

Fluralaner (with Vitamin E) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023
2.14 30.09.2023 914890-00020 Date of first issue: 05.10.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : Fluralaner (with Vitamin E) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Veterinary product
stance/Mixture

Recommended restrictions : Not applicable
on use

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person : EHSDATASTEWARD@msd.com
responsible for the SDS

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Long-term (chronic) aquatic hazard, Category 1 H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Warning

Hazard statements : H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P273 Avoid release to the environment.

Fluralaner (with Vitamin E) Formulation

Version 2.14 Revision Date: 30.09.2023 SDS Number: 914890-00020 Date of last issue: 04.04.2023
 Date of first issue: 05.10.2016

Response:

P391 Collect spillage.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Fluralaner	864731-61-3	Repr. 2; H361d Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 1.000	>= 1 - < 2,5

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- 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).
- 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.

Fluralaner (with Vitamin E) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.14	30.09.2023	914890-00020	Date of first issue: 05.10.2016

Get medical attention if irritation develops and persists.

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

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Chlorine compounds
Fluorine compounds

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

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

Fluralaner (with Vitamin E) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.14	30.09.2023	914890-00020	Date of first issue: 05.10.2016

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage : Keep in properly labelled containers. Store in accordance with

Fluralaner (with Vitamin E) Formulation

Version 2.14 Revision Date: 30.09.2023 SDS Number: 914890-00020 Date of last issue: 04.04.2023
 Date of first issue: 05.10.2016

areas and containers the particular national regulations.

Advice on common storage : Do not store with the following product types:
 Strong oxidizing agents
 Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

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

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Diethylene glycol monoethyl ether	Workers	Inhalation	Long-term systemic effects	61 mg/m ³
	Workers	Inhalation	Long-term local effects	30 mg/m ³
	Workers	Skin contact	Long-term systemic effects	83 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	37 mg/m ³
	Consumers	Inhalation	Long-term local effects	18 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	25 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	50 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Vitamin E	Fresh water	0,516 mg/l
	Marine water	0,0516 mg/l
	Intermittent use/release	0,1 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	280000 mg/kg
	Marine sediment	28000 mg/kg
	Soil	228000 mg/kg
Diethylene glycol monoethyl ether	Fresh water	1,98 mg/l
	Marine water	0,198 mg/l

Fluralaner (with Vitamin E) Formulation

Version 2.14 Revision Date: 30.09.2023 SDS Number: 914890-00020 Date of last issue: 04.04.2023
 Date of first issue: 05.10.2016

	Freshwater - intermittent	19,8 mg/l
	Sewage treatment plant	500 mg/l
	Fresh water sediment	7,32 mg/kg dry weight (d.w.)
	Marine sediment	0,732 mg/kg dry weight (d.w.)
	Soil	0,34 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	444 mg/kg food

8.2 Exposure controls

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

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.
Hand protection	:	
Material	:	Chemical-resistant gloves
Skin and body protection	:	Work uniform or laboratory coat.
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 (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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

Fluralaner (with Vitamin E) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.14	30.09.2023	914890-00020	Date of first issue: 05.10.2016

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.

9.2 Other information

Flammability (liquids)	:	No data available
Molecular weight	:	Not applicable
Particle size	:	Not applicable

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	Can react with strong oxidizing agents.
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10.4 Conditions to avoid

Conditions to avoid	:	None known.
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Fluralaner (with Vitamin E) Formulation

Version 2.14 Revision Date: 30.09.2023 SDS Number: 914890-00020 Date of last issue: 04.04.2023
Date of first issue: 05.10.2016

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:**Fluralaner:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Remarks: No mortality observed at this dose.
No significant adverse effects were reported

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Remarks: No significant adverse effects were reported

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.

Fluralaner (with Vitamin E) Formulation

Version 2.14 Revision Date: 30.09.2023 SDS Number: 914890-00020 Date of last issue: 04.04.2023
Date of first issue: 05.10.2016

Respiratory sensitisation

Not classified based on available information.

Components:**Fluralaner:**

Test Type : Maximisation Test
Exposure routes : Dermal
Species : Guinea pig
Result : Not a skin sensitizer.

Germ cell mutagenicity

Not classified based on available information.

Components:**Fluralaner:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

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.

Fluralaner (with Vitamin E) Formulation

Version 2.14 Revision Date: 30.09.2023 SDS Number: 914890-00020 Date of last issue: 04.04.2023
 Date of first issue: 05.10.2016

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

Fluralaner (with Vitamin E) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.14	30.09.2023	914890-00020	Date of first issue: 05.10.2016

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

12.1 Toxicity

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
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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
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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
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Toxicity to fish (Chronic tox-	:	NOEC: >= 0,049 mg/l
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Fluralaner (with Vitamin E) Formulation

Version 2.14 Revision Date: 30.09.2023 SDS Number: 914890-00020 Date of last issue: 04.04.2023
 Date of first issue: 05.10.2016

icity) Exposure time: 21 d
 Species: Zebrafish
 Method: OECD Test Guideline 204
 Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,0736 µg/l
 Exposure time: 21 d
 Species: Daphnia magna (Water flea)
 Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1.000

12.2 Persistence and degradability

No data available

12.3 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

12.4 Mobility in soil

Components:

Fluralaner:

Distribution among environmental compartments : log Koc: 4,1

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Components:

Fluralaner:

Assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

12.6 Other adverse effects

Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation

Fluralaner (with Vitamin E) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.14	30.09.2023	914890-00020	Date of first issue: 05.10.2016

(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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

14.1 UN number

ADN	:	UN 3082
ADR	:	UN 3082
RID	:	UN 3082
IMDG	:	UN 3082
IATA	:	UN 3082

14.2 UN proper shipping name

ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Fluralaner)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Fluralaner)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Fluralaner)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Fluralaner)
IATA	:	Environmentally hazardous substance, liquid, n.o.s. (Fluralaner)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	:	9
ADR	:	9
RID	:	9

Fluralaner (with Vitamin E) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.14	30.09.2023	914890-00020	Date of first issue: 05.10.2016

IMDG : 9

IATA : 9

14.4 Packing group

ADN

Packing group : III
 Classification Code : M6
 Hazard Identification Number : 90
 Labels : 9

ADR

Packing group : III
 Classification Code : M6
 Hazard Identification Number : 90
 Labels : 9
 Tunnel restriction code : (-)

RID

Packing group : III
 Classification Code : M6
 Hazard Identification Number : 90
 Labels : 9

IMDG

Packing group : III
 Labels : 9
 EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft) : 964
 Packing instruction (LQ) : Y964
 Packing group : III
 Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
 Packing instruction (LQ) : Y964
 Packing group : III
 Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

Fluralaner (with Vitamin E) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.14	30.09.2023	914890-00020	Date of first issue: 05.10.2016

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H361d : Suspected of damaging the unborn child.

H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard

Repr. : Reproductive toxicity

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships car-

Fluralaner (with Vitamin E) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.14	30.09.2023	914890-00020	Date of first issue: 05.10.2016

rying 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

Aquatic Chronic 1 H410

Classification procedure:

Calculation method

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.

ZA / EN