according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

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 name of supplier : Merck & Co., Inc Address : 37 McCarville Street

Charlottetown, PE C1E 2A7

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 Hazardous Products Regulations

Reproductive toxicity : Category 2

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H361d Suspected of damaging the unborn child.

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

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 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

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Starch	Sago starch	9005-25-8	>= 10 - < 25
Fluralaner	No data availa- ble	864731-61-3	>= 5 - < 15
Glycerine	1,2,3- Propanetriol	56-81-5	>= 5 - <= 10
Sucrose	.alphaD- Glucopyra- noside, .beta D- fructofuranosyl	57-50-1	>= 5 - <= 10
Sodium dodecyl sul- phate	Sulfuric acid monododecyl ester sodium salt	151-21-3	>= 1 - <= 5

SECTION 4. FIRST AID MEASURES

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

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. Flush eyes with water as a precaution.

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.
Suspected of damaging the unborn child.

Most important symptoms and effects, both acute and

Protection of first-aiders

delayed

ind effects, both acute and

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 prod: :

ucts

: Carbon oxides

Chlorine compounds Fluorine compounds

Sulfur oxides Metal oxides Sodium oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment:

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 10/02/2025 401059-00031 Date of first issue: 12/10/2015 9.1

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency 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 Advice on safe handling Use only with adequate ventilation. 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Starch	9005-25-8	TWA	10 mg/m ³	CA AB OEL
		TWA (Total	10 mg/m ³	CA BC OEL
		dust)		

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 10/02/2025 401059-00031 Date of first issue: 12/10/2015 9.1

		TWA (respirable dust fraction)	3 mg/m³	CA BC OEL		
		TWAEV (to-	10 mg/m³	CA QC OEL		
		TWA	10 mg/m ³	ACGIH		
Fluralaner	864731-61-3	TWA	100 μg/m3 (OEB 2)	Internal		
	Further information: Skin					
		Wipe limit	1000 μg/100 cm ²	Internal		
Glycerine	56-81-5	TWA (Mist)	10 mg/m ³	CA AB OEL		
		TWA (Mist)	10 mg/m ³	CA BC OEL		
		TWA (Respirable mist)	3 mg/m³	CA BC OEL		
		TWAEV (Mist)	10 mg/m³	CA QC OEL		
Sucrose	57-50-1	TWA	10 mg/m ³	CA AB OEL		
		TWA (Total dust)	10 mg/m³	CA BC OEL		
		TWA (respirable dust fraction)	3 mg/m³	CA BC OEL		
		TWAEV	10 mg/m ³	CA QC OEL		
		TWA	10 mg/m ³	ACGIH		

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

If adequate local exhaust ventilation is not available or Respiratory protection

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type Hand protection Combined particulates and organic vapor type

Material Chemical-resistant gloves

Wear safety glasses with side shields or goggles. Eye protection

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,

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version 9.1

Revision Date: 10/02/2025

SDS Number: 401059-00031

Date of last issue: 07/31/2025 Date of first issue: 12/10/2015

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet, pellets

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

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

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

Explosive properties : Not explosive

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

Particle characteristics

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 reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

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: > 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

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

Glycerine:

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

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

Sodium dodecyl sulphate:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Method: OECD Test Guideline 401

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

Method: OECD Test Guideline 402

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

Fluralaner:

Species : Rabbit

Result : No skin irritation

Glycerine:

Species : Rabbit

Result : No skin irritation

Sodium dodecyl sulphate:

Species : Rabbit Result : Skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Starch:

Species : Rabbit

Result : No eye irritation

Fluralaner:

Species : Rabbit

Result : Mild eye irritation

Glycerine:

Species : Rabbit

Result : No eye irritation

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

Sodium dodecyl sulphate:

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:

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

Sodium dodecyl sulphate:

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

Fluralaner:

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

Result: negative

Test Type: Mouse Lymphoma

Result: negative

Test Type: Chromosomal aberration

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow Application Route: Oral 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

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

Sucrose:

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

Result: negative

Sodium dodecyl sulphate:

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

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

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

Species: Mouse

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Fluralaner:

Carcinogenicity - Assess-

No data available

ment

Glycerine:

Species : Rat Application Route : Ingestion

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

Exposure time : 2 Years Result : negative

Sodium dodecyl sulphate:

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

Method : OECD Test Guideline 453

Result : negative

Remarks : Based on data from similar materials

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Fluralaner:

Effects on fertility : Test Type: Two-generation study

Species: Rat

Application Route: Oral

General Toxicity Parent: NOAEL: 50 mg/kg body weight General Toxicity F1: LOAEL: 100 mg/kg body weight

Result: No effects on fertility., Postimplantation loss., Adverse

neonatal effects.

