SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 8.0  Revision Date: 2020/10/01  SDS Number: 412184-00014  Date of last issue: 2019/03/01

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Fluralaner / Diethyltoluamide Liquid Formulation

Supplier's company name, address and phone number

Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: 1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P241 Use explosion-proof electrical/ventilating/lighting equip-
ment.
P242 Use non-sparking tools.
P243 Take action to prevent static discharges.
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.
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.

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
Important symptoms and outlines of the emergency assumed: 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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>32.1</td>
<td>2-723</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 25 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>&gt;= 10 - &lt; 20</td>
<td>3-1321</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>&gt;= 10 - &lt; 20</td>
<td>2-542</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. 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, protection, or emergency response: Remove all sources of ignition.
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<table>
<thead>
<tr>
<th>Active equipment and emergency procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilate the area.</td>
</tr>
<tr>
<td>Use personal protective equipment.</td>
</tr>
<tr>
<td>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Environmental precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoid release to the environment.</td>
</tr>
<tr>
<td>Prevent further leakage or spillage if safe to do so.</td>
</tr>
<tr>
<td>Prevent spreading over a wide area (e.g. by containment or oil barriers).</td>
</tr>
<tr>
<td>Retain and dispose of contaminated wash water.</td>
</tr>
<tr>
<td>Local authorities should be advised if significant spillages cannot be contained.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Methods and materials for containment and cleaning up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-sparking tools should be used.</td>
</tr>
<tr>
<td>Soak up with inert absorbent material.</td>
</tr>
<tr>
<td>Suppress (knock down) gases/vapours/mists with a water spray jet.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Clean up remaining materials from spill with suitable absorbent.</td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

7. HANDLING AND STORAGE

<table>
<thead>
<tr>
<th>Handling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical measures</td>
</tr>
<tr>
<td>See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Local/Total ventilation</th>
</tr>
</thead>
<tbody>
<tr>
<td>If sufficient ventilation is unavailable, use with local exhaust ventilation.</td>
</tr>
<tr>
<td>Use explosion-proof electrical, ventilating and lighting equipment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Advice on safe handling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not get on skin or clothing.</td>
</tr>
<tr>
<td>Do not breathe vapours or spray mist.</td>
</tr>
<tr>
<td>Do not swallow.</td>
</tr>
<tr>
<td>Avoid contact with eyes.</td>
</tr>
<tr>
<td>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.</td>
</tr>
<tr>
<td>Non-sparking tools should be used.</td>
</tr>
<tr>
<td>Keep container tightly closed.</td>
</tr>
<tr>
<td>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</td>
</tr>
<tr>
<td>Take precautionary measures against static discharges.</td>
</tr>
<tr>
<td>Take care to prevent spills, waste and minimize release to the environment.</td>
</tr>
</tbody>
</table>

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Avoidance of contact

Hygiene measures: Oxidizing agents
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.

Storage

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:
Oxidizing solids
Oxidizing liquids

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>OEL-M 10 ppm, 36 mg/m³</td>
<td></td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Group 2: Substances presumed to cause reproductive toxicity in humans, Skin absorption, Group 2B: possibly carcinogenic to humans</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACL 10 ppm, TWA 10 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>OEL-M 200 ppm, 470 mg/m³</td>
<td></td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACL 500 ppm, TWA 250 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL 500 ppm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Target substance</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>Within 2 h prior to end of shift</td>
<td>40 mg/l</td>
<td>JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></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 equipment.
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.

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: Work uniform or laboratory coat.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: liquid
Colour : yellow
Odour : No data available
Odour Threshold : No data available
Melting point/freezing point : No data available
Boiling point, initial boiling point and boiling range : 103 °C
Flammability (solid, gas) : Not applicable
Flammability (liquids) : Not applicable

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available

Flash point : 7 °C

Decomposition temperature : No data available
pH : No data available
Evaporation rate : No data available
Auto-ignition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : 67 hPa (20 °C)
Density and / or relative density
Relative density : No data available
Density : 1.059 g/cm3
Relative vapour density : No data available

Explosive properties : Not explosive
### 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

**Components:**

<table>
<thead>
<tr>
<th>N,N-Dimethylacetamide:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
</tr>
</tbody>
</table>
| Acute inhalation toxicity | LC50 (Rat): 2.2 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist |
<table>
<thead>
<tr>
<th>Component</th>
<th>Acute dermal toxicity</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Skin corrosion/irritation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td>LC50 (Rat): 5.95 mg/l</td>
<td>Not classified based on available information.</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>LD50 (Rat): 1,950 mg/kg</td>
<td>LD50 (Rat): 5,000 mg/kg</td>
<td>LC50 (Rat): 5.95 mg/l</td>
<td></td>
</tr>
</tbody>
</table>
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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
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.

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

**Fluralaner:**
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Test Type: Mouse Lymphoma
  Result: negative
  Test Type: Chromosomal aberration
  Result: negative

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

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

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

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

Carcinogenicity:
Not classified based on available information.

