SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formula-

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fluralaner / Diethyltoluamide Liquid Formulation

Manufacturer or supplier's details
Company      : MSD
Address      : Briahnager - Off Pune Nagar Road
              Wagholi - Pune - India  412 207
Telephone    : +1-908-740-4000
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

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Very highly flammable liquids

GHS Classification
Flammable liquids : Category 2
Acute toxicity (Inhalation) : Category 5
Reproductive toxicity : Category 1B
Aspiration hazard : Category 2
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms : 

Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.
H305 May be harmful if swallowed and enters airways.
H333 May be harmful if inhaled.
H360D May damage the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention:
P203 Obtain, read and follow all safety 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:
P301 + P316 IF SWALLOWED: Get emergency medical help immediately.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse affected areas with water.
P304 + P317 IF INHALED: Get medical help.
P318 IF exposed or concerned, get medical advice.
P331 Do NOT induce vomiting.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

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

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>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 be harmful if swallowed and enters airways. May be harmful if inhaled. 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, protection: Remove all sources of ignition.
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
  - 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>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></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Further information: Skin</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>TWA</td>
<td>750 ppm</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>2,375 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>500 ppm</td>
<td>ACGIH</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>
<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 exposure ceases)</td>
<td>25 mg/l</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

**Engineering measures:** Use explosion-proof electrical, ventilating and lighting equip-
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

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

**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.

9. 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</td>
<td>103 °C</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 7.0 | Revision Date: 07.12.2020 | SDS Number: 462539-00015 | Date of last issue: 01.10.2020
| Date of first issue: 15.01.2016

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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:
May be harmful if inhaled.

Product:

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

Acute inhalation toxicity: Acute toxicity estimate: 5.95 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

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

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

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

**Acetone:**
- **Species:** Rabbit
- **Method:** OECD Test Guideline 405
- **Result:** Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

Product:

**Test Type:** Maximisation Test
**Exposure routes:** Dermal
**Species:** Guinea pig
**Result:** Not a skin sensitizer.

Components:

**N,N-Dimethylacetamide:**
- **Exposure routes:** Skin contact
- **Species:** Guinea pig
- **Result:** negative

**Fluralaner:**
- **Test Type:** Maximisation Test
- **Exposure routes:** Dermal
- **Species:** Guinea pig
- **Result:** Not a skin sensitizer

**Acetone:**
- **Test Type:** Maximisation Test
- **Exposure routes:** Skin contact
Species: Guinea pig
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

Fluralaner:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

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

Acetone:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

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

Effects on foetal development

Test Type: Embryo-foetal development
### 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>

<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>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</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, thymus gland</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<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>
**SAFETY DATA SHEET**

**Fluralaner / Diethyltoluamide Liquid Formulation**

**Version** 7.0  
**Revision Date:** 07.12.2020  
**SDS Number:** 462539-00015  
**Date of last issue:** 01.10.2020  
**Date of first issue:** 15.01.2016

### 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**

May be harmful if swallowed and enters airways.

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

## Toxicity to fish
- **Fluralaner:**
  - 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
- **Fluralaner:**
  - 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
- **Fluralaner:**
  - 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)
- **Fluralaner:**
  - NOEC: >= 0.049 mg/l
  - Exposure time: 21 d
  - Species: Zebrafish
  - Method: OECD Test Guideline 204
  - Remarks: No toxicity at the limit of solubility

## Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- **Fluralaner:**
  - NOEC: 0.000047 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)
  - Method: OECD Test Guideline 211

## M-Factor (Chronic aquatic toxicity)
- **Fluralaner:**
  - 1,000

## N,N-Diethyl-m-toluamide:
- Toxicity to fish:
  - LC50 (Pimephales promelas (fathead minnow)): 110 mg/l
  - Exposure time: 96 h

## Acetone:
- Toxicity to fish:
  - LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg/l
  - Exposure time: 96 h

- Toxicity to daphnia and other aquatic invertebrates:
  - EC50 (Daphnia pulex (Water flea)): 8,800 mg/l
  - Exposure time: 48 h
### Toxicity to algae/aquatic plants

NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l
Exposure time: 96 h

### Toxicity to microorganisms

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

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC: >= 79 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

### 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

### 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
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10. octanol/water

Mobility in soil

Components:

Fluralaner:

Distribution among environmental compartments: log Koc: 3.4

Other adverse effects

Components:

Fluralaner:

Results of PBT and vPvB assessment: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

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
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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 IMO instruments
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

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)
IN OEL: India. Permissible levels of certain chemical substances in work environment.

ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formula-
tion

Version 7.0 Revision Date: 07.12.2020 SDS Number: 462539-00015 Date of last issue: 01.10.2020 Date of first issue: 15.01.2016

IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)
IN OEL / STEL : Short-term exposure Limit STEL (15 min)

AliC - 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 Chemicals and 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 (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; 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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