

**Fluralaner (with Vitamin E) Formulation  
(AU/NZ)**

Version 2.1      Revision Date: 12.03.2024      SDS Number: 11357765-00003      Date of last issue: 04.03.2024  
Date of first issue: 28.02.2024

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**Section 1: Identification**

Product name : Fluralaner (with Vitamin E) Formulation (AU/NZ)  
Other means of identification : FLEXOLT ORAL LICE TREATMENT FOR SHEEP WITH ANY LENGTH OF WOOL (91565)  
FLEXOLT (A011971)

**Manufacturer or supplier's details**

Company : MSD  
Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand  
Telephone : 0800 800 543  
Emergency telephone number : 0800 764 766 (0800 POISON)    0800 243 622 (0800 CHEMCALL)  
E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product  
Restrictions on use : Not applicable

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**Section 2: Hazard identification****GHS Classification**

Reproductive toxicity : Category 2  
Hazardous to the aquatic environment - chronic hazard : Category 1

**GHS label elements**

Hazard pictograms :  

Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.  
H410 Very toxic to aquatic life with long lasting effects.

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Precautionary statements :

**Prevention:**  
 P201 Obtain special instructions before use.  
 P202 Do not handle until all safety precautions have been read and understood.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
 P391 Collect spillage.

**Storage:**  
 P405 Store locked up.

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

### Other hazards which do not result in classification

None known.

### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

| Chemical name | CAS-No.     | Concentration (% w/w) |
|---------------|-------------|-----------------------|
| Fluralaner    | 864731-61-3 | >= 1 -< 2.5           |

### 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.

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|   |   |   |
|---|---|---|
| Most important symptoms and effects, both acute and delayed | : | Rinse mouth thoroughly with water.<br>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.   |

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### Section 5: Fire-fighting measures

|   |   |   |
|---|---|---|
| Suitable extinguishing media                  | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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<br>Chlorine compounds<br>Fluorine compounds   |
| Specific extinguishing methods                | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |
| Hazchem Code                                  | : | 3Z  |

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### Section 6: Accidental release measures

|   |   |  |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).   |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can   |

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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

- 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.
- 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.
- 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

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

| Components                | CAS-No.     | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | 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** : Ensure adequate ventilation, especially in confined areas.  
Minimize workplace exposure concentrations.

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**Personal protective equipment**

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Combined particulates and organic vapour type
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
- Eye protection : Wear the following personal protective equipment:  
Safety glasses
- Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
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**Section 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

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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<sup>3</sup> (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<sup>2</sup>/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

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**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.

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### Section 11: Toxicological information

Exposure routes : 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

#### 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

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Species : Guinea pig  
Result : Not a skin sensitizer.

**Chronic toxicity****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

**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



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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.

### 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

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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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**Section 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 : NOEC (Pseudokirchneriella subcapitata (green algae)): >=

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plants : 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):  $\geq 0.049$  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  $\mu$ g/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 : Substance is not persistent, bioaccumulative, and toxic (PBT).

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**Section 13: Disposal considerations****Disposal methods**

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

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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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### 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

##### 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  
 Marine pollutant : yes

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

Not applicable for product as supplied.

#### National Regulations

##### NZS 5433

UN number : UN 3082  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Fluralaner)  
 Class : 9

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Packing group : III  
Labels : 9  
Hazchem Code : 3Z  
Marine pollutant : yes

**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.

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**Section 15: Regulatory information****Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100758 Veterinary Medicines Non dispersive Closed System Application Group Standard

## Tolerable Exposure Limits (TEL)

Not applicable

## Environmental Exposure Limits (EEL)

Not applicable

**HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**Section 16: Other information**

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**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/>

Date format : dd.mm.yyyy

**Full text of other abbreviations**

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AIIIC - 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 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 Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; 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 - 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; 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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