SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fluralaner / Diethyltoluamide Liquid Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Fluralaner / Diethyltoluamide Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone: 353-51-601000

E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
- Flammable liquids, Category 2: H225: Highly flammable liquid and vapour.
- Reproductive toxicity, Category 1B: H360D: May damage the unborn child.
- Long-term (chronic) aquatic hazard, Category 1: H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
- Hazard pictograms:
  - Flammable
  - Reproductive toxicity
  - Long-term aquatic hazard

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.
Hazardous components which must be listed on the label:
N,N-Dimethylacetamide

Additional Labelling
Restricted to professional users.

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>204-826-4</td>
<td>616-011-00-4</td>
<td>Acute Tox. 4; H332 Acute Tox. 4; H312 Eye Irrit. 2; H319 Rep. 1B; H360D</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>
### SECTION 4: First aid measures

#### 4.1 Description of 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.

**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).

**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.

For explanation of abbreviations see section 16.
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.

4.2 Most important symptoms and effects, both acute and delayed
Risks:
May damage the unborn child.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment:
Treat symptomatically and supportively.

SECTION 5: Firefighting measures

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

Unsuitable extinguishing media:
High volume water jet

5.2 Special hazards arising from the substance or mixture
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)

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: 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).

6.2 Environmental precautions

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. bycontainment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.
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</tr>
</thead>
</table>

**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.

**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.

### 7.2 Conditions for safe storage, including any incompatibilities

**Requirements for storage areas and containers:**

**Advice on common storage:**
- 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

### 7.3 Specific end use(s)

**Specific use(s):**
- No data available
### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>TWA</td>
<td>10 ppm 35 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
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<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>TWA 10 ppm 36 mg/m³</td>
<td>2000/39/EC</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>20 ppm 72 mg/m³</td>
<td>2000/39/EC</td>
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</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>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
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<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>TWA</td>
<td>125 ppm 295 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>500 ppm 1.210 mg/m³</td>
<td>2000/39/EC</td>
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</table>

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>36 mg/m³</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>36 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>13.6 mg/kg bw/day</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>7 mg/m³</td>
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<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2.7 mg/kg bw/day</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>1 mg/kg bw/day</td>
</tr>
<tr>
<td>Acetone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1210 mg/m³</td>
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<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>2420 mg/m³</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>186 mg/kg bw/day</td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>200 mg/m³</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Consumers</th>
<th>Skin contact</th>
<th>Long-term systemic effects</th>
<th>62 mg/kg bw/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>62 mg/kg bw/day</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Fresh water</td>
<td>0.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0966 mg/l</td>
</tr>
<tr>
<td>Intermittent use/release</td>
<td>5 mg/l</td>
<td></td>
</tr>
<tr>
<td>Sewage treatment plant</td>
<td>485 mg/l</td>
<td></td>
</tr>
<tr>
<td>Fresh water sediment</td>
<td>2.27 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Soil</td>
<td>0.15 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>Fresh water</td>
<td>10.6 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>1.06 mg/l</td>
</tr>
<tr>
<td>Intermittent use/release</td>
<td>21 mg/l</td>
<td></td>
</tr>
<tr>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
<td></td>
</tr>
<tr>
<td>Fresh water sediment</td>
<td>30.4 mg/kg dry weight (d.w.)</td>
<td></td>
</tr>
<tr>
<td>Marine sediment</td>
<td>3.04 mg/kg dry weight (d.w.)</td>
<td></td>
</tr>
<tr>
<td>Soil</td>
<td>29.5 mg/kg dry weight (d.w.)</td>
<td></td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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

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.
If the work environment or activity involves dusty conditions, wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material: Chemical-resistant gloves

Remarks: Take note that the product is flammable, which may impact the selection of hand protection.

Skin and body protection

Material: Work uniform or laboratory coat.

Respiratory protection

Material: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to NS EN 137
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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: liquid
Colour: yellow
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: 103 °C
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
Flash point: 7 °C
Auto-ignition temperature: No data available
Decomposition temperature: No data available
pH: No data available
Viscosity
  Viscosity, kinematic: No data available
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
  Vapour pressure: 67 hPa (20 °C)
Relative density: No data available
Density: 1,059 g/cm³
Relative vapour density: No data available
Particle characteristics
  Particle size: Not applicable
9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : No data available
Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Highly flammable liquid and vapour.
                      Vapours may form explosive mixture with air.
                      Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
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
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</thead>
</table>

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 toxicity estimate: 2.2 mg/l
  - Test atmosphere: dust/mist
  - Method: Calculation method

**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 toxicity estimate: 1.892 mg/kg
  - Method: Expert judgement
  - Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

- **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:
- 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: Skin irritation
- Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

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

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

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

- **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**: Maximisation Test
- **Exposure routes**: Skin contact
- **Species**: Guinea pig
- **Result**: negative

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

### Components:

#### N,N-Dimethylacetamide:
- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- **Genotoxicity in vivo**: Test Type: Rodent dominant lethal test (germ cell) (in vivo)
  - **Species**: Rat
  - **Application Route**: Inhalation
  - **Method**: OECD Test Guideline 478
  - **Result**: negative
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Fluralaner:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

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

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

Acetone:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

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

Test Type: Chromosome aberration test in vitro
Result: negative

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

Carcinogenicity
Not classified based on available information.

