

# SAFETY DATA SHEET



## Fluralaner (with Vitamin E) Formulation

Version  
12.0

Revision Date:  
2025/10/02

SDS Number:  
914883-00027

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

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### 1. PRODUCT AND COMPANY IDENTIFICATION

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

#### Supplier's company name, address and phone number

Company name of supplier : MSD  
Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan  
Telephone : 03-6272-1099  
E-mail address : EHSDATASTEWARD@msd.com  
Emergency telephone number : +1-908-423-6000

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Long-term (chronic) aquatic hazard : Category 1

#### GHS label elements

Hazard pictograms : 

Signal word : Warning

Hazard statements : H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.  
**Response:**  
P391 Collect spillage.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

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### Other hazards which do not result in classification

None known.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name                     | CAS-No.     | Concentration (% w/w) | ENCS No.    |
|-----------------------------------|-------------|-----------------------|-------------|
| Diethylene glycol monoethyl ether | 111-90-0    | >= 20 - < 30          | 2-422, 7-97 |
| Fluralaner                        | 864731-61-3 | >= 1 - < 2.5          |             |

## 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.

In case of eye contact : Thoroughly clean shoes before reuse.  
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 : None known.

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 (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

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

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## 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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

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## 7. HANDLING AND STORAGE

### Handling

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 vapour or mist.  
Do not swallow.  
Avoid contact with eyes.

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|-----------------|------------------------------|-----------------------------|---|

|  |  |
|--|--|
| Avoidance of contact<br>Hygiene measures | <p>Avoid prolonged or repeated contact with skin.<br/>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br/>Take care to prevent spills, waste and minimize release to the environment.</p> <p>: Oxidizing agents<br/>: 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.</p> |
|--|--|

### Storage

|                             |  |
|-----------------------------|--|
| Conditions for safe storage | : Keep in properly labelled containers.<br>Store in accordance with the particular national regulations. |
| Materials to avoid          | : Do not store with the following product types:<br>Oxidizing solids<br>Oxidizing liquids                |
| Packaging material          | : Unsuitable material: None known.   |

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Threshold limit value and permissible exposure limits for each component in the work environment

| Components | CAS-No.                   | Value type<br>(Form of<br>exposure) | Control parame-<br>ters / Concentra-<br>tion standard /<br>Permissible con-<br>centration | Basis    |
|------------|---------------------------|-------------------------------------|---|----------|
| 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., dripless 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 : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

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|                          |  |
|--------------------------|--|
| Filter type              | : Combined particulates and organic vapour type  |
| Hand protection          | : 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.   |

### 9. PHYSICAL AND CHEMICAL PROPERTIES

|  |                                  |
|--|----------------------------------|
| Physical state   | : liquid                         |
| Colour   | : yellow                         |
| Odour  | : No data available              |
| Odour Threshold  | : No data available              |
| Melting point/freezing point   | : No data available              |
| Boiling point, initial boiling point and boiling range               | : No data available              |
| Flammability (solid, gas)  | : Not applicable                 |
| Flammability (liquids)   | : No data available              |
| Lower explosion limit and upper explosion limit / flammability limit |                                  |
| Upper explosion limit / Up-<br>per flammability limit                | : No data available              |
| Lower explosion limit /<br>Lower flammability limit                  | : No data available              |
| Flash point  | : 103 °C                         |
| Decomposition temperature  | : No data available              |
| pH   | : No data available              |
| Evaporation rate   | : No data available              |
| Auto-ignition temperature  | : No data available              |
| Viscosity  |                                  |
| Viscosity, dynamic   | : 0.145 Pas (25 °C)              |
| Viscosity, kinematic   | : 139 mm <sup>2</sup> /s (25 °C) |
| Solubility(ies)  |                                  |

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|  |   |  |
|--|---|--|
| Water solubility                       | : | soluble  |
| Partition coefficient: n-octanol/water | : | Not applicable   |
| Vapour pressure                        | : | No data available  |
| Density and / or relative density      | : |  |
| Relative density                       | : | No data available  |
| Density                                | : | 1,045 kg/m <sup>3</sup> (25 °C)                          |
| Relative vapour density                | : | No data available  |
| 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   |

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## 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. |

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## 11. TOXICOLOGICAL INFORMATION

|  |   |  |
|--|---|--|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |
|--|---|--|

### Acute toxicity

Not classified based on available information.

