

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Section 1: Identification

Product identifier : Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD
Address : 50 Tuas West Drive
Singapore - Singapore 638408
Telephone : +1-908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification**Classification of the substance or mixture**

Reproductive toxicity : Category 2
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS Label elements, including precautionary statements

Hazard pictograms :



Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

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/ hearing protection.

Response:

P308 + P313 IF exposed or concerned: 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 Labelling

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	>= 1 -< 10
Sodium n-dodecyl sulfate	151-21-3	>= 1 -< 3
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**Description of necessary 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.

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
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. Thoroughly clean shoes before reuse.
In case of eye contact	:	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

Risks	:	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).

Indication of any immediate medical attention and special treatment needed

Treatment	:	Treat symptomatically and supportively.
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Section 5: Fire-fighting measures**Extinguishing media**

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.

Special hazards arising from the substance or mixture

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) Sulphur oxides Metal oxides Silicon oxides

Special protective actions for fire-fighters

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.

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

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

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
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.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage**Precautions for safe handling**

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.

Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 3.0 Revision Date: 06.07.2024 SDS Number: 7900799-00011 Date of last issue: 13.04.2024
Date of first issue: 17.03.2021

Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

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

Conditions for safe storage, including any incompatibilities

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	PEL (long term)	10 mg/m ³	SG 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 (Aluminium)	ACGIH
2,6-Di-tert-butyl-p-cresol	128-37-0	PEL (long term)	10 mg/m ³	SG OEL

Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 3.0 Revision Date: 06.07.2024 SDS Number: 7900799-00011 Date of last issue: 13.04.2024
 Date of first issue: 17.03.2021

		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

Appropriate engineering control 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.

Individual protection measures, such as personal protective equipment (PPE)

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.

Skin protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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.

Section 9: Physical and chemical properties

Appearance : solid

Colour : light pink, to, light brown

Odour : aromatic

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

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
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition 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

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

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	:	Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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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
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Fluralaner:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
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**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

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 n-dodecyl sulfate:

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:

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

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Acute toxicity (other routes of administration) : LD50 (Rat): 394 mg/kg
Application Route: Intraperitoneal

LD50 (Mouse): 84 mg/kg
Application Route: Intraperitoneal

LD50 (Rat): > 640 mg/kg
Application Route: Subcutaneous

LD50 (Mouse): 263 mg/kg
Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.

Components:**Fluralaner:**

Species : Rabbit
Result : No skin irritation

Magnesium Aluminometasilicate:

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

Sodium n-dodecyl sulfate:

Species : Rabbit
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.

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Components:**Fluralaner:**

Species	:	Rabbit
Result	:	Mild eye irritation

Magnesium Aluminometasilicate:

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

Sodium n-dodecyl sulfate:

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 sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Fluralaner:**

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

Magnesium Aluminometasilicate:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Result : negative
Remarks : Based on data from similar materials

Sodium n-dodecyl sulfate:

Test Type : Maximisation Test
Exposure routes : 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)
Exposure routes : Skin contact
Species : Humans
Result : negative

Moxidectin:

Test Type : Buehler Test
Exposure routes : 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
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)

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Result: negative

Test Type: Mouse Lymphoma
Result: negativeTest 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 n-dodecyl sulfate:

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
Result: negative

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

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

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

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

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

Genotoxicity in vivo : Test Type: Chromosomal aberration
Species: Rat
Cell type: Bone marrow
Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with
mammalian liver cells in vivo
Species: Rat
Cell type: Liver cells
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Cellulose:**

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

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Fluralaner:

Carcinogenicity - Assessment : No data available

Magnesium Aluminometasilicate:

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

Sodium n-dodecyl sulfate:

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
Result : negative

Reproductive toxicity

Suspected of damaging the unborn child.

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Components:**Cellulose:**

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

Effects on foetal 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 foetal development : Test Type: Embryo-foetal 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-foetal 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.

Test Type: One-generation reproduction toxicity study
Species: Dog
Application Route: Oral
Fertility: NOAEL: 75 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.
Remarks: No significant adverse effects were reported

Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the off-spring 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.

Magnesium Aluminometasilicate:

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

Sodium n-dodecyl sulfate:

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 foetal development : Test Type: Embryo-foetal 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 foetal development : Test Type: Embryo-foetal development
Species: Rat

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

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
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
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.

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.

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Moxidectin:

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

Repeated dose toxicity**Components:****Cellulose:**

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

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Target Organs : Liver
Remarks : No significant adverse effects were reported

Species : Juvenile dog
LOAEL : 56 - 280 mg/kg
Application Route : Oral
Exposure time : 24 Weeks
Symptoms : Diarrhoea

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

Magnesium Aluminometasilicate:

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

Sodium n-dodecyl sulfate:

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

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

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

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

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

Aspiration toxicity

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, Diarrhoea, 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.

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Section 12: Ecological information**Toxicity****Components:****Cellulose:**

Toxicity to fish : LC50 (*Oryzias latipes* (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

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 (*Oncorhynchus mykiss* (rainbow trout)): > 0.0488 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 0.015 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : NOEC (*Pseudokirchneriella subcapitata* (green algae)): >= 0.08 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : NOEC (Zebrafish): >= 0.049 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 204
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 0.0736 µg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1,000

Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Magnesium Aluminometasilicate:

Ecotoxicology Assessment

Chronic aquatic toxicity : No toxicity at the limit of solubility

Sodium n-dodecyl sulfate:

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
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 / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

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

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

Biodegradability : Result: Readily biodegradable.

Sodium n-dodecyl sulfate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 95 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

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

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

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 n-dodecyl sulfate:

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 environmental compartments : log Koc: 4.1

Other adverse effects**Components:****Fluralaner:**

Results of PBT and vPvB assessment : Substance is not persistent, bioaccumulative, and toxic (PBT).

Section 13: Disposal considerations**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Contaminated packaging : Dispose of in accordance with local regulations.
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
UN proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner, Moxidectin)
Transport hazard class(es)	: 9
Packing group	: III
Labels	: 9
Environmental hazards	: yes

IATA-DGR

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

IMDG-Code

UN number	: UN 3077
Proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner, Moxidectin)
Transport hazard class(es)	: 9
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
Marine pollutant	: yes

Transport in bulk according to IMO instruments

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.

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

Section 15: Regulatory information**Safety, health and environmental regulations specific for the product in question**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable
Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 06.07.2024

Further information

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

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
SG OEL : Singapore. Workplace Safety and Health (General Provisions)
Regulations - First Schedule Permissible Exposure Limits of
Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule;

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.04.2024
3.0	06.07.2024	7900799-00011	Date of first issue: 17.03.2021

ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

SG / EN