1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner / Diethyltoluamide Liquid Formulation

Manufacturer or supplier’s details

Company: MSD
Address: No. 485 Jing Tai Road
              Pu Tuo District - Shanghai - China  200331
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance: liquid
Colour: yellow
Odour: No data available

Highly flammable liquid and vapour. May be harmful if swallowed and enters airways. May be harmful if inhaled. May damage the unborn child. Very toxic to aquatic life with long lasting effects.

GHS Classification

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

GHS label elements

Hazard pictograms: [Image]
Signal word: Danger
**Safety Data Sheet**

According to GB/T 16483 and GB/T 17519

**Fluralaner / Diethyltoluamide Liquid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 2019/03/01</th>
<th>Date of first issue: 2016/01/15</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1</td>
<td>2020/10/01</td>
<td>412178-00014</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Hazard statements**

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

**Precautionary statements**

- **Prevention:**
  - 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.
  - P273 Avoid release to the environment.
  - P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

- **Response:**
  - P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
  - P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
  - P304 + P312 IF INHALED: Call a POISON CENTER/ doctor if you feel unwell.
  - P308 + P313 IF exposed or concerned: Get medical advice/ attention.
  - P331 Do NOT induce vomiting.
  - 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.

**Physical and chemical hazards**

Highly flammable liquid and vapour.

**Health hazards**

May be harmful if inhaled. May damage the unborn child. May be harmful if swallowed and enters airways.

**Environmental hazards**

Very toxic to aquatic life with long lasting effects.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Fluralaner / Diethyltoluamide Liquid Formula-
tion

Version 6.1
Revision Date: 2020/10/01
SDS Number: 412178-00014
Date of last issue: 2019/03/01
Date of first issue: 2016/01/15

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

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>N,N-Dimethylacetamide</td>
</tr>
<tr>
<td></td>
<td>Fluralaner</td>
</tr>
<tr>
<td></td>
<td>N,N-Diethyl-m-toluamide</td>
</tr>
<tr>
<td></td>
<td>Acetone</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: May be harmful if swallowed and enters airways. May be harmful if inhaled. May damage the unborn child.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Fluralaner / Diethyltoluamide Liquid Formula-
tion

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.
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- 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.
7. HANDLING AND STORAGE

Handling
Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.
Advice on safe handling : Do not get on skin or clothing.
Do not breathe vapours or spray mist.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact : Oxidizing agents
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:
Self-reactive substances and mixtures
Organic peroxides
Oxidizing agents
Flammable gases
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Poisonous gases
Explosives
Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters
Fluralaner / Diethyltoluamide Liquid Formula-
tion

Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
---|---|---|---|---|
N,N-Dimethylacetamide | 127-19-5 | PC-TWA | 20 mg/m³ | CN OEL |
Further information: Skin TWA | 10 ppm | ACGIH |
Fluralaner | 864731-61-3 | TWA | 100 µg/m³ (OEB 2) | Internal |
Further information: Skin Wipe limit | 1000 µg/100 cm² | Internal |
Acetone | 67-64-1 | PC-TWA | 300 mg/m³ | CN OEL |
PC-STEL | 450 mg/m³ | CN OEL |
TWA | 250 ppm | ACGIH |
STEL | 500 ppm | ACGIH |

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>
</table>
N,N-Dimethylacetamide | 127-19-5 | N-Methyla-
cetamide | Urine | End of last shift of the week | 20 mg/g Creatinine | CN BEI |
N-Methyla-
cetamide | Urine | End of shift at end of work-week | 30 mg/g Creatinine | ACGIH BEI |
Acetone | 67-64-1 | Acetone | Urine | End of shift | 50 mg/l | CN BEI |
Acetone | Urine | End of shift (As soon as possible after exposure ceases) | 25 mg/l | ACGIH BEI |

Engineering measures : Use explosion-proof electrical, ventilating and lighting equip-
ment.
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-
less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

Personal protective equipment
Respiratory protection : If adequate local exhaust ventilation is not available or expo-
sure assessment demonstrates exposures outside the rec-


