SAFETY DATA SHEET
according to the Hazardous Products Regulations

Fluralaner Solid Formulation

SECTION 1. IDENTIFICATION

Product name : Fluralaner Solid Formulation
Other means of identification : No data available

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Reproductive toxicity : Category 2

GHS label elements
Hazard pictograms :

Signal Word : Warning
Hazard Statements : H361d Suspected of damaging the unborn child.
Precautionary Statements :

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.
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Additional Labeling

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 %

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Starch</td>
</tr>
<tr>
<td></td>
<td>Glycerine</td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
</tr>
<tr>
<td></td>
<td>Fluralaner</td>
</tr>
<tr>
<td></td>
<td>Sodium n-dodecyl sulfate</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

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

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

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.

Most important symptoms: Suspected of damaging the unborn child.
and effects, both acute and delayed
Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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
Sulfur oxides
Metal oxides
Sodium oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency 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.
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.
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.
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SECTION 7. HANDLING AND STORAGE

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 vapors.
- 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.

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

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>TWA (Mist)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable mist)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Mist)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Further information: Skin

| Wipe limit | 1000 µg/100 cm² | Internal |

**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**

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

**Filter type**: Combined particulates and organic vapor type

**Hand protection Material**: Chemical-resistant gloves

**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.

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

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

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: Pasty solid
- **Color**: light brown
- **Odor**: No data available
- **Odor Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: Not applicable
Evaporation rate : 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
Vapor pressure : No data available
Relative vapor density : No data available
Relative density : No data available
Density : No data available
Solubility(ies) Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.
SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

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

Components:

Starch:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Glycerine:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

Sucrose:
Acute oral toxicity : LD50 (Rat): 29,700 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 n-dodecyl sulfate:
Acute oral toxicity : LD50 (Rat): 1,200 mg/kg
Method: OECD Test Guideline 401

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

Skin corrosion/irritation
Not classified based on available information.
Components:

Glycerine:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

Fluralaner:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

Sodium n-dodecyl sulfate:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Skin irritation</td>
</tr>
</tbody>
</table>

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

Components:

Starch:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

Glycerine:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

Fluralaner:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

Sodium n-dodecyl sulfate:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irreversible effects on the eye</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
</tbody>
</table>

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Starch:
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
</tbody>
</table>
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**Result**: negative

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

**Sodium n-dodecyl sulfate**
- **Test Type**: Maximization Test
- **Routes of exposure**: Skin contact
- **Species**: Guinea pig
- **Result**: negative
- **Remarks**: Based on data from similar materials

**Germ cell mutagenicity**
Not classified based on available information.

**Components**

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

- **Glycerine**
  - **Genotoxicity in vitro**: Test Type: In vitro mammalian cell gene mutation test Result: negative
  - Test Type: Bacterial reverse mutation assay (AMES) Result: negative
  - Test Type: Chromosome aberration test in vitro Result: negative
  - Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative

- **Sucrose**
  - **Genotoxicity in vitro**: Test Type: In vitro mammalian cell gene mutation test 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
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Result: negative

Genotoxicity in vivo:
- Test Type: Micronucleus test
  - Species: Mouse
  - Cell type: Bone marrow
  - Application Route: Oral
  - 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

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:

Glycerine:
- Species: Rat
- Application Route: Ingestion
- Exposure time: 2 Years
- Result: negative

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:

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

Effects on fetal development:
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative

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 fetal development:
- Test Type: Development
- Species: Rat
- Application Route: Oral
- Developmental Toxicity: NOAEL: 100 mg/kg body weight
- Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects.
- Test Type: Development
- 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
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**Fluralaner Solid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0</td>
<td>09/30/2023</td>
<td>401059-00024</td>
<td>04/04/2023</td>
<td>12/10/2015</td>
</tr>
</tbody>
</table>

**Application Route:** Ingestion  
**Method:** OECD Test Guideline 416  
**Result:** negative  
**Remarks:** Based on data from similar materials

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

**STOT-single exposure**  
Not classified based on available information.

**STOT-repeated exposure**  
Not classified based on available information.

**Repeated dose toxicity**

**Product:**

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Symptoms</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>25 mg/kg</td>
<td>Oral</td>
<td>168 d</td>
<td>Vomiting</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Components:**

**Starch:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt;= 2,000 mg/kg</td>
<td>Skin contact</td>
<td>28 Days</td>
<td>OECD Test Guideline 410</td>
</tr>
</tbody>
</table>

**Glycerine:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.167 mg/l</td>
<td>0.622 mg/l</td>
<td>inhalation (dust/mist/fume)</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Rat</td>
<td>8,000 - 10,000 mg/kg</td>
<td>Ingestion</td>
<td>2 y</td>
<td></td>
</tr>
<tr>
<td>Rabbit</td>
<td>5,040 mg/kg</td>
<td>Skin contact</td>
<td>45 Weeks</td>
<td></td>
</tr>
</tbody>
</table>
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**Species:** Dog

