remarks: Based on data from similar materials

Species: Bovine cornea
Method: OECD Test Guideline 437
Remarks: Based on data from similar materials
Result: Irritation to eyes, reversing within 21 days

N,N-Diethyl-m-toluamide:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

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

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

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

**Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**
- **Test Type:** KeratinoSens assay
- **Method:** OECD Test Guideline 442D
- **Result:** negative
- **Remarks:** Based on data from similar materials

- **Remarks:** Direct Peptide Reactivity Assay (DPRA)
  - **Method:** OECD Test Guideline 442C
  - **Result:** positive
  - **Remarks:** Based on data from similar materials

- **Remarks:** Dendritic cell activation test
  - **Method:** OECD Test Guideline 442E
  - **Result:** negative
  - **Remarks:** Based on data from similar materials

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

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl].omega.-hydroxy-:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative
  Remarks: Based on data from similar materials

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 cytogenetic assay)
  Species: Mouse
  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

### 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

**Reproductive toxicity**

May damage the unborn child.

**Components:**

### N,N-Dimethylacetamide:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Inhalation
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Inhalation
Result: positive

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

### Fluralaner:

Effects on fertility : Test Type: Two-generation study
Species: Rat
Application Route: Oral
General Toxicity - Parent: NOAEL: 50 mg/kg body weight
General Toxicity F1: LOAEL: 100 mg/kg body weight
Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects.

Test Type: One-generation reproduction toxicity study
Species: Dog
Application Route: Oral
Fertility: NOAEL: 75 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.
Remarks: No significant adverse effects were reported

Effects on foetal development:
- Test Type: Development
  Species: Rat
  Application Route: Oral
  Developmental Toxicity: NOAEL: 100 mg/kg body weight
  Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects

  Test Type: Development
  Species: Rabbit
  Application Route: Oral
  Developmental Toxicity: NOAEL: 10 mg/kg body weight
  Result: Skeletal malformations, Visceral malformations
  Remarks: Maternal toxicity observed.

  Test Type: Development
  Species: Rabbit
  Application Route: Dermal
  Developmental Toxicity: NOAEL: 100 mg/kg body weight
  Result: Skeletal malformations

  Test Type: Development
  Species: Rat
  Application Route: Ingestion
  Result: negative

Reproductive toxicity - Assessment:
Suspected of damaging the unborn child.

N,N-Diethyl-m-toluamide:
Effects on foetal development:
- Test Type: Embryo-foetal development
  Species: Rat
  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 foetal development:
- Test Type: Embryo-foetal development
  Species: Rat
  Application Route: inhalation (vapour)
  Result: negative

STOT - single exposure
Not classified based on available information.
Fluralaner / Diethyltoluamide Liquid Formulation

Components:

**Acetone:**
- **Assessment:** May cause drowsiness or dizziness.

**STOT - repeated exposure**
Not classified based on available information.

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

**Species:** Rat
- **NOAEL:** 400 mg/kg
- **Application Route:** Oral
- **Exposure time:** 90 Days
- **Target Organs:** Liver, thymus 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
Fluralaner / Diethyltoluamide Liquid Formulation

Exposure time: 90 Days
Species: Rat
NOAEL: 45 mg/l
Application Route: inhalation (vapour)
Exposure time: 8 Weeks

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

Product:
Skin contact: Remarks: May irritate skin.
Eye contact: Remarks: May cause eye irritation.

Components:

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

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

  Toxicity to algae/aquatic plants:
  EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
  Exposure time: 72 h
  EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l
  Exposure time: 72 h
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to microorganisms</th>
<th>Toxicity to fish</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>M-Factor (Chronic aquatic toxicity)</th>
<th>Toxicity to algae/aquatic plants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td>EC10: &gt; 1,995 mg/l Exposure time: 30 min</td>
<td>LC50 (Onorchynchos mykiss (rainbow trout)): &gt; 0.0488 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 0.015 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): &gt;= 0.08 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility</td>
<td>NOEC (Zebrafish): &gt;= 0.049 mg/l Exposure time: 21 d Method: OECD Test Guideline 204 Remarks: No toxicity at the limit of solubility</td>
<td>NOEC (Daphnia magna (Water flea)): 0.000047 mg/l Exposure time: 21 d Method: OECD Test Guideline 211</td>
<td>1,000</td>
<td></td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials</td>
<td>EC10 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

according to GB/T 16483 and GB/T 17519

**Fluralaner / Diethyltoluamide Liquid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 2020/12/07</th>
<th>Date of first issue: 2016/01/15</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.0</td>
<td>2021/09/21</td>
<td>412178-00016</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to fish**
- LC50 (Oncorhynchus mykiss (rainbow trout)): 97 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

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

**Toxicity to algae/aquatic plants**
- ErC50 (Selenastrum capricornutum (green algae)): 41 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- NOEC (Selenastrum capricornutum (green algae)): 7.6 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- NOEC (Daphnia magna (Water flea)): 3.7 mg/l
  - Exposure time: 21 d

**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

**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.

**Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**
- Biodegradability: Result: Not readily biodegradable.
  - Method: OECD Test Guideline 301F
  - Remarks: Based on data from similar materials
Fluralaner / Diethyltoluamide Liquid Formulation

Biodegradability:
- N,N-Diethyl-m-toluamide:
  - Result: Readily biodegradable.
  - Biodegradation: 83.8%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301B
- Acetone:
  - 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

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:
- Partition coefficient: n-octanol/water: log Pow: < 4
  - Remarks: Calculation

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

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 (Fluralaner)
Class: 3
Packing group: II
Labels: 3
EmS Code: F-E, S-D
Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

GB 6944/12268
UN number: UN 1090
Proper shipping name: ACETONE SOLUTION
Class: 3
Fluralaner / Diethyltoluamide Liquid Formulation

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.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases
Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : Listed

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)

<table>
<thead>
<tr>
<th>No. / Code</th>
<th>Chemical name / Category</th>
<th>Threshold quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>WS.3</td>
<td>Flammable liquids</td>
<td>1,000 t</td>
</tr>
</tbody>
</table>

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

Date format : yyyy/mm/dd

Full text of other abbreviations
- ACGIH : USA. ACGIH Threshold Limit Values (TLV)
- ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
- CN BEI : China. Biological Occupational Exposure Indices
- CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.
- ACGIH / TWA : 8-hour, time-weighted average
- ACGIH / STEL : Short-term exposure limit
- CN OEL / PC-TWA : Permissible concentration - time weighted average
Fluralaner / Diethyltoluamide Liquid Formula-

Version 8.0 | Revision Date: 2021/09/21 | SDS Number: 412178-00016 | Date of last issue: 2020/12/07
Date of first issue: 2016/01/23

CN OEL / PC-STEL : Permissible concentration - short term exposure limit

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International 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 Chemicals in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; 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

Disclaimer
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.

CN / EN