

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version
6.0

Revision Date:
2025/10/02

SDS Number:
914877-00025

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

1. PRODUCT AND COMPANY 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 : MSD
Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331
Telephone : +1-908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : liquid
Colour : yellow
Odour : No data available

May be harmful if swallowed or in contact with skin. Very toxic to aquatic life with long lasting effects.

GHS Classification

Acute toxicity (Oral) : Category 5
Acute toxicity (Dermal) : Category 5
Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :



SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version 6.0 Revision Date: 2025/10/02 SDS Number: 914877-00025 Date of last issue: 2025/04/14
Date of first issue: 2016/10/05

| | | |
|--------------------------|---|---|
| Signal word | : | Warning |
| Hazard statements | : | H303 + H313 May be harmful if swallowed or in contact with skin. H410 Very toxic to aquatic life with long lasting effects. |
| Precautionary statements | : | Prevention: P273 Avoid release to the environment. Response: P301 + P317 IF SWALLOWED: Get medical help. P302 + P352 + P317 IF ON SKIN: Wash with plenty of water. Get medical help. P391 Collect spillage. Disposal: P501 Dispose of contents/ container to an approved waste disposal plant. |

Physical and chemical hazards

Not classified based on available information.

Health hazards

May be harmful if swallowed. May be harmful in contact with skin.

Environmental hazards

Very toxic to aquatic life with long lasting effects.

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) |
|---------------|-------------|-----------------------|
| 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. |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

| | | | |
|----------------|------------------------------|-----------------------------|---|
| Version 6.0 | Revision Date: 2025/10/02 | SDS Number: 914877-00025 | Date of last issue: 2025/04/14 Date of first issue: 2016/10/05 |
|----------------|------------------------------|-----------------------------|---|

| | |
|---|---|
| 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 | : May be harmful if swallowed or in contact with skin. |
| 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 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 |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version
6.0

Revision Date:
2025/10/02

SDS Number:
914877-00025

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

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.

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.
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.

Avoidance of contact : Oxidizing agents

Storage

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

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
|------------|---------------------------|-------------------------------------|--|----------|
| Fluralaner | 864731-61-3 | TWA | 100 µg/m ³ (OEB 2) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 1000 µg/100 cm ² | Internal |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version
6.0

Revision Date:
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SDS Number:
914877-00025

Date of last issue: 2025/04/14
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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

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

Hand protection
Material : Chemical-resistant gloves

Hygiene measures : 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 |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version 6.0 Revision Date: 2025/10/02 SDS Number: 914877-00025 Date of last issue: 2025/04/14
Date of first issue: 2016/10/05

| | |
|--|--|
| 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 |
| Density | : 1,045 kg/m ³ (25 °C) |
| 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 characteristics | |
| 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. |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version 6.0 Revision Date: 2025/10/02 SDS Number: 914877-00025 Date of last issue: 2025/04/14
Date of first issue: 2016/10/05

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

May be harmful if swallowed or in contact with skin.

Product:

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg
Method: OECD Test Guideline 423

Acute dermal toxicity : LD50 (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402

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

Skin corrosion/irritation

Not classified based on available information.

Product:

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

Components:

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version 6.0 Revision Date: 2025/10/02 SDS Number: 914877-00025 Date of last issue: 2025/04/14
Date of first issue: 2016/10/05

Method : OECD Test Guideline 405

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.

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:

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 |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version
6.0

Revision Date:
2025/10/02

SDS Number:
914877-00025

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

Carcinogenicity

Not classified based on available information.

Components:

Fluralaner:

||| Carcinogenicity - Assessment : No data available

Reproductive toxicity

Not classified based on available information.

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.

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.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version
6.0

Revision Date:
2025/10/02

SDS Number:
914877-00025

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

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 | : | 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. |

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version 6.0 Revision Date: 2025/10/02 SDS Number: 914877-00025 Date of last issue: 2025/04/14
Date of first issue: 2016/10/05

| | | |
|--|---|---|
| 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)): 0.0736 µg/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 environmental compartments | : | log Koc: 4.1 |
|---|---|--------------|

Other adverse effects

Components:

Fluralaner:

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version 6.0 Revision Date: 2025/10/02 SDS Number: 914877-00025 Date of last issue: 2025/04/14
Date of first issue: 2016/10/05

13. DISPOSAL CONSIDERATIONS

Disposal methods

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

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 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) 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.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version
6.0

Revision Date:
2025/10/02

SDS Number:
914877-00025

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

National Regulations

GB 6944/12268

| | | |
|----------------------|---|---|
| UN number | : | UN 3082 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Fluralaner) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Marine pollutant | : | no |

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

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

| | | |
|----------------------------------|---|---|
| Catalogue of Hazardous Chemicals | : | This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination. |
|----------------------------------|---|---|

| | | |
|---|---|------------|
| Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218) | : | Not listed |
|---|---|------------|

| | | |
|--|---|------------|
| Hazardous Chemicals for Priority Management under SAWs | : | Not listed |
|--|---|------------|

| | | |
|---|---|------------|
| Catalogue of Specially Controlled Hazardous Chemicals | : | Not listed |
|---|---|------------|

| | | |
|------------------------------|---|------------|
| List of Explosive Precursors | : | Not listed |
|------------------------------|---|------------|

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

| | | |
|-------------------------------------|---|------------|
| Catalogue of Highly Toxic Chemicals | : | Not listed |
|-------------------------------------|---|------------|

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

| | | |
|---|---|------------|
| China Severely Restricted Toxic Chemicals for Import and Export | : | Not listed |
|---|---|------------|

Regulation on the Administration of Precursor Chemicals

| | | |
|---|---|------------|
| Catalogue and Classification of Precursor Chemicals | : | Not listed |
|---|---|------------|

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version
6.0

Revision Date:
2025/10/02

SDS Number:
914877-00025

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

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import : Not listed
and Export

List of Controlled Ozone Depleting Substances : Not listed

Environmental Protection Law

List of Priority Controlled Chemicals : Not listed

List of Key Controlled New Pollutants : Not listed

List of Toxic and Hazardous Water Pollutants : Not listed

List of Toxic and Hazardous Air Pollutants : Not listed

List of Toxic and Hazardous Soil Pollutants : Not listed

Measures for the Administration of Non-Medical Use of Narcotic Drugs and Psychotropic Substances

Catalogue of Controlled Narcotic Drugs and Psychotropic Substances with Non-Medical Use : Not listed

Measures for the Administration on Import and Export Licenses for Dual-Use Items and Technologies

Catalogue for Dual-Use Items and Technologies : Not listed

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

AICS : not determined

CA. DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2025/10/02

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Fluralaner (with Vitamin E) Formulation

Version
6.0

Revision Date:
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SDS Number:
914877-00025

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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 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; 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

Disclaimer

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.

CN / EN