SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fluralaner / Diethyltoluamide Liquid Formulation

Manufacturer or supplier's details
Company : MSD
Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
Telephone : 908-740-4000
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 in accordance with ABNT NBR 14725 Standard
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 in accordance with ABNT NBR 14725 Standard
Hazard pictograms :

Signal Word : Danger
Hazard Statements : H225 Highly flammable liquid and vapor.
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.
P210 Keep away from heat/ sparks/ open flames/ hot surfaces.
No smoking.
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.
P391 Collect spillage.

**Other hazards which do not result in classification**
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>

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>Flammable liquids, Category 4 Acute toxicity (Oral), Category 5 Acute toxicity (Inhalation), Category 4 Acute toxicity (Dermal), Category 4 Eye irritation, Category 2A Reproductive toxicity, Category 1B</td>
<td>&gt;= 30 -&lt; 50</td>
<td></td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>Reproductive toxicity, Category 2 Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 25 -&lt; 30</td>
<td></td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl), α-([(tetrahydro-2-furanyl)methyl]-ω-hydroxy-</td>
<td>31692-85-0</td>
<td>Eye irritation, Category 2A</td>
<td>&gt;= 10 -&lt; 20</td>
<td></td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>Acute toxicity (Oral), Category 4 Acute toxicity (Inhalation), Category 5 Acute toxicity (Dermal), Category 5 Eye irritation, Category 2A Short-term (acute) aquatic hazard,</td>
<td>&gt;= 10 -&lt; 20</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

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<table>
<thead>
<tr>
<th>Category 3</th>
<th>Flammable liquids, Category 2</th>
<th>Eye irritation, Category 2A</th>
<th>Specific target organ toxicity - single exposure, Category 3</th>
<th>Aspiration hazard, Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td></td>
<td></td>
<td>&gt;= 10 &lt; 20</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 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 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 and enters airways. May be harmful if inhaled. May damage the unborn child.

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)

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
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 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/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

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 vapors 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.

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</th>
<th>Control parameter</th>
<th>Basis</th>
</tr>
</thead>
</table>

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## 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 workday at end of workweek</td>
<td>30 mg/g Creatinine</td>
<td>BR BEI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>Acetone</td>
<td>Urine</td>
<td>End of workday</td>
<td>25 mg/l</td>
<td>BR BEI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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.
SAFETY DATA SHEET

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Version 10.0  Revision Date: 21.09.2021  SDS Number: 412174-00016  Date of last issue: 07.12.2020

Date of first issue: 15.01.2016

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: Chemical-resistant gloves

Remarks: 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Color: yellow

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: 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

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: 67 hPa (20 °C)

Relative vapor density: No data available
Relative density: No data available
Density: 1,059 g/cm³
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.
Molecular weight: No data available
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 inhaled.

Product:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
  Remarks: No mortality observed at this dose.
Acute inhalation toxicity: Acute toxicity estimate: 5.95 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
Symptoms: Erythema

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

Poly(oxy-1,2-ethanediyl), α-[[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-:}
• Acute oral toxicity: LD50 (Rat, female): > 2.000 mg/kg
  Method: OECD Test Guideline 423
  Remarks: Based on data from similar materials

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

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), α-[(tetrahydro-2-furanyl)methyl]-ω-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

Components:

N,N-Dimethylacetamide:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
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**Fluralaner:**
- **Species:** Rabbit
- **Result:** Mild eye irritation

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

**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 sensitization**

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

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

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

**Components:**

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

**Fluralaner:**
- **Test Type:** Maximization Test
- **Routes of exposure:** Dermal
<table>
<thead>
<tr>
<th>Species</th>
<th>Guinea pig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

**Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-**:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>KeratinoSens assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 442D</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

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

**Acetone**:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

**Components**:

**N,N-Dimethylacetamide**:

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

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Rodent dominant lethal test (germ cell) (in vivo)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Inhalation</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 478</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Fluralaner**:

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

Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Result: negative

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

Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-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

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

Genotoxicity in vitro: 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 (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

**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 : 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

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

**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 (vapor)
### Exposition time

24 Months

### Fluralaner:

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>52 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Juvenile dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>56 - 280 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>24 Weeks</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Diarrhea</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>400 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>500 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Dermal</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

