

Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 10.0 06.07.2024 412186-00026 Date of first issue: 15.01.2016

SECTION 1. PRODUCT AND COMPANY 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 : MSD

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@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

GHS label elements

Hazard pictograms





Signal Word : Danger



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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.

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/

face protection.

Response:

P301 + P310 IF SWALLOWED: Immediately call a POISON

CENTER or doctor/ physician.

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 or doctor/

physician if you feel unwell.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P331 Do NOT induce vomiting.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal 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-	31692-85-0	>= 10 -< 20
furanyl)methyl]-ω-hydroxy-		
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



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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. 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.

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

nedia

High volume water jet

Specific hazards during fire

fighting

riigir voidirio water jet

re.

Flash back possible over considerable distance. Vapors may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

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

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.

Special protective equipment :

for fire-fighters

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

Use personal protective equipment.



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SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, 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

iet.

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.

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



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other ignition sources. No smoking.

Take precautionary measures against static discharges.

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

environment.

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.

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	VLE-PPT	10 ppm	NOM-010- STPS-2014	
		TWA	10 ppm	ACGIH	
Fluralaner	864731-61-3	TWA	100 μg/m3 (OEB 2)	Internal	
	Further information: Skin				
		Wipe limit	1000 μg/100 cm ²	Internal	
Acetone	67-64-1	VLE-PPT	500 ppm	NOM-010- STPS-2014	
		VLE-CT	750 ppm	NOM-010- STPS-2014	



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	TWA	250 ppm	ACGIH
	STEL	500 ppm	ACGIH

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	N- methylaceta mide	Urine	End of shift at end of work- week	30 mg/g creatinine	MX 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	MX 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., dripless 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



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potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

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/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



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Viscosity, kinematic No data available

Explosive properties Not explosive

The substance or mixture is not classified as oxidizing. Oxidizing properties

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.

Vapors may form explosive mixture with air. tions

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 INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

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 toxicity estimate: 5.95 mg/l Acute inhalation toxicity

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

LD50 (Rat): > 2,000 mg/kg Acute dermal toxicity

Symptoms: Erythema

Components:

N,N-Dimethylacetamide:



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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

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



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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 : Mild eye irritation

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



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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

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



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Remarks Based on data from similar materials

Test Type : Dendritic cell activation test Method : OECD Test Guideline 442E

Result : negative

: Based on data from similar materials Remarks

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

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



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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
Exposure time : 104 weeks
Result : negative

Acetone:

Species: MouseApplication Route: Skin contactExposure time: 424 daysResult: negative

Reproductive toxicity

May damage the unborn child.



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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

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.



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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: RatNOAEL: 90 mg/m³LOAEL: 360 mg/m³Application 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



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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: RatNOAEL: 900 mg/kgLOAEL: 1,700 mg/kgApplication Route: IngestionExposure 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.

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.



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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 :

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



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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

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

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/l

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



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> 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), 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

Partition coefficient: n-

octanol/water

: log Pow: 4.5

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

Partition coefficient: n-: loa Pow: < 4

octanol/water Remarks: Calculation

N,N-Diethyl-m-toluamide:

Partition coefficient: n-

: log Pow: 2.02

octanol/water

Acetone:



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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

Substance is 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

IATA-DGR

UN/ID No. : UN 1090
Proper shipping name : Acetone solution

Class : 3 Packing group : II

Labels : Flammable Liquids

Packing instruction (cargo

aircraft)

Packing instruction (passen:

ger aircraft)

364

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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

NOM-002-SCT

UN number : UN 1090

Proper shipping name : ACETONE, SOLUTION

Class : 3
Packing group : II
Labels : 3

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

Federal Law for the control of chemical precursors, : Acetone essential chemical products and machinery for producing capsules, tablets and pills.

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 06.07.2024 Date format : dd.mm.yyyy

Full text of other abbreviations

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



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Official Mexican Norm NOM-047-SSA1-2011, Environmental MX BEI

Health - Biological exposure indices for workers occupational-

ly exposed to chemical agents

Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting NOM-010-STPS-2014

the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

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

NOM-010-STPS-2014 / VLE-Time weighted average limit value

NOM-010-STPS-2014 / VLE- : Short term exposure limit value

CT

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

Sources of key data used to compile the Material Safety **Data Sheet**

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

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



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The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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