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

1.1 Product identifier
   Trade name: Fluralaner Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company: MSD
   Kilsheean
   Clonmel Tipperary, IE
   Telephone: 353-51-601000
   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
   Long-term (chronic) aquatic hazard, Category 1
   H361d: Suspected of damaging the unborn child.
   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.
   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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fluralaner Solid Formulation

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

Storage:
P405  Store locked up.

Hazardous components which must be listed on the label:
Fluralaner

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown acute oral toxicity: 2 %
The following percentage of the mixture consists of ingredient(s) with unknown acute dermal toxicity: 2 %
The following percentage of the mixture consists of ingredient(s) with unknown acute inhalation toxicity: 2 %

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.

Ecological information: 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.

Toxicological information: 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 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td></td>
<td></td>
<td>Repr. 2; H361d</td>
<td>&gt;= 5 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 1;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>H410</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td></td>
<td>Acute Tox. 4; H302</td>
<td>&gt;= 1 - &lt;= 5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Irrit. 2; H315</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Dam. 1; H318</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fluralaner Solid Formulation

<table>
<thead>
<tr>
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</thead>
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<tr>
<td>3.4</td>
<td>19.03.2021</td>
<td>406413-00017</td>
<td>23.03.2020</td>
<td>10.12.2015</td>
</tr>
</tbody>
</table>

Aquatic Chronic 3; H412
specific concentration limit
Eye Irrit. 2; H319
10 - < 20 %
Eye Dam. 1; H318
>= 20 %

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.

In case of eye contact: Flush eyes with water as a precaution. 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.

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 firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Chlorine compounds
Fluorine compounds
Sulphur oxides
Metal oxides
Sodium 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.

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 con-
tainer for disposal. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures
See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation
Use only with adequate ventilation.

Advice on safe handling
Do not get on skin or clothing.
Avoid breathing vapours.
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.
Take care to prevent spills, waste and minimize release to the environment.

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

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers
Keep in properly labelled containers. Store locked up. 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
Fluralaner Solid Formulation

Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
---|---|---|---|---|
Fluralaner | 864731-61-3 | TWA | 100 µg/m3 (OEB 2) | Internal |

Further information: Skin

- Wipe limit: 1000 µg/100 cm² Internal

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>285 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4060 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>85 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2440 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>24 mg/kg bw/day</td>
</tr>
<tr>
<td>Glycerine</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>56 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>229 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>33 mg/m³</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>Fresh water</td>
<td>0,176 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0,018 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1,35 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>6,97 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0,697 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>1,29 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Glycerine</td>
<td>Fresh water</td>
<td>0,885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0,0885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>8,85 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>3,3 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0,33 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0,141 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures

Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

**Personal protective equipment**

- **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. 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**: Chemical-resistant gloves

- **Skin and body protection**: Work uniform or laboratory coat.

- **Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387
  
  - **Filter type**: Combined particulates and organic vapour type (A-P)

**SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

- **Physical state**: Pasty solid
- **Colour**: Light brown
- **Odour**: No data available
- **Odour Threshold**: No data available

- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flammability (solid, gas)**: Not classified as a flammability hazard

- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available

- **Flash point**: Not applicable
- **Auto-ignition temperature**: No data available

- **Decomposition temperature**: No data available

- **pH**: No data available

- **Viscosity**: No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Vapour pressure : No data available
Relative density : No data available
Density : No data available
Relative vapour density : No data available
Particle characteristics
Particle size : No data available

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : 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
Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : None known.

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 hazard classes as defined in Regulation (EC) No 1272/2008
Information on likely routes of exposure : Skin contact
Ingestion
Eye contact
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<table>
<thead>
<tr>
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</tr>
</tbody>
</table>

## Acute toxicity
Not classified based on available information.

### Product:

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

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

**Sodium n-dodecyl sulfate**
- LD50 (Rat): 1.200 mg/kg
  - Method: OECD Test Guideline 401

### Components:

#### Fluralaner:
- **Species**: Rabbit
- **Result**: No skin irritation

#### Sodium n-dodecyl sulfate:
- **Species**: Rabbit
- **Result**: Skin irritation

## Skin corrosion/irritation
Not classified based on available information.

### Components:

#### Fluralaner:
- **Species**: Rabbit
- **Result**: No skin irritation

#### Sodium n-dodecyl sulfate:
- **Species**: Rabbit
- **Method**: OECD Test Guideline 405
- **Result**: Irreversible effects on the eye

## Serious eye damage/eye irritation
Not classified based on available information.

### Components:

#### Fluralaner:
- **Species**: Rabbit
- **Result**: Mild eye irritation

#### Sodium n-dodecyl sulfate:
- **Species**: Rabbit
- **Method**: OECD Test Guideline 405
- **Result**: Irreversible effects on the eye
Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

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

Sodium n-dodecyl sulfate:
- Test Type: Maximisation Test
- Exposure routes: Skin contact
- Species: Guinea pig
- Result: negative
- Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Sodium n-dodecyl sulfate:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative
  Test Type: In vitro mammalian cell gene mutation test
  Result: negative
Fluralaner Solid Formulation

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

Carcinogenicity
Not classified based on available information.