Components:

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

Fluralaner:
Carcinogenicity - Assessment:
- No data available

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

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

Reproductive toxicity:
May damage the unborn child.
Components:

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

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

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

**Fluralaner:**
- **Effects on fertility**: Test Type: Two-generation study
  - Species: Rat
  - Application Route: Oral
  - General Toxicity - Parent: NOAEL: 50 mg/kg body weight
  - General Toxicity F1: LOAEL: 100 mg/kg body weight
  - Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects.
  - Test Type: One-generation reproduction toxicity study
  - Species: Dog
  - Application Route: Oral
  - Fertility: NOAEL: 75 mg/kg body weight
  - Result: No effects on fertility and early embryonic development were detected.
  - Remarks: No significant adverse effects were reported

- **Effects on foetal development**: Test Type: Development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: NOAEL: 100 mg/kg body weight
  - Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects
  - Test Type: Development
  - Species: Rabbit
  - Application Route: Oral
  - Developmental Toxicity: NOAEL: 10 mg/kg body weight
  - Result: Skeletal malformations, Visceral malformations
  - Remarks: Maternal toxicity observed.
  - Test Type: Development
  - Species: Rabbit
  - Application Route: Dermal
  - Developmental Toxicity: NOAEL: 100 mg/kg body weight
  - Result: Skeletal malformations
Reproductive toxicity - Assessment: Suspected of damaging the unborn child.

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

**Acetone:**
- Effects on fertility: Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
- Effects on foetal development: Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Inhalation (vapour)
  - Result: negative

**STOT - single exposure**
Not classified based on available information.

**Components:**

**Acetone:**
- Assessment: May cause drowsiness or dizziness.

**STOT - repeated exposure**
Not classified based on available information.

**Repeated dose toxicity**

**Components:**

**N,N-Dimethylacetamide:**
- Species: Rat
- NOAEL: 90 mg/m^3
- LOAEL: 360 mg/m^3
- 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
## Fluralaner / Diethyltoluamide Liquid Formulation

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>56 - 280 mg/kg</td>
<td>Oral</td>
<td>24 Weeks</td>
<td>Diarrhoea</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>400 mg/kg</td>
<td>Oral</td>
<td>90 Days</td>
<td>Liver, thymus gland</td>
<td></td>
</tr>
</tbody>
</table>

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

### Acetone:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>900 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Liver</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>45 mg/l</td>
<td>inhalation (vapour)</td>
<td>8 Weeks</td>
<td>Liver</td>
<td></td>
</tr>
</tbody>
</table>

**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

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

#### Toxicity to fish
- **LC50 (Pimephales promelas (fathead minnow)):** 110 mg/l
- **Exposure time:** 96 h

#### Toxicity to daphnia and other aquatic invertebrates
- **EC50 (Daphnia magna (Water flea)):** 75 mg/l
- **Exposure time:** 48 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 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

### Biodegradability

#### 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

Mobility in soil

Components:

Fluralaner:

Distribution among environmental compartments: log Koc: 3.4

Hazardous to the ozone layer
Not applicable

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
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version: 8.0  Revision Date: 2020/10/01  SDS Number: 412184-00014  Date of last issue: 2019/03/01
Date of first issue: 2016/01/15

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: no

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

National Regulations
Refer to section 15 for specific national regulation.

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

Related Regulations

Fire Service Law
Group 4, Type 1 petroleum, Water insoluble liquid, (200 litre), Hazardous rank II

Chemical Substance Control Law

<table>
<thead>
<tr>
<th>Priority Assessment Chemical Substance</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td></td>
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<tr>
<td>Acetone</td>
<td>114</td>
</tr>
</tbody>
</table>


Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
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<tbody>
<tr>
<td>N,N-dimethylacetamide</td>
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</table>

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
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<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>284</td>
<td>&gt;=30 - &lt;40</td>
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<tr>
<td>Acetone</td>
<td>17</td>
<td>&gt;=10 - &lt;20</td>
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</table>

Substances Subject to be Indicated Names

<table>
<thead>
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<th>Chemical name</th>
<th>Number</th>
</tr>
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<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>284</td>
</tr>
<tr>
<td>Acetone</td>
<td>17</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Organic Solvents Class 2

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Inflammable Substance

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Class I Designated Chemical Substances

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
</table>
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 8.0 Revision Date: 2020/10/01 SDS Number: 412184-00014 Date of last issue: 2019/03/01 Date of first issue: 2016/01/15

| N,N-Dimethylacetamide | 213 | 32 |

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Flammable liquids (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Flammable liquid (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance (Category Z)
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Specially Controlled Industrial Waste

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
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
JP OEL ISHL : Japan. Administrative Control Levels
**SAFETY DATA SHEET**

Fluralaner / Diethyltoluamide Liquid Formula- 

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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<th>Date of first issue:</th>
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<td>2020/10/01</td>
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<td>2019/03/01</td>
<td>2016/01/15</td>
</tr>
</tbody>
</table>


**JSOH**: Occupational exposure limits based on biological monitoring (JSOH).

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

**ACGIH / STEL**: Short-term exposure limit

**JP OEL ISHL / ACL**: Administrative Control level

**JP OEL JSOH / OEL-M**: Occupational Exposure Limit-Mean

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; ENC - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth 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; LC50 - 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 - Transport 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.

JP / EN