

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner (with Vitamin E) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/14/2025  |
| 8.0     | 10/02/2025     | 914889-00025 | Date of first issue: 10/05/2016 |

### SECTION 1. IDENTIFICATION

Product name : Fluralaner (with Vitamin E) Formulation  
Other means of identification : EXZOLT (A011389)  
EXZOLT FLURALANER ORAL SOLUTION FOR CHICKENS  
(85688)

#### 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 OSHA Hazard Communication Standard (29 CFR 1910.1200)**

#### Hazards for the product as supplied

Reproductive toxicity : Category 2

#### Other hazards

None known.

#### 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:

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P405 Store locked up.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name                     | CAS No./Unique ID | Concentration (% w/w) | Trade secret |
|-----------------------------------|-------------------|-----------------------|--------------|
| Diethylene glycol monoethyl ether | 111-90-0*         | $\geq 10 - \leq 30$   | TSC          |
| Fluralaner                        | 864731-61-3*      | $\geq 0.5 - \leq 1.5$ | TSC          |

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

## 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 soap and 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 (CO<sub>2</sub>)

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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

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.  
Prevent spreading over a wide area (e.g., by containment or oil barriers).  
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 : Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
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

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- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Avoid inhalation of vapor or mist.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
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 in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components                        | CAS-No.     | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|-----------------------------------|-------------|----------------------------------|--|----------|
| Diethylene glycol monoethyl ether | 111-90-0    | TWA                              | 25 ppm   | US WEEL  |
| Fluralaner                        | 864731-61-3 | TWA                              | 100 µg/m <sup>3</sup> (OEB 2)                  | Internal |
| Further information: Skin         |             |                                  |  |          |
|                                   |             | Wipe limit                       | 1000 µg/100 cm <sup>2</sup>                    | Internal |

- Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Laboratory operations do not require special containment.

#### 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.

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|                          |  |
|--------------------------|--|
| Hand protection          |  |
| Material                 | : Chemical-resistant gloves  |
| Eye protection           | : Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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                                       | : liquid            |
| Color  | : yellow            |
| 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                                      | : 217 °F / 103 °C   |
| Evaporation rate                                 | : No data available |
| Flammability (solid, gas)                        | : Not applicable    |
| 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 |

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|  |   |  |
|--|---|--|
| Relative vapor density                 | : | No data available  |
| Relative density                       | : | No data available  |
| Density                                | : | 1,045 kg/m <sup>3</sup> (77 °F / 25 °C)                  |
| Solubility(ies)                        | : |  |
| Water solubility                       | : | soluble  |
| Partition coefficient: n-octanol/water | : | Not applicable   |
| Autoignition temperature               | : | No data available  |
| Decomposition temperature              | : | No data available  |
| Viscosity                              | : |  |
| Viscosity, dynamic                     | : | 0.145 Pas (77 °F / 25 °C)                                |
| Viscosity, kinematic                   | : | 139 mm <sup>2</sup> /s (77 °F / 25 °C)                   |
| Explosive properties                   | : | Not explosive  |
| Oxidizing properties                   | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight                       | : | Not applicable   |
| Particle characteristics               | : |  |
| Particle size                          | : | Not applicable   |

### 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

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

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### **Product:**

|                       |   |   |
|-----------------------|---|---|
| Acute oral toxicity   | : | LD50 (Rat, female): > 2,000 mg/kg<br>Method: OECD Test Guideline 423          |
| Acute dermal toxicity | : | LD50 (Rat, male and female): > 2,000 mg/kg<br>Method: OECD Test Guideline 402 |

### **Components:**

#### **Diethylene glycol monoethyl ether:**

|                           |   |  |
|---------------------------|---|--|
| Acute oral toxicity       | : | LD50 (Rat): > 5,000 mg/kg  |
| Acute inhalation toxicity | : | LC50 (Rat): > 5.24 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: OECD Test Guideline 403 |
| Acute dermal toxicity     | : | LD50 (Rabbit): 9,143 mg/kg   |

#### **Fluralaner:**

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

### **Skin corrosion/irritation**

Not classified based on available information.

