

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade 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)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Veterinary product

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Flammable liquids, Category 2	H225: Highly flammable liquid and vapour.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Reproductive toxicity, Category 1B	H360D: May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

Fluralaner / Moxidectin Liquid Formulation

Version 13.2 Revision Date: 02.10.2025 SDS Number: 656891-00027 Date of last issue: 14.04.2025
 Date of first issue: 02.05.2016

egory 1 effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements :
 H225 Highly flammable liquid and vapour.
 H319 Causes serious eye irritation.
 H360D May damage the unborn child.
 H373 May cause damage to organs through prolonged or repeated exposure.
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
 P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P391 Collect spillage.

Hazardous components which must be listed on the label:

N,N-Dimethylacetamide
 Moxidectin

Additional Labelling

Restricted to professional users.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No.	Classification	Concentration (% w/w)

Fluralaner / Moxidectin Liquid Formulation

Version 13.2 Revision Date: 02.10.2025 SDS Number: 656891-00027 Date of last issue: 14.04.2025
 Date of first issue: 02.05.2016

	Registration number		
N,N-Dimethylacetamide	127-19-5 204-826-4 616-011-00-4	Acute Tox. 4; H332 Acute Tox. 4; H312 Eye Irrit. 2; H319 Repr. 1B; H360D	>= 30 - < 50
Fluralaner	864731-61-3	Repr. 2; H361d Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 1.000	>= 25 - < 30
Poly(oxy-1,2-ethanediyl), .alpha.- [(tetrahydro-2-furanyl)methyl]- .omega.-hydroxy-	31692-85-0	Eye Irrit. 2; H319	>= 20 - < 30
N,N-Diethyl-m-toluamide	134-62-3 205-149-7 616-018-00-2	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319	>= 10 - < 20
Acetone	67-64-1 200-662-2 606-001-00-8	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	>= 10 - < 20
Moxidectin	113507-06-5	Acute Tox. 3; H301 Acute Tox. 4; H332 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10.000 M-Factor (Chronic aquatic toxicity): 10.000	>= 1 - < 2,5
2,6-Di-tert-butyl-p-cresol	128-37-0 204-881-4	Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	>= 0,1 - < 0,25

For explanation of abbreviations see section 16.

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

SECTION 4: First aid measures**4.1 Description of 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. |
| 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). |
| 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 centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person. |

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|-------|---|--|
| Risks | : | Causes serious eye irritation.
May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure. |
|-------|---|--|

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|
-

SECTION 5: Firefighting measures**5.1 Extinguishing media**

- | | | |
|------------------------------|---|--|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
| Unsuitable extinguishing | : | High volume water jet |
-

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

media

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Chlorine compounds
Fluorine compounds
Nitrogen oxides (NO_x)

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : 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).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Non-sparking tools should be used.
Soak up with inert absorbent material.
Suppress (knock down) gases/vapours/mists with a water spray jet.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

- | | | |
|-------------------------|---|--|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment. |
| Advice on safe handling | : | Do not get on skin or clothing.
Do not breathe mist or vapours.
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. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition. |
| Advice on common storage | : | Do not store with the following product types: |

Fluralaner / Moxidectin Liquid Formulation

Version 13.2 Revision Date: 02.10.2025 SDS Number: 656891-00027 Date of last issue: 14.04.2025
 Date of first issue: 02.05.2016

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

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
N,N-Dimethylacetamide	127-19-5	OEL-RL	20 ppm	ZA OEL
	Further information: danger of cutaneous absorption, Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents			
		TWA	10 ppm 36 mg/m ³	2000/39/EC
		STEL	20 ppm 72 mg/m ³	2000/39/EC
		TWA	10 ppm 36 mg/m ³	2004/37/EC
		STEL	20 ppm 72 mg/m ³	2004/37/EC
Fluralaner	864731-61-3	TWA	100 µg/m ³ (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 µg/100 cm ²	Internal
Acetone	67-64-1	OEL- RL STEL/C	1.000 ppm	ZA OEL
	Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents			
		OEL-RL	500 ppm	ZA OEL
	Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents			
		TWA	500 ppm 1.210 mg/m ³	2000/39/EC
Moxidectin	113507-06-5	TWA	10 µg/m ³ (OEB 3)	Internal
		Wipe limit	100 µg/100 cm ²	Internal

