

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Diethyltoluamide Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
12.0	07/06/2024	412190-00026	Date of first issue: 01/15/2016

### SECTION 1. IDENTIFICATION

Product 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)

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Flammable liquids : Category 2  
Reproductive toxicity : Category 1B

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H225 Highly flammable liquid and vapor.

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H360D May damage the unborn child.

### Precautionary Statements

:

#### Prevention:

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P210 Keep away from heat, sparks, open flame and hot surfaces. No smoking.  
P233 Keep container tightly closed.  
P241 Use explosion-proof electrical, ventilating and lighting equipment.  
P242 Use only non-sparking tools.  
P243 Take precautionary measures against static discharge.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

#### Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.  
P308 + P313 IF exposed or concerned: Get medical attention.

#### Storage:

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

#### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### Other hazards

Vapors may form explosive mixture with air.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

: Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
N,N-Dimethylacetamide	127-19-5	>= 30 - < 50
Fluralaner	864731-61-3	>= 20 - < 30
Poly(oxy-1,2-ethanediyl), α- [(tetrahydro-2-furanyl)methyl]-ω- hydroxy-	31692-85-0	>= 10 - < 20
N,N-Diethyl-m-toluamide	134-62-3	>= 10 - < 20
Acetone	67-64-1	>= 10 - < 20

Actual concentration is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

General advice

:

In the case of accident or if you feel unwell, seek medical advice immediately.

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		When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control center 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.

### SECTION 5. FIRE-FIGHTING 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. Vapors 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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- |   |  |
|---|--|
| Personal precautions, protective equipment and emergency procedures | :<br>Remove all sources of ignition.<br>Ventilate the area.<br>Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).  |
| Environmental precautions   | :<br>Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.   |
| Methods and materials for containment and cleaning up               | :<br>Non-sparking tools should be used.<br>Soak up with inert absorbent material.<br>Suppress (knock down) gases/vapors/mists with a water spray jet.<br>For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

### SECTION 7. HANDLING AND STORAGE

- |                         |   |
|-------------------------|---|
| Technical measures      | :<br>See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  |
| Local/Total ventilation | :<br>If sufficient ventilation is unavailable, use with local exhaust ventilation.<br>Use explosion-proof electrical, ventilating and lighting equipment.   |
| Advice on safe handling | :<br>Do not get on skin or clothing.<br>Do not breathe vapors or spray mist.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Non-sparking tools should be used.<br>Keep container tightly closed. |

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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.

Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.

Materials to avoid : Keep away from heat and sources of ignition.  
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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	TWA	10 ppm	ACGIH
		TWA	10 ppm 35 mg/m <sup>3</sup>	NIOSH REL
		TWA	10 ppm 35 mg/m <sup>3</sup>	OSHA Z-1
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	250 ppm	ACGIH
		STEL	500 ppm	ACGIH
		TWA	250 ppm 590 mg/m <sup>3</sup>	NIOSH REL
		TWA	1,000 ppm 2,400 mg/m <sup>3</sup>	OSHA Z-1

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### Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam-pling time	Permissible concentra-tion	Basis
N,N-Dimethylacetamide	127-19-5	N-Methylaceta-mide	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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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.

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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.  
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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid  
Color : yellow  
Odor : No data available  
Odor Threshold : No data available  
pH : No data available  
Melting point/freezing point : No data available  
Initial boiling point and boiling range : 217 °F / 103 °C  
Flash point : 45 °F / 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  
Vapor pressure : 67 hPa (68 °F / 20 °C)  
Relative vapor density : No data available  
Relative density : No data available  
Density : 1.059 g/cm<sup>3</sup>  
Solubility(ies)

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Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition 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 characteristics	:	
Particle size	:	Not applicable

### SECTION 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 vapor. Vapors 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.

### SECTION 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: 5.95 mg/l



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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 judgment  
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): 1,892 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

#### **Acetone:**

Acute oral toxicity : LD50 (Rat): 5,800 mg/kg  
Acute inhalation toxicity : LC50 (Rat): 76 mg/l  
Exposure time: 4 h  
Test atmosphere: vapor

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

## Respiratory or skin sensitization

### Skin sensitization

Not classified based on available information.

