SAFETY DATA SHEET

Fluralaner Solid Formulation

SECTION 1. IDENTIFICATION

Product name : Fluralaner Solid Formulation

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
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/ face protection.

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

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards
None known.
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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>&gt;= 10 - &lt;= 20</td>
</tr>
<tr>
<td></td>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 25</td>
</tr>
<tr>
<td></td>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 5 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&gt;= 5 - &lt;= 10</td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
<td>57-50-1</td>
<td>&gt;= 5 - &lt;= 10</td>
</tr>
<tr>
<td></td>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>&gt;= 1 - &lt;= 5</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 and effects, both acute and delayed : Suspected of damaging the unborn child.

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

Hazardous combustion products : Carbon oxides
Chlorine compounds
Fluorine compounds
Sulfur oxides
Metal 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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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.

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. 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/PERSOANL 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>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>TWA (aerosol)</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>TWA</th>
<th>1000 µg/100 cm²</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
</tbody>
</table>

#### 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**

General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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 face shield 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.
- 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.

Hygiene measures
- 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Pasty solid</td>
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<tr>
<td>Color</td>
<td>light brown</td>
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<tr>
<td>Odor</td>
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<tr>
<td>Odor Threshold</td>
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<tr>
<td>pH</td>
<td>No data available</td>
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<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
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<tr>
<td>Initial boiling point and boiling range</td>
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</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
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<tr>
<td>Evaporation rate</td>
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<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
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</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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: > 5,000 mg/kg
Method: Calculation method

Components:
Polyethylene glycol:
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials
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Starch:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 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

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

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:

Polyethylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Fluralaner:
Species: Rabbit
Result: No skin irritation

Glycerine:
Species: Rabbit
Result: No skin irritation

Sodium n-dodecyl sulfate:

7 / 20
Species: Rabbit
Result: Skin irritation

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

**Components:**

**Polyethylene glycol:**
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

**Starch:**
Species: Rabbit
Result: No eye irritation

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

**Glycerine:**
Species: Rabbit
Result: No eye irritation

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

**Respiratory or skin sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components:**

**Polyethylene glycol:**
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

**Starch:**
Test Type: Maximization Test
Routes of exposure: Skin contact
### Fluralaner Solid Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fluralaner:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Routes of exposure</td>
<td>Dermal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type</td>
<td>Maximization Test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sodium n-dodecyl sulfate:</strong></td>
<td>Maximization Test</td>
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<td></td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Germ cell mutagenicity</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Components:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Polyethylene glycol:</strong></td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
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</tr>
<tr>
<td>Genotoxicity in vitro</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Starch:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotoxicity in vitro</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
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<tr>
<td><strong>Fluralaner:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotoxicity in vitro</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Micronucleus test</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Mouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cell type: Bone marrow</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Mouse Lymphoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosomal aberration</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Glycerine:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotoxicity in vitro</td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

Sodium n-dodecyl sulfate:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Genotoxicity in vitro : 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:

Fluralaner:
Carcinogenicity - Assessment : No data available

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

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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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 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.

**Glycerine:**

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

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

**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 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:**

Species  
Dog

LOAEL  
25 mg/kg

Application Route  
Oral

Exposure time  
168 d

Symptoms  
Vomiting

Remarks  
No significant adverse effects were reported

**Components:**

**Starch:**

Species  
Rat

NOAEL  
>= 2,000 mg/kg

Application Route  
Skin contact

Exposure time  
28 Days

Method  
OECD Test Guideline 410

**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 : 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

Glycerine:
Species : Rat
NOAEL : 0.167 mg/l
LOAEL : 0.622 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 13 Weeks

Species : Rat
NOAEL : 8,000 - 10,000 mg/kg
Application Route : Ingestion
Exposure time : 2 y

Species : Rabbit
NOAEL : 5,040 mg/kg
Application Route : Skin contact
Exposure time : 45 Weeks

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:

Polyethylene glycol:
- Toxicity to fish: LC50 (Poecilia reticulata (guppy)): > 100 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203
  Remarks: Based on data from similar materials

