1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner / Diethyltoluamide Liquid Formulation

Manufacturer or supplier's details
Company: MSD
Address: 50 Tuas West Drive
          Singapore - Singapore 638408
Telephone: +1-908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

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

GHS label elements
Hazard pictograms: 

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

Precautionary statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat/ sparks/ open flames/ hot surfaces.
No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equip-
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version: 8.0  Revision Date: 21.09.2021  SDS Number: 412189-00016  Date of last issue: 07.12.2020

P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

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

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

Other hazards which do not result in classification
Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 25 - &lt; 30</td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl), .alpha.-{(tetrahydro-2-furanyl)methyl}.omega.-hydroxy-</td>
<td>31692-85-0</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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

If inhaled : If inhaled, remove to fresh air.
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.

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

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Chlorine compounds
Fluorine compounds
Nitrogen oxides (NOx)

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil
Methods and materials for containment and cleaning up:

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

7. HANDLING AND STORAGE

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.

Conditions for safe storage:
- 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.

Materials to avoid:
- Do not store with the following product types:
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Oxidizing agents
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>PEL (long term)</td>
<td>10 ppm 36 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Internal</td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Further information: Skin**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>N-Methylaacetamide</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>30 mg/g Creatinine</td>
<td>ACGIH BEI</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>Acetone</td>
<td>Urine</td>
<td>End of shift (As soon as possible after exposure ceases)</td>
<td>25 mg/l</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

### Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
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<td>End of shift (As soon as possible after exposure ceases)</td>
<td>25 mg/l</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

### Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.
Use explosion-proof electrical, ventilating and lighting equipment.

**Personal protective equipment**

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

- **Filter type**
  - **Hand protection**: Self-contained breathing apparatus

- **Material**: Chemical-resistant gloves

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

**Eye protection**: Wear safety glasses with side shields or goggles.

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

**Skin and body protection**

**Hygiene measures**: Work uniform or laboratory coat.

- 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.

**9. 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
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formula-

Version: 8.0
Revision Date: 21.09.2021
SDS Number: 412189-00016
Date of last issue: 07.12.2020
Date of first issue: 15.01.2016

10. STABILITY AND REACTIVITY

Reactivity: Not classifie
d as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reac-
tions: Highly flammable liquid and vapour.
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.
Conditions to avoid: Heat, flames and sparks.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.
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:

<table>
<thead>
<tr>
<th>N,N-Dimethylacetamide:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity     : LD50 (Rat): 4,800 mg/kg</td>
</tr>
<tr>
<td>Acute inhalation toxicity: LC50 (Rat): 2.2 mg/l</td>
</tr>
</tbody>
</table>
  Exposure time: 4 h
  Test atmosphere: Dust/mist |
| Acute dermal toxicity   : Acute toxicity estimate: 1,100 mg/kg |
  Method: Expert judgement |
  Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI |

<table>
<thead>
<tr>
<th>Fluralaner:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity     : LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
</tbody>
</table>
  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 |

<table>
<thead>
<tr>
<th>Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-omega.-hydroxy-:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity          : LD50 (Rat, female): &gt; 2,000 mg/kg</td>
</tr>
</tbody>
</table>
  Method: OECD Test Guideline 423 |
  Remarks: Based on data from similar materials |

<table>
<thead>
<tr>
<th>N,N-Diethyl-m-toluamide:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity     : LD50 (Rat): 1,950 mg/kg</td>
</tr>
<tr>
<td>Acute inhalation toxicity: LC50 (Rat): 5.95 mg/l</td>
</tr>
</tbody>
</table>
Exposure time: 4 h  
Test atmosphere: dust/mist

**Acute dermal toxicity**  
LD50 (Rat): 5,000 mg/kg

**Acetone:**

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

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

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

**Skin corrosion/irritation**

Not classified based on available information.

**Product:**

**Species**  
Rabbit

**Result**  
No skin irritation

**Components:**

**N,N-Dimethylacetamide:**

**Species**  
Rabbit

**Result**  
No skin irritation

**Fluralaner:**

**Species**  
Rabbit

**Result**  
No skin irritation

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

**Species**  
reconstructed human epidermis (RhE)

**Method**  
OECD Test Guideline 439

**Remarks**  
Based on data from similar materials

**Result**  
No skin irritation

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

**Species**  
Rabbit

**Result**  
No skin irritation

**Acetone:**

**Assessment**  
Repeated exposure may cause skin dryness or cracking.

**Serious eye damage/eye irritation**

Not classified based on available information.
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version: 8.0  Revision Date: 21.09.2021  SDS Number: 412189-00016  Date of last issue: 07.12.2020
Date of first issue: 15.01.2016

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

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

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

Fluralaner / Diethyltoluamide Liquid Formulation

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

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

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

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

Acetone:
Genotoxicity in vitro:
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Chromosome aberration test in vitro
  Result: negative

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

Carcinogenicity:
Not classified based on available information.

Components:

N,N-Dimethylacetamide:
Species: Rat
Application Route: inhalation (vapour)
Exposure time: 18 month(s)
Result: negative
Fluralaner:  
Carcinogenicity - Assessment: No data available

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

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

Reproductive toxicity
May damage the unborn child.

