

# Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 15.04.2024 8.0 06.07.2024 401075-00028 Date of first issue: 10.12.2015

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

1.1 Product identifier

Trade name : Fluralaner Solid Formulation

Other means of identification : Bravecto chew (A011019)

BRAVECTO 1000 MG FLURALANER CHEWABLE TABLETS

FOR LARGE DOGS (68870)

BRAVECTO 112.5 MG FLURALANER CHEWABLE

TABLETS FOR VERY SMALL DOGS (68867)

BRAVECTO 1400 MG FLURALANER CHEWABLE TABLETS

FOR VERY LARGE DOGS (68873)

BRAVECTO 1-MONTH 100 MG FLURALANER CHEWABLE

TABLETS FOR SMALL DOGS (87862)

BRAVECTO 1-MONTH 200 MG FLURALANER CHEWABLE

TABLETS FOR MEDIUM DOGS (87861)

BRAVECTO 1-MONTH 400 MG FLURALANER CHEWABLE

TABLETS FOR LARGE DOGS (87860)

BRAVECTO 1-MONTH 45 MG FLURALANER CHEWABLE

TABLETS FOR VERY SMALL DOGS (87863)

BRAVECTO 1-MONTH 560 MG FLURALANER CHEWABLE

TABLETS FOR VERY LARGE DOGS (87859)

BRAVECTO 250 MG FLURALANER CHEWABLE TABLETS

FOR SMALL DOGS (68872)

BRAVECTO 500 MG FLURALANER CHEWABLE TABLETS

FOR MEDIUM DOGS (68871)

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

20 Spartan Road

1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000



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#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

Reproductive toxicity, Category 2 Long-term (chronic) aquatic hazard, Cat-

egory 1

H361d: Suspected of damaging the unborn child. 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 : H361d Suspected of damaging the unborn child.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P391 Collect spillage.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

Fluralaner

The following percentage of the mixture consists of ingredient(s) with unknown acute oral toxicity: 2 %

The following percentage of the mixture consists of ingredient(s) with unknown acute dermal toxicity: 2 %

The following percentage of the mixture consists of ingredient(s) with unknown acute inhalation toxicity: 2 %

#### 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.



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## **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

| Chemical name            | CAS-No. EC-No. Index-No. Registration number | Classification  | Concentration<br>(% w/w) |
|--------------------------|--|---|--------------------------|
| Soya oil                 | 8001-22-7<br>232-274-4                       | Aquatic Chronic 4;<br>H413  | >= 10 - <= 20            |
| Fluralaner               | 864731-61-3                                  | Repr. 2; H361d Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 1.000          | >= 5 - < 20              |
| Sodium n-dodecyl sulfate | 151-21-3<br>205-788-1                        | Acute Tox. 4; H302<br>Skin Irrit. 2; H315<br>Eye Dam. 1; H318<br>Aquatic Chronic 3;<br>H412 | >= 1 - <= 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.

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 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.



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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

Risks : Suspected of damaging the unborn child.

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

Chlorine compounds Fluorine compounds Sulphur oxides Metal oxides Sodium oxides

Carbon oxides

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 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).



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#### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. 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 : Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

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 : Do not get on skin or clothing.

Avoid breathing vapours.

Do not swallow.

Avoid contact with eyes.

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 locked up. Store in

accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents



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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    |
|------------|---|-------------------------------|-----------------------------|----------|
| Starch     | 9005-25-8   | OEL-RL                        | 10 mg/m3                    | ZA OEL   |
|            | Further information: Occupational Exposure Limits - Restricted Limits For |                               |                             |          |
|            | Hazardous Chemical Agents   |                               |                             |          |
| Sucrose    | 57-50-1   | OEL-RL                        | 10 mg/m3                    | ZA OEL   |
|            | Further information: Occupational Exposure Limits - Restricted Limits For |                               |                             |          |
|            | Hazardous Chemical Agents   |                               |                             |          |
| Fluralaner | 864731-61-  | TWA                           | 100 μg/m3 (OEB 2)           | Internal |
|            | 3   |                               |                             |          |
|            | 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                |
| Sodium n-dodecyl sulfate | Workers   | Inhalation      | Long-term systemic effects   | 285 mg/m3            |
|                          | Workers   | Skin contact    | Long-term systemic effects   | 4060 mg/kg<br>bw/day |
|                          | Consumers | Inhalation      | Long-term systemic effects   | 85 mg/m3             |
|                          | Consumers | Skin contact    | Long-term systemic effects   | 2440 mg/kg<br>bw/day |
|                          | Consumers | Ingestion       | Long-term systemic effects   | 24 mg/kg<br>bw/day   |
| Glycerine                | Workers   | Inhalation      | Long-term local ef-<br>fects | 56 mg/m3             |
|                          | Consumers | Ingestion       | Long-term systemic effects   | 229 mg/kg<br>bw/day  |
|                          | Consumers | Inhalation      | Long-term local ef-<br>fects | 33 mg/m3             |

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

| Substance name           | Environmental Compartment | Value                            |
|--------------------------|---------------------------|----------------------------------|
| Fluralaner               | Water                     | 7 ng/l                           |
| Sodium n-dodecyl sulfate | Fresh water               | 0,176 mg/l                       |
|                          | Marine water              | 0,018 mg/l                       |
|                          | Sewage treatment plant    | 1,35 mg/l                        |
|                          | Fresh water sediment      | 6,97 mg/kg dry<br>weight (d.w.)  |
|                          | Marine sediment           | 0,697 mg/kg dry<br>weight (d.w.) |



