Fluralaner / Diethyltoluamide Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
10.0	2024/09/28	412178-00027	Date of first issue: 2016/01/15

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 : MSD

Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : liquid
Colour : yellow
Odour : No data available

Highly flammable liquid and vapour. May be harmful if swallowed and enters airways. May be harmful if inhaled. May damage the unborn child. Very toxic to aquatic life with long lasting effects.

GHS Classification

Flammable liquids	:	Category 2
Acute toxicity (Inhalation)	:	Category 5
Reproductive toxicity	:	Category 1B
Aspiration hazard	:	Category 2
Long-term (chronic) aquatic hazard	:	Category 1

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements :
H225 Highly flammable liquid and vapour.
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/ sparks/ open flames/ hot surfaces. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
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 immediate-

ly all contaminated clothing. Rinse skin with water/ shower.
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:

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

Disposal:

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

Physical and chemical hazards

Highly flammable liquid and vapour.

Health hazards

May be harmful if inhaled. May damage the unborn child. May be harmful if swallowed and enters airways.

Environmental hazards

Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification

Vapours may form explosive mixture with air.

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	>= 25 -< 30
Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-	31692-85-0	>= 10 -< 20
N,N-Diethyl-m-toluamide	134-62-3	>= 10 -< 20
Acetone	67-64-1	>= 10 -< 20

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 centre 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.

5. FIREFIGHTING 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. Vapours 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 (NOx)
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 firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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/vapours/mists with a water spray jet. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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.

7. HANDLING AND STORAGE

Handling

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 vapours 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.

Avoidance of contact : Oxidizing agents

Storage

Conditions for safe storage : Keep in properly labelled 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:
Self-reactive substances and mixtures
Organic peroxides
Oxidizing agents
Flammable gases
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Poisonous gases
Explosives

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	PC-TWA	20 mg/m3	CN OEL
	Further information: Skin			
		TWA	10 ppm	ACGIH
Fluralaner	864731-61-3	TWA	100 µg/m3 (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 µg/100 cm²	Internal
Acetone	67-64-1	PC-TWA	300 mg/m3	CN OEL
		PC-STEL	450 mg/m3	CN OEL

		TWA	250 ppm	ACGIH
		STEL	500 ppm	ACGIH

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	N-Methylacetamide	Urine	End of last shift of the week	20 mg/g creatinine	CN BEI
		N-Methylacetamide	Urine	End of shift at end of workweek	30 mg/g creatinine	ACGIH BEI
Acetone	67-64-1	Acetone	Urine	End of shift	50 mg/l	CN 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 : Self-contained breathing apparatus

Eye/face 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.

Hand protection

Material	:	Chemical-resistant gloves
Remarks	:	Take note that the product is flammable, which may impact the selection of hand protection.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	yellow
Odour	:	No data available
Odour 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
Vapour pressure	:	67 hPa (20 °C)

Relative vapour 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
Auto-ignition 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

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Highly flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes	:	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 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 judgement 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: vapour
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

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 sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

Test Type	:	Maximisation Test
Exposure routes	:	Dermal
Species	:	Guinea pig
Result	:	Not a skin sensitizer.

Components:

N,N-Dimethylacetamide:

Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Fluralaner:

Test Type	:	Maximisation Test
Exposure routes	:	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	:	Maximisation Test
Exposure routes	:	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), .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 (vapour)
Exposure time	:	18 month(s)
Result	:	negative

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 foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Inhalation Result: positive

Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on development, based on animal experiments.

Fluralaner:

Effects on fertility	:	Test Type: Two-generation study Species: Rat Application Route: Oral General Toxicity - Parent: NOAEL: 50 mg/kg body weight General Toxicity F1: LOAEL: 100 mg/kg body weight Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects. Test Type: One-generation reproduction toxicity study 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 foetal development	:	Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: Skeletal malformations, Visceral malformations Remarks: Maternal toxicity observed. Test Type: Development Species: Rabbit Application Route: Dermal Developmental Toxicity: NOAEL: 100 mg/kg body weight Result: Skeletal malformations
Reproductive toxicity - Assessment	:	Suspected of damaging the unborn child.

N,N-Diethyl-m-toluamide:

Effects on foetal development	:	Test Type: Embryo-foetal 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 foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: inhalation (vapour) Result: negative

STOT - single exposure

Not classified based on available information.

Components:

Acetone:

Assessment	:	May cause drowsiness or dizziness.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

N,N-Dimethylacetamide:

Species	:	Rat
NOAEL	:	90 mg/m3
LOAEL	:	360 mg/m3
Application Route	:	inhalation (vapour)
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	:	Diarrhoea

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 (vapour)
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.
Eye contact	:	Remarks: May cause eye irritation.

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 toxicity)	:	NOEC (Zebrafish): >= 0.049 mg/l Exposure time: 21 d Method: OECD Test Guideline 204 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.0736 µg/l Exposure time: 21 d Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity)	:	1,000

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 Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 75 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Selenastrum capricornutum (green algae)): 41 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Selenastrum capricornutum (green algae)): 7.6 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 3.7 mg/l Exposure time: 21 d

Acetone:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia pulex (Water flea)): 8,800 mg/l Exposure time: 48 h
Toxicity to algae/aquatic	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000

plants		mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): >= 79 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	EC50: 61,150 mg/l Exposure time: 30 min Method: ISO 8192

Persistence and degradability

Components:

N,N-Dimethylacetamide:

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

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

Biodegradability	:	Result: Not readily biodegradable. Method: OECD Test Guideline 301F Remarks: Based on data from similar materials

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-	:	log Pow: 4.5

octanol/water

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-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 environmental compartments : log Koc: 4.1

Other adverse effects

Components:

Fluralaner:

Results of PBT and vPvB assessment : Substance is not persistent, bioaccumulative, and toxic (PBT).

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 1090
Proper shipping name : ACETONE SOLUTION

Class	:	3
Packing group	:	II
Labels	:	3
Environmentally hazardous	:	no

IATA-DGR

UN/ID No.	:	UN 1090
Proper shipping name	:	Acetone solution
Class	:	3
Packing group	:	II
Labels	:	Flammable Liquids
Packing instruction (cargo aircraft)	:	364
Packing instruction (passenger aircraft)	:	353

IMDG-Code

UN number	:	UN 1090
Proper shipping name	:	ACETONE SOLUTION (Fluralaner)
Class	:	3
Packing group	:	II
Labels	:	3
EmS Code	:	F-E, S-D
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

UN number	:	UN 1090
Proper shipping name	:	ACETONE SOLUTION
Class	:	3
Packing group	:	II
Labels	:	3
Marine pollutant	:	no

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.

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals	:	Listed

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)

No. / Code	Chemical name / Category	Threshold quantity
W5.3	Flammable liquids	1,000 t

Hazardous Chemicals for Priority Management under SAWS : Listed

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export : Not listed

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2024/09/28

Further information

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

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

Date format : yyyy/mm/dd

Full text of other abbreviations

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

CN OEL	:	Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
CN OEL / PC-TWA	:	Permissible concentration - time weighted average
CN OEL / PC-STEL	:	Permissible concentration - short term exposure limit

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

Disclaimer

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.

CN / EN