

## Fluralaner Solid Formulation

Version 10.1      Revision Date: 29.11.2023      SDS Number: 401072-00027      Date of last issue: 20.11.2023  
Date of first issue: 10.12.2015

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### Section 1: Identification

Product 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)

#### Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON)    0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

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### Section 2: Hazard identification

#### GHS Classification

Reproductive toxicity : Category 2

## Fluralaner Solid Formulation

Version 10.1      Revision Date: 29.11.2023      SDS Number: 401072-00027      Date of last issue: 20.11.2023  
 Date of first issue: 10.12.2015

Hazardous to the aquatic environment - chronic hazard : Category 1

### GHS label elements

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.  
 P202 Do not handle until all safety precautions have been read and understood.  
 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.

**Disposal:**  
 P501 Dispose of contents/ container to an approved waste disposal plant.

### 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 %

### Other hazards which do not result in classification

None known.

## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
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## Fluralaner Solid Formulation

Version 10.1      Revision Date: 29.11.2023      SDS Number: 401072-00027      Date of last issue: 20.11.2023  
 Date of first issue: 10.12.2015

Starch	9005-25-8	>= 10 -< 25
Soya oil	8001-22-7	>= 10 -<= 20
Glycerine	56-81-5	>= 5 -<= 10
Sucrose	57-50-1	>= 5 -<= 10
Fluralaner	864731-61-3	>= 5 -< 20
Sodium n-dodecyl sulfate	151-21-3	>= 1 -<= 5

**Section 4: First-aid measures**

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
 When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
 Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water.  
 Remove contaminated clothing and shoes.  
 Get medical attention.  
 Wash clothing before reuse.  
 Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
 Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
 Get medical attention.  
 Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Suspected of damaging the unborn child.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

**Section 5: Fire-fighting measures**

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
 Chlorine compounds  
 Fluorine compounds  
 Sulphur oxides  
 Metal oxides  
 Sodium oxides

## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.11.2023
10.1	29.11.2023	401072-00027	Date of first issue: 10.12.2015

---

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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

Hazchem Code : 2Z

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### Section 6: Accidental release measures

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

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.

Methods and materials for containment and 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.

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### Section 7: Handling and storage

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,

## Fluralaner Solid Formulation

Version 10.1      Revision Date: 29.11.2023      SDS Number: 401072-00027      Date of last issue: 20.11.2023  
 Date of first issue: 10.12.2015

appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labelled containers. Store locked up.

Materials to avoid : Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	WES-TWA	10 mg/m <sup>3</sup>	NZ OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Glycerine	56-81-5	WES-TWA (Mist)	10 mg/m <sup>3</sup>	NZ OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Sucrose	57-50-1	WES-TWA	10 mg/m <sup>3</sup>	NZ OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
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

**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

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

Filter type : Combined particulates and organic vapour type

Hand protection : Chemical-resistant gloves

Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

### Section 9: Physical and chemical properties

**Fluralaner Solid Formulation**

Version 10.1      Revision Date: 29.11.2023      SDS Number: 401072-00027      Date of last issue: 20.11.2023  
Date of first issue: 10.12.2015

---

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

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 20.11.2023
10.1	29.11.2023	401072-00027	Date of first issue: 10.12.2015

---

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

Particle size : No data available

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**Section 10: Stability and reactivity**

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Can react with strong oxidizing agents.  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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**Section 11: Toxicological information**

Exposure routes : Skin contact  
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:****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

**Fluralaner:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: No mortality observed at this dose.  
No significant adverse effects were reported

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 20.11.2023
10.1	29.11.2023	401072-00027	Date of first issue: 10.12.2015

---

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:****Glycerine:**

Species : Rabbit  
Result : No skin irritation

**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.

**Components:****Starch:**

Species : Rabbit  
Result : No eye irritation

**Glycerine:**

Species : Rabbit  
Result : No eye irritation

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Species : Rabbit  
Result : Mild eye irritation

**Sodium n-dodecyl sulfate:**

Species : Rabbit



**Fluralaner Solid Formulation**

Version 10.1      Revision Date: 29.11.2023      SDS Number: 401072-00027      Date of last issue: 20.11.2023  
Date of first issue: 10.12.2015

---

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

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Starch:**

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

**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

**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

**Components:****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

**Fluralaner Solid Formulation**

Version 10.1      Revision Date: 29.11.2023      SDS Number: 401072-00027      Date of last issue: 20.11.2023  
Date of first issue: 10.12.2015

---

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

**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

**Carcinogenicity**

Not classified based on available information.

