SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 8.0  Revision Date: 21.09.2021  SDS Number: 412191-00016  Date of last issue: 07.12.2020  Date of first issue: 15.01.2016

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
   20 Spartan Road
   1619 Spartan, South Africa
   Telephone: +27119239300
   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:
   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.
   P210: Keep away from heat, hot surfaces, sparks, open
Fluralaner / Diethyltoluamide Liquid Formulation

flames and other ignition sources. No smoking.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

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.
Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<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 Repr. 1B; H360D</td>
<td>&gt;= 30 - &lt; 50</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>Acute Tox. 4; H332 Acute Tox. 4; H312 Eye Irrit. 2; H319 Repr. 1B; H360D</td>
<td>&gt;= 25 - &lt; 30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Poly(oxy-1,2-ethanediyl), .alpha.-[[tetrahydro-2-furanylmethyl]-omega.-hydroxy-</td>
<td>31692-85-0</td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>205-149-7</td>
<td>616-018-00-2</td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Acetone</td>
<td>67-64-1</td>
<td>200-662-2</td>
<td>Flam. Liq. 2; H225 Eye Irrit. 2; H319</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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STOT SE 3; H336

For explanation of abbreviations see section 16.

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.
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
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. by containment 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. 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: Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep
away from heat and sources of ignition.

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

<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 OEL-RL</td>
<td>10 ppm 36 mg/m3</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL</td>
<td>20 ppm 71 mg/m3</td>
<td>ZA OEL</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>Acetone</td>
<td>67-64-1</td>
<td>STEL OEL-RL</td>
<td>1.500 ppm 3.560 mg/m3</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>

Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Substance name</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Sampling time</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance name</td>
<td>End Use</td>
<td>Exposure routes</td>
<td>Potential health effects</td>
<td>Value</td>
</tr>
<tr>
<td>---------------</td>
<td>---------</td>
<td>-----------------</td>
<td>--------------------------</td>
<td>-------</td>
</tr>
<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>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>36 mg/m3</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>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>7 mg/m3</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>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>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>2420 mg/m3</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>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>200 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>62 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<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></td>
<td>Intermittent use/release</td>
<td>5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>485 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>2.27 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.15 mg/kg</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></td>
<td>Intermittent use/release</td>
<td>21 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>30.4 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>3.04 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>29.5 mg/kg dry weight (d.w.)</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. 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**: Work uniform or laboratory coat.

- **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

SECTION 9: Physical and chemical properties

**9.1 Information on basic physical and chemical properties**

- **Appearance**: liquid
- **Colour**: yellow
- **Odour**: No data available
- **Odour 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
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.0</td>
<td>21.09.2021</td>
<td>412191-00016</td>
<td>07.12.2020</td>
</tr>
</tbody>
</table>

**Flammability limit**

- Vapour pressure: 67 hPa (20 °C)
- Relative vapour density: No data available
- Relative density: No data available

**Density**

- 1,059 g/cm³

**Solubility(ies)**

- Water solubility: No data available
- Partition coefficient: n-octanol/water: Not applicable
- Auto-ignition 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.

**9.2 Other information**

- Flammability (liquids): Not applicable
- Molecular weight: No data available
- Particle size: Not applicable

**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 toxicological effects
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 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
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<table>
<thead>
<tr>
<th>Component Description</th>
<th>Acute oral toxicity</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poly(oxy-1,2-ethanediyl), .alpha.-(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-</td>
<td>LD50 (Rat, female): &gt; 2.000 mg/kg</td>
<td>OECD Test Guideline 423</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>LD50 (Rat): 1.950 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>LD50 (Rat): 1.950 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): 5.800 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>LC50 (Rat): 5.95 mg/l</td>
<td>Expert judgement</td>
<td>Based on harmonised classification in EU regulation 1272/2008, Annex VI</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): 5.000 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 (Rat): 76 mg/l</td>
<td></td>
<td>Based on harmonised classification in EU regulation 1272/2008, Annex VI</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: vapour</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Rabbit): 7.426 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Rabbit): 7.426 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Not classified based on available information.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product:**

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

**Components:**

<table>
<thead>
<tr>
<th>Component Description</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl), .alpha.-(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-</td>
<td>reconstructed human epidermis (RhE)</td>
<td>OECD Test Guideline 439</td>
</tr>
</tbody>
</table>
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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

**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
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  
Application Route: Ingestion  
Result: negative

**Acetone:**

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

Effects on 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:
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
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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

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.

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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**Date of first issue**: 15.01.2016

**Toxicity to daphnia and other aquatic invertebrates**

| Method | EC50 (Daphnia magna (Water flea)): > 500 mg/l  
| Exposure time: 48 h  

**Toxicity to algae/aquatic plants**

| Method | 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**

| Method | EC10: > 1.995 mg/l  
| Exposure time: 30 min |

**Fluralaner**

**Toxicity to fish**

| Method | 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**

| Method | 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**

| Method | 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)**

| Method | 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)**

| Method | NOEC: 0,000047 mg/l  
| Exposure time: 21 d  
| Species: Daphnia magna (Water flea)  
| Method: OECD Test Guideline 211  
| Remarks: Based on data from similar materials |

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

| Method | 1.000 |

**Poly(oxy-1,2-ethanediyl), alpha-[(tetrahydro-2-furanyl)methyl]-omega-hydroxy-**

**Toxicity to daphnia and other aquatic invertebrates**

| Method | 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**

| Method | EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
| Exposure time: 72 h |
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**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:**
  - ER50 (Selenastrum capricornutum (green algae)): 41 mg/l
  - Exposure time: 72 h

- **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 (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 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 Other adverse effects

**Product:**

| Endocrine disrupting potential | 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. |

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. 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. |

**Contaminated packaging** |

SECTION 14: Transport information

14.1 UN number
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ADN : UN 1090
ADR : UN 1090
RID : UN 1090
IMDG : UN 1090
IATA : UN 1090

14.2 UN proper shipping name

ADN : ACETONE, SOLUTION
ADR : ACETONE, SOLUTION
RID : ACETONE, SOLUTION
IMDG : ACETONE, SOLUTION
IATA : Acetone, solution

14.3 Transport hazard class(es)

ADN : 3
ADR : 3
RID : 3
IMDG : 3
IATA : 3

14.4 Packing group

ADN
Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3

ADR
Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3
Tunnel restriction code : (D/E)

RID
Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3

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

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

IATA (Passenger)
Packing instruction (passen-
ger 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 Transport in bulk according to Annex II of Marpol and the IBC Code

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

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.
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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
ZA BEI : South Africa. Hazardous Chemical Substances Regulations, Biological Exposure Indices.
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
2000/39/EC / TWA : Limit Value - eight hours
2000/39/EC / STEL : Short term exposure limit
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended 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; 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; 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; KECL - 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
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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; 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: Classification procedure:
Flam. Liq. 2 H225 Based on product data or assessment
Repr. 1B H360D Calculation method
Aquatic Chronic 1 H410 Calculation method

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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.

ZA / EN