### **Product:**

|         |   |                         |
|---------|---|-------------------------|
| Species | : | Rabbit                  |
| Method  | : | OECD Test Guideline 404 |
| Result  | : | No skin irritation      |

### **Components:**

#### **Diethylene glycol monoethyl ether:**

|         |   |                    |
|---------|---|--------------------|
| Species | : | Rabbit             |
| Result  | : | No skin irritation |

#### **Fluralaner:**

|         |   |                    |
|---------|---|--------------------|
| Species | : | Rabbit             |
| Result  | : | No skin irritation |

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Product:**

|         |   |        |
|---------|---|--------|
| Species | : | Rabbit |
|---------|---|--------|

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|        |   |                         |
|--------|---|-------------------------|
| Result | : | No eye irritation       |
| Method | : | OECD Test Guideline 405 |

### Components:

#### Diethylene glycol monoethyl ether:

|         |   |                         |
|---------|---|-------------------------|
| Species | : | Rabbit                  |
| Result  | : | No eye irritation       |
| Method  | : | OECD Test Guideline 405 |

#### Fluralaner:

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

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

### Product:

|           |   |                         |
|-----------|---|-------------------------|
| Test Type | : | Maximization Test       |
| Species   | : | Guinea pig              |
| Method    | : | OECD Test Guideline 406 |
| Result    | : | negative                |

### Components:

#### Fluralaner:

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

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Diethylene glycol monoethyl ether:

|                       |   |  |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative  |
| Genotoxicity in vivo  | : | Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |



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### Fluralaner:

|                       |   |   |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative  |
|                       |   | Test Type: Mouse Lymphoma<br>Result: negative   |
|                       |   | Test Type: Chromosomal aberration<br>Result: negative   |
| Genotoxicity in vivo  | : | Test Type: Micronucleus test<br>Species: Mouse<br>Cell type: Bone marrow<br>Application Route: Oral<br>Result: negative |

### Carcinogenicity

Not classified based on available information.

### Components:

#### Fluralaner:

|                              |   |                   |
|------------------------------|---|-------------------|
| Carcinogenicity - Assessment | : | No data available |
|------------------------------|---|-------------------|

**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:

#### Diethylene glycol monoethyl ether:

|                      |   |   |
|----------------------|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study |
|                      |   | Species: Mouse  |
|                      |   | 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 |
|----------------------|---|---------------------------------|

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|                                    |  |
|------------------------------------|--|
|                                    | Species: Rat<br>Application Route: Oral<br>General Toxicity Parent: NOAEL: 50 mg/kg body weight<br>General Toxicity F1: LOAEL: 100 mg/kg body weight<br>Result: No effects on fertility., Postimplantation loss., Adverse neonatal effects.  |
| Effects on fetal development       | : Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 100 mg/kg body weight<br>Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects.<br><br>Test Type: Development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 10 mg/kg body weight<br>Result: Skeletal malformations., Visceral malformations.<br>Remarks: Maternal toxicity observed.<br><br>Test Type: Development<br>Species: Rabbit<br>Application Route: Dermal<br>Developmental Toxicity: NOAEL: 100 mg/kg body weight<br>Result: Skeletal malformations. |
| Reproductive toxicity - Assessment | : Suspected of damaging the unborn child.  |

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### Components:

##### Diethylene glycol monoethyl ether:

|                   |                               |
|-------------------|-------------------------------|
| Species           | : Dog                         |
| NOAEL             | : 1,000 mg/kg                 |
| Application Route | : Ingestion                   |
| Exposure time     | : 13 Weeks                    |
| Species           | : Rat                         |
| NOAEL             | : >= 1.06 mg/l                |
| Application Route | : inhalation (dust/mist/fume) |
| Exposure time     | : 28 Days                     |
| Species           | : Rabbit                      |
| NOAEL             | : >= 1,000 mg/kg              |
| Application Route | : Skin contact                |

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|| Exposure time : 28 Days

### 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 : 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

### 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:

#### Diethylene glycol monoethyl ether:

|| Toxicity to fish : LC50 (Ictalurus catus (catfish)): 6,010 mg/l  
Exposure time: 96 h  
|| Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,982 mg/l  
aquatic invertebrates Exposure time: 48 h

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|                                  |   |
|----------------------------------|---|
| Toxicity to algae/aquatic plants | : EC50 (Selenastrum capricornutum (green algae)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials<br><br>NOEC (Selenastrum capricornutum (green algae)): >= 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials |
| Toxicity to microorganisms       | : IC50: > 5,000 mg/l<br>Exposure time: 16 h   |

### Fluralaner:

|  |  |
|--|--|
| Toxicity to fish   | : LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.0488 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203<br>Remarks: No toxicity at the limit of solubility.          |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): > 0.015 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>Remarks: No toxicity at the limit of solubility.                    |
| Toxicity to algae/aquatic plants                                       | : NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility. |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC (Zebrafish): >= 0.049 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 204<br>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<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211   |

### Persistence and degradability

#### Components:

#### Diethylene glycol monoethyl ether:

|                  |  |
|------------------|--|
| Biodegradability | : Result: Readily biodegradable.<br>Biodegradation: 100 %<br>Exposure time: 16 d<br>Method: OECD Test Guideline 301B |
|------------------|--|

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### Bioaccumulative potential

#### Components:

##### Diethylene glycol monoethyl ether:

Partition coefficient: n-octanol/water : log Pow: -0.54

##### Fluralaner:

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

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

### Mobility in soil

#### Components:

##### Fluralaner:

Distribution among environmental compartments : log Koc: 4.1

### Other adverse effects

#### Components:

##### Fluralaner:

Results of PBT and vPvB assessment : Not persistent, bioaccumulative, and toxic (PBT).

