

Fluralaner / Diethyltoluamide Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.11.2024
11.1	02.10.2025	462527-00028	Date of first issue: 15.01.2016

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 : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 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

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Flammable liquids : Category 2

Acute toxicity (Inhalation) : Category 5

Reproductive toxicity : Category 1B

Aspiration hazard : Category 2

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version 11.1	Revision Date: 02.10.2025	SDS Number: 462527-00028	Date of last issue: 14.11.2024 Date of first issue: 15.01.2016
-----------------	------------------------------	-----------------------------	---

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H225 Highly flammable liquid and vapor.
H305 May be harmful if swallowed and enters airways.
H333 May be harmful if inhaled.
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.
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.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304 + P312 IF INHALED: Call a POISON CENTER/ doctor if you feel unwell.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P331 Do NOT induce vomiting.
P391 Collect spillage.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Fluralaner / Diethyltoluamide Liquid Formula- tion

Version 11.1 Revision Date: 02.10.2025 SDS Number: 462527-00028 Date of last issue: 14.11.2024
Date of first issue: 15.01.2016

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
N,N-Dimethylacetamide	127-19-5	>= 30 -< 50
Fluralaner	864731-61-3	>= 25 -< 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

SECTION 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.

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 be harmful if swallowed and enters airways.
May be harmful if inhaled.
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 (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.

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version 11.1	Revision Date: 02.10.2025	SDS Number: 462527-00028	Date of last issue: 14.11.2024 Date of first issue: 15.01.2016
-----------------	------------------------------	-----------------------------	---

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_x)

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.

SECTION 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/vapors/mists with a water spray jet.
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.

Fluralaner / Diethyltoluamide Liquid Formula- tion

Version 11.1 Revision Date: 02.10.2025 SDS Number: 462527-00028 Date of last issue: 14.11.2024
Date of first issue: 15.01.2016

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 equipment.
- 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 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.
- Materials to avoid : 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	CMP	10 ppm	AR OEL
Further information: Skin				
		TWA	10 ppm	ACGIH

Fluralaner / Diethyltoluamide Liquid Formula- tion

Version 11.1 Revision Date: 02.10.2025 SDS Number: 462527-00028 Date of last issue: 14.11.2024
Date of first issue: 15.01.2016

Fluralaner	864731-61-3	TWA	100 µg/m ³ (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 µg/100 cm ²	Internal
Acetone	67-64-1	CMP	500 ppm	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			
		CMP - CPT	750 ppm	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			
		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	after the last shift of the last day of the work week	30 mg/g creatinine	AR BEI
		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	50 mg/l	AR BEI
		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

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version 11.1	Revision Date: 02.10.2025	SDS Number: 462527-00028	Date of last issue: 14.11.2024 Date of first issue: 15.01.2016
-----------------	------------------------------	-----------------------------	---

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.
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 : No data available

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version 11.1	Revision Date: 02.10.2025	SDS Number: 462527-00028	Date of last issue: 14.11.2024 Date of first issue: 15.01.2016
-----------------	------------------------------	-----------------------------	---

flammability limit

Vapor pressure : 67 hPa (20 °C)

Relative vapor density : No data available

Relative density : No data available

Density : 1,059 g/cm³

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-
octanol/water : Not applicable

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 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 : No hazardous decomposition products are known.
products

SECTION 11. TOXICOLOGICAL INFORMATIONInformation on likely routes of : Inhalation
exposure Skin contact
Ingestion
Eye contact

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version 11.1	Revision Date: 02.10.2025	SDS Number: 462527-00028	Date of last issue: 14.11.2024 Date of first issue: 15.01.2016
-----------------	------------------------------	-----------------------------	---

Acute toxicity

May be harmful if inhaled.

