1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Fluralaner / Diethyltoluamide Liquid Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Flammable liquids : Category 2
Reproductive toxicity : Category 1B
Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :

Signal word : Danger
Hazard statements : H225 Highly flammable liquid and vapour.
H360D May damage the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equip-
ment.
P242 Use non-sparking tools.
P243 Take action to prevent static discharges.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

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

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

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed:
Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>32.1</td>
<td>2-723</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 25 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-</td>
<td>31692-85-0</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>&gt;= 10 - &lt; 20</td>
<td>3-1321</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>&gt;= 10 - &lt; 20</td>
<td>2-542</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice:
In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled:
If inhaled, remove to fresh air.
In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

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

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

Most important symptoms and effects, both acute and delayed: 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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Remove all sources of ignition.
Ventilate the area.
Emergency procedures

Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions

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

Methods and materials for containment and cleaning up

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

7. HANDLING AND STORAGE

Handling

Technical measures

See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

If sufficient ventilation is unavailable, use with local exhaust ventilation. Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling

Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Non-sparking tools should be used. Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact

Oxidizing agents
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.

Storage


Materials to avoid: Do not store with the following product types:
- Oxidizing solids
- Oxidizing liquids

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>ACL</td>
<td>10 ppm</td>
<td>JP OEL ISHL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-M</td>
<td>10 ppm 36 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Further information: Group 2: Substances presumed to cause reproductive toxicity in humans, Skin absorption, Group 2B: possibly carcinogenic to humans</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>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>ACL</td>
<td>500 ppm</td>
<td>JP OEL ISHL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-M</td>
<td>200 ppm 470 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>250 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>500 ppm</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Target substance</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 shift at end of workweek</td>
<td>30 mg/g Creatinine</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>BEI</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>Acetone</td>
<td>Urine</td>
<td>Within 2 h prior to end of shift</td>
<td>40 mg/l</td>
<td>JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Urine</td>
<td>End of shift (As soon as possible after exposure ceases)</td>
<td>25 mg/l</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>BEI</td>
</tr>
</tbody>
</table>

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

Respiratory protection

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Self-contained breathing apparatus

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: liquid
### SAFETY DATA SHEET

**Fluralaner / Diethyltoluamide Liquid Formulation**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>103 °C</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>7 °C</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>67 hPa (20 °C)</td>
</tr>
<tr>
<td>Density and / or relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1.059 g/cm³</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
</tbody>
</table>

**Version**: 10.0  
**Revision Date**: 2021/09/21  
**SDS Number**: 412184-00016  
**Date of last issue**: 2020/12/07  
**Date of first issue**: 2016/01/15
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 vapour. Vapours 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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure: Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity: Not classified based on available information.

Product:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Remarks: No mortality observed at this dose.

Acute inhalation toxicity: Acute toxicity estimate: > 5 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 judgement
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), .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

**Acetone:**

Acute oral toxicity: LD50 (Rat): 5,800 mg/kg

Acute inhalation toxicity: LC50 (Rat): 76 mg/l
Exposure time: 4 h
Test atmosphere: vapour

Acute dermal toxicity: LD50 (Rabbit): 7,426 mg/kg

**Skin corrosion/irritation**
Not classified based on available information.

**Product:**
Species: Rabbit
Result: No skin irritation

**Components:**

**N,N-Dimethylacetamide:**
Species: Rabbit
Result: No skin irritation
Fluralaner / Diethyltoluamide Liquid Formulation

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

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
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Result: Irritation to eyes, reversing within 21 days
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

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

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

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

Components:

N,N-Dimethylacetamide:
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

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

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

Remarks: Direct Peptide Reactivity Assay (DPRA)
Result: positive
Remarks: Based on data from similar materials

Remarks: Dendritic cell activation test
Result: negative
Remarks: Based on data from similar materials
Acetone:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

N,N-Dimethylacetamide:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo:
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
Result: negative

Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo:
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

Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

N,N-Dimethylacetamide:
Species : Rat
Application Route : inhalation (vapour)
Exposure time : 18 month(s)
Result : negative

Fluralaner:

Carcinogenicity - Assessment : No data available

N,N-Diethyl-m-toluamide:
Species : Rat
Application Route : Ingestion
Exposure time : 104 weeks
Result : negative

Acetone:
Species : Mouse
Application Route : Skin contact
Exposure time : 424 days
Result : negative

Reproductive toxicity
May damage the unborn child.

Components:

N,N-Dimethylacetamide:
Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Inhalation
Result: negative
Effects on foetal development:

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

Reproductive toxicity - Assessment:

- Clear evidence of adverse effects on development, based on animal experiments.

**Fluralaner:**

Effects on fertility:

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

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

Effects on foetal development:

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

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

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

Reproductive toxicity - Assessment:

- Suspected of damaging the unborn child.

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

Effects on foetal development:

- Test Type: Embryo-foetal development
  - Species: Rat
## Acetone:

**Application Route:** Ingestion  
**Result:** negative

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

**Effects on foetal development**
- **Test Type:** Embryo-foetal development  
- **Species:** Rat  
- **Application Route:** inhalation (vapour)  
- **Result:** negative

### STOT - single exposure

Not classified based on available information.