Fluralaner / Moxidectin Liquid Formulation

Version 13.2 Revision Date: 02.10.2025 SDS Number: 656891-00027 Date of last issue: 14.04.2025
 Date of first issue: 02.05.2016

Biological occupational exposure limits

Substance name	CAS-No.	Control parameters	Sampling time	Basis
N,N-Dimethylacetamide	127-19-5	N-Methylacetamide: 30 mg/g creatinine (Urine)	End of shift at end of workweek	ZA BEI
Acetone	67-64-1	Acetone: 25 mg/l (Urine)	End of shift	ZA BEI

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
N,N-Dimethylacetamide	Workers	Inhalation	Long-term systemic effects	36 mg/m ³
	Workers	Inhalation	Acute systemic effects	36 mg/m ³
	Workers	Skin contact	Acute systemic effects	13,6 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	7 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	2,7 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	1 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	1 mg/kg bw/day
Acetone	Workers	Inhalation	Long-term systemic effects	1210 mg/m ³
	Workers	Inhalation	Acute local effects	2420 mg/m ³
	Workers	Skin contact	Long-term systemic effects	186 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	200 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	62 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	62 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	62 mg/kg bw/day
2,6-Di-tert-butyl-p-cresol	Workers	Inhalation	Long-term systemic effects	3,5 mg/m ³
	Workers	Dermal	Long-term systemic effects	0,5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,86 mg/m ³
	Consumers	Dermal	Long-term systemic effects	0,25 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,25 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,25 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,25 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Fluralaner	Water	7 ng/l
Moxidectin	Water	0,3 ng/l
N,N-Dimethylacetamide	Fresh water	0,5 mg/l
	Marine water	0,0966 mg/l
	Intermittent use/release	5 mg/l
	Sewage treatment plant	485 mg/l
	Sewage treatment plant	485 mg/l

Fluralaner / Moxidectin Liquid Formulation

Version 13.2 Revision Date: 02.10.2025 SDS Number: 656891-00027 Date of last issue: 14.04.2025
 Date of first issue: 02.05.2016

	Fresh water sediment	2,27 mg/kg
	Soil	0,15 mg/kg
Acetone	Fresh water	10,6 mg/l
	Marine water	1,06 mg/l
	Intermittent use/release	21 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	30,4 mg/kg dry weight (d.w.)
	Marine sediment	3,04 mg/kg dry weight (d.w.)
	Soil	29,5 mg/kg dry weight (d.w.)
2,6-Di-tert-butyl-p-cresol	Fresh water	0,199 µg/l
	Intermittent use/release	0,02 µg/l
	Marine water	0,02 µg/l
	Sewage treatment plant	0,17 mg/l
	Fresh water sediment	0,0996 mg/kg dry weight (d.w.)
	Marine sediment	0,00996 mg/kg dry weight (d.w.)
	Soil	0,04769 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	8,33 mg/kg food

8.2 Exposure controls

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

- Eye/face protection : Wear safety glasses with side shields or goggles.
 If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
 Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- 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.
- 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

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

Respiratory protection	:	contaminated clothing. 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

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state	:	liquid
Form	:	liquid
Colour	:	Colorless to pale yellow
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	1,06
Density	:	1,08 g/cm ³
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

Viscosity		
Viscosity, kinematic	:	7,5 mm ² /s
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Particle size	:	Not applicable
---------------	---	----------------

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	Highly flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
---------------------	---	--

10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks.
---------------------	---	--------------------------

10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
--------------------	---	------------------

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

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, female): > 2.000 mg/kg Method: OECD Test Guideline 423
---------------------	---	--

Acute inhalation toxicity	:	Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist
---------------------------	---	---

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

Method: Calculation method

Acute dermal toxicity : LD50 (Rat, male and female): > 2.000 mg/kg
Method: OECD Test Guideline 402

Components:**N,N-Dimethylacetamide:**

Acute oral toxicity : LD50 (Rat): 4.800 mg/kg

Acute inhalation toxicity : LC50 (Rat): 2,2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : Acute toxicity estimate: 1.100 mg/kg
Method: Expert judgement
Remarks: Based on national or regional regulation.

