

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

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### 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 Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Walton Manor, Walton  
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

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

#### 1.4 Emergency telephone number

+1-908-423-6000

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Reproductive toxicity, Category 2      H361d: Suspected of damaging the unborn child.  
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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

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 protection/ 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

#### Additional Labelling

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 %

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

### 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)
Soya oil	8001-22-7 232-274-4	Aquatic Chronic 4; 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	151-21-3 205-788-1	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412  specific concentra- tion limit Eye Irrit. 2; H319 10 - < 20 % Eye Dam. 1; H318 >= 20 %	>= 1 - <= 5
Substances with a workplace exposure limit :			
Starch	9005-25-8 232-679-6		>= 10 - < 25
Glycerine	56-81-5 200-289-5		>= 5 - <= 10
Sucrose	57-50-1 200-334-9		>= 5 - <= 10

For explanation of abbreviations see section 16.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	20.11.2023	9372476-00008	Date of first issue: 27.08.2021

### 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 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

- 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 (CO<sub>2</sub>)  
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.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	20.11.2023	9372476-00008	Date of first issue: 27.08.2021

---

Hazardous combustion products : Carbon oxides  
Chlorine compounds  
Fluorine compounds  
Sulphur oxides  
Metal oxides  
Sodium 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 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.

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## 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).

### 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.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container 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 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.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

- 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 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 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

### 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	TWA (inhalable dust)	10 mg/m <sup>3</sup>	GB EH40
		TWA (Respirable dust)	4 mg/m <sup>3</sup>	GB EH40
Glycerine	56-81-5	TWA (Mist)	10 mg/m <sup>3</sup>	GB EH40
Sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	GB EH40
		STEL	20 mg/m <sup>3</sup>	GB EH40
Fluralaner	864731-61-3	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: Skin				
		Wipe limit	1000 µg/100 cm <sup>2</sup>	Internal

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

### Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium n-dodecyl sulfate	Workers	Inhalation	Long-term systemic effects	285 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	4060 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	85 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	2440 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	24 mg/kg bw/day
Glycerine	Workers	Inhalation	Long-term local effects	56 mg/m <sup>3</sup>
	Consumers	Ingestion	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	33 mg/m <sup>3</sup>

### Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
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 weight (d.w.)
	Marine sediment	0.697 mg/kg dry weight (d.w.)
	Soil	1.29 mg/kg dry weight (d.w.)
	Glycerine	Fresh water
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 weight (d.w.)
Marine sediment		0.33 mg/kg dry weight (d.w.)
Soil		0.141 mg/kg dry 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.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	20.11.2023	9372476-00008	Date of first issue: 27.08.2021

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.  
Equipment should conform to BS 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

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

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



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	20.11.2023	9372476-00008	Date of first issue: 27.08.2021

---

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

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## 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.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

#### Acute toxicity

Not classified based on available information.

#### Product:

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

---

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

#### **Starch:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

#### **Glycerine:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

#### **Sucrose:**

Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

### **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

#### **Glycerine:**

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

---

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

##### Sodium n-dodecyl sulfate:

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

##### Starch:

Species : Rabbit  
Result : No eye irritation

##### Glycerine:

Species : Rabbit  
Result : No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Fluralaner:

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

##### Sodium n-dodecyl sulfate:

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

##### Starch:

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	20.11.2023	9372476-00008	Date of first issue: 27.08.2021

---

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

### 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

#### 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

#### Starch:

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

#### Glycerine:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

---

Test Type: Chromosome aberration test in vitro  
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

### Sucrose:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

#### Fluralaner:

Carcinogenicity - Assessment : 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

#### Glycerine:

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

### 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

---

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.

### **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 development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

### **Glycerine:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

---

Result: negative

### 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

#### 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  
Remarks : No significant adverse effects were reported

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

---

### Sodium n-dodecyl sulfate:

Species : Rat  
NOAEL : 488 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

### Starch:

Species : Rat  
NOAEL :  $\geq 2,000$  mg/kg  
Application Route : Skin contact  
Exposure time : 28 Days  
Method : OECD Test Guideline 410

### Glycerine:

Species : Rat  
NOAEL : 0.167 mg/l  
LOAEL : 0.622 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 13 Weeks

Species : Rat  
NOAEL : 8,000 - 10,000 mg/kg  
Application Route : Ingestion  
Exposure time : 2 yr

Species : Rabbit  
NOAEL : 5,040 mg/kg  
Application Route : Skin contact  
Exposure time : 45 Weeks

### 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.



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

### 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 toxicity) : 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 (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

##### **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  
NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l  
Exposure time: 72 h

Toxicity to microorganisms : EC50 : 135 mg/l  
Exposure time: 3 h

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	20.11.2023	9372476-00008	Date of first issue: 27.08.2021

---

Toxicity to fish (Chronic toxicity) : NOEC:  $\geq$  1.357 mg/l  
Exposure time: 42 d  
Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.88 mg/l  
Exposure time: 7 d  
Species: Ceriodaphnia dubia (water flea)

### Glycerine:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,955 mg/l  
Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida):  $>$  10,000 mg/l  
Exposure time: 16 h  
Method: DIN 38 412 Part 8

## 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

#### Glycerine:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 %  
Exposure time: 30 d  
Method: OECD Test Guideline 301D

## 12.3 Bioaccumulative potential

### Components:

#### Soya oil:

Partition coefficient: n-octanol/water : log Pow:  $>$  4  
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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	20.11.2023	9372476-00008	Date of first issue: 27.08.2021

---

### **Sodium n-dodecyl sulfate:**

Partition coefficient: n-octanol/water : log Pow: 0.83

### **Glycerine:**

Partition coefficient: n-octanol/water : log Pow: -1.75

### **Sucrose:**

Partition coefficient: n-octanol/water : Pow: < 1

## 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 Endocrine disrupting properties

### Product:

Assessment : 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.

## 12.7 Other adverse effects

No data available

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## 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	20.11.2023	9372476-00008	Date of first issue: 27.08.2021

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 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)
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
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# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version 4.2      Revision Date: 20.11.2023      SDS Number: 9372476-00008      Date of last issue: 30.09.2023  
Date of first issue: 27.08.2021

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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 aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 956  
Packing instruction (LQ) : Y956  
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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	20.11.2023	9372476-00008	Date of first issue: 27.08.2021

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Not applicable		
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable		
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable		
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable		
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable		
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	:	Not applicable		
Control of Major Accident Hazards Regulations 2015 (COMAH)			Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS		100 t	200 t

#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

#### 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.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	20.11.2023	9372476-00008	Date of first issue: 27.08.2021

### Full text of H-Statements

H302	:	Harmful if swallowed.
H315	:	Causes skin irritation.
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
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	:	Short-term exposure limit (15-minute reference period)

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
4.2	20.11.2023	9372476-00008	Date of first issue: 27.08.2021

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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:

Repr. 2	H361d
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
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.

GB / EN