### Components:

#### Acetone:

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

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

### Components:

#### N,N-Dimethylacetamide:

<table>
<thead>
<tr>
<th><strong>Species</strong></th>
<th><strong>NOAEL</strong></th>
<th><strong>LOAEL</strong></th>
<th><strong>Application Route</strong></th>
<th><strong>Exposure time</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>90 mg/m³</td>
<td>360 mg/m³</td>
<td>inhalation (vapour)</td>
<td>24 Months</td>
</tr>
</tbody>
</table>

#### Fluralaner:

<table>
<thead>
<tr>
<th><strong>Species</strong></th>
<th><strong>NOAEL</strong></th>
<th><strong>Application Route</strong></th>
<th><strong>Exposure time</strong></th>
<th><strong>Target Organs</strong></th>
<th><strong>Remarks</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>1 mg/kg</td>
<td>Oral</td>
<td>52 Weeks</td>
<td>Liver</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Juvenile dog</td>
<td>56 - 280 mg/kg</td>
<td>Oral</td>
<td>24 Weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>400 mg/kg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Symptoms:** Diarrhoea
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>
<tbody>
<tr>
<td>10.0</td>
<td>2021/09/21</td>
<td>412184-00016</td>
<td>2020/12/07</td>
<td>2016/01/15</td>
</tr>
</tbody>
</table>

### Application Route
- **Oral**
- **Dermal**

### Exposure time
- **90 Days**

### Target Organs
- Liver, thymus gland

### Species
- Rat

### NOAEL

#### Application Route
- **Dermal**
- **Ingestion**

#### Exposure time
- **90 Days**

#### Target Organs
- Liver

#### Remarks
- No significant adverse effects were reported

### Acetone:

#### Species
- Rat

#### NOAEL

#### LOAEL
- 1,700 mg/kg

#### Application Route
- Ingestion

#### Exposure time
- 90 Days

#### Aspiration toxicity
- Not classified based on available information.

### Components:

#### Fluralaner:
- Not applicable

#### Acetone:
- The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

### Experience with human exposure

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

### Components:

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

Ecotoxicity

Components:

**N,N-Dimethylacetamide:**
- **Toxicity to fish**
  - LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
  - Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates**
  - EC50 (Daphnia magna (Water flea)): > 500 mg/l
  - Exposure time: 48 h
- **Toxicity to algae/aquatic plants**
  - EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
  - Exposure time: 72 h
  - EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l
  - Exposure time: 72 h
- **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

**M-Factor (Chronic aquatic toxicity)**
- 1,000

**Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-**
## SAFETY DATA SHEET

**Fluralaner / Diethyltoluamide Liquid Formula-**

<table>
<thead>
<tr>
<th>Version</th>
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<td>2016/01/15</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water flea)</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>&gt; 100 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncorhynchus mykiss (rainbow trout)</td>
<td>97 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water flea)</td>
<td>75 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Substance</th>
<th>ErC50</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selenastrum capricornutum (green algae)</td>
<td>41 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>Selenastrum capricornutum (green algae)</td>
<td>7.6 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water flea)</td>
<td>3.7 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

### Acetone:

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncorhynchus mykiss (rainbow trout)</td>
<td>5,540 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia pulex (Water flea)</td>
<td>8,800 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>7,000 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water flea)</td>
<td>&gt;= 79 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>61,150 mg/l</td>
<td></td>
</tr>
</tbody>
</table>
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

Bioaccumulative potential

Components:

Fluralaner:
Bioaccumulation: Species: Zebrafish
Bioconcentration factor (BCF): 79.4
Method: OECD Test Guideline 305
Partition coefficient: n-octanol/water: log Pow: 4.5

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

N,N-Diethyl-m-toluamide:
Partition coefficient: n-octanol/water: log Pow: 2.02

Acetone:
Partition coefficient: n-octanol/water : log Pow: -0.27 - -0.23

Mobility in soil

Components:

Fluralaner:
Distribution among environmental compartments : log Koc: 3.4

Hazardous to the ozone layer
Not applicable

Other adverse effects

Components:

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

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
Empty containers retain residue and can be dangerous.
Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 1090
Proper shipping name : ACETONE SOLUTION
Class : 3
Packing group : II
Labels : Flammable Liquids

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 (passen- : 353
IMDG Code

UN number: UN1090

Proper shipping name: ACETONE SOLUTION (Fluralaner)

Class: 3

Packing group: II

Labels: 3

EmS Code: F-E, S-D

Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

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

## 15. REGULATORY INFORMATION

### Related Regulations

**Fire Service Law**

Group 4, Type 1 petroleums, Water insoluble liquid, (200 litre), Hazardous rank II

**Chemical Substance Control Law**

Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>114</td>
</tr>
</tbody>
</table>

**Industrial Safety and Health Law**

**Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

**Substances Prevented From Impairment of Health**

<table>
<thead>
<tr>
<th>Chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-dimethylacetamide</td>
</tr>
</tbody>
</table>

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable
Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>284</td>
<td>&gt;=30 - &lt;40</td>
</tr>
<tr>
<td>Acetone</td>
<td>17</td>
<td>&gt;=10 - &lt;20</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>284</td>
</tr>
<tr>
<td>Acetone</td>
<td>17</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Organic Solvents Class 2

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Inflammable Substance

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Class I Designated Chemical Substances

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>213</td>
<td>32</td>
</tr>
</tbody>
</table>

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Flammable liquids (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Flammable liquid (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance(Category Z)
Pack transportation : Classified as marine pollutant
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.

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
JP OEL ISHL / ACL: Administrative Control level
JP OEL JSOH / OEL-M: Occupational Exposure Limit-Mean

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 concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemi-
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 10.0 Revision Date: 2021/09/21 SDS Number: 412184-00016 Date of last issue: 2020/12/07

Date of first issue: 2016/01/15

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.

JP / EN