### Respiratory sensitization

Not classified based on available information.

### Product:

Test Type	: Maximization Test
Routes of exposure	: Dermal
Species	: Guinea pig
Result	: Not a skin sensitizer.

### Components:

#### N,N-Dimethylacetamide:

Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative

### Fluralaner:

Test Type	: Maximization Test
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Routes of exposure	: 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	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### N,N-Dimethylacetamide:

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

#### Fluralaner:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Mouse Lymphoma Result: negative
	Test Type: Chromosomal aberration Result: negative

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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 (vapor)  
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

IARC	Group 2B: Possibly carcinogenic to humans N,N-Dimethylacetamide	127-19-5
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OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
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NTP	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
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### 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 fetal development	: Test Type: Embryo-fetal 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
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	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 fetal 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 fetal development	: Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative
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### **Acetone:**

Effects on fertility	: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on fetal development	: Test Type: Embryo-fetal development Species: Rat Application Route: inhalation (vapor) 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 (vapor)
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	: Diarrhea

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



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Exposure time	: 90 Days
Species	: Rat
NOAEL	: 45 mg/l
Application Route	: inhalation (vapor)
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

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

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

### Fluralaner:

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

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

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

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

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

### Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-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  
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

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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)): >= 79 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

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

### Persistence and degradability

#### Components:

##### N,N-Dimethylacetamide:

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 70 %  
Exposure time: 28 d  
Remarks: The 10 day time window criterion is not fulfilled.

##### 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

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

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

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 91 % Exposure time: 28 d
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### **Bioaccumulative potential**

#### **Components:**

##### **Fluralaner:**

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

Partition coefficient: n-octanol/water	:	log Pow: 2.02
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##### **Acetone:**

Partition coefficient: n-octanol/water	:	log Pow: -0.27 - -0.23
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### **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	:	Substance is not persistent, bioaccumulative, and toxic (PBT).
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### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations. 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 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

#### 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
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.

#### Domestic regulation

#### 49 CFR

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UN/ID/NA number : UN 1090  
Proper shipping name : Acetone SOLUTION  
Class : 3  
Packing group : II  
Labels : FLAMMABLE LIQUID  
ERG Code : 127  
Marine pollutant : yes(Fluralaner)

### 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.

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Acetone	67-64-1	5000	46728

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Flammable (gases, aerosols, liquids, or solids)  
Reproductive toxicity

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

N,N-Dimethylacetamide	127-19-5
Fluralaner	864731-61-3
Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-	31692-85-0
N,N-Diethyl-m-toluamide	134-62-3
Acetone	67-64-1

#### California Prop. 65

WARNING: This product can expose you to chemicals including N,N-Dimethylacetamide, which is/are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

#### California List of Hazardous Substances

N,N-Dimethylacetamide	127-19-5
Acetone	67-64-1

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### California Permissible Exposure Limits for Chemical Contaminants

N,N-Dimethylacetamide	127-19-5
Acetone	67-64-1

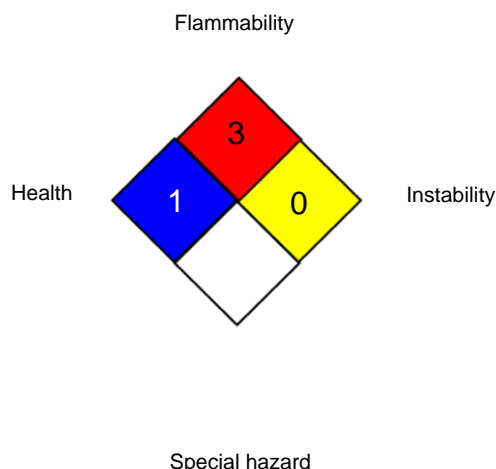
### The ingredients of this product are reported in the following inventories:

AICS	: not determined
DSL	: not determined
IECSC	: not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

HEALTH	*	2
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	: ACGIH - Biological Exposure Indices (BEI)
NIOSH REL	: USA. NIOSH Recommended Exposure Limits
OSHA Z-1	: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	: 8-hour, time-weighted average
ACGIH / STEL	: Short-term exposure limit
NIOSH REL / TWA	: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	: 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the

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German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 07/06/2024

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

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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