#### 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 |

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

**Components:****Diethylene glycol monoethyl ether:**

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

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Method : OECD Test Guideline 405

**Fluralaner:**

Species : Rabbit  
Result : Mild eye irritation

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Product:**

Test Type : Maximisation Test  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

**Components:****Fluralaner:**

Test Type : Maximisation Test  
Exposure routes : 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)  
Method: OECD Test Guideline 471  
Result: negative

Genotoxicity in vivo : Test Type: Unscheduled DNA synthesis (UDS) test with  
mammalian liver cells in vivo  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Fluralaner:**

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

Test Type: Mouse Lymphoma  
Result: negative

Test Type: Chromosomal aberration

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Result: negative

**Genotoxicity in vivo**

: Test Type: Micronucleus test  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Oral  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Fluralaner:**

**Carcinogenicity - Assessment** : No data available

**Reproductive toxicity**

Not classified based on available information.

**Components:****Diethylene glycol monoethyl ether:**

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

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

**Fluralaner:**

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

**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

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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.

### 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   |
| 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 |

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|                   |   |  |
|-------------------|---|--|
| 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. |

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

### Components:

#### Diethylene glycol monoethyl ether:

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

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

### 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 |
|------------------|---|--|

### Bioaccumulative potential

#### Components:

##### Diethylene glycol monoethyl ether:

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

#### **Fluralaner:**

|  |   |  |
|--|---|--|
| Bioaccumulation                        | : | Species: Zebrafish<br>Bioconcentration factor (BCF): 79.4<br>Method: OECD Test Guideline 305 |
| Partition coefficient: n-octanol/water | : | log Pow: 4.5   |

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### Mobility in soil

#### Components:

##### Fluralaner:

|| Distribution among environmental compartments : log Koc: 4.1

### Hazardous to the ozone layer

Not applicable

### Other adverse effects

#### Components:

##### Fluralaner:

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

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## 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.

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## 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

#### 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)

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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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

Refer to section 15 for specific national regulation.

### 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.

||

ERG Code : 171

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## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Group 4, Type 3 petroleums, Water soluble liquid, (4000 litre), Hazardous rank III

#### Chemical Substance Control Law

Priority Assessment Chemical Substance

| Chemical name             | Number |
|---------------------------|--------|
| 2-(2-Ethoxyethoxy)ethanol | 110    |

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

#### Substances Prevented From Impairment of Health

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

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### **Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

### **Substances Subject to be Notified Names**

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

| Chemical name                     | Concentration (%) | Remarks |
|-----------------------------------|-------------------|---------|
| Diethylene glycol monoethyl ether | >=20 - <30        | -       |

### **Substances Subject to be Indicated Names**

Law Article 57 (Ministerial Order Article 30 Appended Table 2)

| Chemical name                     | Remarks |
|-----------------------------------|---------|
| Diethylene glycol monoethyl ether | -       |

### **Skin and Eye Damage Substances (ISHL MO Art. 594-2)**

Not applicable

### **Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

### **Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

### **Ordinance on Prevention of Lead Poisoning**

Not applicable

### **Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

### **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

### **Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

### **Poisonous and Deleterious Substances Control Law**

Not applicable

### **Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

### **High Pressure Gas Safety Act**

Not applicable

### **Explosive Control Law**

Not applicable

### **Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

### **Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

# SAFETY DATA SHEET



## Fluralaner (with Vitamin E) Formulation

|                 |                              |                             |   |
|-----------------|------------------------------|-----------------------------|---|
| Version<br>12.0 | Revision Date:<br>2025/10/02 | SDS Number:<br>914883-00027 | Date of last issue: 2025/04/14<br>Date of first issue: 2016/10/05 |
|-----------------|------------------------------|-----------------------------|---|

### Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Y)  
Pack transportation : Classified as marine pollutant

### Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)  
Not applicable  
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)  
Not applicable

### Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined  
CA. DSL : not determined  
IECSC : not determined

## 16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

### Further information

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

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

Date format : yyyy/mm/dd

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonised System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Con-

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## Fluralaner (with Vitamin E) Formulation

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centration 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

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