SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fluralaner / Diethyltoluamide Liquid Formulation

Version 6.1 Revision Date: 01.10.2020 SDS Number: 462538-00014 Date of last issue: 01.03.2019 Date of first issue: 15.01.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Fluralaner / Diethyltoluamide Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Flammable liquids, Category 2 H225: Highly flammable liquid and vapour.
Reproductive toxicity, Category 1B H360D: May damage the unborn child.
Long-term (chronic) aquatic hazard, Category 1 H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms:
- Flammable
- Reproductive toxicity
- Aquatic hazard

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.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:
N,N-Dimethylacetamide

Additional Labelling
Restricted to professional users.

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

2.3 Other hazards
Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>204-826-4</td>
<td>616-011-00-4</td>
<td>Acute Tox. 4; H332 Acute Tox. 4; H312 Eye Irrit. 2; H319 Repr. 1B; H360D</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td></td>
<td></td>
<td>Repr. 2; H361d Aquatic Chronic 1; H410</td>
<td>&gt;= 25 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 1,000</td>
<td></td>
</tr>
<tr>
<td>N,N-Diethyl-m-toluamide</td>
<td>134-62-3</td>
<td>205-149-7</td>
<td>616-018-00-2</td>
<td>Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Aquatic Chronic 3; H412</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Acetone</td>
<td>67-64-1</td>
<td></td>
<td></td>
<td>Flam. Liq. 2; H225</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>
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SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May damage the unborn child.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray Alcohol-resistant foam Carbon dioxide (CO2)
5.2 Special hazards arising from the substance or mixture

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)

5.3 Advice for firefighters

Special protective equipment for firefighters:

In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:

- 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).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.

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.
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7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: 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.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Flammable solids
- Pyrophoric liquids
- Pyrophoric solids
- Self-heating substances and mixtures
- Substances and mixtures, which in contact with water, emit flammable gases
- Explosives
- Gases

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>127-19-5</td>
<td>STEL</td>
<td>20 ppm 72 mg/m^3</td>
<td>2000/39/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm 36 mg/m^3</td>
<td>2000/39/EC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 ppm 36 mg/m^3</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 15 min (STEL)</td>
<td>20 ppm 72 mg/m^3</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-</td>
<td>TWA</td>
<td>100 µg/m^3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>36 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>36 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>13.6 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>7 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2.7 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>1 mg/kg bw/day</td>
</tr>
<tr>
<td>Acetone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1210 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>2420 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>186 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>200 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>62 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>62 mg/kg bw/day</td>
</tr>
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</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylacetamide</td>
<td>Fresh water</td>
<td>0.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0966 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>485 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>2.27 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.15 mg/kg</td>
</tr>
<tr>
<td>Acetone</td>
<td>Fresh water</td>
<td>10.6 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>1.06 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>21 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
</tbody>
</table>
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8.2 Exposure controls

Engineering measures
Use explosion-proof electrical, ventilating and lighting equipment.
Use appropriate engineering controls and manufacturing technologies to control airborne concentra-
tions (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
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.

Hand protection
Material : Chemical-resistant gloves
Remarks : Take note that the product is flammable, which may impact
the selection of hand protection.

Skin and body protection : Work uniform or laboratory coat.
Respiratory protection : If adequate local exhaust ventilation is not available or expo-
sure assessment demonstrates exposures outside the rec-
ommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 137

Filter type : Self-contained breathing apparatus

SECTION 9: Physical and chemical properties

9.1 Information on basic 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

<table>
<thead>
<tr>
<th></th>
<th>Fresh water sediment</th>
<th>Marine sediment</th>
<th>Soil</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30.4 mg/kg dry weight (d.w.)</td>
<td>3.04 mg/kg dry weight (d.w.)</td>
<td>29.5 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>
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Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
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.

9.2 Other information
  Flammability (liquids) : Not applicable
  Molecular weight : No data available
  Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Highly flammable liquid and vapour.
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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
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<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>01.10.2020</td>
<td>462538-00014</td>
<td>01.03.2019</td>
<td>15.01.2016</td>
</tr>
</tbody>
</table>

Remarks: No mortality observed at this dose. No significant adverse effects were reported

<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-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.
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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
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days

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:
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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

**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
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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 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
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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 were reported

Species: Juvenile dog
LOAEL: 56 - 280 mg/kg
Application Route: Oral
Exposure time: 24 Weeks
Symptoms: Diarrhoea
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Species: Rat
LOAEL: 400 mg/kg
Application Route: Oral
Exposure time: 90 Days
Target Organs: Liver, thymus gland

