1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner / Diethyltoluamide Liquid Formulation

Manufacturer or supplier's details
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASETWARD@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
- Flammable liquids: Category 2
- Reproductive toxicity: Category 1B
- Long-term (chronic) aquatic hazard: Category 1

GHS label elements
- Hazard pictograms: Flammable, Reproductive toxicity, Aquatic toxicity
- Signal word: Danger
- Hazard statements:
  - H225 Highly flammable liquid and vapour.
  - H360D May damage the unborn child.
  - H410 Very toxic to aquatic life with long lasting effects.
- Precautionary statements:
  - Prevention:
    - P201 Obtain special instructions before use.
    - P202 Do not handle until all safety precautions have been read and understood.
    - P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
    - P233 Keep container tightly closed.
    - P241 Use explosion-proof electrical/ventilating/lighting equip-
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version: 7.0  Revision Date: 03/01/2019  SDS Number: 412184-00013  Date of last issue: 2019/02/25
Date of first issue: 2016/01/15

- 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.

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 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.

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.
emergency procedures
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions
Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

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 contain-
ment 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 absor-

tent.
Local or national regulations may apply to releases and dis-
posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-
mine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling
Technical measures
See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation
Use with local exhaust ventilation.
Use only in an area equipped with explosion-proof exhaust ventilation if advised by assessment of the local exposure potential

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 and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact

Hygiene measures
Oxidizing agents
Ensure that eye flushing systems and safety showers are
located 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 decontamination 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</td>
<td>10 ppm</td>
<td>JP OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>36 mg/m³</td>
<td>JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Group 2: Substances presumed to cause reproductive toxicity in humans. Skin absorption</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACL</td>
<td>10 ppm</td>
<td>JP OEL ISHL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>OEL-M</td>
<td>200 ppm</td>
<td>JP OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>470 mg/m³</td>
<td>JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACL</td>
<td>500 ppm</td>
<td>JP OEL ISHL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>250 ppm</td>
<td>ACGIH</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>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-Methy lacetamide</td>
<td>Urine</td>
<td>End of shift at end of</td>
<td>30 mg/g Creatinine</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formula-
tion

Version 7.0  Revision Date: 03/01/2019  SDS Number: 412184-00013  Date of last issue: 2019/02/25
Date of first issue: 2016/01/15

<table>
<thead>
<tr>
<th></th>
<th>work-week</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>Acetone</td>
<td>Urine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Within 2 h prior to end of shift</td>
<td>40 mg/l</td>
<td>JSOH</td>
<td></td>
</tr>
<tr>
<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 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**

Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

**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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance** : liquid
- **Colour** : yellow
- **Odour** : No data available
- **Odour Threshold** : No data available
- **pH** : No data available
- **Melting point/freezing point** : No data available
- **Initial boiling point and boiling** : 103 °C
10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Highly flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Heat, flames and sparks.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
</tbody>
</table>
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

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
Fluralaner / Diethyltoluamide Liquid Formulation

Test atmosphere: dust/mist

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

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

Skin corrosion/irritation
Not classified based on available information.

Product:
Species : Rabbit
Result : No skin irritation

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

Fluralaner:
Species : Rabbit
Result : No skin irritation

N,N-Diethyl-m-toluamide:
Species : Rabbit
Result : Skin irritation

Acetone:
Assessment : Repeated exposure may cause skin dryness or cracking.

Serious eye damage/eye irritation
Not classified based on available information.

Product:
Species : Rabbit
Result : Mild eye irritation

Components:
N,N-Dimethylacetamide:
Species : Rabbit


SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formula-
tion

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:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

**Components:**

**N,N-Dimethylacetamide:**

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Fluralaner:**

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Dermal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

**Acetone:**

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>
### 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

**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

**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

**Fluralaner**
- **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: 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
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formula-
tion

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.0</td>
<td>03/01/2019</td>
<td>412184-00013</td>
<td>2019/02/25</td>
<td>2016/01/15</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
</tbody>
</table>
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects
Remarks: Maternal toxicity observed.

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

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

Reproductive toxicity - Assessment:

Suspected of damaging the unborn child.

N,N-Diethyl-m-toluamide:

Effects on foetal development:

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
</tr>
</tbody>
</table>
Result: negative

Acetone:

Effects on fertility:

<table>
<thead>
<tr>
<th>Test Type: One-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
</tr>
</tbody>
</table>
Result: negative

Effects on foetal development:

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: inhalation (vapour)</td>
</tr>
</tbody>
</table>
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
NOAEL: 500 mg/kg
Application Route: Dermal
Exposure time: 90 Days
Target Organs: Liver
Remarks: No significant adverse effects were reported

Acetone:
Species: Rat
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 7.0  Revision Date: 03/01/2019  SDS Number: 412184-00013  Date of last issue: 2019/02/25  Date of first issue: 2016/01/15

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

Product:

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)): \( \geq 79 \text{ mg/l} \)
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.

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 environ- : log Koc: 3.4
mental compartments

**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.

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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
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 petroleums, Water insoluble liquid, (200 litre)

Chemical Substance Control Law

Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<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>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-dimethylacetamide</td>
</tr>
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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
Article 57-2 (Enforcement Order Table 9)

<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>
<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>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 7.0  Revision Date: 03/01/2019  SDS Number: 412184-00013  Date of last issue: 2019/02/25
Date of first issue: 2016/01/15

<table>
<thead>
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<th>Number</th>
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</thead>
<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>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>213</td>
<td>32</td>
</tr>
</tbody>
</table>

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
Not applicable
Specific Narcotic or Psychotropic Raw Material
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
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

AICS - Australian Inventory of Chemical Substances; 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; CPR - Controlled Products Regulations; 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; IECSSC - 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 Pre-
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