

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078945507

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

078938603 078938604 078938605 078946911 078946912

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

### SECTION 1. 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 : 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  
Eye irritation : Category 2A  
Reproductive toxicity : Category 1B  
Specific target organ toxicity : Category 1 (Central nervous system)  
- repeated exposure

#### GHS label elements

Hazard pictograms :   

Signal Word : Danger

Hazard Statements : H225 Highly flammable liquid and vapor.  
H319 Causes serious eye irritation.  
H360D May damage the unborn child.  
H372 Causes damage to organs (Central nervous system)

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Version 7.8      Revision Date: 12/06/2023      SDS Number: 656890-00021      Date of last issue: 09/30/2023  
Date of first issue: 05/02/2016

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, 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.  
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 and face protection.

#### Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308 + P313 IF exposed or concerned: Get medical attention.  
P337 + P313 If eye irritation persists: 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	>= 20 - < 30
N,N-Diethyl-m-toluamide	134-62-3	>= 10 - < 20
Acetone	67-64-1	>= 10 - < 20
Moxidectin	113507-06-5	>= 1 - < 5

# SAFETY DATA SHEET

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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.<br>When symptoms persist or in all cases of doubt seek medical advice.  |
| If inhaled  | : If inhaled, remove to fresh air.<br>Get medical attention.  |
| In case of skin contact                                     | : In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.  |
| If swallowed  | : If swallowed, DO NOT induce vomiting.<br>If vomiting occurs have person lean forward.<br>Call a physician or poison control center immediately.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person. |
| Most important symptoms and effects, both acute and delayed | : Causes serious eye irritation.<br>May damage the unborn child.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Flash back possible over considerable distance.<br>Vapors may form explosive mixtures with air.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products         | : Carbon oxides<br>Chlorine compounds<br>Fluorine compounds<br>Nitrogen oxides (NO <sub>x</sub> )   |

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Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

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.

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Version 7.8      Revision Date: 12/06/2023      SDS Number: 656890-00021      Date of last issue: 09/30/2023  
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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.

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/m <sup>3</sup>	NIOSH REL
		TWA	10 ppm 35 mg/m <sup>3</sup>	OSHA Z-1
Fluralaner	864731-61-3	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: Skin				
		Wipe limit	1000 µg/100 cm <sup>2</sup>	Internal
Acetone	67-64-1	TWA	250 ppm	ACGIH
		STEL	500 ppm	ACGIH
		TWA	250 ppm	NIOSH REL

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Version 7.8      Revision Date: 12/06/2023      SDS Number: 656890-00021      Date of last issue: 09/30/2023  
Date of first issue: 05/02/2016

			590 mg/m <sup>3</sup>	
		TWA	1,000 ppm 2,400 mg/m <sup>3</sup>	OSHA Z-1
Moxidectin	113507-06-5	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	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	ACGIH BEI
Acetone	67-64-1	Acetone	Urine	End of shift (As soon as possible after exposure ceases)	25 mg/l	ACGIH BEI

### Engineering measures

- : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
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 : 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

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7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

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.
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	: 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	: 36 °F / 2 °C Method: closed cup
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: Not applicable



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7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

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/cm <sup>3</sup>
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 mm <sup>2</sup> /s
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
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

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Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

Ingestion  
Eye contact

### Acute toxicity

Not classified based on available information.

### Product:

Acute oral toxicity	: Acute toxicity estimate: 3,547 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), $\alpha$ -[(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
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#### 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

# SAFETY DATA SHEET

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## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

### 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 (Rat): > 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), $\alpha$ -[(tetrahydro-2-furanyl)methyl]- $\omega$ -hydroxy-:

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

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), $\alpha$ -[(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

# SAFETY DATA SHEET

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## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

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

Test Type : KeratinoSens assay  
Method : OECD Test Guideline 442D  
Result : negative  
Remarks : Based on data from similar materials

Test Type : Direct Peptide Reactivity Assay (DPRA)  
Method : OECD Test Guideline 442C  
Result : positive  
Remarks : Based on data from similar materials

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

#### Acetone:

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

### 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), $\alpha$ -[(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
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#### N,N-Diethyl-m-toluamide:

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

Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test Result: negative
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# SAFETY DATA SHEET

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Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

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

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### **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

<b>IARC</b>	Group 2B: Possibly carcinogenic to humans N,N-Dimethylacetamide	127-19-5
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<b>OSHA</b>	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
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<b>NTP</b>	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.
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### **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
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Effects on fetal development	:	Test Type: Embryo-fetal development
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according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

### 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

### 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/m<sup>3</sup>  
LOAEL : 360 mg/m<sup>3</sup>  
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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

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### 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	: 0.3 mg/kg
LOAEL	: 0.87 mg/kg
Application Route	: Oral
Exposure time	: 52 Weeks
Target Organs	: Central nervous system
Symptoms	: Tremors, Lachrymation

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Fluralaner:

Not applicable

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

### 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)):  $\geq$  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):  $\geq$  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  $\mu$ g/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

### **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) : NOEC (Daphnia magna (Water flea)): 3.7 mg/l  
Exposure time: 21 d

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

ic toxicity)

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

Biodegradability	:	Result: Not readily biodegradable. Method: OECD Test Guideline 301F
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# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

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), $\alpha$ -[(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

##### **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:**



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

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  
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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version 7.8      Revision Date: 12/06/2023      SDS Number: 656890-00021      Date of last issue: 09/30/2023  
Date of first issue: 05/02/2016

### 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, Moxidectin)

### 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	33333

### 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  
Specific target organ toxicity (single or repeated exposure)  
Serious eye damage or eye irritation

**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
Acetone	67-64-1
N,N-Diethyl-m-toluamide	134-62-3

#### 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](http://www.P65Warnings.ca.gov).

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

### 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

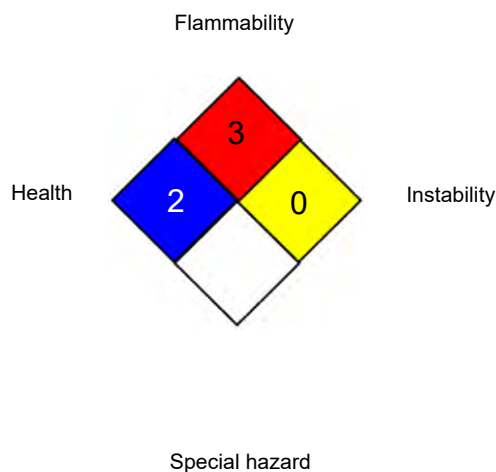
### The ingredients of this product are reported in the following inventories:

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

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.8	12/06/2023	656890-00021	Date of first issue: 05/02/2016

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 : 12/06/2023

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.

US / Z8