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

**Acetone:**
Species: Rat
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.
SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**N,N-Dimethylacetamide:**
- Toxicty to fish: $\text{LC50 (Leuciscus idus (Golden orfe)): } > 500\text{ mg/l}$
  - Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates: $\text{EC50 (Daphnia magna (Water flea)): } > 500\text{ mg/l}$
  - Exposure time: 48 h
- Toxicity to algae/aquatic plants: $\text{EC50 (Desmodesmus subspicatus (green algae)): } > 500\text{ mg/l}$
  - Exposure time: 72 h
- EC10 (Desmodesmus subspicatus (green algae)): $> 500\text{ mg/l}$
  - Exposure time: 72 h
- Toxicity to microorganisms: EC10: $> 1,995\text{ mg/l}$
  - Exposure time: 30 min

**Fluralaner:**
- Toxicity to fish: $\text{LC50 (Oncorhynchus mykiss (rainbow trout)): } > 0.0488\text{ mg/l}$
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - Remarks: No toxicity at the limit of solubility
- Toxicity to daphnia and other aquatic invertebrates: $\text{EC50 (Daphnia magna (Water flea)): } > 0.015\text{ mg/l}$
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: No toxicity at the limit of solubility
- Toxicity to algae/aquatic plants: $\text{NOEC (Pseudokirchneriella subcapitata (green algae)): } \geq 0.08\text{ mg/l}$
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility
- Toxicity to fish (Chronic toxicity): NOEC: $\geq 0.049\text{ mg/l}$
  - Exposure time: 21 d
  - Species: Zebrafish
  - Method: OECD Test Guideline 204
  - Remarks: No toxicity at the limit of solubility
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: $0.000047\text{ mg/l}$
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)
  - Method: OECD Test Guideline 211
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Date of first issue: 15.01.2016

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 microorganisms: EC50: 61,150 mg/l
Exposure time: 30 min
Method: ISO 8192
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: >= 79 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

12.2 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
12.3 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

12.4 Mobility in soil

**Components:**

**Fluralaner:**
- Distribution among environmental compartments: log Koc: 3.4

12.5 Results of PBT and vPvB assessment

**Components:**

**Fluralaner:**
- Assessment: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product:**
- Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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

14.1 UN number

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<tr>
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14.2 UN proper shipping name

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14.3 Transport hazard class(es)

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14.4 Packing group

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IMDG
Packing group : II  
Labels : 3  
EmS Code : F-E, S-D

IATA (Cargo)
Packing instruction (cargo aircraft) : 364  
Packing instruction (LQ) : Y341  
Packing group : II  
Labels : Flammable Liquids

IATA (Passenger)
Packing instruction (passenger aircraft) : 353  
Packing instruction (LQ) : Y341  
Packing group : II  
Labels : Flammable Liquids

14.5 Environmental hazards

ADN
Environmentally hazardous : no

ADR
Environmentally hazardous : no

RID
Environmentally hazardous : no

IMDG
Marine pollutant : no

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3 N,N-Dimethylacetamide (Number on list 72, 30)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). REACH - List of substances subject to authorisation : N,N-Dimethylacetamide : Not applicable
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(Annex XIV)
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Quantity 1 Quantity 2
E1 ENVIRONMENTAL HAZARDS 100 t 200 t
P5c FLAMMABLE LIQUIDS 5,000 t 50,000 t

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H225: Highly flammable liquid and vapour.
H302: Harmful if swallowed.
H312: Harmful in contact with skin.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H332: Harmful if inhaled.
H360D: May cause drowsiness or dizziness.
H361d: Suspected of damaging the unborn child.
H410: Very toxic to aquatic life with long lasting effects.
H412: Harmful to aquatic life with long lasting effects.

Full text of other abbreviations
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<th>Date of last issue:</th>
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<td>462538-00014</td>
<td>01.03.2019</td>
<td>15.01.2016</td>
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Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Repr. : Reproductive toxicity
Skin Irrit. : Skin irritation
STOT SE : Specific target organ toxicity - single exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
2000/39/EC / TWA : Limit Value - eight hours
2000/39/EC / STEL : Short term exposure limit
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL) : Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Standardisation; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information
Sources of key data used to compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
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Classification of the mixture:

| Flam. Liq. 2 | H225 | Based on product data or assessment |
| Repr. 1B | H360D | Calculation method |
| Aquatic Chronic 1 | H410 | Calculation method |

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.

IE / EN