

## Fluralaner / Diethyltoluamide Liquid Formulation

Version 10.6      Revision Date: 30.09.2023      SDS Number: 412174-00022      Date of last issue: 04.04.2023  
Date of first issue: 15.01.2016

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### 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

Restrictions on use : Not applicable

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### 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.

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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

Substance / Mixture : Mixture

### Components

| Chemical name  | CAS-No.     | Classification  | Concentration (% w/w) |
|--|-------------|---|-----------------------|
| N,N-Dimethylacetamide  | 127-19-5    | Flammable liquids, Category 4<br>Acute toxicity (Oral), Category 5<br>Acute toxicity (Inhalation), Category 4<br>Acute toxicity (Dermal), Category 4<br>Eye irritation, Category 2A<br>Reproductive toxicity, Category 1B | >= 30 -< 50           |
| Fluralaner   | 864731-61-3 | Reproductive toxicity, Category 2<br>Long-term (chronic) aquatic hazard, Category 1   | >= 25 -< 30           |
| Poly(oxy-1,2-ethanediyl), $\alpha$ -[(tetrahydro-2-furanyl)methyl]- $\omega$ -hydroxy- | 31692-85-0  | Eye irritation, Category 2A   | >= 10 -< 20           |
| N,N-Diethyl-m-toluamide  | 134-62-3    | Acute toxicity (Oral), Category 4<br>Acute toxicity (Inhalation), Category 5<br>Acute toxicity (Dermal), Category 5<br>Eye irritation,  | >= 10 -< 20           |

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|---------|---------|--|-------------|
|         |         | Category 2A<br>Short-term (acute)<br>aquatic hazard,<br>Category 3   |             |
| Acetone | 67-64-1 | Flammable liquids,<br>Category 2<br>Eye irritation,<br>Category 2A<br>Specific target organ<br>toxicity - single expo-<br>sure, Category 3<br>Aspiration hazard,<br>Category 2 | >= 10 -< 20 |

### 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 (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing : High volume water jet

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- media
- 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 (NO<sub>x</sub>)
- 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.
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### 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.

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### 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.<br>Use explosion-proof electrical, ventilating and lighting equipment.  |
| Advice on safe handling     | : | Do not get on skin or clothing.<br>Do not breathe vapors or spray mist.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Non-sparking tools should be used.<br>Keep container tightly closed.<br>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br>Take precautionary measures against static discharges.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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.<br>Store locked up.<br>Keep tightly closed.<br>Keep in a cool, well-ventilated place.<br>Store in accordance with the particular national regulations.<br>Keep away from heat and sources of ignition.   |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Flammable solids<br>Pyrophoric liquids<br>Pyrophoric solids<br>Self-heating substances and mixtures<br>Substances and mixtures which in contact with water emit flammable gases<br>Explosives<br>Gases<br>Very acutely toxic substances and mixtures   |

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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components            | CAS-No.  | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis    |
|-----------------------|--|-------------------------------|--|----------|
| N,N-Dimethylacetamide | 127-19-5   | LT                            | 8 ppm<br>28 mg/m <sup>3</sup>                  | BR OEL   |
|                       | Further information: Absorption through the skin, Degree of harmfulness: maximum |                               |  |          |
|                       |  | TWA                           | 10 ppm   | ACGIH    |
| Fluralaner            | 864731-61-3  | TWA                           | 100 µg/m <sup>3</sup> (OEB 2)                  | Internal |
|                       | Further information: Skin  |                               |  |          |
|                       |  | Wipe limit                    | 1000 µg/100 cm <sup>2</sup>                    | Internal |
| Acetone               | 67-64-1  | LT                            | 780 ppm<br>1.870 mg/m <sup>3</sup>             | BR OEL   |
|                       | Further information: Degree of harmfulness: minimum                              |                               |  |          |
|                       |  | TWA                           | 250 ppm  | ACGIH    |
|                       |  | STEL                          | 500 ppm  | ACGIH    |

#### Biological occupational exposure limits

| Components            | CAS-No.  | Control parameters | Biological specimen | Sampling time  | Permissible concentration | Basis     |
|-----------------------|----------|--------------------|---------------------|--|---------------------------|-----------|
| N,N-Dimethylacetamide | 127-19-5 | N-methylacetamide  | Urine               | End of workday at end of work-week                       | 30 mg/g creatinine        | BR BEI    |
|                       |          | N-Methylacetamide  | Urine               | End of shift at end of work-week                         | 30 mg/g creatinine        | ACGIH BEI |
| Acetone               | 67-64-1  | Acetone            | Urine               | End of workday   | 25 mg/l                   | BR BEI    |
|                       |          | Acetone            | Urine               | End of shift (As soon as possible after exposure ceases) | 25 mg/l                   | ACGIH BEI |

**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.

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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.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.   |

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**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                    | : | No data available |

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flammability limit

Vapor pressure : 67 hPa (20 °C)

Relative vapor density : No data available

Relative density : No data available

Density : 1,059 g/cm<sup>3</sup>

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

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**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.

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**SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact



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**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 national or regional regulation.

**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),  $\alpha$ -[(tetrahydro-2-furanyl)methyl]- $\omega$ -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

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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: 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),  $\alpha$ -[(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 national or regional regulation.

**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

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Result : negative

### Fluralaner:

Test Type : Maximization Test  
 Routes of exposure : 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

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

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

### Acetone:

Test Type : Maximization Test  
 Routes of exposure : 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

#### Fluralaner:

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

Test Type: Mouse Lymphoma

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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 (vapor)  
Exposure time : 18 month(s)  
Result : negative

**Fluralaner:**

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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

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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.

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**Repeated dose toxicity****Components:****N,N-Dimethylacetamide:**

Species : Rat  
NOAEL : 90 mg/m<sup>3</sup>  
LOAEL : 360 mg/m<sup>3</sup>  
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  
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.



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### 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

EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l  
 Exposure time: 72 h

Toxicity to microorganisms : EC10: > 1.995 mg/l  
 Exposure time: 30 min

#### **Fluralaner:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 0,0488 mg/l  
 Exposure time: 96 h  
 Method: OECD Test Guideline 203  
 Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0,015 mg/l  
 Exposure time: 48 h

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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)): 0,0736 µg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1.000

### **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

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

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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

##### 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

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**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: 4,1

**Other adverse effects****Components:****Fluralaner:**

Results of PBT and vPvB assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
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.

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**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : UN 1090  
Proper shipping name : ACETONE SOLUTION  
Class : 3  
Packing group : II  
Labels : 3  
Environmentally hazardous : no

**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****ANTT**

UN number : UN 1090  
Proper shipping name : ACETONE, SOLUTION  
Class : 3  
Packing group : II  
Labels : 3  
Hazard Identification Number : 33

**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.

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### 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

Revision Date : 30.09.2023  
Date format : dd.mm.yyyy

#### Further information

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 Agency, <http://echa.europa.eu/>

#### 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

AIIC - 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 con-

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centration; 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; TECl - 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

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.

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