Components:

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

Fluralaner:
Carcinogenicity - Assessment: No data available

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

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

Reproductive toxicity
May damage the unborn child.

Components:

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

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

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

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

Test Type: One-generation reproduction toxicity study
Species: Dog
**Effects on foetal development**

- **N,N-Diethyl-m-toluamide:**
  - Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

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

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

Acetone:
Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

N,N-Dimethylacetamide:
Species: Rat
NOAEL: 90 mg/m3
LOAEL: 360 mg/m3
Application Route: inhalation (vapour)
Exposure time: 24 Months

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

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

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 (vapour)
Exposure time: 8 Weeks

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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

12.1 Toxicity

Components:

N,N-Dimethylacetamide:
Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
Exposure time: 96 h
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**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 (Onchorhynchus 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: >= 0,049 mg/l

Exposure time: 21 d

Species: Zebrafish

Method: OECD Test Guideline 204

Remarks: No toxicity at the limit of solubility

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

NOEC: 0,000047 mg/l

Exposure time: 21 d

Species: Daphnia magna (Water flea)

Method: OECD Test Guideline 211

**M-Factor (Chronic aquatic toxicity)**

1.000

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**Poly(oxy-1,2-ethanediyl), alpha-[(tetrahydro-2-furanyl)methyl]-omega-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
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<table>
<thead>
<tr>
<th>plants</th>
<th>mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
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</tr>
</tbody>
</table>

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 (Onchorhynchus mykiss (rainbow trout)): 97 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

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

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

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

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

Acetone:

Toxicity to fish: LC50 (Onchorhynchus 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 microorganisms: EC50: 61.150 mg/l
Exposure time: 30 min
Method: ISO 8192

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: >= 79 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
12.2 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

12.3 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
12.4 Mobility in soil

- **Components:**
  - **Fluralaner:**
    - Distribution among environmental compartments: log Koc: 3.4

12.5 Results of PBT and vPvB assessment

- **Product:**
  - **Assessment:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

- **Components:**
  - **Fluralaner:**
    - **Assessment:** This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

12.6 Endocrine disrupting properties

- **Product:**
  - **Assessment:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

- No data available

### SECTION 13: Disposal considerations

13.1 Waste treatment methods

- **Product:** Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

- **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

14.1 UN number or ID number

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14.2 UN proper shipping name

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14.3 Transport hazard class(es)

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14.4 Packing group

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Packing group: II
Labels: 3
EmS Code: F-E, S-D

IATA (Cargo)
Packing instruction (cargo aircraft): 364
Packing instruction (LQ): Y341
Packing group: II
Labels: Flammable Liquids

IATA (Passenger)
Packing instruction (passenger aircraft): 353
Packing instruction (LQ): Y341
Packing group: II
Labels: Flammable Liquids

14.5 Environmental hazards

ADN
Environmentally hazardous: yes

ADR
Environmentally hazardous: yes

RID
Environmentally hazardous: yes

IMDG
Marine pollutant: yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered: Number on list 3 N,N-Dimethylacetamide (Number on list 72, 30)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): N,N-Dimethylacetamide

REACH - List of substances subject to authorisation (Annex XIV): Not applicable

Regulation (EC) No 1005/2009 on substances that de-
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plicate the ozone layer
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import
of dangerous chemicals
Regulation (EU) 2019/1148 on the marketing and use of explosives precursors
This product is regulated by Regulation (EU) 2019/1148: all suspicious transactions, and significant disappearances and thefts
should be reported to the relevant national contact point. Please see https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-we-do/policies/crisis-and-terrorism/explosives/explosives-precursors/docs/list_of_competent_authorities_and_national_contact_points_en.pdf
major-accident hazards involving dangerous substances.

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<tr>
<td>5.000 t</td>
<td>50.000 t</td>
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</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information
Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
H225 : Highly flammable liquid and vapour.
H302 : Harmful if swallowed.
H312 : Harmful in contact with skin.
H315 : Causes skin irritation.
H319 : Causes serious eye irritation.
H332 : Harmful if inhaled.
H336 : May cause drowsiness or dizziness.
H360D : May damage the unborn child.
H361d : Suspected of damaging the unborn child.
H410 : Very toxic to aquatic life with long lasting effects.
EUH066 : Repeated exposure may cause skin dryness or cracking.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Repr. : Reproductive toxicity
Skin Irrit. : Skin irritation
STOT SE : Specific target organ toxicity - single exposure
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
2000/39/EC / TWA : Limit Value - eight hours
2000/39/EC / STEL : Short term exposure limit
FOR-2011-12-06-1358 / TWA : Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; 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 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet;
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SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

Classification of the mixture:
- Flam. Liq. 2 H225 Based on product data or assessment
- Repr. 1B H360D Calculation method
- Aquatic Chronic 1 H410 Calculation method

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

NO / EN