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)): 0.000047 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211

Glycerine:
- Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
  Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 1,955 mg/l
  Exposure time: 48 h
- Toxicity to microorganisms: NOEC (Pseudomonas putida): > 10,000 mg/l
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<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>7.1</td>
<td>03/23/2020</td>
<td>401074-00016</td>
<td>09/13/2019</td>
<td>12/10/2015</td>
</tr>
</tbody>
</table>

Exposure time: 16 h  
Method: DIN 38 412 Part 8

**Sodium n-dodecyl sulfate:**
- **Toxicity to fish:** LC50 (Pimephales promelas (fathead minnow)): 29 mg/l  
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l  
  Exposure time: 48 h
- **Toxicity to algae/aquatic plants:** ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l  
  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:**

**Polyethylene glycol:**
- Biodegradability: Result: rapidly degradable
  Remarks: Based on data from similar materials

**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:**

**Polyethylene glycol:**
- Partition coefficient: n-  
  log Pow: < 3
Fluralaner Solid Formulation

octanol/water

**Fluralaner:**

Bioaccumulation : Species: Zebrafish
Bioconcentration factor (BCF): 79.4
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4.5

**Glycerine:**

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

**Sucrose:**

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

**Sodium n-dodecyl sulfate:**

Partition coefficient: n-octanol/water : log Pow: 0.83

**Mobility in soil**

**Components:**

**Fluralaner:**

Distribution among environmental compartments : log Koc: 3.4

**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 : 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
### SAFETY DATA SHEET

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<table>
<thead>
<tr>
<th>Version</th>
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<th>SDS Number:</th>
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</tr>
</tbody>
</table>

| Packing group | III |
| Labels        | 9   |

**IATA-DGR**

<table>
<thead>
<tr>
<th>UN/ID No.</th>
<th>UN 3077</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper shipping name</td>
<td>Environmentally hazardous substance, solid, n.o.s. (Fluralaner)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Class</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
<td>Miscellaneous,</td>
</tr>
<tr>
<td>Packing instruction (cargo aircraft)</td>
<td>956</td>
</tr>
</tbody>
</table>

| Packing instruction (passenger aircraft) | 956 |
| Environmentally hazardous | yes |

**IMDG-Code**

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN 3077</th>
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<tbody>
<tr>
<td>Proper shipping name</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Class</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subsidiary risk</td>
<td>ENVIRONM.</td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
<td>9 (ENVIRONM.)</td>
</tr>
<tr>
<td>EmS Code</td>
<td>F-A, S-F</td>
</tr>
<tr>
<td>Marine pollutant</td>
<td>yes</td>
</tr>
</tbody>
</table>

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

Not applicable for product as supplied.

**Domestic regulation**

**49 CFR**

<table>
<thead>
<tr>
<th>UN/ID/NA number</th>
<th>UN 3077</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper shipping name</td>
<td>Environmentally hazardous substance, solid, n.o.s. (Fluralaner)</td>
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</tbody>
</table>

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<tr>
<th>Class</th>
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</tr>
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<tbody>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
<td>CLASS 9</td>
</tr>
<tr>
<td>ERG Code</td>
<td>171</td>
</tr>
<tr>
<td>Marine pollutant</td>
<td>yes(Fluralaner)</td>
</tr>
<tr>
<td>Remarks</td>
<td>Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.</td>
</tr>
</tbody>
</table>

**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.
EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Polyethylene glycol 25322-68-3
- Starch 9005-25-8
- Fluralaner 864731-61-3
- Soya oil 8001-22-7
- Glycerine 56-81-5
- Sucrose 57-50-1

California Permissible Exposure Limits for Chemical Contaminants
- Starch 9005-25-8
- Glycerine 56-81-5
- Sucrose 57-50-1

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

SECTION 16. OTHER INFORMATION

Further information
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NFPA 704:

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>0</td>
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</table>

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average
US WEEL / TWA : 8-hr TWA

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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 Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; IECS - 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; KECL - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office
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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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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 Bioaccumulative


Revision Date: 03/23/2020

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.

US / Z8