Components:

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

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

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

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

Test Type: One-generation reproduction toxicity study
Species: Dog  
Application Route: Oral
Fertility: NOAEL: 75 mg/kg body weight
Result: No effects on fertility and early embryonic develop-
### Fluralaner / Diethyltoluamide Liquid Formulation

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

**N,N-Dimethylacetamide:**

Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h

Toxicity to microorganisms: EC10: > 1,995 mg/l
Exposure time: 30 min

**Fluralaner:**

Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.0488 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility
| **Toxicity to daphnia and other aquatic invertebrates** | EC50 (Daphnia magna (Water flea)): > 0.015 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: No toxicity at the limit of solubility |
| **Toxicity to algae/aquatic plants** | NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility |
| **Toxicity to fish (Chronic toxicity)** | NOEC (Zebrafish): >= 0.049 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 204  
Remarks: No toxicity at the limit of solubility |
| **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)** | NOEC (Daphnia magna (Water flea)): 0.000047 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211 |
| **M-Factor (Chronic aquatic toxicity)** | 1,000 |

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

| **Toxicity to daphnia and other aquatic invertebrates** | EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials |
| **Toxicity to algae/aquatic plants** | EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials  
EC10 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials |

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

| **Toxicity to fish** | LC50 (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** | ErC50 (Selenastrum capricornutum (green algae)): 41 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201 |
NOEC (Selenastrum capricornutum (green algae)): 7.6 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

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

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

Toxicity to microorganisms:  
EC50: 61,150 mg/l  
Exposure time: 30 min  
Method: ISO 8192

Persistence and degradability

Components:

**N,N-Dimethylacetamide:**
Biodegradability:  
Result: Not readily biodegradable.  
Biodegradation: 70 %  
Exposure time: 28 d  
Remarks: The 10 day time window criterion is not fulfilled.

**Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**
Biodegradability:  
Result: Not readily biodegradable.  
Method: OECD Test Guideline 301F  
Remarks: Based on data from similar materials

**N,N-Diethyl-m-toluamide:**
Biodegradability:  
Result: Readily biodegradable.  
Biodegradation: 83.8 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**Acetone:**
Biodegradability:  
Result: Readily biodegradable.
1. IDENTIFICATION AND初IDENTIFICATION AND RISK MANAGEMENT

1.1. Product identification

Fluralaner / Diethyltoluamide Liquid Formulation

1.2. Supplier identification

MSD

1.3. Hazard identification

None

2. COMPOSITION/COMPONENTS

Components:

- Fluralaner
- N,N-Diethyl-m-toluamide
- Acetone

3. HAZARDS IDENTIFICATION

3.1. Physical and chemical properties

- Biodegradation: 91%
- Exposure time: 28 d
- Bioaccumulative potential

3.2. Epidemiological information

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

4. FIRST AID MEASURES

4.1. Specific first aid measures

4.2. Fire-fighting measures

4.3. Spill response measures

5. HANDLING AND STORAGE

5.1. Precautions for safe handling

5.2. Precautions for safe storage

5.3. Incompatibilities

6. EXPOSURE CONTROLS/PERSONAL PROTECTION

6.1. Control parameters

6.2. Personal protective equipment

7. TOXICOLOGICAL INFORMATION

7.1. Acute toxicity

7.2. Chronic toxicity

7.3. Sensitivity

8. LABORATORY TESTS

8.1. Human studies

8.2. Other studies

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Physical state

9.2. Stability

9.3. rekakta

9.4. Reactions

10. STABILITY AND REACTIVITY

10.1. Reactivity

10.2. Chemical stability

11. ENVIRONMENTAL INFORMATION

11.1. Ecotoxicological data

11.2. Exposure controls

11.3. Disposal considerations

12. ECOLOGICAL INFORMATION

12.1. Biological data

12.2. Ecological significance

13. DISPOSAL CONSIDERATIONS

13.1. Disposal methods

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

14. TRANSPORT INFORMATION

International Regulations

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

IATA-DGR
UN/ID No. : UN 1090
Proper shipping name : Acetone solution
Class : 3
Packing group : II
Labels : Flammable Liquids
Packing instruction (cargo aircraft) : 364
Packing instruction (passenger aircraft) : 353

IMDG-Code
UN number : UN 1090
Proper shipping name : ACETONE SOLUTION (Fluralaner)
Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

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

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations : Not applicable
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 8.0  Revision Date: 21.09.2021  SDS Number: 412189-00016  Date of last issue: 07.12.2020  Date of first issue: 15.01.2016

Fire Safety (Petroleum and Flammable Materials)  :  Acetone

The components of this product are reported in the following inventories:

AICS  :  not determined

DSL :  not determined

IECSC :  not determined

16. OTHER INFORMATION

Further information


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

Date format :  dd.mm.yyyy

Full text of other abbreviations

ACGIH :  USA. ACGIH Threshold Limit Values (TLV)

ACGIH BEI :  ACGIH - Biological Exposure Indices (BEI)


ACGIH / TWA :  8-hour, time-weighted average

ACGIH / STEL :  Short-term exposure limit

SG OEL / PEL (long term) :  Permissible Exposure Level (PEL) Long Term

SG OEL / PEL (short term) :  Permissible Exposure Level (PEL) Short Term

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Civil Aviation Organization; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

SG / EN