SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 5.0  Revision Date: 03/01/2019  SDS Number: 412181-00013  Date of last issue: 2019/02/25
Date of first issue: 2016/01/15

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner / Diethyltoluamide Liquid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
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

2. HAZARDS IDENTIFICATION

GHS Classification
Flammable liquids: Category 2
Reproductive toxicity: Category 1B
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms:

Signal word: Danger

Hazard statements:
H225 Highly flammable liquid and vapour.
H360D May damage the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat/sparks/open flames/hot surfaces.
No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting 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:
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

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

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

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

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>: Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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

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

In case of skin contact : In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes.
### 4. FIRST AID MEASURES
- **In case of eye contact**: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
- **If swallowed**: If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
- **Most important symptoms and effects, both acute and delayed**: May damage the unborn child.
- **Protection of first-aiders**: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.
- **Notes to physician**: Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES
- **Suitable extinguishing media**: Water spray. Alcohol-resistant foam. Carbon dioxide (CO2). Dry chemical.
- **Unsuitable extinguishing media**: High volume water jet.
- **Specific hazards during firefighting**: Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.
- **Hazardous combustion products**: Carbon oxides. Chlorine compounds. Fluorine compounds. Nitrogen oxides (NOx).
- **Specific extinguishing methods**: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
- **Special protective equipment for firefighters**: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES
- **Personal precautions, protective equipment and emergency procedures**: Remove all sources of ignition. Ventilate the area. 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.

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.

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.
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>NAB</td>
<td>10 ppm 36 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Adopted in Year 1996, Liver damage, Embryo/fetal damage, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals, Identifies chemicals that need a BEI (= Biological Exposure Indices)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA 10 ppm ACGIH</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td>NAB</td>
<td>500 ppm 1,187.12 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Chemicals with a limit value higher than the Allowable Exposure Limit (PEL) of OSHA and/or the recommended NIOSH limit value, Damage to the central nervous system, Upper respiratory tract irritation, Eye irritation, Hematologic effects, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals, Identifies chemicals that need a BEI (= Biological Exposure Indices)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>PSD 750 ppm 1,780 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Chemicals with a limit value higher than the Allowable Exposure Limit (PEL) of OSHA and/or the recommended NIOSH limit value, Damage to the central nervous system, Upper respiratory tract irritation, Eye irritation, Hematologic effects, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals, Identifies chemicals that need a BEI (= Biological Exposure Indices)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA 250 ppm ACGIH</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STEL 500 ppm ACGIH</td>
<td></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**: 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.

- Wear safety glasses with side shields or goggles.
- Wear a face shield 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.

- 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.
## 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 flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>67 hPa (20 °C)</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1.059 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

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

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

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure: Inhalation, Skin contact, Ingestion, Eye contact

Acute toxicity:
Not classified based on available information.

Product:

Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Remarks: No mortality observed at this dose.

Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
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:

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

Components:

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

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

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

Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Result: negative

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

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

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

Test Type: Bacterial reverse mutation assay (AMES)
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

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

12 / 21
Application Route: Inhalation
Result: positive

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

**Fluralaner:**

Effects on fertility:
Test Type: Two-generation study
Species: Rat
Application Route: Oral
General Toxicity - Parent: NOAEL: 50 mg/kg body weight
General Toxicity F1: LOAEL: 100 mg/kg body weight
Result: No effects on fertility, Postimplantation loss, Adverse neonatal effects.

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

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

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

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

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

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

Effects on foetal development:
Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formula-
tion

Version 5.0  Revision Date: 03/01/2019  SDS Number: 412181-00013  Date of last issue: 2019/02/25
Date of first issue: 2016/01/15

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 were reported

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

Species: Rat
LOAEL: 400 mg/kg
Application Route: Oral
Exposure time: 90 Days
Target Organs: Liver, thymus gland
**SAFETY DATA SHEET**

**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>5.0</td>
<td>03/01/2019</td>
<td>412181-00013</td>
<td>2019/02/25</td>
<td>2016/01/15</td>
</tr>
</tbody>
</table>

Species: Rat  
NOAEL: 500 mg/kg  
Application Route: Dermal  
Exposure time: 90 Days  
Target Organs: Liver  
Remarks: No significant adverse effects were reported

**Acetone:**

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

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

**Aspiration toxicity**

Not classified based on available information.

**Components:**

**Fluralaner:**
Not applicable

**Acetone:**
The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

**Experience with human exposure**

**Product:**

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

**Components:**

**Fluralaner:**

- **Skin contact**: Remarks: May irritate skin.
- **Eye contact**: Remarks: May cause eye irritation.
12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Components:

N,N-Dimethylacetamide:

Toxicity to fish:
- LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 500 mg/l
  Exposure time: 48 h

Toxicity to algae/aquatic plants:
- EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
  Exposure time: 72 h
- EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l
  Exposure time: 72 h

Toxicity to microorganisms:
- EC10: > 1,995 mg/l
  Exposure time: 30 min

Fluralaner:

Toxicity to fish (Chronic toxicity):
- NOEC (Zebrafish): >= 0.049 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 204
  Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): 0.000047 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity):
- 1,000
N,N-Diethyl-m-toluamide:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 110 mg/l
Exposure time: 96 h

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

Acetone:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia pulex (Water flea)): 8,800 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): >= 79 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms: EC50: 61,150 mg/l
Exposure time: 30 min
Method: ISO 8192

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
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formula-
tion

Bioconcentration factor (BCF): 79.4
Method: OECD Test Guideline 305

Partition coefficient: n-
octanol/water : log Pow: 4.5

N,N-Diethyl-m-toluamide:
Partition coefficient: n-
octanol/water : log Pow: 2.02

Acetone:
Partition coefficient: n-
octanol/water : log Pow: -0.27 - -0.23

Mobility in soil

Components:

Fluralaner:
Distribution among environ-
mental compartments : log Koc: 3.4

Other adverse effects

Components:

Fluralaner:
Results of PBT and vPvB
assessment : This substance is not considered to be persistent, bioaccumu-
lating 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 han-
dling site for recycling or disposal. Empty containers retain residue and can be dangerous.
Do not pressurize, cut, weld, braze, solder, drill, grind, or ex-
pose 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 : 3

IATA-DGR
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 5.0  Revision Date: 03/01/2019  SDS Number: 412181-00013  Date of last issue: 2019/02/25

Date of first issue: 2016/01/15

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.

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

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use: Not applicable
Prohibited substances: Not applicable
Restricted substances: Not applicable
Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Types of Hazardous Materials governed by Import Regulations: Not applicable
Types of Hazardous Materials of which the Distribution and Supervision is Regulated: Not applicable

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

16. OTHER INFORMATION

Further information

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

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
ID OEL: Indonesia. Occupational Exposure Limits

ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
ID OEL / NAB: Long term exposure limit
ID OEL / PSD: Short term exposure limit

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 Chemi-
SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version 5.0  Revision Date: 03/01/2019  SDS Number: 412181-00013  Date of last issue: 2019/02/25

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

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.

ID / EN