1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner / Diethyltoluamide Liquid Formulation

Manufacturer or supplier's details

Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
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-
ment.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Chemical name</td>
</tr>
<tr>
<td>127-19-5</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
</tr>
<tr>
<td>Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl].omega.-hydroxy-</td>
<td>31692-85-0</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</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 spill response).
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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/PERSOAL 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
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</tr>
</tbody>
</table>

**Flammable gases**

**Pyrophoric liquids**

**Pyrophoric solids**

**Self-heating substances and mixtures**

**Poisonous gases**

**Explosives**

### 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>NAB</td>
<td>10 ppm 36 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>10 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>NAB</td>
<td>250 ppm 1,187.12 mg/m³</td>
<td>ID OEL</td>
</tr>
</tbody>
</table>

**Further information:** Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals, Skin

#### 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>
<td>127-19-5</td>
<td>N-Methylacetamide</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)</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: Self-contained breathing apparatus

Hand protection

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
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Melting point/freezing point: No data available
Initial boiling point and boiling range: 103 °C
Flash point: 7 °C
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: 67 hPa (20 °C)
Relative vapour density: No data available
Relative density: No data available
Density: 1.059 g/cm³
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity
Viscosity, kinematic: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: 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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Product:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Remarks: No mortality observed at this dose.

Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Symptoms: Erythema

Components:
N,N-Dimethylacetamide:
Acute oral toxicity: LD50 (Rat): 4,800 mg/kg

Acute inhalation toxicity: LC50 (Rat): 2.2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: Acute toxicity estimate: 1,100 mg/kg
Method: Expert judgement
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

Fluralaner:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Remarks: No mortality observed at this dose. No significant adverse effects were reported

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Remarks: No significant adverse effects were reported
Poly(oxy-1,2-ethanediyl), alpha-[(tetrahydro-2-furanyl)methyl]-omega-hydroxy-:
Acute oral toxicity: LD50 (Rat, female): > 2,000 mg/kg
   Method: OECD Test Guideline 423
   Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:
Acute oral toxicity: LD50 (Rat): 1,950 mg/kg
Acute inhalation toxicity: LC50 (Rat): 5.95 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rat): 5,000 mg/kg

Acetone:
Acute oral toxicity: LD50 (Rat): 5,800 mg/kg
Acute inhalation toxicity: LC50 (Rat): 76 mg/l
   Exposure time: 4 h
   Test atmosphere: vapour
Acute dermal toxicity: LD50 (Rabbit): 7,426 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Product:
Species: Rabbit
Result: No skin irritation

Components:

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

Fluralaner:
Species: Rabbit
Result: No skin irritation

Poly(oxy-1,2-ethanediyl), alpha-[(tetrahydro-2-furanyl)methyl]-omega-hydroxy-:
Species: reconstructed human epidermis (RhE)
Method: OECD Test Guideline 439
Remarks: Based on data from similar materials
Result: No skin irritation

N,N-Diethyl-m-toluamide:
Species: Rabbit
Result: No 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

**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.

**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

- **Remarks:** Direct Peptide Reactivity Assay (DPRA)
  - **Method:** OECD Test Guideline 442C
  - **Result:** positive
  - **Remarks:** Based on data from similar materials

- **Remarks:** Dendritic cell activation test
  - **Method:** OECD Test Guideline 442E
  - **Result:** negative
  - **Remarks:** Based on data from similar materials

**Acetone:**
- **Test Type:** Maximisation Test
- **Exposure routes:** Skin contact
- **Species:** Guinea pig
- **Result:** negative
Germ cell mutagenicity
Not classified based on available information.

Components:

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

Genotoxicity in vivo: Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Rat
Application Route: Inhalation
Method: OECD Test Guideline 478
Result: negative

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

**Carcinogenicity**
- Not classified based on available information.

**Components:**

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

**Fluralaner:**
- Carcinogenicity - Assessment: No data available

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

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

**Reproductive toxicity**
- May damage the unborn child.

**Components:**

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

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

- Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments.
Fluralaner:  
Effects on fertility  
: Test Type: Two-generation study  
Species: Rat  
Application Route: Oral  
General Toxicity - Parent: NOAEL: 50 mg/kg body weight  
General Toxicity F1: LOAEL: 100 mg/kg body weight  
Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects.  

Test Type: One-generation reproduction toxicity study  
Species: Dog  
Application Route: Oral  
Fertility: NOAEL: 75 mg/kg body weight  
Result: No effects on fertility and early embryonic development were detected.  
Remarks: No significant adverse effects were reported.

Effects on foetal development  
: Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 100 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects  

Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 10 mg/kg body weight  
Result: Skeletal malformations, Visceral malformations  
Remarks: Maternal toxicity observed.  

Test Type: Development  
Species: Rabbit  
Application Route: Dermal  
Developmental Toxicity: NOAEL: 100 mg/kg body weight  
Result: Skeletal malformations

Reproductive toxicity - Assessment  
: Suspected of damaging the unborn child.

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

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

Species: Rat
- LOAEL: 500 mg/kg
- Application Route: Dermal
- Exposure time: 90 Days
Target Organs: Liver
Remarks: No significant adverse effects were reported

Acetone:
Species: Rat
NOAEL: 900 mg/kg
LOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Species: Rat
NOAEL: 45 mg/l
Application Route: Inhalation (vapour)
Exposure time: 8 Weeks

Aspiration toxicity
Not classified based on available information.

Components:

Fluralaner:
Not applicable

Acetone:
The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

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
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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

Remarks: 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.
  - Biodegradation: 91 %
  - Exposure time: 28 d

**Bioaccumulative potential**

**Components**:

**Fluralaner**:

- **Bioaccumulation**: Species: Zebrafish
  - Bioconcentration factor (BCF): 79.4
  - Method: OECD Test Guideline 305
- **Partition coefficient: n-octanol/water**: \(\log K_{oc}\): 4.5

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

- **Partition coefficient: n-octanol/water**: \(\log K_{oc}\): \(< 4\)
  - Remarks: Calculation

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

- **Partition coefficient: n-octanol/water**: \(\log K_{oc}\): 2.02

**Acetone**:

- **Partition coefficient: n-octanol/water**: \(\log K_{oc}\): -0.27 - -0.23

**Mobility in soil**

**Components**:

**Fluralaner**:

- **Distribution among environmental compartments**: \(\log K_{oc}\): 3.4

**Other adverse effects**

**Components**:

**Fluralaner**
13. DISPOSAL CONSIDERATIONS

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
15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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 : yyyy/mm/dd

Full text of other abbreviations
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formula-
tion

Version 7.0  Revision Date: 2021/09/21  SDS Number: 412181-00016  Date of last issue: 2020/12/07
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ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
ID OEL / NAB : Long term exposure limit
ID OEL / PSD : Short term exposure limit

AICL - 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 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect 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 (EU) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SAFTD - 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.

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