

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Fluralaner / Diethyltoluamide Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.3	02.10.2025	462538-00032	Date of first issue: 15.01.2016

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

#### 1.1 Product identifier

Trade name : Fluralaner / Diethyltoluamide Liquid Formulation

Other means of identification : BRAVECTO SPOT-ON (A011261)  
BRAVECTO 1000 MG FLURALANER SPOT-ON SOLUTION  
FOR LARGE DOGS (82794)  
BRAVECTO 112.5 MG FLURALANER SPOT-ON SOLUTION  
FOR SMALL CATS (82807)  
BRAVECTO 112.5 MG FLURALANER SPOT-ON SOLUTION  
FOR VERY SMALL DOGS (82798)  
BRAVECTO 1400 MG FLURALANER SPOT-ON SOLUTION  
FOR VERY LARGE DOGS (82795)  
BRAVECTO 250 MG FLURALANER SPOT-ON SOLUTION  
FOR MEDIUM CATS (82806)  
BRAVECTO 250 MG FLURALANER SPOT-ON SOLUTION  
FOR SMALL DOGS (82797)  
BRAVECTO 500 MG FLURALANER SPOT-ON SOLUTION  
FOR LARGE CATS (82804)  
BRAVECTO 500 MG FLURALANER SPOT-ON SOLUTION  
FOR MEDIUM DOGS (82796)

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-  
stance/Mixture : Veterinary product

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Drynam Road  
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### 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 :



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	<b>Prevention:</b>	
	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.
	<b>Response:</b>	
	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.

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
N,N-Dimethylacetamide	127-19-5 204-826-4 616-011-00-4	Acute Tox. 4; H332 Acute Tox. 4; H312 Eye Irrit. 2; H319 Repr. 1B; H360D  Acute toxicity estimate  Acute inhalation toxicity (dust/mist): 2.2 mg/l Acute dermal toxicity: 1,100 mg/kg	>= 30 - < 50
Fluralaner	864731-61-3	Repr. 2; H361d Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 1,000	>= 25 - < 30
Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-	31692-85-0	Eye Irrit. 2; H319	>= 10 - < 20
N,N-Diethyl-m-toluamide	134-62-3 205-149-7 616-018-00-2	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319  Acute toxicity estimate  Acute oral toxicity:	>= 10 - < 20

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Acetone	67-64-1 200-662-2 606-001-00-8	1,892 mg/kg Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336 EUH066	>= 10 - < 20
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For explanation of abbreviations see section 16.

### 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.<br>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.<br>Get medical attention.  |
| In case of skin contact    | : In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse.                           |
| In case of eye contact     | : Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.  |
| If swallowed               | : If swallowed, DO NOT induce vomiting.<br>If vomiting occurs have person lean forward.<br>Call a physician or poison control centre immediately.<br>Rinse mouth thoroughly with water.<br>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. |
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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : High volume water jet

#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.  
Flash back possible over considerable distance.  
Vapours may form explosive mixtures with air.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Chlorine compounds  
Fluorine compounds  
Nitrogen oxides (NO<sub>x</sub>)

#### 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

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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 contain-  
ment 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 absor-  
bent.  
Local or national regulations may apply to releases and dis-  
posal of this material, as well as those materials and items  
employed in the cleanup of releases. You will need to deter-  
mine 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 equip-  
ment.

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 as-  
sessment  
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

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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.

### 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  
Self-reactive substances and mixtures  
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  
Very acutely toxic substances and mixtures

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
N,N-Dimethylacetamide	127-19-5	TWA	10 ppm 36 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	20 ppm 72 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		OELV - 8 hrs (TWA)	10 ppm 36 mg/m <sup>3</sup>	IE OEL

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	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body, Repr 1B - Substances which are presumed human reproductive toxicants			
		OELV - 15 min (STEL)	20 ppm 72 mg/m <sup>3</sup>	IE OEL
	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body, Repr 1B - Substances which are presumed human reproductive toxicants			
		TWA	10 ppm 36 mg/m <sup>3</sup>	2004/37/EC
	Further information: Skin, Carcinogens or mutagens			
		STEL	20 ppm 72 mg/m <sup>3</sup>	2004/37/EC
	Further information: Skin, Carcinogens or mutagens			
Fluralaner	864731-61-3	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 µg/100 cm <sup>2</sup>	Internal
Acetone	67-64-1	TWA	500 ppm 1,210 mg/m <sup>3</sup>	2000/39/EC
	Further information: Indicative			
		OELV - 8 hrs (TWA)	500 ppm 1,210 mg/m <sup>3</sup>	IE OEL

