SAFETY DATA SHEET

Fluralaner (with Vitamin E) Formulation

Section 1: Identification

Product name : Fluralaner (with Vitamin E) Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
            Upper Hutt - New Zealand
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

Section 2: Hazard identification

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>&lt; 3</td>
</tr>
</tbody>
</table>

Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice
immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty
of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed:
If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
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.

Section 5: Fire-fighting measures

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
None known.

Specific hazards during firefighting:
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.

Hazchem Code:
3Z

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spills cannot be contained.

Methods and materials for:
Soak up with inert absorbent material.
containment and cleaning up

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.

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.

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.

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluralaner</td>
<td>864731-61-3</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>1000 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
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

Eye 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.

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
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
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Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : 1,045 kg/m³ (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 mm²/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

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

Section 11: Toxicological information

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
- 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**  
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.  
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.

**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
Remarks: No significant adverse effects were reported

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:**

<table>
<thead>
<tr>
<th>Exposure Type</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td>May irritate skin.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>May cause eye irritation.</td>
</tr>
</tbody>
</table>

### Section 12: Ecological information

#### Ecotoxicity

**Components:**

**Fluralaner:**

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>EC50/LC50 (mg/l)</th>
<th>Exposure Time (h)</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>&gt; 0.0488</td>
<td>96</td>
<td>OECD 203</td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>&gt; 0.015</td>
<td>48</td>
<td>OECD 202</td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>&gt;= 0.08</td>
<td>72</td>
<td>OECD 201</td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>&gt;= 0.049</td>
<td>21 d</td>
<td>OECD 204</td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>0.000047</td>
<td>21 d</td>
<td>OECD 211</td>
<td></td>
</tr>
</tbody>
</table>

#### Persistence and degradability

No data available

#### Bioaccumulative potential

**Components:**

**Fluralaner:**

<table>
<thead>
<tr>
<th>Bioaccumulation</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Zebrafish</td>
</tr>
</tbody>
</table>
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: 3.4

Other adverse effects

Components:

Fluralaner:
Results of PBT and vPvB assessment
: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

Section 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.

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

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
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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
Packing group : III
Labels : 9
Hazchem Code : 3Z

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.

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

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
Section 16: Other information

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations

AllC - 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 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.

NZ / EN