SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

SECTION 1. IDENTIFICATION

Product name: Fluralaner / Diethyltoluamide Liquid Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Flammable liquids: Category 2
Reproductive toxicity: Category 1B

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements: H225 Highly flammable liquid and vapor.
H360D May damage the unborn child.

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.
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.

Storage:
SECTION 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; 60</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
</tbody>
</table>

Actual concentration or concentration range is withheld as a trade secret.

SECTION 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 center 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.

SECTION 5. FIRE-FIGHTING MEASURES
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Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
- High volume water jet

Specific hazards during fire fighting:
- Do not use a solid water stream as it may scatter and spread fire.
- Flash back possible over considerable distance.
- Vapors 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 fire-fighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Remove all sources of ignition.
- Ventilate the area.
- Use personal protective equipment.
- Follow safe handling advice 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/vapors/mists with a water spray jet.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items...
employed in the cleanup of releases. You will need to
determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding
certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

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 vapors or spray mist.
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.

Conditions for safe storage : Keep in properly labeled 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:
Strong oxidizing agents
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures which in contact with water emit
flammable gases
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>CA AB OEL</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 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 : 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

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.

Hygiene measures : 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 degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid
Color : yellow
Odor : No data available
Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : 103 °C

Flash point : 7 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable
Flammability (liquids) : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : 67 hPa (20 °C)
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Relative vapor density: No data available
Relative density: No data available
Density: 1.059 g/cm³
Solubility(ies):
Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity:
Viscosity, kinematic: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: Not applicable

SECTION 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 vapor.
Vapors 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.

SECTION 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.
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Components:

N,N-Dimethylacetamide:
Acute oral toxicity: LD50 (Rat): 4,800 mg/kg
Acute inhalation toxicity: LC50 (Rat): 2.2 mg/l
Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg

Fluralaner:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): 5.95 mg/l
Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg

N,N-Diethyl-m-toluamide:
Acute oral toxicity: LD50 (Rat): 1,950 mg/kg
Acute inhalation toxicity: LC50 (Rat): 5.95 mg/l
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
Acute dermal toxicity: LD50 (Rabbit): 7,426 mg/kg

Skin corrosion/irritation
Not classified based on available information.
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.0</td>
<td>03/01/2019</td>
<td>412175-00013</td>
<td>02/25/2019</td>
</tr>
</tbody>
</table>

**Product:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Components:**

**N,N-Dimethylacetamide:**

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<tr>
<th>Species</th>
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**Fluralaner:**

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<tbody>
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<td>Rabbit</td>
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**N,N-Diethyl-m-toluamide:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Skin irritation</td>
</tr>
</tbody>
</table>

**Acetone:**

<table>
<thead>
<tr>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeated exposure may cause skin dryness or cracking.</td>
</tr>
</tbody>
</table>

**Serious eye damage/eye irritation**

Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

**Components:**

**N,N-Dimethylacetamide:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
</tbody>
</table>

**Fluralaner:**

<table>
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<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
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<td>Rabbit</td>
<td>Mild eye irritation</td>
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**N,N-Diethyl-m-toluamide:**

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**Acetone:**

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<tr>
<td>Rabbit</td>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
</tbody>
</table>

**Method:** OECD Test Guideline 405
Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</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>Routes of exposure</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>Test Type</th>
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</tr>
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</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>Not a skin sensitizer.</td>
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</tbody>
</table>

Acetone:

<table>
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<tr>
<th>Test Type</th>
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<tr>
<td>Routes of exposure</td>
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</tr>
<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:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>
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 (vapor)  
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 fetal development: Test Type: Embryo-fetal 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 fetal 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 fetal development: Test Type: Embryo-fetal 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 fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: inhalation (vapor)
Result: negative

STOT-single exposure

Not classified based on available information.

Components:

Acetone:
Assessment: May cause drowsiness or dizziness.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

N,N-Dimethylacetamide:
Species: Rat
NOAEL: 90 mg/m³
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LOAEL: 360 mg/m³
Application Route: inhalation (vapor)
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: Diarrhea

Species: Rat
NOAEL: 400 mg/kg
Application Route: Oral
Exposure time: 90 Days
Target Organs: Liver, thymus gland
Remarks: No significant adverse effects were reported

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

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

Aspiration toxicity
Not classified based on available information.

Components:

Fluralaner:
Not applicable
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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. |

SECTION 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

**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

**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 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).

SECTION 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.
SECTION 14. TRANSPORT INFORMATION

International Regulations

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

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

IMDG-Code
UN number : UN 1090
Proper shipping name : ACETONE SOLUTION
(Fluralaner)
Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : no

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

Domestic regulation

TDG
UN number : UN 1090
Proper shipping name : ACETONE SOLUTION
Class : 3
Packing group : II
Labels : 3
ERG Code : 127
Marine pollutant : no

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.
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Fluralaner / Diethyltoluamide Liquid Formula-

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA AB OEL / STEL : 15-minute occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA BC OEL / STEL : short-term exposure limit
CA QC OEL / TWAEV : Time-weighted average exposure value
CA QC OEL / STEV : Short-term exposure value

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; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Preven-
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

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Sources of key data used to compile the Material Safety Data Sheet:
- Internal technical data
- Data from raw material SDSs
- OECD eChem Portal search results

Revision Date: 03/01/2019

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

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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