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

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

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 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Fluralaner)

Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

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### IATA-DGR

|  |  |
|--|--|
| UN/ID No.                                | : UN 3082  |
| Proper shipping name                     | : Environmentally hazardous substance, liquid, n.o.s. (Fluralaner)   |
| Class                                    | : 9  |
| Packing group                            | : III  |
| Labels                                   | : Miscellaneous  |
| Packing instruction (cargo aircraft)     | : 964  |
| Packing instruction (passenger aircraft) | : 964  |
| Environmentally hazardous                | : yes  |
| Remarks                                  | : Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids. |

### IMDG-Code

|                      |  |
|----------------------|--|
| UN number            | : UN 3082  |
| Proper shipping name | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Fluralaner)   |
| Class                | : 9  |
| Packing group        | : III  |
| Labels               | : 9  |
| EmS Code             | : F-A, S-F   |
| Marine pollutant     | : yes  |
| Remarks              | : Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids. |

### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

|                      |  |
|----------------------|--|
| UN/ID/NA number      | : UN 3082  |
| Proper shipping name | : Environmentally hazardous substance, liquid, n.o.s. (Fluralaner)   |
| Class                | : 9  |
| Packing group        | : III  |
| Labels               | : CLASS 9  |
| ERG Code             | : 171  |
| Marine pollutant     | : yes(Fluralaner)  |
| Remarks              | : Above applies only to containers over 119 gallons (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids. 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. |

### 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner (with Vitamin E) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 04/14/2025  |
| 8.0     | 10/02/2025     | 914889-00025 | Date of first issue: 10/05/2016 |

### SECTION 15. REGULATORY INFORMATION

#### 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** : The following components are subject to reporting levels established by SARA Title III, Section 313:

|                   |          |                |
|-------------------|----------|----------------|
| Diethylene glycol | 111-90-0 | >= 20 - < 30 % |
| monoethyl ether   |          |                |

#### US State Regulations

##### Pennsylvania Right To Know

|   |           |
|---|-----------|
| Polyethylene glycol sorbitan monooleate | 9005-65-6 |
| Diethylene glycol monoethyl ether       | 111-90-0  |
| Vitamin E                               | 59-02-9   |

#### The ingredients of this product are reported in the following inventories:

AICS : not determined

CA. DSL : not determined

IECSC : not determined

### SECTION 16. OTHER INFORMATION

#### Further information

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Fluralaner (with Vitamin E) Formulation

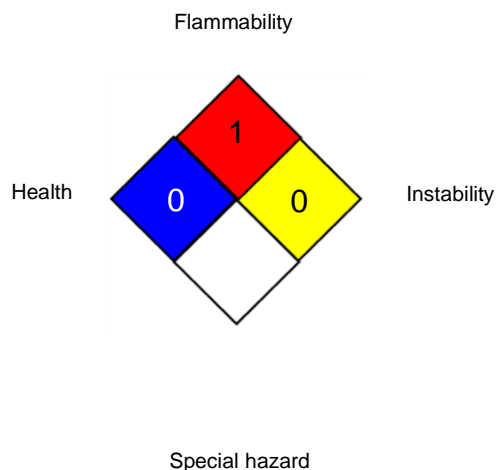
Version  
8.0

Revision Date:  
10/02/2025

SDS Number:  
914889-00025

Date of last issue: 04/14/2025  
Date of first issue: 10/05/2016

### NFPA 704:



### HMIS® IV:

|                 |   |   |
|-----------------|---|---|
| HEALTH          | * | 1 |
| FLAMMABILITY    |   | 1 |
| PHYSICAL HAZARD |   | 0 |

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

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)  
US WEEL / TWA : 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; 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 Standardization; 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; 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 Organization 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; 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 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, Authorization 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



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according to the OSHA Hazard Communication Standard



## Fluralaner (with Vitamin E) Formulation

|         |                |              |                                 |
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Inventory; 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 10/02/2025

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.

US / Z8