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 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), α -[(tetrahydro-2-furanyl)methyl]- ω -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

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 14.11.2024
11.1	02.10.2025	462527-00028	Date of first issue: 15.01.2016

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

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), α -[(tetrahydro-2-furanyl)methyl]- ω -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

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 14.11.2024
11.1	02.10.2025	462527-00028	Date of first issue: 15.01.2016

Components:**N,N-Dimethylacetamide:**

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

Fluralaner:

Species	:	Rabbit
Result	:	Mild eye irritation

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

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 14.11.2024
11.1	02.10.2025	462527-00028	Date of first issue: 15.01.2016

Species : Guinea pig
Result : negative

Fluralaner:

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

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

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version 11.1	Revision Date: 02.10.2025	SDS Number: 462527-00028	Date of last issue: 14.11.2024 Date of first issue: 15.01.2016
-----------------	------------------------------	-----------------------------	---

Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Poly(oxy-1,2-ethanediyl), α -[(tetrahydro-2-furanyl)methyl]- ω -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 / Diethyltoluamide Liquid Formula-
tion**

Version 11.1	Revision Date: 02.10.2025	SDS Number: 462527-00028	Date of last issue: 14.11.2024 Date of first issue: 15.01.2016
-----------------	------------------------------	-----------------------------	---

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 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.

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.

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 14.11.2024
11.1	02.10.2025	462527-00028	Date of first issue: 15.01.2016

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

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

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 14.11.2024
11.1	02.10.2025	462527-00028	Date of first issue: 15.01.2016

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 : 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

May be harmful if swallowed and enters airways.

Components:**Fluralaner:**

Not applicable

Acetone:

The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version 11.1	Revision Date: 02.10.2025	SDS Number: 462527-00028	Date of last issue: 14.11.2024 Date of first issue: 15.01.2016
-----------------	------------------------------	-----------------------------	---

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
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-	: NOEC (Zebrafish): >= 0,049 mg/l

Version	Revision Date:	SDS Number:	Date of last issue: 14.11.2024
11.1	02.10.2025	462527-00028	Date of first issue: 15.01.2016

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 5.540 mg/l
Exposure time: 96 h

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version 11.1	Revision Date: 02.10.2025	SDS Number: 462527-00028	Date of last issue: 14.11.2024 Date of first issue: 15.01.2016
-----------------	------------------------------	-----------------------------	---

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: 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), α -[(tetrahydro-2-furanyl)methyl]- ω -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
-----------------	---	--

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version 11.1	Revision Date: 02.10.2025	SDS Number: 462527-00028	Date of last issue: 14.11.2024 Date of first issue: 15.01.2016
-----------------	------------------------------	-----------------------------	---

Partition coefficient: n-
octanol/water : log Pow: 4,5

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

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version 11.1	Revision Date: 02.10.2025	SDS Number: 462527-00028	Date of last issue: 14.11.2024 Date of first issue: 15.01.2016
-----------------	------------------------------	-----------------------------	---

Packing group : II
Labels : 3
Environmentally hazardous : no

MERCOSUR

UN number : UN 1090
Proper shipping name : ACETONE SOLUTION
Class : 3
Packing group : II
Labels : 3
Environmental hazards : 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.

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 14.11.2024
11.1	02.10.2025	462527-00028	Date of first issue: 15.01.2016

CA. DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date	: 02.10.2025
Date format	: dd.mm.yyyy

Further information

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/
--	---

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	: ACGIH - Biological Exposure Indices (BEI)
AR BEI	: Argentina. Biological Exposure Indices
AR OEL	: Argentina. Occupational Exposure Limits
ACGIH / TWA	: 8-hour, time-weighted average
ACGIH / STEL	: Short-term exposure limit
AR OEL / CMP	: TLV (Threshold Limit Value)
AR OEL / CMP - CPT	: STEL (Short Term Limit 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

**Fluralaner / Diethyltoluamide Liquid Formula-
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 14.11.2024
11.1	02.10.2025	462527-00028	Date of first issue: 15.01.2016

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; TECL - 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; 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.

AR / Z8