Fluralaner:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Remarks: No mortality observed at this dose.
No significant adverse effects were reported

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Remarks: No significant adverse effects were reported

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

Acute oral toxicity : LD50 (Rat, female): > 2.000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:

Acute oral toxicity : LD50 (Rat): 1.892 mg/kg

Acute inhalation toxicity : LC50 (Rat): 5,95 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): 5.000 mg/kg

Acetone:

Acute oral toxicity : LD50 (Rat): 5.800 mg/kg

Acute inhalation toxicity : LC50 (Rat): 76 mg/l
Exposure time: 4 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): 7.426 mg/kg

Moxidectin:

Acute oral toxicity : LD50 (Rat): 106 mg/kg

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

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

2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity : LD50 (Rat): > 6.000 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

Product:

Species : Rabbit
Assessment : No skin irritation
Method : OECD Test Guideline 404

Components:**N,N-Dimethylacetamide:**

Species : Rabbit
Result : No skin irritation

Fluralaner:

Species : Rabbit
Result : No skin irritation

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

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

Species	: reconstructed human epidermis (RhE)
Method	: OECD Test Guideline 439
Remarks	: Based on data from similar materials
Result	: No skin irritation

N,N-Diethyl-m-toluamide:

Species	: Rabbit
Result	: Skin irritation
Remarks	: Based on national or regional regulation.

Acetone:

Assessment	: Repeated exposure may cause skin dryness or cracking.
------------	---

Moxidectin:

Species	: Rabbit
Result	: Mild skin irritation

2,6-Di-tert-butyl-p-cresol:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation
Remarks	: Based on data from similar materials

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Species	: Rabbit
Method	: OECD Test Guideline 405
Result	: Irritation to eyes, reversing within 21 days

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

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

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
Method	:	OECD Test Guideline 405
Result	:	Irritation to eyes, reversing within 21 days

Moxidectin:

Species	:	Rabbit
Result	:	Moderate eye irritation

2,6-Di-tert-butyl-p-cresol:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	No eye irritation
Remarks	:	Based on data from similar materials

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

Test Type	:	Local lymph node assay (LLNA)
Method	:	OECD Test Guideline 429
Result	:	negative

Components:**N,N-Dimethylacetamide:**

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

Fluralaner:

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

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

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

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

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

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

Acetone:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative

Moxidectin:

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

2,6-Di-tert-butyl-p-cresol:

Test Type	: Human repeat insult patch test (HRIPT)
Exposure routes	: Skin contact
Species	: Humans
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)
-----------------------	--

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

Result: negative

Test Type: Mouse Lymphoma

Result: negative

Test Type: Chromosomal aberration

Result: negative

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

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

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

N,N-Diethyl-m-toluamide:

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

Acetone:

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

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

Test Type: Chromosome aberration test in vitro
Result: negative

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

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 assay
Test system: Escherichia coli
Result: negative

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

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

2,6-Di-tert-butyl-p-cresol:

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

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

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**N,N-Dimethylacetamide:**

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

Fluralaner:

Carcinogenicity - Assessment : No data available

N,N-Diethyl-m-toluamide:

Species : Rat
Application Route : Ingestion
Exposure time : 104 weeks
Result : negative

Acetone:

Species : Mouse
Application Route : Skin contact
Exposure time : 424 days

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

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

2,6-Di-tert-butyl-p-cresol:

Species : Rat
Application Route : Ingestion
Exposure time : 22 Months
Result : negative

Reproductive toxicity

May damage the unborn child.

