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:
   ![Flammable](image1) ![Reproductive](image2) ![Aquatic](image3)
   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
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.

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 17.4 %

2.3 Other hazards
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></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></td>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td></td>
<td></td>
<td></td>
<td>Repr. 2; H361d Aquatic Chronic 1; H410</td>
<td>&gt;= 25 - &lt; 30</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></td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Aquatic Chronic 3; H412</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<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 SE 3; 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 (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

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. 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 dyeing or other appropriate containment to keep material from spreading. If dyed material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absor-
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
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 7.0  Revision Date: 07.12.2020  SDS Number: 412191-00015  Date of last issue: 01.10.2020

Date of first issue: 15.01.2016

- 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</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>36 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL</td>
<td>20 ppm</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>71 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>20 ppm</td>
<td>2000/39/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>72 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
<td>2000/39/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>36 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>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</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.780 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL</td>
<td>1.500 ppm</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3.560 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>500 ppm</td>
<td>2000/39/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.210 mg/m³</td>
<td></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:
### Substance name | End Use | Exposure routes | Potential health effects | Value
---|---|---|---|---
N,N-Dimethylacetamide | Workers | Inhalation | Long-term systemic effects | 36 mg/m³
| Workers | Inhalation | Acute systemic effects | 36 mg/m³
| Workers | Skin contact | Acute systemic effects | 13,6 mg/kg bw/day
| Consumers | Inhalation | Long-term local effects | 7 mg/m³
| Consumers | Skin contact | Long-term systemic effects | 2,7 mg/kg bw/day
| Consumers | Ingestion | Long-term systemic effects | 1 mg/kg bw/day
Acetone | Workers | Inhalation | Long-term systemic effects | 1210 mg/m³
| Workers | Inhalation | Acute local effects | 2420 mg/m³
| Workers | Skin contact | Long-term systemic effects | 186 mg/kg bw/day
| Consumers | Inhalation | Long-term systemic effects | 200 mg/m³
| Consumers | Skin contact | Long-term systemic effects | 62 mg/kg bw/day
| Consumers | Ingestion | Long-term systemic effects | 62 mg/kg bw/day

### 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 explosion-proof electrical, ventilating and lighting equipment.
- 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**

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**

<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>
</tbody>
</table>
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 : Inhalation
### SAFETY DATA SHEET

**Fluralaner / Diethyltoluamide Liquid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.0</td>
<td>07.12.2020</td>
<td>412191-00015</td>
<td>01.10.2020</td>
<td>15.01.2016</td>
</tr>
</tbody>
</table>

**exposure**

- Skin contact
- Ingestion
- Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

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

**Components:**

- **N,N-Dimethylacetamide:**
  - Acute oral toxicity: LD50 (Rat): 4.800 mg/kg
  - Acute inhalation toxicity: LC50 (Rat): 2.2 mg/l
  - 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

- **N,N-Diethyl-m-toluamide:**
  - Acute oral toxicity: LD50 (Rat): 1.950 mg/kg
  - Acute inhalation toxicity: LC50 (Rat): 5.95 mg/l
    - Exposure time: 4 h
    - Test atmosphere: dust/mist
  - Acute dermal toxicity: LD50 (Rat): 5.000 mg/kg

- **Acetone:**
Acute oral toxicity: LD50 (Rat): 5.800 mg/kg

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

Acute dermal toxicity: LD50 (Rabbit): 7.426 mg/kg

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

Product:
Species: Rabbit
Result: No skin irritation

Components:

N,N-Dimethylacetamide:
Species: Rabbit
Result: No skin irritation

Fluralaner:
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
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version | Revision Date: | SDS Number: | Date of last issue: | Date of first issue:
7.0      | 07.12.2020    | 412191-00015 | 01.10.2020          | 15.01.2016

**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)
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)
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
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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
Remarks: Maternal toxicity observed.

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
Remarks: Maternal toxicity observed.

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:**

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

**Fluralaner:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>52 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Species**

<table>
<thead>
<tr>
<th>Species</th>
<th>Juvenile dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>56 - 280 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>24 Weeks</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Diarrhoea</td>
</tr>
</tbody>
</table>

**Species**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>400 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Species**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>500 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Dermal</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Acetone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>900 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>1,700 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>
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

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
<table>
<thead>
<tr>
<th></th>
<th>Fluralaner:</th>
<th>N,N-Diethyl-m-toluamide:</th>
<th>Acetone:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 0.0488 mg/l</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 110 mg/l</td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): 5.540 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td>Exposure time: 96 h</td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 0.015 mg/l</td>
<td>EC50 (Daphnia magna (Water flea)): 75 mg/l</td>
<td>EC50 (Daphnia pulex (Water flea)): 8.800 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td>Exposure time: 48 h</td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): &gt;= 0.08 mg/l</td>
<td>NOEC: 0.000047 mg/l</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 7.000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>NOEC: &gt;= 0.049 mg/l</td>
<td></td>
<td>NOEC:</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
<td></td>
<td>61.150 mg/l</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC: 0.000047 mg/l</td>
<td></td>
<td>Exposure time: 30 min</td>
</tr>
<tr>
<td></td>
<td>Species: Zebrafish</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 204</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>M-Factor (Chronic aquatic toxicity)</strong></td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.

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
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Date of first issue: 15.01.2016

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

14.4 Packing group

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

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

IMDG
Packing group : II
Labels : 3

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

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Environmentally hazardous : yes
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Version: 7.0  Revision Date: 07.12.2020  SDS Number: 412191-00015  Date of last issue: 01.10.2020

Date of first issue: 15.01.2016

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.

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
# SAFETY DATA SHEET

## Fluralaner / Diethyltoluamide Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<td>7.0</td>
<td>07.12.2020</td>
<td>412191-00015</td>
<td>01.10.2020</td>
<td>15.01.2016</td>
</tr>
</tbody>
</table>

**STOT SE 2000/39/EC**  
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; 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

**Sources of key data used to compile the Safety Data Sheet:**  

**Classification of the mixture:**

| Flam. Liq. 2 | H225 |

**Classification procedure:**  
Based on product data or assessment
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7.0        07.12.2020        412191-00015        Date of first issue: 15.01.2016

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.

ZA / EN