Components:

Fluralaner:

Carcinogenicity - Assessment: No data available

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

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Fluralaner:

Effects on fertility: Test Type: Two-generation study Species: Rat Application Route: Oral General Toxicity - Parent: NOAEL: 50 mg/kg body weight General Toxicity F1: LOAEL: 100 mg/kg body weight Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects.

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

Effects on foetal development: Test Type: Development Species: Rat Application Route: Oral 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 n-dodecyl sulfate:

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

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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Product:
Species: Dog  
LOAEL: 25 mg/kg  
Application Route: Oral  
Exposure time: 168 d  
Symptoms: Vomiting  
Remarks: No significant adverse effects were reported

Components:

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

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

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

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

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

Aspiration toxicity
Not classified based on available information.

Components:

Fluralaner:
Not applicable

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: 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.

Experience with human exposure

Components:

Fluralaner:
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**Skin contact**  
Remarks: May irritate skin.

**Eye contact**  
Remarks: May cause eye irritation.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

**Fluralaner:**
- **Toxicity to fish:**  
  Remarks: No toxicity at the limit of solubility

- **Toxicity to daphnia and other aquatic invertebrates:**  
  Remarks: No toxicity at the limit of solubility

- **Toxicity to algae/aquatic plants:**  
  Remarks: No toxicity at the limit of solubility

- **Toxicity to fish (Chronic toxicity):**  
  Remarks: No toxicity at the limit of solubility

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**  
  Remarks: No toxicity at the limit of solubility

- **M-Factor (Chronic aquatic toxicity):**  
  1.000

**Sodium n-dodecyl sulfate:**
- **Toxicity to fish:**  
  Remarks: No toxicity at the limit of solubility

- **Toxicity to daphnia and other aquatic invertebrates:**  
  Remarks: No toxicity at the limit of solubility

- **Toxicity to algae/aquatic plants:**  
  Remarks: No toxicity at the limit of solubility

- **Toxicity to microorganisms:**  
  EC50 : 135 mg/l
Exposure time: 3 h

Toxicity to fish (Chronic toxicity): NOEC: \( \geq 1,357 \text{ mg/l} \)
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)

12.2 Persistence and degradability

Components:

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

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 n-dodecyl sulfate:
Partition coefficient: n-octanol/water: \( \log Pow: 0.83 \)

12.4 Mobility in soil

Components:

Fluralaner:
Distribution among environmental compartments: \( \log Koc: 3.4 \)

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 : This substance is not considered to be persistent, bioaccumulating 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.
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 or ID number
ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name
ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner)
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fluralaner Solid Formulation

N.O.S.
(Fluralaner)

IATA : Environmentally hazardous substance, solid, n.o.s.
(Fluralaner)

14.3 Transport hazard class(es)

| 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 |
|Labels : 9 |
|EmS Code : F-A, S-F |

| IATA (Cargo) | Packing instruction (cargo aircraft) : 956 |
|Packing instruction (LQ) : Y956 |
Packing group : III |
|Labels : Miscellaneous |

| IATA (Passenger) | Packing instruction (passenger aircraft) : 956 |
|Packing instruction (LQ) : Y956 |
Packing group : III |
|Labels : Miscellaneous |

14.5 Environmental hazards

| ADN |

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17 / 20
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 Maritime transport in bulk according to IMO instruments
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
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1 ENVIRONMENTAL HAZARDS</td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

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

H302 : Harmful if swallowed.
H315 : Causes skin irritation.
H318 : Causes serious eye damage.
H361d : Suspected of damaging the unborn child.
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 Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Repr. : Reproductive toxicity
Skin Irrit. : Skin irritation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; 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 - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Fluralaner Solid Formulation

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Date of first issue: 10.12.2015

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; 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 Bio-accumulative

Further information

Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:

Repr. 2 H361d Calculation method
Aquatic Chronic 1 H410 Calculation method

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

NO / EN