

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078946904

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078940498 078940499 078940500 078940501 078946903 078946905 078946906 078946907

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

---

**SECTION 1. IDENTIFICATION**

Product name : Fluralaner Solid Formulation

**Manufacturer or supplier's details**

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

---

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Reproductive toxicity : Category 2

**GHS label elements**

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H361d Suspected of damaging the unborn child.

Precautionary Statements :

**Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.

**Storage:**  
P405 Store locked up.

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

## Fluralaner Solid Formulation

Version 8.6      Revision Date: 04/04/2023      SDS Number: 401074-00023      Date of last issue: 10/01/2022  
 Date of first issue: 12/10/2015

### Additional Labeling

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

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Starch	9005-25-8	$\geq 10 - < 25$
Polyethylene glycol	25322-68-3	$\geq 10 - \leq 20$
Glycerine	56-81-5	$\geq 5 - \leq 10$
Sucrose	57-50-1	$\geq 5 - \leq 10$
Fluralaner	864731-61-3	$\geq 5 - < 20$
Sodium n-dodecyl sulfate	151-21-3	$\geq 1 - \leq 5$

## 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.

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

- |  |   |   |
|--|---|---|
| Specific hazards during fire fighting          | : | Exposure to combustion products may be a hazard to health.  |
| Hazardous combustion products                  | : | Carbon oxides<br>Chlorine compounds<br>Fluorine compounds<br>Sulfur oxides<br>Metal oxides<br>Sodium oxides   |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- |   |   |   |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).  |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

**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.<br>Avoid breathing vapors.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.   |

## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

Materials to avoid : Store locked up.  
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

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
Polyethylene glycol	25322-68-3	TWA (aerosol)	10 mg/m <sup>3</sup>	US WEEL
Sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

---

Hand protection	adequate protection.
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.
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.

---

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	: Pasty solid
Color	: light brown
Odor	: No data available
Odor 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
Vapor pressure	: No data available

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

Relative vapor 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
Autoignition 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.
Particle size	:	No data available

**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.

**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
---------------------	---	--

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

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

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

---

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

**Polyethylene glycol:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: Based on data from similar materials

**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

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:****Polyethylene glycol:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

**Glycerine:**

Species : Rabbit  
Result : No skin irritation

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

---

**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

**Polyethylene glycol:**

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405
Remarks	:	Based on data from similar materials

**Glycerine:**

Species	:	Rabbit
Result	:	No eye irritation

**Fluralaner:**

Species	:	Rabbit
Result	:	Mild eye irritation

**Sodium n-dodecyl sulfate:**

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

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

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

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

---

**Polyethylene glycol:**

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative
Remarks	: Based on data from similar materials

**Fluralaner:**

Test Type	: Maximization Test
Routes of exposure	: Dermal
Species	: Guinea pig
Result	: Not a skin sensitizer.

**Sodium n-dodecyl sulfate:**

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative
Remarks	: Based on data from similar materials

**Germ cell mutagenicity**

Not classified based on available information.

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

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

**Polyethylene glycol:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials
-----------------------	---

**Glycerine:**

Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test Result: negative
	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	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:**

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

---

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:**

Carcinogenicity - Assessment : No data available

**Sodium n-dodecyl sulfate:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Method : OECD Test Guideline 453

## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

---

Result : negative  
Remarks : Based on data from similar materials

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**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 fetal development : Test Type: Embryo-fetal 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 fetal 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

## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

---

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 fetal development : Test Type: Embryo-fetal 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

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

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

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

---

**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 y

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	: Diarrhea

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

**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.

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

---

**Components:****Fluralaner:**

Not applicable

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

Skin contact	:	Remarks: May irritate skin.
Eye contact	:	Remarks: May cause eye irritation.

---

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Polyethylene glycol:**

Toxicity to fish	:	LC50 ( <i>Poecilia reticulata</i> (guppy)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
------------------	---	---

**Glycerine:**

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

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

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

**Fluralaner:**

Toxicity to fish	:	LC50 ( <i>Oncorhynchus mykiss</i> (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 ( <i>Daphnia magna</i> (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 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): >= 0.08 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility.
----------------------------------	---	--

## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

Toxicity to fish (Chronic toxicity) : NOEC (Zebrafish):  $\geq 0.049$  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)):  $0.0736 \mu\text{g/l}$   
Exposure time: 21 d  
Method: OECD Test Guideline 211

**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)):  $\geq 1.357$  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

**Persistence and degradability****Components:****Polyethylene glycol:**

Biodegradability : Result: rapidly degradable  
Remarks: Based on data from similar materials

**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

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

---

**Bioaccumulative potential****Components:****Polyethylene glycol:**

Partition coefficient: n-octanol/water : log Pow: < 3

**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

**Other adverse effects****Components:****Fluralaner:**

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

---

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues	: Dispose of in accordance with local regulations. 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.

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

**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

**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
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.

**Domestic regulation****49 CFR**

UN/ID/NA number	: UN 3077
Proper shipping name	: Environmentally hazardous substance, solid, n.o.s. (Fluralaner)
Class	: 9
Packing group	: III
Labels	: CLASS 9
ERG Code	: 171
Marine pollutant	: yes(Fluralaner)
Remarks	: Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

**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.

**SECTION 15. REGULATORY INFORMATION****CERCLA Reportable Quantity**

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Reproductive toxicity

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**US State Regulations****Pennsylvania Right To Know**

Starch	9005-25-8
Polyethylene glycol	25322-68-3
Pork by products	Not Assigned
Soya oil	8001-22-7
Glycerine	56-81-5
Sucrose	57-50-1
Fluralaner	864731-61-3
Sodium hydroxide	1310-73-2

**California Permissible Exposure Limits for Chemical Contaminants**

Starch	9005-25-8
Glycerine	56-81-5
Sucrose	57-50-1

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

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

**SECTION 16. OTHER INFORMATION****Further information**

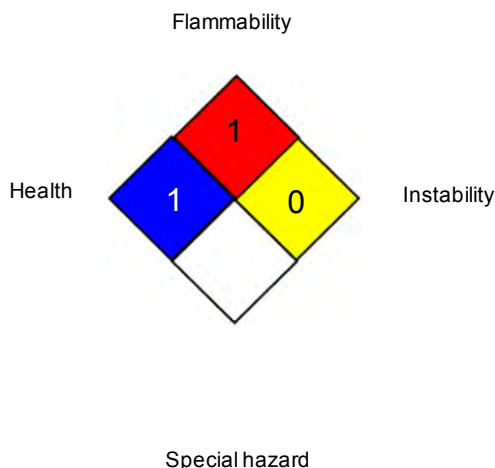
# SAFETY DATA SHEET



## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

### NFPA 704:



### HMIS® IV:

HEALTH	*	1
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average
US WEEL / TWA	:	8-hr TWA

AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; IECS - 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; KECL - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office

**Fluralaner Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10/01/2022
8.6	04/04/2023	401074-00023	Date of first issue: 12/10/2015

---

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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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

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

Revision Date : 04/04/2023

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.

US / Z8