**SAFETY DATA SHEET**
according to GB/T 16483 and GB/T 17519

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>6.1</td>
<td>2020/10/01</td>
<td>412178-00014</td>
<td>2019/03/01</td>
<td>2016/01/15</td>
</tr>
</tbody>
</table>

---

**Filter type**
: Self-contained breathing apparatus

**Eye/face 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.

**Hand protection**
: Chemical-resistant gloves

**Remarks**
: Take note that the product is flammable, which may impact the selection of hand protection.

**Hygiene measures**
: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

---

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>103 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>7 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Fluralaner / Diethyltoluamide Liquid Formulation

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
- Highly flammable liquid and vapour. Vapours may form explosive mixture with air.
- Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
- Skin contact
- Ingestion
Eye contact

**Acute toxicity**
May be harmful if inhaled.

**Product:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks:</td>
<td>No mortality observed at this dose.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute inhalation toxicity</th>
<th>Acute toxicity estimate: 5.95 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>4 h</td>
</tr>
<tr>
<td>Test atmosphere:</td>
<td>dust/mist</td>
</tr>
<tr>
<td>Method:</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute dermal toxicity</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms:</td>
<td>Erythema</td>
</tr>
</tbody>
</table>

**Components:**

**N,N-Dimethylacetamide:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 4,800 mg/kg</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Acute inhalation toxicity</th>
<th>LC50 (Rat): 2.2 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>4 h</td>
</tr>
<tr>
<td>Test atmosphere:</td>
<td>dust/mist</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute dermal toxicity</th>
<th>Acute toxicity estimate: 1,100 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method:</td>
<td>Expert judgement</td>
</tr>
<tr>
<td>Remarks:</td>
<td>Based on harmonised classification in EU regulation 1272/2008, Annex VI</td>
</tr>
</tbody>
</table>

**Fluralaner:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks:</td>
<td>No mortality observed at this dose.</td>
</tr>
<tr>
<td></td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute dermal toxicity</th>
<th>LD50 (Rat): &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks:</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**N,N-Diethyl-m-toluidine:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 1,950 mg/kg</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Acute inhalation toxicity</th>
<th>LC50 (Rat): 5.95 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>4 h</td>
</tr>
<tr>
<td>Test atmosphere:</td>
<td>dust/mist</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acute dermal toxicity</th>
<th>LD50 (Rat): 5,000 mg/kg</th>
</tr>
</thead>
</table>

**Acetone:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 5,800 mg/kg</th>
</tr>
</thead>
</table>
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Fluralaner / Diethyltoluamide Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue: 2019/03/01</th>
<th>Date of first issue: 2016/01/15</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1</td>
<td>2020/10/01</td>
<td>412178-00014</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Fluralaner / Diethyltoluamide Liquid Formulation

Version: 6.1  Revision Date: 2020/10/01  SDS Number: 412178-00014  Date of last issue: 2019/03/01  Date of first issue: 2016/01/15

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

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

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

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

Components:

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

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

N,N-Dimethylacetamide:
<table>
<thead>
<tr>
<th>Fluralaner / Diethyltoluamide Liquid Formulation</th>
</tr>
</thead>
</table>

<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>6.1</td>
<td>2020/10/01</td>
<td>412178-00014</td>
<td>2019/03/01</td>
<td>2016/01/15</td>
</tr>
</tbody>
</table>

- **Ge notoxicity in vitro**
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative

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

**Fluralaner:**

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

  - Test Type: Mouse Lymphoma
  - Result: negative

  - Test Type: Chromosomal aberration
  - Result: negative

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

**N,N-Diethyl-m-toluamide:**

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

**Acetone:**

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

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

  - Test Type: Chromosome aberration test in vitro
  - Result: negative

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

**Carcinogenicity**

Not classified based on available information.
Components:

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

Fluralaner:
- Carcinogenicity - Assessment: No data available

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

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

Reproductive toxicity
May damage the unborn child.

Components:

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

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

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

Fluralaner:
- Effects on fertility: Test Type: Two-generation study
  Species: Rat
  Application Route: Oral
  General Toxicity - Parent: NOAEL: 50 mg/kg body weight
  General Toxicity F1: LOAEL: 100 mg/kg body weight
Fluralaner / Diethyltoluamide Liquid Formulation

Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects.