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
N,N-Dimethylacetamide	Workers	Inhalation	Long-term systemic effects	36 mg/m <sup>3</sup>
	Workers	Inhalation	Acute systemic effects	36 mg/m <sup>3</sup>
	Workers	Skin contact	Acute systemic effects	13.6 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	7 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	2.7 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	1 mg/kg bw/day
Acetone	Workers	Inhalation	Long-term systemic effects	1210 mg/m <sup>3</sup>
	Workers	Inhalation	Acute local effects	2420 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	186 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	200 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	62 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic	62 mg/kg



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			effects	bw/day
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### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Fluralaner	Water	7 ng/l
N,N-Dimethylacetamide	Fresh water	0.5 mg/l
	Marine water	0.0966 mg/l
	Intermittent use/release	5 mg/l
	Sewage treatment plant	485 mg/l
	Fresh water sediment	2.27 mg/kg
	Soil	0.15 mg/kg
Acetone	Fresh water	10.6 mg/l
	Marine water	1.06 mg/l
	Intermittent use/release	21 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	30.4 mg/kg dry weight (d.w.)
	Marine sediment	3.04 mg/kg dry weight (d.w.)
	Soil	29.5 mg/kg dry weight (d.w.)

## 8.2 Exposure controls

### Engineering measures

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.

Use explosion-proof electrical, ventilating and lighting equipment.

### Personal protective equipment

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.

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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to I.S. EN 137

Filter type : Self-contained breathing apparatus

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Physical state	: liquid
Form	: liquid
Colour	: yellow
Odour	: No data available
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: 103 °C
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: Not applicable
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: 7 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Vapour pressure	: 67 hPa (20 °C)
Relative density	: No data available

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Density	:	1.059 g/cm <sup>3</sup>
Relative vapour density	:	No data available
Particle characteristics	:	
Particle size	:	Not applicable

### 9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	No data available
Molecular weight	:	No data available

## 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.
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### 10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks.
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### 10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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### 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 national or regional regulation.

#### **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

#### **Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**

Acute oral toxicity	: LD50 (Rat, female): > 2,000 mg/kg Method: OECD Test Guideline 423 Remarks: Based on data from similar materials
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#### **N,N-Diethyl-m-toluamide:**

Acute oral toxicity	: LD50 (Rat): 1,892 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

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### 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

#### Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Species	:	reconstructed human epidermis (RhE)
Method	:	OECD Test Guideline 439
Remarks	:	Based on data from similar materials
Result	:	No skin irritation

#### N,N-Diethyl-m-toluamide:

Species	:	Rabbit
Result	:	Skin irritation
Remarks	:	Based on national or regional regulation.

### 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.

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### **Product:**

Species	: Rabbit
Result	: No eye irritation

### **Components:**

#### **N,N-Dimethylacetamide:**

Species	: Rabbit
Result	: Irritation to eyes, reversing within 21 days

#### **Fluralaner:**

Species	: Rabbit
Result	: Mild eye irritation

#### **Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**

Species	: Tissue Culture
Method	: OECD Test Guideline 492
Remarks	: Based on data from similar materials

Species	: Bovine cornea
Method	: OECD Test Guideline 437
Remarks	: Based on data from similar materials

Result	: Irritation to eyes, reversing within 21 days
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#### **N,N-Diethyl-m-toluamide:**

Species	: Rabbit
Result	: Irritation to eyes, reversing within 21 days
Remarks	: Based on national or regional regulation.

#### **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
Assessment	: Does not cause skin sensitisation.

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Result : negative

### 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.

#### **Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**

Test Type : KeratinoSens assay  
Method : OECD Test Guideline 442D  
Result : negative  
Remarks : Based on data from similar materials

Test Type : Direct Peptide Reactivity Assay (DPRA)  
Method : OECD Test Guideline 442C  
Result : positive  
Remarks : Based on data from similar materials

Test Type : Dendritic cell activation test  
Method : OECD Test Guideline 442E  
Result : negative  
Remarks : Based on data from similar materials

#### **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

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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

### Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

### 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.



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### Components:

#### **N,N-Dimethylacetamide:**

Species	:	Rat
Application Route	:	inhalation (vapour)
Exposure time	:	18 month(s)
Result	:	negative

#### **Fluralaner:**

Carcinogenicity - Assessment	:	No data available
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#### **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
----------------------	---	--

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General Toxicity F1: LOAEL: 100 mg/kg body weight  
Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects.

Effects on foetal develop-  
ment

: Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 100 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the off-  
spring 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 - As-  
sessment

: Suspected of damaging the unborn child.