Components:**N,N-Dimethylacetamide:**

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Inhalation
Result: negative

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

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

Fluralaner:

Effects on fertility : Test Type: Two-generation study
Species: Rat
Application Route: Oral
General Toxicity - Parent: NOAEL: 50 mg/kg body weight
General Toxicity F1: LOAEL: 100 mg/kg body weight

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

- Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects.
- Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects
- Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: Skeletal malformations, Visceral malformations
Remarks: Maternal toxicity observed.
- Test Type: Development
Species: Rabbit
Application Route: Dermal
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Skeletal malformations
- Reproductive toxicity - Assessment : Suspected of damaging the unborn child.
- N,N-Diethyl-m-toluamide:**
- Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
- Acetone:**
- Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
- Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: inhalation (vapour)
Result: negative
- 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 foetal weight, foetal mortality
Result: No effects on fertility, Some evidence of adverse effects on development, based on animal experiments.
- Test Type: Three-generation reproduction toxicity study

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

Species: Rat
Application Route: Oral
General Toxicity F1: LOAEL: 0,8 mg/kg body weight
Symptoms: Reduced foetal weight, foetal mortality
Result: No effects on fertility, Some evidence of adverse effects on development, based on animal experiments.

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 10 mg/kg body weight
Embryo-foetal toxicity: LOAEL: 10 mg/kg body weight
Result: Skeletal malformations
Remarks: The effects were seen only at maternally toxic doses.

Test Type: Embryo-foetal 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.

2,6-Di-tert-butyl-p-cresol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

STOT - single exposure

Not classified based on available information.

Components:**Acetone:**

Assessment : May cause drowsiness or dizziness.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:**Moxidectin:**

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

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

2,6-Di-tert-butyl-p-cresol:

Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity**Components:****N,N-Dimethylacetamide:**

Species : Rat
NOAEL : 90 mg/m³
LOAEL : 360 mg/m³
Application Route : inhalation (vapour)
Exposure time : 24 Months

Fluralaner:

Species : Dog
NOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 52 Weeks
Target Organs : Liver
Remarks : No significant adverse effects were reported

Species : Rat
LOAEL : 400 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Liver, thymus gland

Species : Rat
NOAEL : 500 mg/kg
Application Route : Dermal
Exposure time : 90 Days
Target Organs : Liver
Remarks : No significant adverse effects were reported

Acetone:

Species : Rat
NOAEL : 900 mg/kg
LOAEL : 1.700 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Species : Rat
NOAEL : 45 mg/l
Application Route : inhalation (vapour)
Exposure time : 8 Weeks

Moxidectin:

Species : Mouse
NOAEL : 3,9 mg/kg

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

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

2,6-Di-tert-butyl-p-cresol:

Species : Rat
NOAEL : 25 mg/kg
Application Route : Ingestion
Exposure time : 22 Months

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**Components:****Fluralaner:**

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

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

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

12.1 Toxicity

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: >= 0,049 mg/l Exposure time: 21 d Species: Zebrafish Method: OECD Test Guideline 204 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic)	:	NOEC: 0,0736 µg/l Exposure time: 21 d

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

25 / 33

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

Toxicity to microorganisms : EC50 : 61.150 mg/l
Exposure time: 30 min
Method: ISO 8192

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: \geq 79 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

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

M-Factor (Acute aquatic toxicity) : 10.000

M-Factor (Chronic aquatic toxicity) : 10.000

2,6-Di-tert-butyl-p-cresol:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 0,57 mg/l
Exposure time: 96 h
Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,48 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0,24 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,24 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

Toxicity to microorganisms	:	EC50 : > 10.000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	:	NOEC: 0,053 mg/l Exposure time: 30 d Species: Oryzias latipes (Japanese medaka) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0,316 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)
M-Factor (Chronic aquatic toxicity)	:	1

12.2 Persistence and degradability**Components:****N,N-Dimethylacetamide:**

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 70 % Exposure time: 28 d Method: OECD Test Guideline 301C Remarks: The test was conducted equivalent or similar to guideline
------------------	---	---

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

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

N,N-Diethyl-m-toluamide:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 83,8 % Exposure time: 28 d Method: OECD Test Guideline 301B
------------------	---	---

Acetone:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 91 % Exposure time: 28 d
------------------	---	---

2,6-Di-tert-butyl-p-cresol:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 4,5 % Exposure time: 28 d Method: OECD Test Guideline 301C
------------------	---	--

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

12.3 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

2,6-Di-tert-butyl-p-cresol:

Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 330 - 1.800

Partition coefficient: n-octanol/water : log Pow: 5,1

12.4 Mobility in soil

Components:**Fluralaner:**

Distribution among environmental compartments : log Koc: 4,1

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Components:**Fluralaner:**

Assessment : Not persistent, bioaccumulative, and toxic (PBT).

