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 name of supplier: MSD
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
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
Flammable liquids: Category 2
Acute toxicity (Inhalation): Category 5
Reproductive toxicity: Category 1B
Aspiration hazard: Category 2

GHS label elements
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.

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.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.
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tion

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name: N,N-Dimethylacetamide</td>
</tr>
<tr>
<td></td>
<td>Fluralaner</td>
</tr>
<tr>
<td></td>
<td>Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-</td>
</tr>
<tr>
<td></td>
<td>N,N-Diethyl-m-toluamide</td>
</tr>
<tr>
<td></td>
<td>Acetone</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.
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tion

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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)
- 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 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:
- Non-sparking tools should be used.
containment and cleaning up

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.
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tion

Materials to avoid
- Keep away from heat and sources of ignition.
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Flammable solids
  - Pyrophoric liquids
  - Pyrophoric solids
  - Self-heating substances and mixtures
  - Substances and mixtures which in contact with water emit flammable gases
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>VLE-PPT</td>
<td>10 ppm</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin
- Wipe limit 1000 µg/100 cm² Internal

Acetone
- VLE-PPT 500 ppm NOM-010-STPS-2014
- VLE-CT 750 ppm NOM-010-STPS-2014
- TWA 250 ppm ACGIH
- STEL 500 ppm ACGIH

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>
</table>
| N,N-Dimethylacetamide    | 127-19-5 | N-methylaceta-
mide          | Urine               | End of shift at end of work-week | 30 mg/g Creatinine          | MX BEI |
|                          |          | N-Methylaceta-
mide          | Urine               | End of shift at end of work-week | 30 mg/g Creatinine          | ACGIH BEI |
| Acetone                  | 67-64-1  | Acetone            | Urine               | End of shift              | 50 mg/l                     | MX BEI |
|                          |          |                     |                     |                          | 25 mg/l                     | ACGIH  |

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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.
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

Hand protection:
Material: 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 reac-
tions
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
## 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>

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

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

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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.
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**Fluralaner / Diethyltoluamide Liquid Formula-**

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

**Components:**

<table>
<thead>
<tr>
<th><strong>N,N-Dimethylacetamide:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Routes of exposure</strong></td>
</tr>
<tr>
<td><strong>Species</strong></td>
</tr>
<tr>
<td><strong>Result</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Fluralaner:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Type</strong></td>
</tr>
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<tr>
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<tr>
<td><strong>Result</strong></td>
</tr>
</tbody>
</table>

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<th><strong>Poly(oxy-1,2-ethanediyl), α-{[tetrahydro-2-furanyl)methyl]-ω-hydroxy-:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Type</strong></td>
</tr>
<tr>
<td><strong>Method</strong></td>
</tr>
<tr>
<td><strong>Result</strong></td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Acetone:</strong></th>
</tr>
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<tbody>
<tr>
<td><strong>Test Type</strong></td>
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<tr>
<td><strong>Routes of exposure</strong></td>
</tr>
<tr>
<td><strong>Species</strong></td>
</tr>
<tr>
<td><strong>Result</strong></td>
</tr>
</tbody>
</table>

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

**Components:**

<table>
<thead>
<tr>
<th><strong>N,N-Dimethylacetamide:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Genotoxicity in vitro</strong></td>
</tr>
<tr>
<td><strong>Result</strong></td>
</tr>
</tbody>
</table>

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**SDS Number:** 412186-00016
**Date of last issue:** 07.12.2020
**Date of first issue:** 15.01.2016
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

Genotoxicity in vitro: Test Type: Mouse Lymphoma  
Result: negative

Genotoxicity in vitro: 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), 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

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  
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
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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)
  - Exposure time: 24 Months

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

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

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

  - 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
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| 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 |

**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

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

Fluralaner:

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

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

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

Toxicity to fish (Chronic toxicity): NOEC (Zebrafish): >= 0.049 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 204
Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.000047 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

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

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:

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

### Exposure time:

### 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

### Exposure time:

### Toxicity to daphnia and other aquatic invertebrates
- **EC50 (Daphnia pulex (Water flea)):** 8,800 mg/l
  - Exposure time: 48 h

### Method:
- **OECD Test Guideline 203**

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

### Exposure time:

### 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), α-[(tetrahydro-2-furanylmethyl]-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**
- 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.

**Domestic regulation**

**NOM-002-SCT**
- UN number: UN 1090
- Proper shipping name: ACETONE, SOLUTION
- Class: 3
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tion

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Packing group: II
Labels: 3

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors: Acetone
essential chemical products and machinery for producing capsules, tablets and pills.

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

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

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
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tion

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- 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; 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Revision Date : 21.09.2021

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

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

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