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|           | Soil                     | 1,29 mg/kg dry<br>weight (d.w.)  |
|-----------|--------------------------|----------------------------------|
| Glycerine | Fresh water              | 0,885 mg/l                       |
|           | Marine water             | 0,0885 mg/l                      |
|           | Intermittent use/release | 8,85 mg/l                        |
|           | Sewage treatment plant   | 1000 mg/l                        |
|           | Fresh water sediment     | 3,3 mg/kg dry<br>weight (d.w.)   |
|           | Marine sediment          | 0,33 mg/kg dry<br>weight (d.w.)  |
|           | Soil                     | 0,141 mg/kg dry<br>weight (d.w.) |

#### 8.2 Exposure controls

## **Engineering measures**

Use feasible engineering controls to minimize exposure to compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

## 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-

ommended 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 : tablet, pellets
Colour : light brown
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 : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : Not classified as a flammability hazard



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Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower :

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available Partition coefficient: n- : Not applicable

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : No data available

Particle size : No data available

# **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



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## 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 : Skin contact exposure Ingestion

Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg

Method: Calculation method

**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

Sodium n-dodecyl sulfate:

Acute oral toxicity : LD50 (Rat): 1.200 mg/kg

Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 402

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Fluralaner:

Species : Rabbit

Result : No skin irritation

Sodium n-dodecyl sulfate:

Species : Rabbit Result : Skin irritation

Serious eye damage/eye irritation

Not classified based on available information.



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#### **Components:**

Fluralaner:

Species : Rabbit

Result : Mild eye irritation

Sodium n-dodecyl sulfate:

Species : Rabbit

Method : OECD Test Guideline 405
Result : Irreversible effects on the eye

#### 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.

## Sodium n-dodecyl sulfate:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Remarks : Based on data from similar materials

## 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



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Result: negative

Sodium n-dodecyl sulfate:

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

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)

Species: Mouse

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

**Components:** 

Fluralaner:

Carcinogenicity - Assess- : No

ment

No data available

Sodium n-dodecyl sulfate:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years

Method : OECD Test Guideline 453

Result : negative

Remarks : Based on data from similar materials

Reproductive toxicity

Suspected of damaging the unborn child.

**Components:** 

Fluralaner:

Effects on fertility : Test Type: Two-generation study

Species: Rat

Application Route: Oral

General Toxicity - Parent: NOAEL: 50 mg/kg body weight General Toxicity F1: LOAEL: 100 mg/kg body weight Result: No effects on fertility, Postimplantation loss., Adverse

neonatal effects.

Test Type: One-generation reproduction toxicity study

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



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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.

Sodium n-dodecyl sulfate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

# STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

Not classified based on available information.

#### Repeated dose toxicity

#### **Product:**

Species : Dog
LOAEL : 25 mg/kg
Application Route : Oral
Exposure time : 168 d
Symptoms : Vomiting

Remarks : No significant adverse effects were reported



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#### Components:

Soya oil:

Species : Rat

NOAEL : 4.000 mg/kg
Application Route : Ingestion
Exposure time : 90 h

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

Target Organs : Liver
Remarks : No significant adverse effects were reported

Sodium n-dodecyl sulfate:

Species : Rat
NOAEL : 488 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

**Aspiration toxicity** 

Not classified based on available information.

**Components:** 

Fluralaner:

Not applicable



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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

Sodium n-dodecyl sulfate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 29 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 5,55 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l

Exposure time: 72 h



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NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC50 : 135 mg/l

Exposure time: 3 h

Toxicity to fish (Chronic tox-

icity)

NOEC: >= 1,357 mg/l Exposure time: 42 d

Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0,88 mg/l Exposure time: 7 d

Species: Ceriodaphnia dubia (water flea)

#### 12.2 Persistence and degradability

#### **Components:**

Sodium n-dodecyl sulfate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 95 % Exposure time: 28 d

Method: OECD Test Guideline 301B

#### 12.3 Bioaccumulative potential

#### **Components:**

Soya oil:

Partition coefficient: n- : log Pow: > 4

octanol/water Remarks: Calculation

Fluralaner:

Bioaccumulation : Species: Zebrafish

Bioconcentration factor (BCF): 79,4 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 4,5

Sodium n-dodecyl sulfate:

Partition coefficient: n-

octanol/water

log Pow: 0,83

## 12.4 Mobility in soil

## **Components:**

Fluralaner:

Distribution among environmental compartments

log Koc: 4,1

#### 12.5 Results of PBT and vPvB assessment

## **Product:**



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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 Other adverse effects

**Product:** 

Endocrine disrupting poten-

tial

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 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.

**SECTION 14: Transport information** 

14.1 UN number

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Fluralaner)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Fluralaner)



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Version Revision Date: SDS Number: Date of last issue: 15.04.2024 8.0 06.07.2024 401075-00028 Date of first issue: 10.12.2015

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Fluralaner)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Fluralaner)

IATA : Environmentally hazardous substance, solid, 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 : M7
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**IMDG** 

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

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956 Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 956

ger aircraft)

Packing instruction (LQ) : Y956



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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 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** 

H302 : Harmful if swallowed. H315 : Causes skin irritation.



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H318 : Causes serious eye damage.

H361d : Suspected of damaging the unborn child.

H410 : Very toxic to aquatic life with long lasting effects.
H412 : Harmful to aquatic life with long lasting effects.
H413 : May cause long lasting harmful effects to aquatic life.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Dam. : Serious eye damage Repr. : Reproductive toxicity

Skin Irrit. : Skin irritation

ZA OEL : South Africa. The Regulations for Hazardous Chemical

Agents, Occupational Exposure Limits

ZA OEL / OEL-RL : Occupational Exposure Limit Restricted limit - 8- hour expo-

sure or equivalent (12 hour shifts)

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; 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**

Sheet

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-

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



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Classification of the mixture: Classification procedure:

Repr. 2 H361d Calculation method Aquatic Chronic 1 H410 Calculation method

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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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