### Acetone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>900 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>1.700 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>45 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (vapor)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>8 Weeks</td>
</tr>
</tbody>
</table>

**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.

### 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 daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): > 500 mg/l Exposure time: 48 h Method: Directive 67/548/EEC, Annex V, C.2.
- **Toxicity to algae/aquatic plants:** 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/aquatic plants:** NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l
### Toxicity to Fish (Chronic Toxicity)
- **NOEC (Zebrafish):** \( \geq 0.049 \text{ mg/l} \)
- **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

### M-Factor (Chronic Aquatic Toxicity)
- **Value:** 1.000

### Poly(oxy-1,2-ethanediyl), \( \alpha-[\text{(tetrahydro-2-furanyl)methyl}]\omega\)-hydroxy-:

<table>
<thead>
<tr>
<th>Toxicity to Daphnia and Other Aquatic Invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</th>
<th>Exposure time: 48 h</th>
<th>Method: OECD Test Guideline 202</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to Algae/Aquatic Plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l</td>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>EC10 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l</td>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Toxicity to Fish</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): 97 mg/l</th>
<th>Exposure time: 96 h</th>
<th>Method: OECD Test Guideline 203</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to Daphnia and Other Aquatic Invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): 75 mg/l</td>
<td>Exposure time: 48 h</td>
<td></td>
</tr>
<tr>
<td>Toxicity to Algae/Aquatic Plants</td>
<td>ErC50 (Selenastrum capricornutum (green algae)): 41 mg/l</td>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>NOEC (Selenastrum capricornutum (green algae)): 7.6 mg/l</td>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)</td>
<td>NOEC (Daphnia magna (Water flea)): 3.7 mg/l</td>
<td>Exposure time: 21 d</td>
<td></td>
</tr>
</tbody>
</table>
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-ethanediy), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-:
Biodegradability: Result: Not readily biodegradable.
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 83,8 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

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

Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-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).

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
### SAFETY DATA SHEET

**Fluralaner / Diethyltoluamide Liquid Formulation**

<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>
</table>

#### UN number
- : UN 1090

#### Proper shipping name
- : ACETONE SOLUTION

#### Class
- : 3

#### Packing group
- : II

#### Labels
- : 3

#### IATA-DGR

<table>
<thead>
<tr>
<th>UN/ID No.</th>
<th>Proper shipping name</th>
<th>Class</th>
<th>Packing group</th>
<th>Labels</th>
<th>Packing instruction (cargo aircraft)</th>
<th>Packing instruction (passenger aircraft)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN 1090</td>
<td>Acetone solution</td>
<td>3</td>
<td>II</td>
<td>Flammable Liquids</td>
<td>364</td>
<td>353</td>
</tr>
</tbody>
</table>

#### IMDG-Code

<table>
<thead>
<tr>
<th>UN number</th>
<th>Proper shipping name</th>
<th>Class</th>
<th>Packing group</th>
<th>Labels</th>
<th>EmS Code</th>
<th>Marine pollutant</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN 1090</td>
<td>ACETONE SOLUTION</td>
<td>3</td>
<td>II</td>
<td>3</td>
<td>F-E, S-D</td>
<td>yes</td>
</tr>
</tbody>
</table>

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

#### Domestic regulation

**ANTT**

<table>
<thead>
<tr>
<th>UN number</th>
<th>Proper shipping name</th>
<th>Class</th>
<th>Packing group</th>
<th>Labels</th>
<th>Hazard Identification Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN 1090</td>
<td>ACETONE SOLUTION</td>
<td>3</td>
<td>II</td>
<td>3</td>
<td>33</td>
</tr>
</tbody>
</table>

#### 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

- **National List of Carcinogenic Agents for Humans - (LINACH)** : Not applicable
- **Brazil. List of chemicals controlled by the Federal Police** : Not applicable
The ingredients of this product are reported in the following inventories:

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

SECTION 16. OTHER INFORMATION

Further information

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

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
- BR BEI: Brazil. NR7. Parameters for Biological Control of Occupational Exposure to Some Chemical Agents
- BR OEL: Brazil. NR 15 - Unhealthy activities and operations
- ACGIH / TWA: 8-hour, time-weighted average
- ACGIH / STEL: Short-term exposure limit
- BR OEL / LT: Up to 48 hours /week
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.

BR / Z8