# This SDS packet was issued with item:

078927999

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078927998 078928000 078928001 078928002 078928003 078928004

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078928005

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 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.

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

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 surfac-

es. 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.

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 04/06/2024 412190-00025 11.9 Date of first issue: 01/15/2016

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

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. May damage the unborn child.

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

High volume water jet

Specific hazards during fire

fighting

Do not use a solid water stream as it may scatter and spread

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

Evacuate area.

Special protective equipment :

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

#### **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.

Soak up with men 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.

#### **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 practice, based on the results of the workplace exposure

assessment

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

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 04/06/2024 412190-00025 Date of first issue: 01/15/2016 11.9

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.

Keep in properly labeled containers. Conditions for safe storage

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	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
N,N-Dimethylacetamide	127-19-5	TWA	10 ppm	ACGIH
		TWA	10 ppm	NIOSH REL
			35 mg/m³	
		TWA	10 ppm	OSHA Z-1
			35 mg/m³	
Fluralaner	864731-61-3	TWA	100 μg/m3 (OEB	Internal
			2)	
	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	NIOSH REL
			590 mg/m³	
		TWA	1,000 ppm	OSHA Z-1
			2,400 mg/m <sup>3</sup>	

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

#### **Biological occupational exposure limits**

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentra-	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.

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

Skin and body protection

Hygiene measures

: Work uniform or laboratory coat.

: 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)

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

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

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

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

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

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

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

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

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

Fluralaner:

Species : Rabbit

Result : Mild eye irritation

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

Species : Tissue Culture

Method : OECD Test Guideline 492

Remarks : Based on data from similar materials

Species : Bovine cornea

Method : OECD Test Guideline 437

Remarks : Based on data from similar materials

Result : Irritation to eyes, reversing within 21 days

N,N-Diethyl-m-toluamide:

Species : Rabbit

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

Acetone:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Respiratory or skin 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

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

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

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

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 - Assess-

ment

: No data available

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

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

**OSHA**No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

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.

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.

Test Type: One-generation reproduction toxicity study

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

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 - 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.

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

#### **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
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

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

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

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 04/06/2024 412190-00025 11.9 Date of first issue: 01/15/2016

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 ma/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 :

aquatic invertebrates (Chron-

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

Exposure time: 21 d

Method: OECD Test Guideline 211 ic toxicity)

#### 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

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

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

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:

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/

Exposure time: 96 h

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: 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

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 12/12/2023

 11.9
 04/06/2024
 412190-00025
 Date of first issue: 01/15/2016

N,N-Diethyl-m-toluamide:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 83.8 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Acetone:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 91 % Exposure time: 28 d

Bioaccumulative potential

**Components:** 

Fluralaner:

Bioaccumulation : Species: Zebrafish

Bioconcentration factor (BCF): 79.4 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 4.5

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

Partition coefficient: n- : log Pow: < 4

octanol/water Remarks: Calculation

N,N-Diethyl-m-toluamide:

Partition coefficient: n-

log Pow: 2.02

octanol/water

Acetone:

Partition coefficient: n-

: log Pow: -0.27 - -0.23

octanol/water

Mobility in soil Components:

Fluralaner:

Distribution among environ-

: log Koc: 4.1

mental compartments

Other adverse effects

Components:

Fluralaner:

Results of PBT and vPvB

assessment

: Substance is not persistent, bioaccumulative, and toxic (PBT).

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

#### **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)

Destrict in the contract of th

364

Packing instruction (passen-

ger 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** 

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

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	Calculated product RQ	
		(lbs)	(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),  $\alpha$ -[(tetrahydro-2-furanyl)methyl]- $\omega$ - 31692-85-0

hydroxy-

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.

#### **California List of Hazardous Substances**

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

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

#### **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**

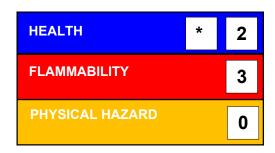
#### **Further information**

#### NFPA 704:

# Flammability Health Instability

Special hazard

#### HMIS® IV:



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 Lim-

its 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

according to the OSHA Hazard Communication Standard



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 12/12/2023 11.9 04/06/2024 412190-00025 Date of first issue: 01/15/2016

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

eChem Portal search results and European Chemicals Agen-

Internal technical data, data from raw material SDSs, OECD

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

Revision Date : 04/06/2024

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.

US / Z8