

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	02.10.2025	7900796-00013	Date of first issue: 17.03.2021

SECTION 1. IDENTIFICATION

Product name : Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Skin corrosion/irritation : Category 3

Reproductive toxicity : Category 2

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H316 Causes mild skin irritation.
H361d Suspected of damaging the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**

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P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

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

Additional Labeling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 18 %

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 20 -< 30
4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1)	22204-24-6	>= 10 -< 20
Fluralaner	864731-61-3	>= 10 -< 20
Magnesium Aluminometasilicate	12511-31-8	>= 5 -< 10
Sodium dodecyl sulphate	151-21-3	>= 1 -< 2,5
2,6-Di-tert-butyl-p-cresol	128-37-0	>= 0,1 -< 0,25
Moxidectin	113507-06-5	>= 0,025 -< 0,1

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

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

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In case of skin contact	:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse.
In case of eye contact	:	Thoroughly clean shoes before reuse. If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Causes mild skin irritation. Suspected of damaging the unborn child. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Chlorine compounds Fluorine compounds Nitrogen oxides (NO _x) Sulfur oxides Metal oxides Silicon oxides
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 measures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal
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|---|---|---|
| agency procedures | : | protective equipment recommendations (see section 8). |
| Environmental precautions | : | <p>Avoid release to the environment.</p> <p>Prevent further leakage or spillage if safe to do so.</p> <p>Retain and dispose of contaminated wash water.</p> <p>Local authorities should be advised if significant spillages cannot be contained.</p> |
| Methods and materials for containment and cleaning up | : | <p>Sweep up or vacuum up spillage and collect in suitable container for disposal.</p> <p>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).</p> <p>Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.</p> <p>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.</p> <p>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.</p> |

SECTION 7. HANDLING AND STORAGE

- | | | |
|-----------------------------|---|--|
| Technical measures | : | <p>Static electricity may accumulate and ignite suspended dust causing an explosion.</p> <p>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</p> |
| Local/Total ventilation | : | Use only with adequate ventilation. |
| Advice on safe handling | : | <p>Do not get on skin or clothing.</p> <p>Do not breathe dust.</p> <p>Do not swallow.</p> <p>Avoid contact with eyes.</p> <p>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment</p> <p>Minimize dust generation and accumulation.</p> <p>Keep container closed when not in use.</p> <p>Keep away from heat and sources of ignition.</p> <p>Take precautionary measures against static discharges.</p> <p>Take care to prevent spills, waste and minimize release to the environment.</p> |
| Conditions for safe storage | : | <p>Keep in properly labeled containers.</p> <p>Store locked up.</p> <p>Store in accordance with the particular national regulations.</p> |
| Materials to avoid | : | <p>Do not store with the following product types:</p> <p>Strong oxidizing agents</p> |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

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Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	CMP	10 mg/m ³	AR OEL
		TWA	10 mg/m ³	ACGIH
4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1)	22204-24-6	TWA	250 µg/m ³ (OEB 2)	Internal
Fluralaner	864731-61-3	TWA	100 µg/m ³ (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 µg/100 cm ²	Internal
Magnesium Aluminometasilicate	12511-31-8	TWA (Respirable particulate matter)	1 mg/m ³ (Aluminum)	ACGIH
2,6-Di-tert-butyl-p-cresol	128-37-0	CMP (Vapour and aerosol, inhalable fraction)	2 mg/m ³	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			
		TWA (Inhalable fraction and vapor)	2 mg/m ³	ACGIH
Moxidectin	113507-06-5	TWA	10 µg/m ³ (OEB 3)	Internal
		Wipe limit	100 µg/100 cm ²	Internal

Engineering measures : 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.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type
Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.
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.

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Skin and body protection	:	Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. 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	:	solid
Color	:	light pink, to, light brown
Odor	:	aromatic
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	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable

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Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
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	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Skin contact Ingestion Eye contact
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Acute toxicity

Not classified based on available information.

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Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Components:

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Acute oral toxicity : LD50 (Rat): > 24.000 mg/kg
LD50 (Mouse): > 24.000 mg/kg
LD50 (Dog): 2.000 mg/kg

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

Magnesium Aluminometasilicate:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 3.500 mg/kg

Sodium dodecyl sulphate:

Acute oral toxicity : LD50 (Rat): 1.200 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

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

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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

Moxidectin:

Acute oral toxicity	:	LD50 (Rat): 106 mg/kg LD50 (Mouse): 42 - 84 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): 3,28 mg/l Exposure time: 5 h Test atmosphere: dust/mist LC50 (Rat): 2,87 - 4,06 mg/l Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2.000 mg/kg Remarks: No significant adverse effects were reported
Acute toxicity (other routes of administration)	:	LD50 (Rat): 394 mg/kg Application Route: Intraperitoneal LD50 (Mouse): 84 mg/kg Application Route: Intraperitoneal LD50 (Rat): > 640 mg/kg Application Route: Subcutaneous LD50 (Mouse): 263 mg/kg Application Route: Subcutaneous

Skin corrosion/irritation

Causes mild skin irritation.

