SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Section 1: Identification

Product name: Fluralaner / Diethyltoluamide Liquid Formulation

Manufacturer or supplier's details

Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

Section 2: Hazard identification

GHS Classification

Flammable liquids: Flam. Liq.2
Reproductive toxicity: Repr.1B

GHS label elements

Hazard pictograms:

Signal word: Danger
Hazard statements: H225 Highly flammable liquid and vapour.
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/sparks/open flames/hot surfaces. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P281 Use personal protective equipment as required.

Response:
P303 + P361 + P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:
P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

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

Other hazards which do not result in classification
Vapours may form explosive mixture with air.

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; 20</td>
</tr>
</tbody>
</table>

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 centre immediately.
Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. May damage the unborn child.

First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.

Treat symptomatically and supportively.

Section 5: Fire-fighting measures

- 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.
  - 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.

- Hazchem Code: 2YE

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/vapours/mists with a water spray jet.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.

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

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 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.

**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.

**Conditions for safe storage**: Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.
Materials to avoid:

Do not store with the following product types:
- Self-reactive substances and mixtures
- Organic peroxides
- Oxidizing agents
- Flammable gases
- Pyrophoric liquids
- Pyrophoric solids
- Self-heating substances and mixtures
- Poisonous gases
- Explosives

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>WES-TWA</td>
<td>10 ppm / 36 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin absorption</td>
<td></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>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>WES-TWA</td>
<td>500 ppm / 1185 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Exposure can also be estimated by biological monitoring</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES- STEL</td>
<td>1,000 ppm / 2375 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Exposure can also be estimated by biological monitoring</td>
<td></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>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</td>
<td>50 mg/l</td>
<td>NZ BEI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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.

Section 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 range
103 °C
Flash point
7 °C
Evaporation rate
No data available
Flammability (solid, gas)
Not applicable
Flammability (liquids)
Not applicable
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 6.0 Revision Date: 03/01/2019 SDS Number: 412188-00013 Date of last issue: 25.02.2019

Date of first issue: 15.01.2016

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: 67 hPa (20 °C)

Relative vapour density: No data available

Relative density: No data available

Density: 1.059 g/cm³

Solubility(ies)
Water solubility: No data available

Partition coefficient: n-octanol/water: Not applicable

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Viscosity
Viscosity, kinematic: No data available

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Molecular weight: No data available

Particle size: Not applicable

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 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.

Section 11: Toxicological information

Exposure routes
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
  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
  - 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>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>

Acetone:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Chronic toxicity

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>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Rodent dominant lethal test (germ cell) (in vivo)</th>
</tr>
</thead>
</table>
Fluralaner / Diethyltoluamide Liquid Formula-

Species: Rat
Application Route: Inhalation
Method: OECD Test Guideline 478
Result: negative

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 develop-
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:

- Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

Acetone:

- Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

- 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

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>NOAEL</th>
<th>LOAEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Rat</td>
<td>inhalation (vapour)</td>
<td>24 Months</td>
<td>90 mg/m³</td>
<td>360 mg/m³</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>Dog</td>
<td>Oral</td>
<td>52 Weeks</td>
<td>1 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Juvenile dog</td>
<td>Oral</td>
<td>24 Weeks</td>
<td>56 - 280 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Oral</td>
<td>90 Days</td>
<td>400 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Dermal</td>
<td>90 Days</td>
<td>500 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>Rat</td>
<td>Oral</td>
<td>90 Days</td>
<td>45 mg/l</td>
<td></td>
</tr>
</tbody>
</table>

Repeated dose toxicity

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>NOAEL</th>
<th>LOAEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Rat</td>
<td>inhalation (vapour)</td>
<td>8 Weeks</td>
<td>4000 mg/l</td>
<td>1700 mg/l</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>Dog</td>
<td>Oral</td>
<td>90 Days</td>
<td>4500 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Dermal</td>
<td>90 Days</td>
<td>500 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acetone</td>
<td>Rat</td>
<td>Oral</td>
<td>90 Days</td>
<td>45 mg/l</td>
<td></td>
</tr>
</tbody>
</table>

Remarks:

- No significant adverse effects were reported.
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.

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)): 0.00047 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 to -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. If not otherwise specified: Dispose of as unused product.

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.

**National Regulations**

**NZS 5433**
- UN number: UN 1090
- Proper shipping name: ACETONE SOLUTION
- Class: 3
- Packing group: II
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

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<th>SDS Number:</th>
<th>Date of last issue:</th>
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- Labels: 3
- Hazchem Code: 2YE

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.

Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
HSW tracking not required.
Refer to WORKSAFE user guide to the HSW regulations for further information.

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

Section 16: Other information

Further information
Sources of key data used to compile the Safety Data Sheet:

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

- Date format: dd.mm.yyyy

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
- NZ BEI: New Zealand. Biological Exposure Indices
- NZ OEL: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- ACGIH / STEL: Short-term exposure limit
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.

NZ / EN