1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Fluralaner Solid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
           Wagholi - Pune - India  412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Skin corrosion/irritation: Category 3
Reproductive toxicity: Category 2
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms:

Signal word: Warning

Hazard statements: H316 Causes mild skin irritation.
                  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.
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P202 Do not handle until all safety precautions have been read and understood.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (%) w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 25</td>
</tr>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&gt;= 5 - &lt; 20</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>&gt;= 5 - &lt;= 10</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>&gt;= 1 - &lt;= 5</td>
</tr>
</tbody>
</table>

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 advice if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms : Causes mild skin irritation.
3. HAZARDS IDENTIFICATION

Health hazards

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.

5. FIREFIGHTING 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
Sulphur 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 firefighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Use personal protective equipment.
Follow safe handling advice 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.

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 labelled containers.
Store locked up.
Store in accordance with the particular national regulations.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<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>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>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</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 vapour 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
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Pasty solid
Colour : light brown
Odour : No data available
Odour Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : 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
Vapour pressure : No data available
Relative vapour 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
Auto-ignition temperature : No data available
Decomposition temperature : No data available
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.

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:

Starch:
- Acute oral toxicity: LD50 (Mouse): > 5,000 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

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
Causes mild skin irritation.

Components:
Fluralaner:
Species: Rabbit
Result: No skin irritation

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

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

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

Experience with human exposure

Components:

Fluralaner:

Skin contact: Remarks: May irritate skin.
Eye contact: Remarks: May cause eye irritation.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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: >= 0.049 mg/l
   Exposure time: 21 d
Species: Zebrafish
Method: OECD Test Guideline 204
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC: 0.000047 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 1,000

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
Exposure time: 72 h

NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l
Exposure time: 72 h

Toxicity to microorganisms:

EC50: 135 mg/l
Exposure time: 3 h

Toxicity to fish (Chronic toxicity):

NOEC: >= 1.357 mg/l
Exposure time: 42 d
Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC: 0.88 mg/l
Exposure time: 7 d
Species: Ceriodaphnia dubia (water flea)

Persistence and degradability

Components:

Sodium n-dodecyl sulfate:

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

Bioaccumulative potential

Components:

Fluralaner:

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

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

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).

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.

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
IATA-DGR
UN/ID No.  :  UN 3077
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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 IMO instruments
Not applicable for product as supplied.

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

15. REGULATORY INFORMATION

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

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

AICS: not determined
DSL: not determined
IECSC: not determined

16. OTHER INFORMATION

Further information

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

Fluralaner Solid Formulation

Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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.

IN / EN