SAFETY DATA SHEET

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
10.0	06.07.2024	656886-00023	Date of first issue: 02.05.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Fluralaner / Moxidectin Liquid Formulation
Other means of identification	:	Bravecto Plus (A011446) BRAVECTO PLUS FLEA, TICK AND WORM 112.5 MG FLURALANER AND 5.6 MG MOXIDECTIN SPOT-ON SOLUTION FOR KITTENS AND SMALL CATS (85418) BRAVECTO PLUS FLEA, TICK AND WORM 250 MG FLURALANER AND 12.5 MG MOXIDECTIN SPOT-ON SOLUTION FOR MEDIUM CATS (85416) BRAVECTO PLUS FLEA, TICK AND WORM 500 MG FLURALANER AND 25 MG MOXIDECTIN SPOT-ON SOLUTION FOR LARGE CATS (85413)

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 (Oral)	:	Category 5
Acute toxicity (Inhalation)	:	Category 5
Acute toxicity (Dermal)	:	Category 5
Serious eye damage/eye irritation	:	Category 2A
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure	:	Category 1 (Central nervous system)
Aspiration hazard	:	Category 2

GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements :

H225 Highly flammable liquid and vapor.
H303 + H313 + H333 May be harmful if swallowed, in contact with skin or if inhaled.
H305 May be harmful if swallowed and enters airways.
H319 Causes serious eye irritation.
H360D May damage the unborn child.
H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

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.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
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.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312 Call a POISON CENTER or doctor/ physician if you feel unwell.
P331 Do NOT induce vomiting.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ 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	>= 20 -< 30
N,N-Diethyl-m-toluamide	134-62-3	>= 10 -< 20
Acetone	67-64-1	>= 10 -< 20
Moxidectin	113507-06-5	>= 1 -< 5

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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.
If vomiting occurs have person lean forward.
Call a physician or poison control center immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : May be harmful if swallowed, in contact with skin or if inhaled.
May be harmful if swallowed and enters airways.
Causes serious eye irritation.
May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

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

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 mist or vapors. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. 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. Do not eat, drink or smoke when using this product. 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 cm²	Internal
Acetone	67-64-1	VLE-PPT	500 ppm	NOM-010-STPS-2014
		VLE-CT	750 ppm	NOM-010-STPS-2014
		TWA	250 ppm	ACGIH
		STEL	500 ppm	ACGIH
Moxidectin	113507-06-5	TWA	10 µg/m3 (OEB 3)	Internal
		Wipe limit	100 µg/100 cm²	Internal

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	MX BEI
		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	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.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

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

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving. 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.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	Colorless to pale 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	:	No data available
Flash point	:	2 °C Method: closed cup

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	:	No data available
Relative vapor density	:	No data available
Relative density	:	1.06
Density	:	1.08 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	:	7.5 mm²/s
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
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 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

May be harmful if swallowed, in contact with skin or if inhaled.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 3,518 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 5.3 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: 2,827 mg/kg Method: Calculation method

Components:

N,N-Dimethylacetamide:

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

Fluralaner:

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

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

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

N,N-Diethyl-m-toluamide:

Acute oral toxicity	:	LD50 (Rat): 1,892 mg/kg

Acute inhalation toxicity	:	LC50 (Rat): 5.95 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rat): 5,000 mg/kg

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

Moxidectin:

Acute oral toxicity	:	LD50 (Rat): 106 mg/kg LD50 (Mouse): 42 - 84 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): 3.28 mg/l Exposure time: 5 h Test atmosphere: dust/mist LC50 (Rat): 2.87 - 4.06 mg/l Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg Remarks: No significant adverse effects were reported
Acute toxicity (other routes of administration)	:	LD50 (Rat): 394 mg/kg Application Route: Intraperitoneal LD50 (Mouse): 84 mg/kg Application Route: Intraperitoneal LD50 (Rat): > 640 mg/kg Application Route: Subcutaneous LD50 (Mouse): 263 mg/kg Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.

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.

