

SAFETY DATA SHEET



Fluralaner (with Vitamin E) Formulation

Version 4.0 Revision Date: 02.10.2025 SDS Number: 914871-00024 Date of last issue: 08.11.2024
Date of first issue: 05.10.2016

SECTION 1: 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 : Intervet Australia Pty Limited (trading as MSD Animal Health)
Address : 91-105 Harpin Street
Bendigo 3550, Victoria Australia
Telephone : 1 800 033 461
Emergency telephone number : Poisons Information Centre: Phone 13 11 26
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

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	< 3

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

SAFETY DATA SHEET



Fluralaner (with Vitamin E) Formulation

Version 4.0 Revision Date: 02.10.2025 SDS Number: 914871-00024 Date of last issue: 08.11.2024
Date of first issue: 05.10.2016

	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. 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.
Hazchem Code	: •3Z

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protection	: Use personal protective equipment.
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Fluralaner (with Vitamin E) Formulation

Version 4.0 Revision Date: 02.10.2025 SDS Number: 914871-00024 Date of last issue: 08.11.2024
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tive equipment and emergency procedures	Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	<ul style="list-style-type: none">: 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	<ul style="list-style-type: none">: 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.

SECTION 7. HANDLING AND STORAGE

Technical measures	<ul style="list-style-type: none">: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	<ul style="list-style-type: none">: Use only with adequate ventilation.
Advice on safe handling	<ul style="list-style-type: none">: 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 assessmentTake care to prevent spills, waste and minimize release to the environment.
Hygiene measures	<ul style="list-style-type: none">: 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	<ul style="list-style-type: none">: Keep in properly labelled containers.Store in accordance with the particular national regulations.
Materials to avoid	<ul style="list-style-type: none">: Do not store with the following product types:Strong oxidizing agents

SAFETY DATA SHEET



Fluralaner (with Vitamin E) Formulation

Version 4.0 Revision Date: 02.10.2025 SDS Number: 914871-00024 Date of last issue: 08.11.2024
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SECTION 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

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

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, 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

SAFETY DATA SHEET



Fluralaner (with Vitamin E) Formulation

Version 4.0 Revision Date: 02.10.2025 SDS Number: 914871-00024 Date of last issue: 08.11.2024
Date of first issue: 05.10.2016

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

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.

SAFETY DATA SHEET



Fluralaner (with Vitamin E) Formulation

Version 4.0 Revision Date: 02.10.2025 SDS Number: 914871-00024 Date of last issue: 08.11.2024
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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.

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
Method : OECD Test Guideline 405

SAFETY DATA SHEET



Fluralaner (with Vitamin E) Formulation

Version 4.0 Revision Date: 02.10.2025 SDS Number: 914871-00024 Date of last issue: 08.11.2024
Date of first issue: 05.10.2016

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.

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.

SAFETY DATA SHEET



Fluralaner (with Vitamin E) Formulation

Version 4.0 Revision Date: 02.10.2025 SDS Number: 914871-00024 Date of last issue: 08.11.2024
Date of first issue: 05.10.2016

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.

Repeated dose toxicity

Components:

Fluralaner:

SAFETY DATA SHEET



Fluralaner (with Vitamin E) Formulation

Version 4.0 Revision Date: 02.10.2025 SDS Number: 914871-00024 Date of last issue: 08.11.2024
Date of first issue: 05.10.2016

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.

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)): >=

SAFETY DATA SHEET



Fluralaner (with Vitamin E) Formulation

Version 4.0 Revision Date: 02.10.2025 SDS Number: 914871-00024 Date of last issue: 08.11.2024
Date of first issue: 05.10.2016

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): >= 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

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
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Other adverse effects

Components:

Fluralaner:

Results of PBT and vPvB assessment	: 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.
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.

SAFETY DATA SHEET



Fluralaner (with Vitamin E) Formulation

Version 4.0 Revision Date: 02.10.2025 SDS Number: 914871-00024 Date of last issue: 08.11.2024
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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
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.

National Regulations

ADG

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

SAFETY DATA SHEET



Fluralaner (with Vitamin E) Formulation

Version 4.0 Revision Date: 02.10.2025 SDS Number: 914871-00024 Date of last issue: 08.11.2024
Date of first issue: 05.10.2016

Environmentally hazardous : 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.

SECTION 15. REGULATORY INFORMATION

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

Therapeutic Goods (Poisons Standard) Instrument : Schedule 5 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

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

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

Revision Date : 02.10.2025
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 : dd.mm.yyyy

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 Sys

SAFETY DATA SHEET



Fluralaner (with Vitamin E) Formulation

Version 4.0	Revision Date: 02.10.2025	SDS Number: 914871-00024	Date of last issue: 08.11.2024 Date of first issue: 05.10.2016
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tem; 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

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.

AU / EN