

Fluralaner (with Vitamin E) Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 07.12.2020 |
| 2.0 | 27.08.2021 | 7663857-00002 | Date of first issue: 07.12.2020 |

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product name : Fluralaner (with Vitamin E) Formulation

Manufacturer or supplier's details

Company : Merck & Co., Inc

Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION**GHS Classification**

Reproductive toxicity : Category 2

Long-term (chronic) aquatic hazard : Category 1

GHS-Labeling

Hazard pictograms :



Signal word : Warning

Hazard statements : 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.
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.
P391 Collect spillage.

Storage:

P405 Store locked up.

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Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Pure substance/mixture : Mixture

Components

| Chemical name | CAS-No. | Classification | MAC value mg/m ³ / TSEL value | Concentration (% w/w) |
|---------------|-------------|--|--|--------------------------|
| Fluralaner | 864731-61-3 | Repr.2; H361d Aquatic Chronic1; H410 | No data available | >= 1 - < 2,5 |

For explanation of abbreviations see section 16.

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.

5. FIREFIGHTING MEASURES

Flammable properties

Flash point : 103 °C

Ignition temperature : No data available

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| | | |
|--|---|---|
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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 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 (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 deter- |

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mine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

- 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.
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.
See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Conditions for safe storage : Keep in properly labelled containers.
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

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Data Source |
|---------------------------|-------------|----------------------------------|--|-------------|
| Fluralaner | 864731-61-3 | TWA | 100 µg/m ³ (OEB 2) | Internal |
| Further information: Skin | | | | |
| | | Wipe limit | 1000 µg/100 cm ² | 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** : 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** : Chemical-resistant gloves
- Material** : Chemical-resistant gloves
- Eye protection** : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions,

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**II Skin and body protection
Hygiene measures**

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.
: Work uniform or laboratory coat.
: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
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 | : liquid |
| Colour | : yellow |
| 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 | : 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 |
| Vapour pressure | : No data available |
| Relative vapour density | : No data available |
| Relative density | : No data available |
| II Density | : 1.045 kg/m ³ (25 °C) |

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II

| | |
|--|--|
| Solubility(ies) | |
| Water solubility | : soluble |
| Partition coefficient: n-octanol/water | : Not applicable |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity | |
| Viscosity, dynamic | : 0,145 Pas (25 °C) |
| Viscosity, kinematic | : 139 mm ² /s (25 °C) |
| Explosive properties | : Not explosive |
| Oxidizing properties | : The substance or mixture is not classified as oxidizing. |
| Molecular weight | : Not applicable |
| Particle size | : Not applicable |

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 | : Inhalation Skin contact Ingestion Eye contact |
|--|--|

Acute toxicity

Not classified based on available information.

Components:**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 |

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Skin corrosion/irritation

Not classified based on available information.

Components:**Fluralaner:**

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

Serious eye damage/eye irritation

Not classified based on available information.

Components:**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.

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:**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 |

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Carcinogenicity

Not classified based on available information.

Components:

Fluralaner:

Carcinogenicity - Assessment : No data available

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.

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STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity**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 |
| 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. |

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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 (Zebrafish): >= 0,049 mg/l Exposure time: 21 d Method: OECD Test Guideline 204 Remarks: No toxicity at the limit of solubility |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0,000047 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 |
| M-Factor (Chronic aquatic toxicity) | : | 1.000 |

Persistence and degradability

No data available

Bioaccumulative potential

Components:

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 environ- | : | log Koc: 3,4 |
|-----------------------------|---|--------------|

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II mental compartments**Other adverse effects****Components:****II** **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**ADR**

| | | |
|------------------------------|---|---|
| UN number | : | UN 3082 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Fluralaner) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Hazard Identification Number | : | 90 |
| Tunnel restriction code | : | (-) |
| 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 |

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 |

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Marine pollutant : yes

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

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

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

Full text of H-Statements

| | |
|-------|---|
| H361d | Suspected of damaging the unborn child. |
| H410 | Very toxic to aquatic life with long lasting effects. |

Full text of other abbreviations

| | |
|-----------------|--------------------------------------|
| Aquatic Chronic | : Long-term (chronic) aquatic hazard |
| Repr. | : Reproductive toxicity |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median

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Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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

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.

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.

RU / EN