

## Fluralaner Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
14.0	2023/11/20	401068-00025	Date of first issue: 2015/12/10

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical 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)

#### Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Reproductive toxicity : Category 2

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Long-term (chronic) aquatic hazard : Category 1

**GHS label elements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.  
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

**Prevention:**  
 P201 Obtain special instructions before use.  
 P202 Do not handle until all safety precautions have been read and understood.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
 P391 Collect spillage.

**Storage:**  
 P405 Store locked up.

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

**Additional Labelling**

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

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

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

**Other hazards which do not result in classification**

None known.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Starch	9005-25-8	>= 10 - < 25	8-98

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Soya oil	8001-22-7	>= 10 - <= 20	
Sucrose	57-50-1	>= 5 - <= 10	
Fluralaner	864731-61-3	>= 5 - < 20	
Sodium n-dodecyl sulfate	151-21-3	2	2-1679
2,6-Di-tert-butyl-p-cresol	128-37-0	<= 1	3-540, 9-1805

## 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.

## 5. FIREFIGHTING MEASURES

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

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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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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### 7. HANDLING AND STORAGE

#### Handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Avoid breathing vapours.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

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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.

### Storage

Conditions for safe storage : Keep in properly labelled 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

Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	ACGIH
Sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	ACGIH
Fluralaner	864731-61-3	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 µg/100 cm <sup>2</sup>	Internal
2,6-Di-tert-butyl-p-cresol	128-37-0	TWA (Inhalable fraction and vapor)	2 mg/m <sup>3</sup>	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

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

Filter type : Combined particulates and organic vapour type

Hand protection  
 Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.

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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.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state	: tablet, pellets
Colour	: light brown
Odour	: No data available
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Boiling point, initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: Not classified as a flammability hazard
Flammability (liquids)	: No data available
Lower explosion limit and upper explosion limit / flammability limit	
Upper explosion limit / Up- per flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: Not applicable
Decomposition temperature	: No data available
pH	: No data available
Evaporation rate	: No data available
Auto-ignition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Vapour pressure	: No data available

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Density and / or relative density  
Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

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

Particle characteristics  
Particle size : No data available

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**10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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**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

**Sucrose:**

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

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**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

**2,6-Di-tert-butyl-p-cresol:**

Acute oral toxicity : LD50 (Rat): > 6,000 mg/kg  
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation**

Not classified based on available information.

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

Species : Rabbit  
Result : No skin irritation

**Sodium n-dodecyl sulfate:**

Species : Rabbit  
Result : Skin irritation

**2,6-Di-tert-butyl-p-cresol:**

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

**Serious eye damage/eye irritation**

Not classified based on available information.



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### Components:

#### Starch:

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

#### 2,6-Di-tert-butyl-p-cresol:

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

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

#### Starch:

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

#### Fluralaner:

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

#### Sodium n-dodecyl sulfate:

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

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### 2,6-Di-tert-butyl-p-cresol:

Test Type	: Human repeat insult patch test (HRIPT)
Exposure routes	: Skin contact
Species	: Humans
Result	: negative

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Starch:

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

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

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
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Test Type: Mouse Lymphoma Result: negative
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Test Type: Chromosomal aberration Result: negative
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Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral Result: negative
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#### Sodium n-dodecyl sulfate:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
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Test Type: In vitro mammalian cell gene mutation test Result: negative
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Genotoxicity in vivo	: Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Mouse Application Route: Ingestion Result: negative
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### 2,6-Di-tert-butyl-p-cresol:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: In vitro mammalian cell gene mutation test Result: negative
		Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo	:	Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

#### Fluralaner:

Carcinogenicity - Assessment	:	No data available
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#### 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

### 2,6-Di-tert-butyl-p-cresol:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	22 Months
Result	:	negative

### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

#### Fluralaner:

Effects on fertility	:	Test Type: Two-generation study
		Species: Rat
		Application Route: Oral
		General Toxicity - Parent: NOAEL: 50 mg/kg body weight
		General Toxicity F1: LOAEL: 100 mg/kg body weight

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		Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects.
		Test Type: One-generation reproduction toxicity study Species: Dog Application Route: Oral Fertility: NOAEL: 75 mg/kg body weight Result: No effects on fertility and early embryonic development were detected. Remarks: No significant adverse effects were reported
Effects on foetal development	:	Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects
		Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: Skeletal malformations, Visceral malformations Remarks: Maternal toxicity observed.
		Test Type: Development Species: Rabbit Application Route: Dermal Developmental Toxicity: NOAEL: 100 mg/kg body weight Result: Skeletal malformations
Reproductive toxicity - Assessment	:	Suspected of damaging the unborn child.