Components:

Fluralaner:

Species	:	Rabbit
Result	:	No skin irritation

Magnesium Aluminometasilicate:

Species	:	Rabbit
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

Sodium dodecyl sulphate:

Species	:	Rabbit
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|| Result : 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

Moxidectin:

|| Species : Rabbit
|| Result : Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Fluralaner:**

|| Species : Rabbit
|| Result : Mild eye irritation

Magnesium Aluminometasilicate:

|| Species : Rabbit
|| Result : No eye irritation
|| Remarks : Based on data from similar materials

Sodium dodecyl sulphate:

|| Species : Rabbit
|| Result : Irreversible effects on the eye
|| Method : OECD Test Guideline 405

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

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

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.

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Components:**Fluralaner:**

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

Magnesium Aluminometasilicate:

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative
Remarks	: Based on data from similar materials

Sodium dodecyl sulphate:

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative
Remarks	: Based on data from similar materials

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

Test Type	: Human repeat insult patch test (HRIPT)
Routes of exposure	: Skin contact
Species	: Humans
Result	: negative

Moxidectin:

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

Germ cell mutagenicity

Not classified based on available information.

Components:**Cellulose:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse

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Application Route: Ingestion
Result: negative

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

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

Magnesium Aluminometasilicate:

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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Sodium dodecyl sulphate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test

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Genotoxicity in vivo	Result: negative
	: Test Type: Rodent dominant lethal test (germ cell) (in vivo)
	Species: Mouse
	Application Route: Ingestion
	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
Genotoxicity in vivo	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

Moxidectin:

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

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Components:**Cellulose:**

Species	: Rat
Application Route	: Ingestion
Exposure time	: 72 weeks
Result	: negative

Fluralaner:

Carcinogenicity - Assessment	: No data available
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Magnesium Aluminometasilicate:

Species	: Rat
Application Route	: Ingestion
Exposure time	: 103 weeks
Result	: negative
Remarks	: Based on data from similar materials

Sodium dodecyl sulphate:

Species	: Rat
Application Route	: Ingestion
Exposure time	: 2 Years
Method	: OECD Test Guideline 453
Result	: negative
Remarks	: Based on data from similar materials

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

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

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|| Result : negative

Reproductive toxicity

Suspected of damaging the unborn child.

Components:**Cellulose:**

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

|| Effects on fetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

|| Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 3.000 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 1.000 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

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.

|| 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

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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.

Magnesium Aluminometasilicate:

Effects on fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Ingestion
 Result: negative
 Remarks: Based on data from similar materials

Sodium dodecyl sulphate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 416
 Result: negative
 Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Ingestion
 Result: negative
 Remarks: Based on data from similar materials

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 fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Ingestion
 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

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		<p>Symptoms: Reduced fetal weight., Fetal mortality. Result: No effects on fertility., Some evidence of adverse effects on development, based on animal experiments.</p> <p>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.</p>
Effects on fetal development	:	<p>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.</p> <p>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.</p>
Reproductive toxicity - Assessment	:	Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Components:

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

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

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

Repeated dose toxicity

Components:

Cellulose:

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Species	: Rat
NOAEL	: >= 9.000 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Species	: Dog
NOAEL	: 10 mg/kg
LOAEL	: 30 mg/kg
Application Route	: Ingestion
Exposure time	: 3 d
Remarks	: No significant adverse effects were reported

Species	: Dog
NOAEL	: 600 mg/kg
Application Route	: Oral
Exposure time	: 19 d
Remarks	: No significant adverse effects were reported

Species	: Dog
NOAEL	: 600 mg/kg
Application Route	: Oral
Exposure time	: 30 d
Remarks	: No significant adverse effects were reported

Species	: Dog
NOAEL	: 600 mg/kg
Application Route	: Oral
Exposure time	: 90 d
Remarks	: No significant adverse effects were reported

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

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Magnesium Aluminometasilicate:

Species	: Rat
	: ≥ 1000 mg/kg
Application Route	: Ingestion
Exposure time	: 100 Days

Sodium dodecyl sulphate:

Species	: Rat
NOAEL	: 488 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days
Remarks	: Based on data from similar materials

