

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

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

Use of the Substance/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)

Reproductive toxicity, Category 2 : H361d: Suspected of damaging the unborn child.

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.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

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

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 8.0	Revision Date: 02.10.2025	SDS Number: 7900797-00013	Date of last issue: 14.04.2025 Date of first issue: 17.03.2021
----------------	------------------------------	------------------------------	---

Precautionary statements	:	Prevention: P201 Obtain special instructions before use. 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. Storage: P405 Store locked up.
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Hazardous components which must be listed on the label:

Fluralaner

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

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.

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

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
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)	22204-24-6 244-837-1		>= 10 - < 20
Fluralaner	864731-61-3	Repr. 2; H361d Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 1.000	>= 10 - < 20
Sodium dodecyl sulphate	151-21-3 205-788-1	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318	>= 1 - < 2,5

Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version
8.0

Revision Date:
02.10.2025

SDS Number:
7900797-00013

Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

		Aquatic Chronic 3; H412	
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
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	>= 0,025 - < 0,1

For explanation of abbreviations see section 16.

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 plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version 8.0	Revision Date: 02.10.2025	SDS Number: 7900797-00013	Date of last issue: 14.04.2025 Date of first issue: 17.03.2021
----------------	------------------------------	------------------------------	---

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.

4.2 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.

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 (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 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

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.

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**Version
8.0Revision Date:
02.10.2025SDS Number:
7900797-00013Date of last issue: 14.04.2025
Date of first issue: 17.03.2021**SECTION 6: Accidental release measures****6.1 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).

6.2 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.

6.3 Methods and material 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.

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 : 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 8.0 Revision Date: 02.10.2025

SDS Number:
7900797-00013

Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

Hygiene measures

- 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.
- : 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. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:
Strong oxidizing agents

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
Cellulose	9004-34-6	OEL-RL	10 mg/m3	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
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/m3 (OEB 2)	Internal
Further information: Skin				
Fluralaner	864731-61-3	TWA	100 µg/m3 (OEB 2)	Internal
Further information: Occupational Exposure Limits - Restricted Limits For				
Magnesium Aluminometasilicate	12511-31-8	OEL-RL (respirable dust fraction)	2 mg/m3 (Aluminium)	ZA OEL

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025 Date of first issue: 17.03.2021

Hazardous Chemical Agents				
Moxidectin	113507-06-5	TWA	10 µg/m3 (OEB 3)	Internal
		Wipe limit	100 µg/100 cm ²	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium dodecyl sulphate	Workers	Inhalation	Long-term systemic effects	285 mg/m3
	Workers	Skin contact	Long-term systemic effects	4060 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	85 mg/m3
	Consumers	Skin contact	Long-term systemic effects	2440 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	24 mg/kg bw/day
2,6-Di-tert-butyl-p-cresol	Workers	Inhalation	Long-term systemic effects	3,5 mg/m3
	Workers	Dermal	Long-term systemic effects	0,5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,86 mg/m3
	Consumers	Dermal	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
Sodium dodecyl sulphate	Fresh water	0,176 mg/l
	Freshwater - intermittent	0,055 mg/l
	Marine water	0,018 mg/l
	Sewage treatment plant	1,35 mg/l
	Fresh water sediment	6,97 mg/kg dry weight (d.w.)
	Marine sediment	0,697 mg/kg dry weight (d.w.)
	Soil	1,29 mg/kg dry weight (d.w.)
Moxidectin	Water	0,3 ng/l
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

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

		dry weight (d.w.)
	Oral (Secondary Poisoning)	8,33 mg/kg food

8.2 Exposure controls**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

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

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

Physical state	: solid
Form	: 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
Initial boiling point and boiling range	: No data available
Flash point	: Not applicable

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

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.

9.2 Other information

Molecular weight	: No data available
Particle size	: No data available

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

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

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 : Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

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):

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

Sodium dodecyl sulphate:

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

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

||| 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

||| 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

Sodium dodecyl sulphate:

||| Species : Rabbit

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

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

Sodium dodecyl sulphate:

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

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

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

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025
8.0 02.10.2025 7900797-00013 Date of first issue: 17.03.2021

Result : Not a skin sensitizer.

Sodium dodecyl sulphate:

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:

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

Sodium dodecyl sulphate

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

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version 8.0

Revision Date: 02.10.2025

SDS Number: 7900797-00013

Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

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:

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

Test Type: In vitro mammalian cell gene mutation test
Result: negativeTest 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: negativeTest 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.

Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version
8.0

Revision Date:
02.10.2025

SDS Number:
7900797-00013

Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

Components:

Fluralaner:

||| Carcinogenicity - Assessment : No data available

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
Result	:	negative

Reproductive toxicity

Suspected of damaging the unborn child.

