SAFETY DATA SHEETS

This SDS packet was issued with item:

078928005

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 078927999 078928000 078928001 078928002 078928003 078928004

SAFETY DATA SHEET

Bravecto® spot-on solution

Section 1: Identification of the Substance and Supplier

Product name	**Bravecto spot-on solution**
Recommended use	For spot-on flea and tick treatment in cats and dogs
Company details	**MSD Animal Health, 33 Whakatiki Street, Upper Hutt** **Phone: 0800 800 543 Fax: 0800 808 100** **Website: www.msd-animal-health.co.nz** **Hours: 8 am – 5 pm, Mon – Fri**
Emergency telephone	**0800 764 766 (0800 POISON) 24 hours human health** **0800 243 622 (0800 CHEMCALL) 24 hours**
Date of preparation	October 2016

Section 2: Hazards Identification

Hazard classifications	3.1B, 6.1E (dermal), 6.3A, 6.4A, 6.8A, 9.1A
Priority identifiers	**DANGER** **Ecotoxic**
Secondary identifier	3.1B Highly flammable liquid and vapour – keep away from sources of ignition 6.1E May be harmful if absorbed through the skin. 6.3A May cause skin irritation 6.4A May cause eye irritation. 6.8A May damage fertility or the unborn child from repeated oral exposure. 9.1A Very toxic to aquatic organisms with long-lasting effects.
Risk & Safety Phrases	R21 Harmful by in contact with skin. R11 Highly flammable R67 Vapours may cause drowsiness and dizziness R50 Very toxic to aquatic organisms

Section 3: Composition/Information on Ingredients

Chemical name	CAS number	Concentration
Fluralaner	846731–61-3	13.64%
Dimethylacetamide (DMA)	127-15-5	30 – 40%
Diethyltoluamide (DEET)	134-62-3	13.2%
Acetone	67-64-1	10 – 20%

Section 4: First Aid Measures

Necessary first aid measures	**SKIN CONTACT** In case of skin contact, carefully remove any contaminated clothing, including shoes. Remove as much as possible using an absorbent material such as tissue paper or cotton. Wash skin thoroughly with soap and water. If there is any remaining sticky residue – this can be removed with alcohol (eg rubbing alcohol or alcohol based skin disinfectant gel). If irritation or symptoms occur or persist, consult a doctor. **EYE CONTACT** In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a doctor. **INGESTION** Rinse mouth with water and drink a glass of water. DO NOT induce vomiting unless under the direction of a qualified medical professional or National Poisons Centre. If symptoms persist, consult a doctor. **INHALATION** Remove affected person promptly to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased.
Required instructions	For advice contact the National Poisons Centre 0800 POISON (0800 764 766) or a doctor.

Section 5: Fire Fighting Measures

Type of hazard	Flammable (contains Acetone and Dimethylacetamide (DMA))
Fire hazard properties	Burning can produce carbon monoxide and/or carbon dioxide
Regulatory requirements	Two fire extinguishers are required where quantities greater than 250L are present.
Extinguishing media and methods	Carbon dioxide (CO2), extinguishing powder or water spray.
Hazchem code	2YE (Contain spillage)
Recommended protective clothing	Wear full protective clothing and self-contained breathing apparatus (SCBA).

Section 6: Accidental Release Measures

Emergency procedures	Wear chemical resistant gloves and overalls, facemask or goggles. Prevent further spillage. Adsorb spilled product with non-combustible absorbent material and place in sealable container for disposal. Wash down affected area with water plus detergent. Absorb and collect washings and place in the same sealable container for disposal. Seek advice from the local authority regarding disposal. Avoid contamination of any water source with product or empty container.

Section 7: Handling and Storage

Precautions for safe handling	Avoid contact with skin, eyes, and mucosa. Keep containers adequately sealed during material transfer, transport, or when not in use. See Section 8 (Exposure Controls) for additional guidance.

Regulatory requirements	Signage required where quantities greater than 100L are present. Emergency Plan required where quantities greater than 100L are present. Two fire extinguishers are required where quantities greater than 250L are present. Location certificate required where quantities greater than 100L are present. Hazardous Atmosphere Zone applicable where quantities greater than 100L are present.
Handling practices	Avoid contact with skin. Keep containers adequately sealed during material transfer, transport, or when not in use.
Approved handlers	Required where quantities greater than 500L are present.
Conditions for safe storage	Store in original packaging. Keep packaging sealed when not in use. Keep out of reach of children. Keep away from heat, sparks, open flame or other sources of ignition.
Store site requirements	Store at room temperature away from foodstuffs in the original package to protect from moisture. Do not refrigerate. Keep away from heat, sparks, open flames, and direct sunlight. Avoid extreme heat. Not to be stored with explosives, flammable gases in bulk, poisonous gasses, spontaneously combustible substances, oxidizing agents, organic peroxides or radioactive substances.
Packaging	Schedule 4

Section 8: Exposure Control/Personal Protection

Workplace exposure standards	No WESs are set for this product.
Application in the workplace	Ensure adequate ventilation. Keep container sealed when not in use.
Exposure standards outside the workplace	TEL – not applicable
Personal protection	Wear chemical resistant gloves, facemask or goggles.