Test Type: One-generation reproduction toxicity study
Species: Dog
Application Route: Oral
Fertility: NOAEL: 75 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.
Remarks: No significant adverse effects were reported

Effects on foetal development:

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects

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

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

Reproductive toxicity - Assessment: Suspected of damaging the unborn child.

N,N-Diethyl-m-toluamide:

Effects on foetal development:

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

Acetone:

Effects on fertility:

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

Effects on foetal development:

Test Type: Embryo-foetal development
Species: Rat
Application Route: inhalation (vapour)
Result: negative
STOT - single exposure
Not classified based on available information.

Components:

Acetone:
Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

N,N-Dimethylacetamide:
Species: Rat
NOAEL: 90 mg/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 reported

Species: Juvenile dog
NOAEL: 56 - 280 mg/kg
Application Route: Oral
Exposure time: 24 Weeks
Symptoms: Diarrhoea

Species: Rat
NOAEL: 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 reported

Acetone:
Species: Rat
**SAFETY DATA SHEET**
according to GB/T 16483 and GB/T 17519

**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>6.1</td>
<td>2020/10/01</td>
<td>412178-00014</td>
<td>2019/03/01</td>
<td>2016/01/15</td>
</tr>
</tbody>
</table>

- **NOAEL**: 900 mg/kg
- **LOAEL**: 1,700 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 90 Days

- **Species**: Rat
- **NOAEL**: 45 mg/l
- **Application Route**: Inhalation (vapour)
- **Exposure time**: 8 Weeks

**Aspiration toxicity**
May be harmful if swallowed and enters airways.

**Components:**
- **Fluralaner**: Not applicable
- **Acetone**: The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

**Experience with human exposure**

**Product:**
- **Skin contact**: Remarks: May irritate skin.
- **Eye contact**: Remarks: May cause eye irritation.

**Components:**
- **Fluralaner**:
  - **Skin contact**: Remarks: May irritate skin.
  - **Eye contact**: Remarks: May cause eye irritation.

12. **ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**N,N-Dimethylacetamide:**
- **Toxicity to fish**: LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 500 mg/l
  Exposure time: 48 h
- **Toxicity to algae/aquatic plants**: EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
  Exposure time: 72 h
**Fluralaner / Diethyltoluamide Liquid Formulation**

<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>6.1</td>
<td>2020/10/01</td>
<td>412178-00014</td>
<td>2019/03/01</td>
<td>2016/01/15</td>
</tr>
</tbody>
</table>

**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
Fluralaner / Diethyltoluamide Liquid Formulation

**Mobility in soil**

**Components:**

Fluralaner:
Distribution among environmental compartments : log Koc: 3.4

**Other adverse effects**

**Components:**

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

### 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

### 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**

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

**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 / Diethyltoluamide Liquid Formulation

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

GB 6944/12268
UN number: UN 1090
Proper shipping name: ACETONE SOLUTION
Class: 3
Packing group: II
Labels: 3

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

National regulatory information
Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals
Catalogue of Hazardous Chemicals: Listed

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)
No. / Code  Chemical name / Category  Threshold quantity
W5.3  Flammable liquids  1,000 t

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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Fluralaner / Diethyltoluamide Liquid Formula-
tion

<table>
<thead>
<tr>
<th>Date format</th>
<th>yyyy/mm/dd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full text of other abbreviations</td>
<td></td>
</tr>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>ACGIH BEI</td>
<td>ACGIH - Biological Exposure Indices (BEI)</td>
</tr>
<tr>
<td>CN BEI</td>
<td>China. Biological Occupational Exposure Indices</td>
</tr>
<tr>
<td>CN OEL</td>
<td>Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>ACGIH / STEL</td>
<td>Short-term exposure limit</td>
</tr>
<tr>
<td>CN OEL / PC-TWA</td>
<td>Permissible concentration - time weighted average</td>
</tr>
<tr>
<td>CN OEL / PC-STEL</td>
<td>Permissible concentration - short term exposure limit</td>
</tr>
</tbody>
</table>

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - 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 Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer
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 mate-
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.

CN / EN