

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
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 : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
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

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.

Additional Labeling

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

Other hazards

None known.

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 Date of first issue: 12/10/2015

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Starch	9005-25-8	>= 10 - < 25
Polyethylene glycol	25322-68-3	>= 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 (CO₂)
 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
 Sulfur oxides

Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/23/2020
8.0	03/19/2021	401074-00017	Date of first issue: 12/10/2015

Metal oxides	
Sodium oxides	
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 fire-fighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

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 vapors. 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.
Conditions for safe storage	: Keep in properly labeled containers. Store locked up. Store in accordance with the particular national regulations.
Materials to avoid	: Do not store with the following product types: Strong oxidizing agents

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 Date of first issue: 12/10/2015

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 ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
Polyethylene glycol	25322-68-3	TWA (aerosol)	10 mg/m ³	US WEEL
Sucrose	57-50-1	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
Fluralaner	864731-61-3	TWA	100 µg/m ³ (OEB 2)	Internal
Further information: Skin				
		Wipe limit	1000 µg/100 cm ²	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 adequate protection.

Hand protection
 Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.
 If the work environment or activity involves dusty conditions,

Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/23/2020
8.0	03/19/2021	401074-00017	Date of first issue: 12/10/2015

Skin and body protection Hygiene measures	: 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. : Work uniform or laboratory coat. : 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
Relative vapor density	: No data available
Relative density	: No data available
Density	: No data available

Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/23/2020
8.0	03/19/2021	401074-00017	Date of first issue: 12/10/2015

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

Polyethylene glycol:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
---------------------	---	---------------------------

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 Date of first issue: 12/10/2015

		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:		
Species	:	Rabbit
Result	:	No skin irritation

Sodium n-dodecyl sulfate:		
----------------------------------	--	--

Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/23/2020
8.0	03/19/2021	401074-00017	Date of first issue: 12/10/2015

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

Polyethylene glycol:

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

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 Date of first issue: 12/10/2015

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:

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)

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 Date of first issue: 12/10/2015

		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
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.

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 Date of first issue: 12/10/2015

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
 Species: Rabbit
 Application Route: Oral
 Developmental Toxicity: NOAEL: 10 mg/kg body weight
 Result: Skeletal malformations., Visceral malformations.
 Remarks: Maternal toxicity observed.

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 Date of first issue: 12/10/2015

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

Glycerine:

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

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 Date of first issue: 12/10/2015

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.

Components:

Fluralaner:
 Not applicable

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 Date of first issue: 12/10/2015

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 (Poecilia reticulata (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 (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:

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.

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 Date of first issue: 12/10/2015

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.000047 mg/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 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 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: 3.4

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.
 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

International Regulations

Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/23/2020
8.0	03/19/2021	401074-00017	Date of first issue: 12/10/2015

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.

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

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 Date of first issue: 12/10/2015

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

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium hydroxide	1310-73-2	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

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

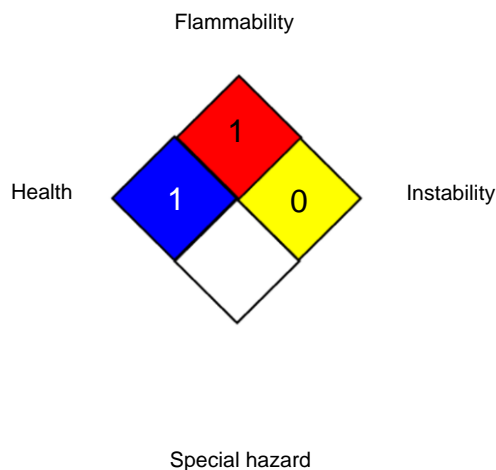
SECTION 16. OTHER INFORMATION

Further information

Fluralaner Solid Formulation

Version 8.0 Revision Date: 03/19/2021 SDS Number: 401074-00017 Date of last issue: 03/23/2020
 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

AIIC - 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); EC_x - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL_x - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC_x - 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; 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; 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: 03/23/2020
8.0	03/19/2021	401074-00017	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; 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 : 03/19/2021

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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