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):

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 develop-

Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 8.0	Revision Date: 02.10.2025	SDS Number: 7900797-00013	Date of last issue: 14.04.2025 Date of first issue: 17.03.2021
----------------	------------------------------	------------------------------	---

ment 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.

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.

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

Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version
8.0

Revision Date:
02.10.2025

SDS Number:
7900797-00013

Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

Result: negative
Remarks: Based on data from similar materials

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

Effects on fertility	: <p>Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative</p>
Effects on foetal development	: <p>Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative</p>

Moxidectin:

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

Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version
8.0

Revision Date:
02.10.2025

SDS Number:
7900797-00013

Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

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:

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

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

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

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

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 8.0 Revision Date: 02.10.2025

SDS Number: 7900797-00013

Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

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.

SECTION 12: Ecological information

12.1 Toxicity

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):

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
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SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025
8.0 02.10.2025 7900797-00013 Date of first issue: 17.03.2021

	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 toxicity)	: NOEC: 0,0736 µg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	: 1.000
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 microorganisms	: EC50 : 135 mg/l Exposure time: 3 h
Toxicity to fish (Chronic toxicity)	: NOEC: >= 1,357 mg/l Exposure time: 42 d Species: Pimephales promelas (fathead minnow)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 0,88 mg/l Exposure time: 7 d Species: Ceriodaphnia dubia (water flea)

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025
8.0 02.10.2025 7900797-00013 Date of first issue: 17.03.2021

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
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

Moxidectin:

Toxicity to fish	: <p>LC50 (<i>Lepomis macrochirus</i> (Bluegill sunfish)): 0,0006 mg/l Exposure time: 96 h Method: OECD Test Guideline 203</p> <p>LC50 (<i>Oncorhynchus mykiss</i> (rainbow trout)): 0,0002 mg/l Exposure time: 96 h Method: OECD Test Guideline 203</p>
Toxicity to daphnia and other aquatic invertebrates	: <p>EC50 (<i>Daphnia magna</i> (Water flea)): 0,00003 mg/l Exposure time: 48 h Method: OECD Test Guideline 202</p>
Toxicity to algae/aquatic plants	: <p>EC50 (<i>Pseudokirchneriella subcapitata</i> (green algae)): 0,087 mg/l Exposure time: 72 h</p>

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 10.000

M-Factor (Chronic aquatic toxicity) : 10.000

12.2 Persistence and degradability**Components:****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

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

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

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

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).

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. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

||| ADN : UN 3077
||| ADR : UN 3077
||| RID : UN 3077

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

IMDG	:	UN 3077
IATA	:	UN 3077

14.2 UN proper shipping name

ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner, Moxidectin)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner, Moxidectin)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner, Moxidectin)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner, Moxidectin)
IATA	:	Environmentally hazardous substance, solid, n.o.s. (Fluralaner, Moxidectin)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	:	9
ADR	:	9
RID	:	9
IMDG	:	9
IATA	:	9

14.4 Packing group

ADN		
Packing group	:	III
Classification Code	:	M7
Hazard Identification Number	:	90
Labels	:	9
ADR		
Packing group	:	III
Classification Code	:	M7
Hazard Identification Number	:	90
Labels	:	9
Tunnel restriction code	:	(-)
RID		
Packing group	:	III
Classification Code	:	M7
Hazard Identification Number	:	90
Labels	:	9
IMDG		
Packing group	:	III

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

Labels	:	9
EmS Code	:	F-A, S-F
Remarks	:	Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids.
IATA (Cargo)		
Packing instruction (cargo aircraft)	:	956
Packing instruction (LQ)	:	Y956
Packing group	:	III
Labels	:	Miscellaneous
Remarks	:	Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids.
IATA (Passenger)		
Packing instruction (passenger aircraft)	:	956
Packing instruction (LQ)	:	Y956
Packing group	:	III
Labels	:	Miscellaneous
Remarks	:	Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids.

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

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

**Fluralaner / Moxidectin / Pyrantel Pamoate
Formulation**

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

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

H301 : Toxic if swallowed.
H302 : Harmful if swallowed.
H315 : Causes skin irritation.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H332 : Harmful if inhaled.
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.
H412 : Harmful 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 Dam. : Serious eye damage
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Skin Irrit. : Skin irritation
STOT RE : Specific target organ toxicity - repeated exposure
ZA OEL : South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL-RL : Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

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 - Emergen-

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version 8.0 Revision Date: 02.10.2025 SDS Number: 7900797-00013 Date of last issue: 14.04.2025
Date of first issue: 17.03.2021

cy 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

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:

Repr. 2	H361d
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
Calculation method
Calculation method

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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