Moxidectin:

Species	:	Rabbit
Result	:	Mild skin irritation

Serious eye damage/eye irritation

Causes serious 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

Moxidectin:

Species	:	Rabbit
Result	:	Moderate eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

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

Moxidectin:

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

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

Moxidectin:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative Test Type: in vitro test Test system: Escherichia coli Result: negative
Genotoxicity in vivo	:	Test Type: Chromosomal aberration Species: Rat Cell type: Bone marrow Result: negative Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo Species: Rat Cell type: Liver cells 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

Moxidectin:

Species	:	Mouse
Application Route	:	Oral
Exposure time	:	2 Years
NOAEL	:	4.5 mg/kg body weight
Result	:	negative

Species	:	Rat
Application Route	:	Oral
Exposure time	:	2 Years
NOAEL	:	4.5 mg/kg body weight
Result	:	negative

Species	:	Dog
Application Route	:	Oral
Exposure time	:	1 Years
NOAEL	:	0.5 mg/kg body weight
Result	:	negative

Reproductive toxicity

May damage the unborn child.

Components:

N,N-Dimethylacetamide:

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Inhalation Result: negative
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Inhalation Result: positive
Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on development, based on animal experiments.

Fluralaner:

Effects on fertility	:	Test Type: Two-generation study

		Species: Rat Application Route: Oral General Toxicity Parent: NOAEL: 50 mg/kg body weight General Toxicity F1: LOAEL: 100 mg/kg body weight Result: No effects on fertility., Postimplantation loss., Adverse neonatal effects. 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

Moxidectin:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity F1: LOAEL: 0.8 mg/kg body weight Symptoms: Reduced fetal weight., Fetal mortality. Result: No effects on fertility., Some evidence of adverse effects on development, based on animal experiments. Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity F1: LOAEL: 0.8 mg/kg body weight Symptoms: Reduced fetal weight., Fetal mortality. Result: No effects on fertility., Some evidence of adverse effects on development, based on animal experiments.
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Oral General Toxicity Maternal: LOAEL: 10 mg/kg body weight Embryo-fetal toxicity.: LOAEL: 10 mg/kg body weight Result: Skeletal malformations. Remarks: The effects were seen only at maternally toxic doses. Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral General Toxicity Maternal: LOAEL: 5 mg/kg body weight Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: No teratogenic effects., No embryotoxic effects.
Reproductive toxicity - Assessment	:	Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

Components:

Acetone:

Assessment	:	May cause drowsiness or dizziness.

STOT-repeated exposure

Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

Components:

Moxidectin:

Target Organs	:	Central nervous system
Assessment	:	Causes damage to organs through prolonged or repeated

exposure.

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

Moxidectin:

Species	:	Mouse
NOAEL	:	3.9 mg/kg
LOAEL	:	15.4 mg/kg
Application Route	:	Oral
Exposure time	:	4 Weeks
Symptoms	:	Tremors

Species	:	Rat
NOAEL	:	3.9 mg/kg
LOAEL	:	7.9 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Target Organs	:	Central nervous system
Symptoms	:	Tremors, Salivation

Species	:	Dog
NOAEL	:	0.3 mg/kg
LOAEL	:	0.9 mg/kg
Application Route	:	Oral
Exposure time	:	90 Days
Target Organs	:	Central nervous system
Symptoms	:	Tremors, Lachrymation, Salivation

Species	:	Dog
NOAEL	:	1.15 mg/kg
Application Route	:	Oral
Exposure time	:	52 Weeks
Target Organs	:	Central nervous system
Symptoms	:	Tremors, Lachrymation

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

Components:

Fluralaner:

Skin contact	:	Remarks: May irritate skin.
Eye contact	:	Remarks: May cause eye irritation.

Moxidectin:

Inhalation	:	Remarks: No human information is available.

Skin contact	:	Remarks: No human information is available.
Eye contact	:	Remarks: No human information is available.
Ingestion	:	Remarks: No human information is available.

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

Moxidectin:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0006 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 LC50 (Oncorhynchus mykiss (rainbow trout)): 0.0002 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0.00003 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 0.087 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

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

Moxidectin:

Partition coefficient: n-octanol/water	:	log Pow: 4.7

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).

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)	:	364
Packing instruction (passenger aircraft)	:	353

IMDG-Code

UN number	:	UN 1090
Proper shipping name	:	ACETONE SOLUTION (Fluralaner, Moxidectin)
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, essential chemical products and machinery for producing capsules, tablets and pills.	:	Acetone

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)
MX BEI	:	Official Mexican Norm NOM-047-SSA1-2011, Environmental Health - Biological exposure indices for workers occupationally exposed to chemical agents
NOM-010-STPS-2014	:	Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
NOM-010-STPS-2014 / VLE-PPT	:	Time weighted average limit value
NOM-010-STPS-2014 / VLE-CT	:	Short term exposure limit value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for 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, Bioaccumu-

lative 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	:	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.

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.

MX / Z8