**Components:****Glycerine:**

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

**Fluralaner Solid Formulation**

Version 10.1      Revision Date: 29.11.2023      SDS Number: 401072-00027      Date of last issue: 20.11.2023  
Date of first issue: 10.12.2015

---

**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

**Reproductive toxicity**

Suspected of damaging the unborn child.

**Components:****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  
Result: negative

**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 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

## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.11.2023
10.1	29.11.2023	401072-00027	Date of first issue: 10.12.2015

---

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

### **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

**Fluralaner Solid Formulation**

Version 10.1      Revision Date: 29.11.2023      SDS Number: 401072-00027      Date of last issue: 20.11.2023  
Date of first issue: 10.12.2015

---

**Components:****Starch:**

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

**Soya oil:**

Species : Rat  
NOAEL : 4,000 mg/kg  
Application Route : Ingestion  
Exposure time : 90 h

**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

**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

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 20.11.2023
10.1	29.11.2023	401072-00027	Date of first issue: 10.12.2015

---

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

**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

**Experience with human exposure****Components:****Fluralaner:**

Skin contact : Remarks: May irritate skin.

Eye contact : Remarks: May cause eye irritation.

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**Section 12: Ecological information****Ecotoxicity****Components:****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

**Fluralaner:**

## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.11.2023
10.1	29.11.2023	401072-00027	Date of first issue: 10.12.2015

---

- 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 (Zebrafish): >= 0.049 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 204  
Remarks: No toxicity at the limit of solubility
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0736 µg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211
- 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 fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): >= 1.357 mg/l  
Exposure time: 42 d
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l  
Exposure time: 7 d
- Toxicity to microorganisms : EC50: 135 mg/l  
Exposure time: 3 h

**Fluralaner Solid Formulation**

Version 10.1      Revision Date: 29.11.2023      SDS Number: 401072-00027      Date of last issue: 20.11.2023  
Date of first issue: 10.12.2015

---

**Persistence and degradability****Components:****Glycerine:**

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

**Sodium n-dodecyl sulfate:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 95 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**Bioaccumulative potential****Components:****Soya oil:**

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

**Glycerine:**

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

**Sucrose:**

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

**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

**Mobility in soil****Components:****Fluralaner:**

Distribution among environmental compartments : log Koc: 4.1



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.11.2023
10.1	29.11.2023	401072-00027	Date of first issue: 10.12.2015

---

### Other adverse effects

#### Components:

##### Fluralaner:

Results of PBT and vPvB assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

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### Section 13: Disposal considerations

#### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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### Section 14: Transport information

#### International Regulations

##### UNRTDG

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Fluralaner)

Class : 9

Packing group : III

Labels : 9

Environmentally hazardous : yes

##### IATA-DGR

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Fluralaner)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 956

Packing instruction (passenger aircraft) : 956

Environmentally hazardous : yes

##### IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Fluralaner)

Class : 9

Packing group : III

Labels : 9

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 20.11.2023
10.1	29.11.2023	401072-00027	Date of first issue: 10.12.2015

---

EmS Code : F-A, S-F  
Marine pollutant : yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**National Regulations****NZS 5433**

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Fluralaner)  
Class : 9  
Packing group : III  
Labels : 9  
Hazchem Code : 2Z  
Marine pollutant : no

**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.

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**Section 15: Regulatory information****Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100757 Veterinary Medicines Limited Pack Size Finished Dose Group Standard

**HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined  
DSL : not determined  
IECSC : not determined

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**Section 16: Other information**

Revision Date : 29.11.2023

**Further information**

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

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## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.11.2023
10.1	29.11.2023	401072-00027	Date of first issue: 10.12.2015

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compile the Safety Data Sheet : eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
 NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average  
 NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

# SAFETY DATA SHEET



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