**NOAEL:** 1 mg/kg

**Application Route:** Oral

**Exposure time:** 52 Weeks

**Target Organs:** Liver

**Remarks:** No significant adverse effects were reported

**Species:** Juvenile dog

**LOAEL:** 56 - 280 mg/kg

**Application Route:** Oral

**Exposure time:** 24 Weeks

**Symptoms:** Diarrhea

**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

**Experience with human exposure**

**Components:**

**Fluralaner:**

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

**Eye contact:** Remarks: May cause eye irritation.
## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

**Glycerine:**
- **Toxicity to fish:** 
  \[LC_{50}\ (Onchorhynchus\ mykiss\ (rainbow\ trout))\]: 54,000 mg/l
  Exposure time: 96 h

- **Toxicity to daphnia and other aquatic invertebrates:** 
  \[EC_{50}\ (Daphnia\ magna\ (Water\ flea))\]: 1,955 mg/l
  Exposure time: 48 h

- **Toxicity to microorganisms:** 
  \[NOEC\ (Pseudomonas\ putida)\]: > 10,000 mg/l
  Exposure time: 16 h
  Method: DIN 38 412 Part 8

**Fluralaner:**
- **Toxicity to fish:** 
  \[LC_{50}\ (Onchorhynchus\ mykiss\ (rainbow\ trout))\]: > 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:** 
  \[EC_{50}\ (Daphnia\ magna\ (Water\ flea))\]: > 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

**Sodium n-dodecyl sulfate:**
- **Toxicity to fish:** 
  \[LC_{50}\ (Pimephales\ promelas\ (fathead\ minnow))\]: 29 mg/l
  Exposure time: 96 h

- **Toxicity to daphnia and other aquatic invertebrates:** 
  \[EC_{50}\ (Ceriodaphnia\ dubia\ (water\ flea))\]: 5.55 mg/l
  Exposure time: 48 h

- **Toxicity to algae/aquatic plants:** 
  \[ErC_{50}\ (Desmodesmus\ subspicatus\ (green\ algae))\]: > 120 mg/l
  Exposure time: 72 h
NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): >= 1.357 mg/l
Exposure time: 42 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l
Exposure time: 7 d

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

Persistence and degradability

Components:

Glycerine:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 92 %
Exposure time: 30 d
Method: OECD Test Guideline 301D

Sodium n-dodecyl sulfate:

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

Bioaccumulative potential

Components:

Glycerine:

Partition coefficient: n-octanol/water: log Pow: -1.75

Sucrose:

Partition coefficient: n-octanol/water: Pow: < 1

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
### Mobility in soil

**Components:**

**Fluralaner:**
- Distribution among environmental compartments: log Koc: 4.1

**Other adverse effects**

**Components:**

**Fluralaner:**
- Results of PBT and vPvB assessment: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

### SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

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

### SECTION 14. TRANSPORT INFORMATION

**International Regulations**

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

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

**IMDG-Code**
- UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner)

Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

TDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner)
Class: 9
Packing group: III
Labels: 9
ERG Code: 171
Marine pollutant: yes (Fluralaner)

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

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL: Canada. British Columbia OEL
CA QC OEL: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA: 8-hour, time-weighted average
CA AB OEL / TWA: 8-hour Occupational exposure limit
# SAFETY DATA SHEET
according to the Hazardous Products Regulations

# Fluralaner Solid Formulation

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CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWA-EV : Time-weighted average exposure value

AIIIC - 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;
GH5 - Globally Harmonized System;
GLP - Good Laboratory Practice;
IARC - International Agency for Research on Cancer;
IATA - International Air Transport Association;
IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk;
IC50 - Half maximal inhibitory concentration;
ICAO - International Civil Aviation Organization;
IECSC - Inventory of Existing Chemical Substances in China;
IMDG - International Maritime Dangerous Goods;
IMO - International Maritime Organization;
ISHL - Industrial Safety and Health Law (Japan);
ISO - International Organisation for Standardization;
KECI - Korea Existing Chemicals Inventory;
LC50 - Lethal Concentration to 50% of a test population;
LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose);
MARPOL - International Convention for the Prevention of Pollution from Ships;
n.o.s. - Not Otherwise Specified;
Nch - Chilean Norm;
NO(A)EC - No Observed (Adverse) Effect Concentration;
NO(A)EL - No Observed (Adverse) Effect Level;
NOELR - No Observable Effect Loading Rate;
NOM - Official Mexican Norm;
NTP - National Toxicology Program;
NZIoC - New Zealand Inventory of Chemicals;
OECD - Organization for Economic Co-operation and Development;
OPPTS - Office of Chemical Safety and Pollution Prevention;
PBT - Persistent, Bioaccumulative and Toxic substance;
PICCS - Philippines Inventory of Chemicals and Chemical Substances;
(Q)SAR - (Quantitative) Structure Activity Relationship;
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

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

Revision Date: 09/30/2023
Date format: mm/dd/yyyy

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

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.
Fluralaner Solid Formulation

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