

# Fluralaner / Diethyltoluamide Liquid Formulation

Version 8.1      Revision Date: 2023/09/30      SDS Number: 412181-00022      Date of last issue: 2023/04/04  
Date of first issue: 2016/01/15

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## 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fluralaner / Diethyltoluamide Liquid Formulation

### Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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## 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.

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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.

### Other hazards which do not result in classification

Vapours may form explosive mixture with air.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
N,N-Dimethylacetamide	127-19-5	>= 30 -< 60
Fluralaner	864731-61-3	>= 25 -< 30
Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-	31692-85-0	>= 10 -< 30
N,N-Diethyl-m-toluamide	134-62-3	>= 10 -< 30
Acetone	67-64-1	>= 10 -< 20

## 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.

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If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	:	May damage the unborn child.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

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### 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire-fighting	:	Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Chlorine compounds Fluorine compounds Nitrogen oxides (NO <sub>x</sub> )
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.

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### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.  
Ventilate the area.  
Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Non-sparking tools should be used.  
Soak up with inert absorbent material.  
Suppress (knock down) gases/vapours/mists with a water spray jet.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
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 : 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

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- other ignition sources. No smoking.  
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  
Organic peroxides  
Oxidizing agents  
Flammable gases  
Pyrophoric liquids  
Pyrophoric solids  
Self-heating substances and mixtures  
Poisonous gases  
Explosives

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	NAB	10 ppm 36 mg/m <sup>3</sup>	ID OEL
	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals, Skin			
		TWA	10 ppm	ACGIH
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	NAB	250 ppm 1,187.12 mg/m <sup>3</sup>	ID OEL
	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals			
		PSD	500 ppm 1,780 mg/m <sup>3</sup>	ID OEL
	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals			
		TWA	250 ppm	ACGIH

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		STEL	500 ppm	ACGIH
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### Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	N-Methylacetamide	Urine	End of shift at end of work-week	30 mg/g creatinine	ACGIH BEI
Acetone	67-64-1	Acetone	Urine	End of shift (As soon as possible after exposure ceases)	25 mg/l	ACGIH BEI

**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

**Respiratory protection** : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

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

**Hand protection**

**Material** : Chemical-resistant gloves

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

**Eye protection** : Wear safety glasses with side shields or goggles.  
 If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
 Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection** : Work uniform or laboratory coat.

**Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

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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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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	yellow
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	103 °C
Flash point	:	7 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	Not applicable
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/cm <sup>3</sup>
Solubility(ies) Water solubility	:	No data available

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Partition coefficient: n-octanol/water : Not applicable  
Auto-ignition temperature : No data available  
Decomposition temperature : No data available  
Viscosity  
  Viscosity, kinematic : No data available  
Explosive properties : Not explosive  
Oxidizing properties : The substance or mixture is not classified as oxidizing.  
Molecular weight : No data available  
Particle size : Not applicable

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**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.

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**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



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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

**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

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**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 : No 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

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**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

**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  
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

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**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  
Method: OECD Test Guideline 478  
Result: negative

**Fluralaner:**

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

Test Type: Mouse Lymphoma

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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.

**Components:**

**N,N-Dimethylacetamide:**

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

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**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

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Result: No effects on fertility and early embryonic development were detected.

Remarks: No significant adverse effects were reported

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

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

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

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

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

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

### **Acetone:**

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

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

### **STOT - single exposure**

Not classified based on available information.

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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/m<sup>3</sup>  
LOAEL : 360 mg/m<sup>3</sup>  
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

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



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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.

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**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****N,N-Dimethylacetamide:**

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

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

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

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

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

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 0.0736 µg/l  
aquatic invertebrates (Chron- : Exposure time: 21 d  
ic toxicity) : Method: OECD Test Guideline 211

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

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

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

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100  
plants : mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

EC10 (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

### **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 (Daphnia magna (Water flea)): 3.7 mg/l  
Exposure time: 21 d

### **Acetone:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia pulex (Water flea)): 8,800 mg/l  
Exposure time: 48 h
- Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)):  $\geq$  79 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

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Remarks: The 10 day time window criterion is not fulfilled.

### **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

### **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:**

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

### **Mobility in soil**

#### **Components:**

##### **Fluralaner:**

Distribution among environmental compartments : log Koc: 4.1

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### Other adverse effects

#### Components:

#### Fluralaner:

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

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### 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

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

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### 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number : UN 1090  
Proper shipping name : ACETONE SOLUTION  
Class : 3  
Packing group : II  
Labels : 3  
Environmentally hazardous : no

##### IATA-DGR

UN/ID No. : UN 1090  
Proper shipping name : Acetone solution  
Class : 3  
Packing group : II  
Labels : Flammable Liquids  
Packing instruction (cargo aircraft) : 364  
Packing instruction (passenger aircraft) : 353

##### IMDG-Code

UN number : UN 1090  
Proper shipping name : ACETONE SOLUTION  
(Fluralaner)  
Class : 3  
Packing group : II

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Labels : 3  
 EmS Code : F-E, S-D  
 Marine pollutant : yes

### 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.

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## 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 Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

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### 16. OTHER INFORMATION

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#### 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/>

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

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; 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 Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recom-

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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.

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