

SAFETY DATA SHEET



Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Version
5.0

Revision Date:
2025/10/02

SDS Number:
7900839-00013

Date of last issue: 2025/04/14
Date of first issue: 2021/03/17

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fluralaner / Moxidectin / Pyrantel Pamoate Formulation

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS Classification

Reproductive toxicity : Category 2

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : 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.

P202 Do not handle until all safety precautions have been read and understood.

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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.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|-------------|-----------------------|
| Cellulose | 9004-34-6 | >= 10 -< 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 -< 30 |
| Fluralaner | 864731-61-3 | >= 10 -< 25 |
| Magnesium Aluminometasilicate | 12511-31-8 | < 10 |
| Sodium dodecyl sulphate | 151-21-3 | >= 1 -< 2.5 |
| 2,6-Di-tert-butyl-p-cresol | 128-37-0 | >= 0.025 -< 0.25 |
| Moxidectin | 113507-06-5 | >= 0.025 -< 0.25 |

4. FIRST AID MEASURES

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

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

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.

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

5. FIREFIGHTING MEASURES

| | |
|---|---|
| Suitable extinguishing media | : Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : None known. |
| Specific hazards during fire-fighting | : Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : Carbon oxides Chlorine compounds Fluorine compounds Nitrogen oxides (NO _x) Sulphur oxides Metal oxides Silicon oxides |
| Specific extinguishing methods | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. |
| Special protective equipment for firefighters | : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

6. ACCIDENTAL RELEASE MEASURES

| | |
|---|--|
| Personal precautions, protective equipment and emergency procedures | : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : Avoid release to the environment. |

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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 : 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.

7. HANDLING AND STORAGE

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.
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.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type | Control param- | Basis |
|------------|---------|------------|----------------|-------|
|------------|---------|------------|----------------|-------|

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| | | (Form of exposure) | ters / Permissible concentration | |
|---|---|-------------------------------------|----------------------------------|----------|
| Cellulose | 9004-34-6 | NAB | 10 mg/m3 | ID OEL |
| | | TWA | 10 mg/m3 | 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/m3 (OEB 2) | Internal |
| Fluralaner | 864731-61-3 | TWA | 100 µg/m3 (OEB 2) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 1000 µg/100 cm ² | Internal |
| Magnesium Aluminometasilicate | 12511-31-8 | NAB (Respirable particulate matter) | 1 mg/m3 (Aluminium) | ID OEL |
| | Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals | | | |
| | | TWA (Respirable particulate matter) | 1 mg/m3 (Aluminium) | ACGIH |
| 2,6-Di-tert-butyl-p-cresol | 128-37-0 | TWA (Inhalable fraction and vapor) | 2 mg/m3 | ACGIH |
| Moxidectin | 113507-06-5 | TWA | 10 µg/m3 (OEB 3) | Internal |
| | | Wipe limit | 100 µg/100 cm ² | Internal |

Engineering measures

- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

| | |
|------------------------|--|
| Respiratory protection | : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
| Filter type | : Particulates type |
| Hand protection | |
| Material | : Chemical-resistant gloves |
| Remarks | : Consider double gloving. |
| Eye protection | : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. |

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|------------------|---|
| | <p>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</p> <p>Skin and body protection</p> <p>: 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.</p> <p>Use appropriate degowning techniques to remove potentially contaminated clothing.</p> |
| Hygiene measures | <p>: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</p> <p>When using do not eat, drink or smoke.</p> <p>Wash contaminated clothing before re-use.</p> <p>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.</p> |

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 |
| 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 |

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| | | |
|--|---|--|
| 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 |

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. |

11. TOXICOLOGICAL INFORMATION

| | | |
|--|---|--|
| Information on likely routes of exposure | : | Skin contact Ingestion Eye contact |
|--|---|--|

Acute toxicity

Not classified based on available information.

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

Components:**Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

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

Acute oral toxicity : LD50 (Rat): > 24,000 mg/kg
LD50 (Mouse): > 24,000 mg/kg
LD50 (Dog): 2,000 mg/kg

Fluralaner:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: No mortality observed at this dose.
No significant adverse effects were reported
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: No significant adverse effects were reported

Magnesium Aluminometasilicate:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials
Acute dermal toxicity : LD50 (Rabbit): > 3,500 mg/kg

Sodium dodecyl sulphate:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg
Method: OECD Test Guideline 401
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

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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 |

Magnesium Aluminometasilicate:

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

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| | | |
|---------|---|-----------------|
| 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.

Components:**Fluralaner:**

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

Magnesium Aluminometasilicate:

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

Sodium dodecyl sulphate:

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

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

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

Moxidectin:

| | | |
|---------|---|-------------------------|
| Species | : | Rabbit |
| Result | : | Moderate eye irritation |

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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 |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

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:**Cellulose:**

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

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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)
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

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Remarks: Based on data from similar materials

Sodium dodecyl sulphate:

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative |
| | Test Type: In vitro mammalian cell gene mutation test 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: 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 |

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Result: negative**Carcinogenicity**

Not classified based on available information.