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

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

Moxidectin:

Species	: Mouse
NOAEL	: 3,9 mg/kg
LOAEL	: 15,4 mg/kg
Application Route	: Oral
Exposure time	: 4 Weeks
Symptoms	: Tremors

Species	: Rat
NOAEL	: 3,9 mg/kg
LOAEL	: 7,9 mg/kg
Application Route	: Oral
Exposure time	: 13 Weeks
Target Organs	: Central nervous system
Symptoms	: Tremors, Salivation

Species	: Dog
NOAEL	: 0,3 mg/kg
LOAEL	: 0,9 mg/kg
Application Route	: Oral
Exposure time	: 90 Days
Target Organs	: Central nervous system
Symptoms	: Tremors, Lachrymation, Salivation

Species	: Dog
NOAEL	: 1,15 mg/kg
Application Route	: Oral
Exposure time	: 52 Weeks
Target Organs	: Central nervous system
Symptoms	: Tremors, Lachrymation

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Aspiration toxicity

Not classified based on available information.

Components:**Fluralaner:**

|| Not applicable

Experience with human exposure**Components:**

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Ingestion	:	Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea, Headache, Dizziness, Fever
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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:****Cellulose:**

Toxicity to fish	:	LC50 (<i>Oryzias latipes</i> (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
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4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Ecotoxicology Assessment

Acute aquatic toxicity	:	Toxic effects cannot be excluded
Chronic aquatic toxicity	:	Toxic effects cannot be excluded

Fluralaner:

Toxicity to fish	:	LC50 (<i>Oncorhynchus mykiss</i> (rainbow trout)): > 0,0488 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility.
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Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 0,015 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility.
Toxicity to algae/aquatic plants	:	NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0,08 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility.
Toxicity to fish (Chronic toxicity)	:	NOEC (Zebrafish): >= 0,049 mg/l Exposure time: 21 d Method: OECD Test Guideline 204 Remarks: No toxicity at the limit of solubility.
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0,0736 µg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1.000

Magnesium Aluminometasilicate:

Ecotoxicology Assessment

Chronic aquatic toxicity	:	No toxicity at the limit of solubility.
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Sodium dodecyl sulphate:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 29 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 5,55 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l Exposure time: 72 h NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l Exposure time: 72 h
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): >= 1,357 mg/l Exposure time: 42 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Ceriodaphnia dubia (water flea)): 0,88 mg/l Exposure time: 7 d
Toxicity to microorganisms	:	EC50: 135 mg/l Exposure time: 3 h

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

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 0,57 mg/l
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	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
Toxicity to fish (Chronic toxicity)	: NOEC (Oryzias latipes (Japanese medaka)): 0,053 mg/l Exposure time: 30 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0,316 mg/l Exposure time: 21 d
M-Factor (Chronic aquatic toxicity)	: 1
Toxicity to microorganisms	: EC50: > 10.000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

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

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||toxicity)

Persistence and degradability**Components:****Cellulose:**

||Biodegradability : Result: Readily biodegradable.

Sodium dodecyl sulphate:||Biodegradability : Result: Readily biodegradable.
Biodegradation: 95 %
Exposure time: 28 d
Method: OECD Test Guideline 301B**2,6-Di-tert-butyl-p-cresol:**||Biodegradability : Result: Not readily biodegradable.
Biodegradation: 4,5 %
Exposure time: 28 d
Method: OECD Test Guideline 301C**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

Sodium dodecyl sulphate:

||Partition coefficient: n-octanol/water : log Pow: 0,83

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

Moxidectin:

||Partition coefficient: n-octanol/water : log Pow: 4,7

Mobility in soil**Components:****Fluralaner:**

||Distribution among environ- : log Koc: 4,1

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II mental compartments**Other adverse effects****Components:****Fluralaner:****II** Results of PBT and vPvB assessment : Not persistent, bioaccumulative, and toxic (PBT).**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
II Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner, Moxidectin)
II Class	:	9
II Packing group	:	III
II Labels	:	9
Environmentally hazardous	:	yes

MERCOSUR

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner, Moxidectin)
II Class	:	9
II Packing group	:	III
II Labels	:	9
Environmentally hazardous	:	yes

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Fluralaner, Moxidectin)
II Class	:	9
II Packing group	:	III
II Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

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Remarks : Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids.

IMDG-Code

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner, Moxidectin)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes
Remarks : Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids.

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

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

CA. DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 02.10.2025
Date format : dd.mm.yyyy

Further information

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/>

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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 other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AR OEL	:	Argentina. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
AR OEL / CMP	:	TLV (Threshold Limit Value)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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