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

12.6 Other adverse effects**Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
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**14.1 UN number**

ADN : UN 1090
ADR : UN 1090
RID : UN 1090
IMDG : UN 1090
IATA : UN 1090

14.2 UN proper shipping name

ADN : ACETONE, SOLUTION
ADR : ACETONE, SOLUTION
RID : ACETONE, SOLUTION
IMDG : ACETONE, SOLUTION
(Fluralaner, Moxidectin)
IATA : Acetone, solution

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 3	

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

ADR	:	3
RID	:	3
IMDG	:	3
IATA	:	3

14.4 Packing group**ADN**

Packing group	:	II
Classification Code	:	F1
Hazard Identification Number	:	33
Labels	:	3

ADR

Packing group	:	II
Classification Code	:	F1
Hazard Identification Number	:	33
Labels	:	3
Tunnel restriction code	:	(D/E)

RID

Packing group	:	II
Classification Code	:	F1
Hazard Identification Number	:	33
Labels	:	3

IMDG

Packing group	:	II
Labels	:	3
EmS Code	:	F-E, S-D

IATA (Cargo)

Packing instruction (cargo aircraft)	:	364
Packing instruction (LQ)	:	Y341
Packing group	:	II
Labels	:	Flammable Liquids

IATA (Passenger)

Packing instruction (passenger aircraft)	:	353
Packing instruction (LQ)	:	Y341
Packing group	:	II
Labels	:	Flammable Liquids

14.5 Environmental hazards**ADN**

Environmentally hazardous	:	yes
---------------------------	---	-----

ADR

Environmentally hazardous	:	yes
---------------------------	---	-----

RID

Environmentally hazardous	:	yes
---------------------------	---	-----

IMDG

Marine pollutant	:	yes
------------------	---	-----

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

AICS : not determined

CA. DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H225	: Highly flammable liquid and vapour.
H301	: Toxic if swallowed.
H302	: Harmful if swallowed.
H312	: Harmful in contact with skin.
H315	: Causes skin irritation.
H319	: Causes serious eye irritation.
H332	: Harmful if inhaled.
H336	: May cause drowsiness or dizziness.
H360D	: May damage the unborn child.
H361d	: Suspected of damaging the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Eye Irrit.	: Eye irritation

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

Flam. Liq.	: Flammable liquids
Repr.	: Reproductive toxicity
Skin Irrit.	: Skin irritation
STOT RE	: Specific target organ toxicity - repeated exposure
STOT SE	: Specific target organ toxicity - single exposure
2000/39/EC	: Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
2004/37/EC	: Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work - Annex III
ZA BEI	: South Africa. The Regulations for Hazardous Chemical Agents, Biological Exposure Indices
ZA OEL	: South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
2000/39/EC / TWA	: Limit Value - eight hours
2000/39/EC / STEL	: Short term exposure limit
2004/37/EC / STEL	: Short term exposure limit
2004/37/EC / TWA	: Long term exposure limit
ZA OEL / OEL-RL	: Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)
ZA OEL / OEL- RL STEL/C	: Occupational Exposure Limit Restricted limit - Short term occupational exposure limits / ceiling limits

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonised 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 Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
13.2	02.10.2025	656891-00027	Date of first issue: 02.05.2016

Further information

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

Classification of the mixture:

Flam. Liq. 2	H225
Eye Irrit. 2	H319
Repr. 1B	H360D
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Based on product data or assessment
Based on product data or assessment
Calculation method
Calculation method
Calculation method
Calculation method

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.

ZA / EN