SAFETY DATA SHEET

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
20 Spartan Road
1619 Spartan, South Africa

Telephone: +27119239300
Telefax: 908-735-1496

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:
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P201 Obtain special instructions before use.
P210 Keep away from heat, hot surfaces, sparks, open 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:

<table>
<thead>
<tr>
<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>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>204-826-4</td>
<td>616-011-00-4</td>
<td></td>
<td>Acute Tox.4; H332 Acute Tox.4; H312 Eye Irrit.2; H319 Repr.1B; H360D</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td></td>
<td></td>
<td></td>
<td>Repr.2; H361d Aquatic Chronic1; H410</td>
<td>&gt;= 25 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 1.000</td>
<td></td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>205-149-7</td>
<td>616-018-00-2</td>
<td></td>
<td>Acute Tox.4; H302 Skin Irrit.2; H315 Eye Irrit.2; H319 Aquatic Chronic3; H412</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>200-662-2</td>
<td>606-001-00-8</td>
<td></td>
<td>Flam. Liq.2; H225 Eye Irrit.2; H319 STOT SE3; H336</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

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.

**If inhaled**: If inhaled, remove to fresh air. Get medical attention.

**In case of skin contact**: In case of contact, immediately flush skin with 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

**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 and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions: Discharge into the environment must be avoided. 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 absor-
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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
Use with local exhaust ventilation. Use only in an area equipped with explosion-proof exhaust ventilation if advised by assessment of the local exposure potential.

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 and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures
Ensure that eye flushing systems and safety showers are located 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

### 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 OEL-RL</td>
<td>10 ppm 36 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>STEL OEL-RL</td>
<td>20 ppm 71 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>STEL</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>Further information</td>
<td></td>
<td>Skin</td>
<td>Wipe limit 1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>TWA OEL-RL</td>
<td>750 ppm 1.780 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>STEL OEL-RL</td>
<td>1.500 ppm 3.560 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>TWA</td>
<td>500 ppm 1.210 mg/m³</td>
<td>2000/39/EC</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>Acetone</td>
<td>67-64-1</td>
<td>Acetone: 100 mg/l (Urine)</td>
<td>End of shift</td>
<td>ZA BEI</td>
</tr>
</tbody>
</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>
</table>
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tion

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<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.

Personal protective equipment

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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: Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.
Filter type: Self-contained breathing apparatus

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<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>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>103 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>7 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</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>Vapour pressure</td>
<td>67 hPa (20 °C)</td>
</tr>
<tr>
<td>Relative vapour 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>Solubility(ies)</td>
<td></td>
</tr>
</tbody>
</table>
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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
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Eye contact

Acute toxicity

Not classified based on available information.

Product:

<table>
<thead>
<tr>
<th></th>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 2.000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Remarks: No mortality observed at this dose.</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td></td>
<td>Acute toxicity estimate: &gt; 5 mg/l</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method: Calculation method</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Acute dermal toxicity</th>
<th>LD50 (Rat): &gt; 2.000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Symptoms: Erythema</td>
</tr>
</tbody>
</table>

Components:

N,N-Dimethylacetamide:

<table>
<thead>
<tr>
<th></th>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 4.800 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
<td></td>
<td>LC50 (Rat): 2.2 mg/l</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td></td>
<td>Acute toxicity estimate: 1.100 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method: Expert judgement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI</td>
</tr>
</tbody>
</table>

Fluralaner:

<table>
<thead>
<tr>
<th></th>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 2.000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Remarks: No mortality observed at this dose.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Acute dermal toxicity</th>
<th>LD50 (Rat): &gt; 2.000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Remarks: No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

N,N-Diethyl-m-toluamide:

<table>
<thead>
<tr>
<th></th>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 1.950 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
<td></td>
<td>LC50 (Rat): 5.95 mg/l</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td></td>
<td>LD50 (Rat): 5.000 mg/kg</td>
</tr>
</tbody>
</table>

Acetone:

<table>
<thead>
<tr>
<th></th>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 5.800 mg/kg</th>
</tr>
</thead>
</table>
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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

N,N-Diethyl-m-toluamide:
   Species: Rabbit
   Result: 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

N,N-Diethyl-m-toluamide:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days

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.

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

### 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

### 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)
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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
- **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:**
- 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
  - 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.

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

Product:

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
### Toxicity to Daphnia and Other Aquatic Invertebrates

**Method:** OECD Test Guideline 203  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Daphnia magna (Water flea))</td>
<td>&gt; 0.015 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to Algae/Aquatic Plants

**Method:** OECD Test Guideline 202  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt;= 0.08 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to Fish (Chronic Toxicity)

**Method:** OECD Test Guideline 204  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC: &gt;= 0.049 mg/l</td>
<td></td>
<td>21 d</td>
<td>Zebrafish</td>
</tr>
</tbody>
</table>

### Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)

**Method:** OECD Test Guideline 211  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC: 0.000047 mg/l</td>
<td></td>
<td>21 d</td>
<td>Daphnia magna (Water flea)</td>
</tr>
</tbody>
</table>

### M-Factor (Chronic Aquatic Toxicity)

**Remarks:** None  
**Value:** 1.000

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

**Method:** OECD Test Guideline 203  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC: 0.000047 mg/l</td>
<td></td>
<td>21 d</td>
<td>Daphnia magna (Water flea)</td>
</tr>
</tbody>
</table>

### Acetone

**Method:** OECD Test Guideline 203  
**Remarks:** No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC: 79 mg/l</td>
<td></td>
<td>21 d</td>
<td>Daphnia magna (Water flea)</td>
</tr>
</tbody>
</table>
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.

**N,N-Diethyl-m-toluamide:**
- Biodegradability: Result: Not readily biodegradable.

**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

**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

**Components:**

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

12.6 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.

SECTION 14: Transport information

14.1 UN number
- **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 (Fluralaner)
- **IATA**: Acetone, solution

14.3 Transport hazard class(es)
- **ADN**: 3
- **ADR**: 3
- **RID**: 3
- **IMDG**: 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 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: no

**ADR**
- Environmentally hazardous: no

**RID**
- Environmentally hazardous: no

**IMDG**
- Marine pollutant: no

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.
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 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

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.
H412: Harmful to aquatic life with long lasting effects.

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.
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 6.0  Revision Date: 01.03.2019  SDS Number: 412191-00013  Date of last issue: 25.02.2019  Date of first issue: 15.01.2016

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; AICS - Australian Inventory of Chemical Substances; 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; 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; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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
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.

ZA / EN