Components:**Cellulose:**

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

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 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 |

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| | | |
|-------------------|---|-----------------------|
| 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:

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. |
| Effects on foetal development | : | Test Type: Development |

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| | |
|---------------------------------------|---|
| ment | 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. |
| 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 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 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 |

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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. |
|------------|--|

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Date of first issue: 2021/03/17**Moxidectin:**Target Organs
Assessment: Central nervous system
: Causes damage to organs through prolonged or repeated exposure.**Repeated dose toxicity****Components:****Cellulose:**Species
NOAEL
Application Route
Exposure time: Rat
: >= 9,000 mg/kg
: Ingestion
: 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
NOAEL
LOAEL
Application Route
Exposure time
Remarks: Dog
: 10 mg/kg
: 30 mg/kg
: Ingestion
: 3 d
: No significant adverse effects were reportedSpecies
NOAEL
Application Route
Exposure time
Remarks: Dog
: 600 mg/kg
: Oral
: 19 d
: No significant adverse effects were reportedSpecies
NOAEL
Application Route
Exposure time
Remarks: Dog
: 600 mg/kg
: Oral
: 30 d
: No significant adverse effects were reportedSpecies
NOAEL
Application Route
Exposure time
Remarks: Dog
: 600 mg/kg
: Oral
: 90 d
: No significant adverse effects were reported**Fluralaner:**Species
NOAEL
Application Route
Exposure time
Target Organs
Remarks: Dog
: 1 mg/kg
: Oral
: 52 Weeks
: Liver
: No significant adverse effects were reported

Species

: Rat

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| | | |
|-------------------|---|--|
| 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 |
| NOAEL | : | >= 1000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 100 Days |

Sodium dodecyl sulphate:

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

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

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

Moxidectin:

| | | |
|-------------------|---|------------------------|
| Species | : | Mouse |
| NOAEL | : | 3.9 mg/kg |
| LOAEL | : | 15.4 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 4 Weeks |
| Symptoms | : | Tremors |
| Species | : | Rat |
| NOAEL | : | 3.9 mg/kg |
| LOAEL | : | 7.9 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 13 Weeks |
| Target Organs | : | Central nervous system |
| Symptoms | : | Tremors, Salivation |
| Species | : | Dog |
| NOAEL | : | 0.3 mg/kg |
| LOAEL | : | 0.9 mg/kg |

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| | | |
|-------------------|---|-----------------------------------|
| 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

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.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

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

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

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Fluralaner:

Toxicity to fish : LC50 (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

Magnesium Aluminometasilicate:**Ecotoxicology Assessment**

Chronic aquatic toxicity : No toxicity at the limit of solubility

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

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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

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

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| | | |
|---|---|--|
| | | 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 dodecyl sulphate:

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

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

| | | |
|------------------|---|--|
| Biodegradability | : | Result: Not readily biodegradable. Biodegradation: 4.5 % Exposure time: 28 d Method: OECD Test Guideline 301C |
|------------------|---|--|

Bioaccumulative potential**Components:****Fluralaner:**

| | | |
|--|---|--|
| Bioaccumulation | : | Species: Zebrafish Bioconcentration factor (BCF): 79.4 Method: OECD Test Guideline 305 |
| Partition coefficient: n-octanol/water | : | log Pow: 4.5 |

Sodium dodecyl sulphate:

| | | |
|---------------------------|---|---------------|
| Partition coefficient: n- | : | log Pow: 0.83 |
|---------------------------|---|---------------|

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||| octanol/water

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

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
||| Dispose of in accordance with local regulations.

||| 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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3077

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

||| Class : 9

||| Packing group : III

||| Labels : 9

||| Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3077

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| | | |
|--|---|--|
| Proper shipping name | : | Environmentally hazardous substance, solid, n.o.s. (Fluralaner, Moxidectin) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | Miscellaneous |
| Packing instruction (cargo aircraft) | : | 956 |
| Packing instruction (passenger aircraft) | : | 956 |
| Environmentally hazardous | : | yes |
| Remarks | : | Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids. |

IMDG-Code

| | | |
|----------------------|---|--|
| UN number | : | UN 3077 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner, Moxidectin) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| EmS Code | : | F-A, S-F |
| Marine pollutant | : | yes |
| Remarks | : | Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids. |

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

Not applicable for product as supplied.

Special precautions for user

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

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

| | | |
|---------------------------------------|---|------------------|
| Hazardous substances approved for use | : | Sodium hydroxide |
| Prohibited substances | : | Not applicable |
| Restricted substances | : | Not applicable |

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Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

CA. DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2025/10/02

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/>

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
ID OEL / NAB : Long term exposure limit

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; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; 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

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Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - 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; 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.

ID / EN