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.

Test Type: Development

Species: Rabbit

Application Route: Dermal

Developmental Toxicity: NOAEL: 100 mg/kg body weight

Result: Skeletal malformations.

Reproductive toxicity - As-

sessment

Suspected of damaging the unborn child.

Glycerine:

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

Species: Rat

Application Route: Ingestion

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

Sodium dodecyl sulphate:

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

Components:

Starch:

Species : Rat

NOAEL : >= 2,000 mg/kg
Application Route : Skin contact
Exposure time : 28 Davs

Method : OECD Test Guideline 410

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 : Rat
LOAEL : 400 mg/kg
Application Route : Oral
Exposure time : 90 Days

Target Organs : Liver, thymus gland

Species : Rat

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

NOAEL : 500 mg/kg
Application Route : Dermal
Exposure time : 90 Days
Target Organs : Liver

Remarks : No significant adverse effects were reported

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

Sodium dodecyl sulphate:

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.

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 Date of first issue: 12/10/2015 9.1 10/02/2025 401059-00031

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Fluralaner:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.0488 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 0.015 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic

plants

NOEC (Pseudokirchneriella subcapitata (green algae)): >=

0.08 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic tox-

icity)

NOEC (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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.0736 µg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

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

NOEC (Pseudomonas putida): > 10,000 mg/l Toxicity to microorganisms

Exposure time: 16 h

Method: DIN 38 412 Part 8

Sodium dodecyl sulphate:

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

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : 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

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

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

Exposure time: 72 h

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): >= 1.357

mg/l

Exposure time: 42 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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:

Glycerine:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 % Exposure time: 30 d

Method: OECD Test Guideline 301D

Sodium dodecyl sulphate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 95 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

Fluralaner:

Bioaccumulation : Species: Zebrafish

Bioconcentration factor (BCF): 79.4 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 4.5

Glycerine:

Partition coefficient: n-

octanol/water

log Pow: -1.75

Sucrose:

Partition coefficient: n-

Pow: < 1

octanol/water

Sodium dodecyl sulphate:

Partition coefficient: n-

octanol/water

log Pow: 0.83

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version **Revision Date:** SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

: log Koc: 4.1

Mobility in soil

Components:

Fluralaner:

Distribution among environ-

mental compartments

Other adverse effects

Components:

Fluralaner:

Results of PBT and vPvB

assessment

Not persistent, bioaccumulative, and toxic (PBT).

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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number UN 3077

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

(Fluralaner)

Class 9 Packing group Ш Labels 9 Environmentally hazardous yes

IATA-DGR

UN/ID No. UN 3077

Environmentally hazardous substance, solid, n.o.s. Proper shipping name

(Fluralaner)

Class 9 Packing group Ш

Miscellaneous Labels

Packing instruction (cargo 956

aircraft)

Packing instruction (passen-

956

ger aircraft)

Environmentally hazardous yes

Above applies only to containers over 119 gallons (450 liters) Remarks

in case of liquids, or 882 lbs. (400 kg) in case of solids.

IMDG-Code

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

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

Remarks : Above applies only to containers over 119 gallons (450 liters)

in case of liquids, or 882 lbs. (400 kg) in case of solids.

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

Not applicable for product as supplied.

Domestic regulation

TDG

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Fluralaner)

Class : 9
Packing group : III
Labels : 9
ERG Code : 171

Marine pollutant : yes(Fluralaner)

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

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

AICS : not determined

CA. DSL : not determined

IECSC : not determined

Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

according to the Hazardous Products Regulations



Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 07/31/2025 9.1 10/02/2025 401059-00031 Date of first issue: 12/10/2015

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average

CA QC OEL / TWAEV : Time-weighted average exposure value

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 Standardization; 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 Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety

 Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

Revision Date : 10/02/2025 Date format : mm/dd/yyyy

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

according to the Hazardous Products Regulations



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shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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