according to the Hazardous Products Regulations



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 11.2 10/02/2025 412175-00029 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 : 37 McCarville Street

Charlottetown, PE C1E 2A7

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 Hazardous Products Regulations

Flammable liquids : Category 2

Reproductive toxicity : Category 1B

**GHS label elements** 

Hazard pictograms :





Signal Word : Danger

Hazard Statements : H225 Highly flammable liquid and vapor.

H360D May damage the unborn child.

according to the Hazardous Products Regulations



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**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, hot surfaces, sparks, open flames

and other ignition sources. No smoking.

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:

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	Common Name/Synonym	CAS-No.	Concentration (% w/w)
N,N- Dimethylacetamide	Acetamide, N,N-dimethyl-	127-19-5	>= 30 - < 60 *
Fluralaner	No data availa- ble	864731-61-3	>= 10 - < 30 *
Poly(oxy-1,2- ethanediyl), α- [(tetrahydro-2- furanyl)methyl]-ω- hydroxy-	Reaction prod- ucts of tetrahy- drofurfuryl alco- hol with eth- ylene oxide	31692-85-0	>= 10 - < 30 *
N,N-Diethyl-m- toluamide	Benzamide, N,N-diethyl-3- methyl-	134-62-3	>= 10 - < 30 *
Acetone	2-Propanone	67-64-1	>= 10 - < 30 *

Actual concentration or concentration range 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

according to the Hazardous Products Regulations



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advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention.
Wash clothing before reuse.

Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

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.

May damage the unborn child.

Never give anything by mouth to an unconscious person.

Most important symptoms

and effects, both acute and

delayed

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 (CO2)

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 prod-

ucts

Carbon oxides

Chlorine compounds Fluorine compounds Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

according to the Hazardous Products Regulations



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for fire-fighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- : tive equipment and emer-

gency 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/vapors/mists with a water spray

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.

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.

#### **SECTION 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 equip-

ment.

Advice on safe handling Do not get on skin or clothing.

Do not breathe vapors or spray mist.

Do not swallow.

Avoid contact with eyes.

Handle in accordance with good industrial hygiene and safety

Materials to avoid

according to the Hazardous Products Regulations



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practice, based on the results of the workplace exposure

assessment

Non-sparking tools should be used. Keep container tightly closed.

Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

Take precautionary measures against static discharges.

Take care to prevent spills, waste and minimize release to the

environment.

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.

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 36 mg/m³	CA AB OEL
		TWA	10 ppm	CA BC OEL
		TWAEV	10 ppm	CA QC OEL
		TWA	10 ppm	ACGIH
Fluralaner	864731-61-3	TWA	100 μg/m3 (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 μg/100 cm <sup>2</sup>	Internal
Acetone	67-64-1	TWA	500 ppm 1,200 mg/m <sup>3</sup>	CA AB OEL
		STEL	750 ppm 1,800 mg/m <sup>3</sup>	CA AB OEL
		TWA	250 ppm	CA BC OEL
		STEL	500 ppm	CA BC OEL

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TWAEV	250 ppm	CA QC OEL
STEV	500 ppm	CA QC OEL
TWA	250 ppm	ACGIH
STEL	500 ppm	ACGIH

### **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 : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type

Hand protection

Self-contained breathing apparatus

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

protection : Work uniform or laboratory coat.

Hygiene measures : If exposure to chemical is likely during typical use, provide

according to the Hazardous Products Regulations



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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

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

Vapor pressure : 67 hPa (20 °C)

Relative vapor density : No data available

Relative density : No data available

Density : 1.059 g/cm<sup>3</sup>

Solubility(ies)

Water solubility : No data available

according to the Hazardous Products Regulations



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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. Stable under normal conditions. Chemical stability Possibility of hazardous reac-Highly flammable liquid and vapor.

tions

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 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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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

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 : No eye irritation

**Components:** 

N,N-Dimethylacetamide:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Fluralaner:

Species : Rabbit

Result : Mild eye irritation

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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 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

Assessment : Does not cause skin sensitization.

Result : negative

**Components:** 

N,N-Dimethylacetamide:

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

Fluralaner:

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

according to the Hazardous Products Regulations



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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

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

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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 - Assess-

No data available

ment

N,N-Diethyl-m-toluamide:

Species : Rat Application Route : Ingestion

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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 fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Inhalation

Result: positive

Reproductive toxicity - As-

sessment

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.

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.

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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 fetal development : Test Type: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: inhalation (vapor)

Result: negative

#### STOT-single exposure

Not classified based on available information.

#### **Components:**

Acetone:

Assessment : May cause drowsiness or dizziness.

## STOT-repeated exposure

Not classified based on available information.

## Repeated dose toxicity

## **Components:**

## N,N-Dimethylacetamide:

Species : Rat

NOAEL : 90 mg/m³

LOAEL : 360 mg/m³

Application Route : inhalation (vapor)

Exposure time : 24 Months

•

Fluralaner:

Species : Dog

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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 (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.

according to the Hazardous Products Regulations



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**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

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 tox-

icity)

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 : NOEC (Daphnia magna (Water flea)): 0.0736 μg/l

according to the Hazardous Products Regulations



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aquatic invertebrates (Chron-

Exposure time: 21 d

ic toxicity)

Method: OECD Test Guideline 211

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

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 100

mq/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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 3.7 mg/l

Exposure time: 21 d

Acetone:

LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg/l Toxicity to fish

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

Exposure time: 96 h

according to the Hazardous Products Regulations



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Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic 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: 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

### **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-:

according to the Hazardous Products Regulations



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Partition coefficient: n- : log Pow: < 4

octanol/water 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 environ-

mental compartments

: log Koc: 4.1

Other adverse effects

**Components:** 

Fluralaner:

Results of PBT and vPvB

assessment

Not persistent, bioaccumulative, and toxic (PBT).

#### **SECTION 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.

#### **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

according to the Hazardous Products Regulations



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**IATA-DGR** 

UN/ID No. : UN 1090

Proper shipping name : Acetone solution

Class : 3 Packing group : II

Labels : Flammable Liquids

Packing instruction (cargo : 364

aircraft)

Packing instruction (passen: 353

ger aircraft)

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**

**TDG** 

UN number : UN 1090

Proper shipping name : ACETONE SOLUTION

Class : 3
Packing group : II
Labels : 3
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**

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

AICS : not determined

CA. DSL : not determined

IECSC : not determined

#### **Canadian lists**

No substances are subject to CEPA Section 84 Ministerial Conditions.

according to the Hazardous Products Regulations



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#### **SECTION 16. OTHER INFORMATION**

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit

CA AB OEL / TWA : 8-hour Occupational exposure limit
CA AB OEL / STEL : 15-minute occupational exposure limit

CA BC OEL / TWA : 8-hour time weighted average CA BC OEL / STEL : short-term exposure limit

CA QC OEL / TWAEV : Time-weighted average exposure value

CA QC OEL / STEV : Short-term exposure value

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 Standardization; 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 Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations

according to the Hazardous Products Regulations



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on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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 Agen-

cy, http://echa.europa.eu/

Revision Date : 10/02/2025 Date format : mm/dd/yyyy

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.

CA / Z8