according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Fluralaner (with Vitamin E) Formulation

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# SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Fluralaner (with Vitamin E) Formulation

Other means of identification : EXZOLT (A011389)

**EXZOLT FLURALANER ORAL SOLUTION FOR CHICKENS** 

(85688)

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

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Piercetown

A86 HD21 Dunboyne, Ireland

Telephone : 908-740-4000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

### 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, Cat- H410: Very toxic to aquatic life with long lasting

egory 1 effects.

### 2.2 Label elements

Signal word

# Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

: Warning

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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

Precautionary statements : Prevention:

P273 Avoid release to the environment.

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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 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 ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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.

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 prod: :

ucts

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 pro-

tective equipment recommendations (see section 8).

### 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 absor-

bent.

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 deter-

mine 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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 as-

sessment

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 contami-

nated 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 areas and containers

Keep in properly labelled containers. Store in accordance with

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/m3 (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 μg/100 cm <sup>2</sup>	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/m3
	Workers	Inhalation	Long-term local effects	30 mg/m3
	Workers	Skin contact	Long-term systemic effects	83 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic	37 mg/m3

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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		effects	
Consume	rs Inhalation	Long-term local ef- fects	18 mg/m3
Consume	rs Skin contact	Long-term systemic effects	25 mg/kg bw/day
Consume	rs 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
Fluralaner	Water	7 ng/l
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
	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 expo-

sure assessment demonstrates exposures outside the rec-

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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ommended guidelines, use respiratory protection.

Filter should conform to I.S. EN 14387

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

Physical state : liquid

Colour : yellow

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

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

Flash point : 103 °C

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, dynamic : 0.145 Pas (25 °C)

Viscosity, kinematic : 139 mm2/s (25 °C)

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

Not applicable

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Vapour pressure : No data available

Relative density : No data available

Density : 1,045 kg/m³ (25 °C)

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : 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.

10.4 Conditions to avoid

Conditions to avoid : None known.

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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## **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

Method : OECD Test Guideline 405

Result : No eye irritation

**Components:** 

Fluralaner:

Species : Rabbit

Result : Mild eye irritation

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### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

# Respiratory sensitisation

Not classified based on available information.

**Product:** 

**Maximisation Test** Test Type

Species Guinea pig

Method **OECD Test Guideline 406** 

Result negative

## **Components:**

Fluralaner:

Test Type **Maximisation Test** 

Exposure routes : Dermal : Guinea pig **Species** 

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

Test Type: Micronucleus test Genotoxicity in vivo

Species: Mouse

Cell type: Bone marrow Application Route: Oral

Result: negative

#### Carcinogenicity

Not classified based on available information.

### **Components:**

#### Fluralaner:

Carcinogenicity - Assess- : No data available

ment

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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#### 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 develop-

ment were detected.

Remarks: No significant adverse effects were reported

Effects on foetal develop-

ment

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 - As-

sessment

Suspected of damaging the unborn child.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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#### 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

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

### 11.2 Information on other hazards

### **Endocrine disrupting properties**

Not classified based on available information.

# **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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### **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

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 0.015 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic

plants

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

0.08 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic tox-

icity)

NOEC: >= 0.049 mg/l

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 (Chron-

ic 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 : Substance is not persistent, bioaccumulative, and toxic (PBT).

### 12.6 Endocrine disrupting properties

## **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

## 12.7 Other adverse effects

No data available

# **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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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# **SECTION 14: Transport information**

#### 14.1 UN number or ID 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
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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 : 964

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 964

ger aircraft)

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

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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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# **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Conditions of restriction for the following entries should be considered: Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not. Not applicable

Not applicable

Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Regulation (EU) No 2024/590 on substances that de-Not applicable

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation Not applicable

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2 200 t

E1 **ENVIRONMENTAL** 100 t

**HAZARDS** 

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Fluralaner (with Vitamin E) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 08.11.2024

 3.4
 14.04.2025
 925358-00027
 Date of first issue: 05.10.2016

**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 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; 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; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

Sources of key data used to compile the Safety Data

: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Sheet cy, http://echa.europa.eu/

Classification of the mixture:

Classification procedure:

Aquatic Chronic 1 H410 Calculation method

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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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