Section 9: Physical and Chemical Properties

Appearance	Yellow liquid
Boiling Point	103°C
Melting/Softening point	Not determined
Vapour Pressure	67 hPA @ 20°C, 1013 hPA @ 101°C
Specific Gravity	Approx. 1.063
Solubility (H_2O)	Not determined for mixture
Percent Volatiles	Not determined
Flash Point	2°C
Evaporation Rate	Not determined

Section 10: Stability and Reactivity

Stability of the substance	Stable under normal conditions. No hazardous reactions known.
Conditions to avoid	Keep away from heat, sparks, open flame and direct sunlight.
Material to avoid	Avoid food products.
Hazardous decomposition products	No dangerous decomposition is expected if used according to manufacturer's specifications.

Section 11: Toxicological Information

Acute effects for individual ingredients only

ORAL	Fluralaner: LD50 >2000 mg/kg (rat); Dimethylacetamide: LD50 2250–10,000 mg/kg (rat); 2600–4900 mg/kg (mouse) Acetone: Oral LD50: 5800 mg/kg (rat)
DERMAL	Fluralaner: LD50 >2000 mg/kg (rat); Dimethylacetamide: LD50: 2200-5000 mg/kg (rabbit), 7500 mg/kg (rat) <940 mg/kg (guinea pig) Acetone was mildly irritating to the skin of rabbits when dossed at 500 mg for 24 hours in a Standard Draize Test. DEET caused minimal to moderate transient dermal irritation in animals, which cleared by day 7.
EYE	Dimethylacetamide produced mild, reversible corneal injury in the eyes of rabbits, mice and dogs. Acetone was moderately irritating to rabbit eyes when dosed at 20 mg for 24 24 hours in a Standard Draize Test.
TEL	No TEL is set for this substance at this time.

Chronic/long term effects for individual ingredients only

Dimethylacetamide was given to rats and rabbits either orally, dermally or by inhalation. Dimethylacetamide caused fetal death or growth retardation in rats at an inhalation dose level of 282 ppm, but not at 100 ppm. There was not an increase in birth defects seen in this study, even at doses toxic to the dam. At high inhalation doses (2000 – 2500 ppm) in rats and (300 – 480 ppm) in mice, dimethylacetamide was associated with reversible testicular toxicity.

Section 12: Environmental Information

Effects for individual ingredients only

AQUATIC	Fluralaner: 96-hr LC50 (Common carp): 2 mg/L 48-hr EC50 (Daphnia magna): 0.0001 - 0.01 mg/L 72-hr EC50 (P. subcapitata): >10 mg/L DEET: 96-hr LC50 (Rainbow Trout): 75 mg/L 48-hr EC50 (Daphnia): 75 mg/L
EEL	Not applicable

Section 13: Disposal Considerations

Disposal information

Disposal of Product and Container
Dispose of used pipette and sachet by wrapping with paper and putting in household waste or in a suitable landfill. Avoid contamination of any water source or the environment with product or empty container.

Section 14: Transport Information

Relevant information

UN1090 Acetone solution.
Class 3
Limited quantities/Consumer commodity 5L
Tracking not required.

UN3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Isoxazoline derivative – Fluralaner and Diethyltoluamide (DEET))
Class 9
Limited quantities/Consumer commodity: 5L

Other requirements

Refer to Haznote.

Section 15: Regulatory Information

Regulatory status

ACVM Registration No: A11261
For conditions of registration see www.foodsafety.govt.nz

HSNO Approval Code: HSR100757.
For a full listing of controls see www.epa.govt.nz

HSNO and ACVM controls

Emergency Plan: 100L
Signage: 100L

Section 16: Other Information

Additional information

Bravecto is a registered trademark.

SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
11.5	04/04/2023	412190-00021	Date of first issue: 01/15/2016

SECTION 1. IDENTIFICATION

Product name : Fluralaner / Diethyltoluamide Liquid Formulation

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.
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 surfaces. 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.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
If vomiting occurs have person lean forward.
Call a physician or poison control center immediately.
Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed	:	May damage the unborn child.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Chlorine compounds Fluorine compounds Nitrogen oxides (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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for	:	Non-sparking tools should be used.

containment and cleaning up	Soak up with inert absorbent material. Suppress (knock down) gases/vapors/mists with a water spray jet. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation. Use explosion-proof electrical, ventilating and lighting equipment.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe vapors or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Non-sparking tools should be used. Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labeled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Flammable solids Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures which in contact with water emit

flammable gases
Explosives
Gases
Very acutely toxic substances and mixtures

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	TWA	10 ppm	ACGIH
		TWA	10 ppm 35 mg/m³	NIOSH REL
		TWA	10 ppm 35 mg/m³	OSHA Z-1
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	TWA	250 ppm	ACGIH
		STEL	500 ppm	ACGIH
		TWA	250 ppm 590 mg/m³	NIOSH REL
		TWA	1,000 ppm 2,400 mg/m³	OSHA Z-1

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 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., 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 : 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.

Skin and body protection : Work uniform or laboratory coat.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available

Initial boiling point and boiling range	:	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/cm³
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	Not applicable

SECTION 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 vapor. Vapors may form explosive mixture with air.

Can react with strong oxidizing agents.

Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Remarks: No mortality observed at this dose.
Acute inhalation toxicity	:	Acute toxicity estimate: 5.95 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Symptoms: Erythema

Components:

N,N-Dimethylacetamide:

Acute oral toxicity	:	LD50 (Rat): 4,800 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): 2.2 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	Acute toxicity estimate: 1,100 mg/kg Method: Expert judgment Remarks: Based on national or regional regulation.

Fluralaner:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Remarks: No mortality observed at this dose. No significant adverse effects were reported
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Remarks: No significant adverse effects were reported

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

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:

Acute oral toxicity : LD50 (Rat): 1,950 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

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
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
Remarks	:	Based on data from similar materials

Test Type	:	Dendritic cell activation test
Method	:	OECD Test Guideline 442E
Result	:	negative
Remarks	:	Based on data from similar materials

Acetone:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Germ cell mutagenicity

Not classified based on available information.

Components:

N,N-Dimethylacetamide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Rat
Application Route: Inhalation
Method: OECD Test Guideline 478
Result: negative

Fluralaner:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Result: negative

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

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

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Acetone:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

N,N-Dimethylacetamide:

Species	:	Rat
Application Route	:	inhalation (vapor)
Exposure time	:	18 month(s)
Result	:	negative

Fluralaner:

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

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 - 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 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 - Assessment	:	Suspected of damaging the unborn child.

N,N-Diethyl-m-toluamide:

Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative

Acetone:

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: inhalation (vapor) Result: negative

STOT-single exposure

Not classified based on available information.

Components:

Acetone:

Assessment	:	May cause drowsiness or dizziness.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

N,N-Dimethylacetamide:

Species	:	Rat
NOAEL	:	90 mg/m³
LOAEL	:	360 mg/m³
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
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
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

Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-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 plants	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): >= 79 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	EC50: 61,150 mg/l Exposure time: 30 min Method: ISO 8192

Persistence and degradability

Components:

N,N-Dimethylacetamide:

Biodegradability	:	Result: 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-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	:	This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

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

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.

Domestic regulation

49 CFR

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 (lbs)	Calculated product RQ (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), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-	31692-85-0
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

California Permissible Exposure Limits for Chemical Contaminants

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

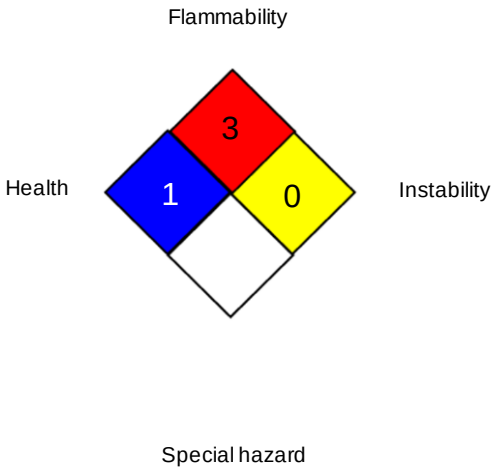
The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

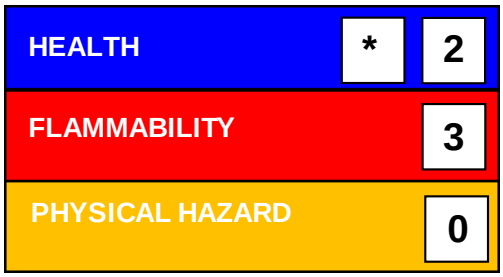
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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 Limits 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 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	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Revision Date	:	04/04/2023

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.

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