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

Effects on foetal develop-  
ment

: 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 develop-  
ment

: Test Type: Embryo-foetal development  
Species: Rat  
Application Route: inhalation (vapour)  
Result: negative

### **STOT - single exposure**

Not classified based on available information.

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### 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	: 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)

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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.

## 11.2 Information on other hazards

### Endocrine disrupting properties

Not classified based on available information.

### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 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:

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

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

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Method: Directive 67/548/EEC, Annex V, C.2.

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

EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l  
Exposure time: 72 h

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

### Fluralaner:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.0488 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0.015 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : NOEC: >= 0.049 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: 0.0736 µg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1,000

### Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h

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Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

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

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 97 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

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

Toxicity to algae/aquatic plants : ErC50 (Selenastrum capricornutum (green algae)): 41 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Selenastrum capricornutum (green algae)): 7.6 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 3.7 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)

### **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

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### 12.2 Persistence and degradability

#### Components:

##### **N,N-Dimethylacetamide:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 70 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C  
Remarks: The test was conducted equivalent or similar to guideline

##### **Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**

Biodegradability : Result: Not readily biodegradable.  
Method: OECD Test Guideline 301F  
Remarks: Based on data from similar materials

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

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 83.8 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

##### **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

##### **Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:**

Partition coefficient: n-octanol/water : log Pow: < 4  
Remarks: Calculation

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

Partition coefficient: n-octanol/water : log Pow: 2.02

##### **Acetone:**

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

### 12.4 Mobility in soil

#### Components:

##### **Fluralaner:**

Distribution among environ-  
mental compartments : log Koc: 4.1

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

#### Components:

##### **Fluralaner:**

Assessment : Not persistent, bioaccumulative, and toxic (PBT).

### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 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. Do not dispose of waste into sewer.
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 ex-



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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.

### SECTION 14: Transport information

#### 14.1 UN number or ID number

ADN	:	UN 1090
ADR	:	UN 1090
RID	:	UN 1090
IMDG	:	UN 1090
IATA	:	UN 1090

#### 14.2 UN proper shipping name

ADN	:	ACETONE, SOLUTION
ADR	:	ACETONE, SOLUTION
RID	:	ACETONE, SOLUTION
IMDG	:	ACETONE, SOLUTION (Fluralaner)
IATA	:	Acetone, solution

#### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	:	3
ADR	:	3
RID	:	3
IMDG	:	3
IATA	:	3

#### 14.4 Packing group

ADN		
Packing group	:	II
Classification Code	:	F1
Hazard Identification Number	:	33
Labels	:	3
ADR		
Packing group	:	II
Classification Code	:	F1
Hazard Identification Number	:	33
Labels	:	3

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Tunnel restriction code : (D/E)

### RID

Packing group : II  
Classification Code : F1  
Hazard Identification Number : 33  
Labels : 3

### 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 : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

## 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 Maritime transport in bulk according to IMO instruments

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

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

: Conditions of restriction for the following entries should be considered:  
Number on list 3

Number on list 30: N,N-Dimethylacetamide

Number on list 72: N,N-Dimethylacetamide

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

: N,N-Dimethylacetamide

Regulation (EU) No 2024/590 on substances that deplete the ozone layer

: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast)

: Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

: Not applicable

REACH - List of substances subject to authorisation (Annex XIV)

: Not applicable

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors

This product is regulated by Regulation (EU) 2019/1148: all suspicious transactions, and significant disappearances and thefts should be reported to the relevant national contact point.

Acetone (ANNEX II)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

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

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### 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

CA. 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.
H336	: May cause drowsiness or dizziness.
H360D	: May damage the unborn child.
H361d	: Suspected of damaging the unborn child.
H410	: Very toxic to aquatic life with long lasting effects.
EUH066	: Repeated exposure may cause skin dryness or cracking.

### Full text of other abbreviations

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
2000/39/EC	: Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
2004/37/EC	: Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work - Annex III
IE OEL	: Ireland. List of Chemical Agents and Carcinogens with Occu-

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	patational Exposure Limit Values - Code of Practice, Schedule 1 and 2
2000/39/EC / TWA	: Limit Value - eight hours
2000/39/EC / STEL	: Short term exposure limit
2004/37/EC / STEL	: Short term exposure limit
2004/37/EC / TWA	: Long 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 - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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 Harmonised 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 Organisation; 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 - Organisation 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; TECI - Thailand Existing Chemicals 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 Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Flam. Liq. 2 H225

### Classification procedure:

Based on product data or assessment

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Fluralaner / Diethyltoluamide Liquid Formula- tion

Version 13.3	Revision Date: 02.10.2025	SDS Number: 462538-00032	Date of last issue: 14.04.2025 Date of first issue: 15.01.2016
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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.

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