**Sodium n-dodecyl sulfate:**

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

**2,6-Di-tert-butyl-p-cresol:**

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

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### 2,6-Di-tert-butyl-p-cresol:

Assessment	: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.
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### 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	: >= 2,000 mg/kg
Application Route	: Skin contact
Exposure time	: 28 Days
Method	: OECD Test Guideline 410

#### Soya oil:

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

#### Fluralaner:

Species	: Dog
NOAEL	: 1 mg/kg
Application Route	: Oral
Exposure time	: 52 Weeks

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Target Organs : Liver  
 Remarks : No significant adverse effects were reported

Species : Juvenile dog  
 LOAEL : 56 - 280 mg/kg  
 Application Route : Oral  
 Exposure time : 24 Weeks  
 Symptoms : Diarrhoea

Species : Rat  
 LOAEL : 400 mg/kg  
 Application Route : Oral  
 Exposure time : 90 Days  
 Target Organs : Liver, thymus gland

Species : Rat  
 NOAEL : 500 mg/kg  
 Application Route : Dermal  
 Exposure time : 90 Days  
 Target Organs : Liver  
 Remarks : No significant adverse effects were reported

### Sodium n-dodecyl sulfate:

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

### 2,6-Di-tert-butyl-p-cresol:

Species : Rat  
 NOAEL : 25 mg/kg  
 Application Route : Ingestion  
 Exposure time : 22 Months

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Fluralaner:

Not applicable

### Experience with human exposure

### Components:

#### Fluralaner:

Skin contact : Remarks: May irritate skin.

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Eye contact : Remarks: May cause eye irritation.

## 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 toxicity)	:	NOEC (Zebrafish): >= 0.049 mg/l Exposure time: 21 d Method: OECD Test Guideline 204 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.0736 µg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1,000

**Sodium n-dodecyl sulfate:**

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 29 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l Exposure time: 72 h  NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l Exposure time: 72 h
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): >= 1.357

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icity)	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

**2,6-Di-tert-butyl-p-cresol:**

Toxicity to fish	: LC50 (Danio rerio (zebra fish)): > 0.57 mg/l Exposure time: 96 h Method: Directive 67/548/EEC, Annex V, C.1.
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 0.48 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	: NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 1
Toxicity to fish (Chronic toxicity)	: NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l Exposure time: 30 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0.316 mg/l Exposure time: 21 d
M-Factor (Chronic aquatic toxicity)	: 1
Toxicity to microorganisms	: EC50: > 10,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

**Persistence and degradability****Components:****Sodium n-dodecyl sulfate:**

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

**2,6-Di-tert-butyl-p-cresol:**

Biodegradability : Result: Not readily biodegradable.  
 Biodegradation: 4.5 %  
 Exposure time: 28 d  
 Method: OECD Test Guideline 301C

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

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

**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

**2,6-Di-tert-butyl-p-cresol:**

Bioaccumulation : Species: Cyprinus carpio (Carp)  
 Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n-octanol/water : log Pow: 5.1

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

Distribution among environmental compartments : log Koc: 4.1

**Hazardous to the ozone layer**

Not applicable

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### Other adverse effects

#### Components:

#### Fluralaner:

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

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## 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

#### IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Fluralaner)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

#### IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluralaner)
Class	:	9
Packing group	:	III
Labels	:	9

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

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

Not applicable for product as supplied.

### National Regulations

Refer to section 15 for specific national regulation.

### 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.

ERG Code : 171

## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Sodium alkyl(C=8-18) sulfate	214
2,6-Di-tert-butyl-4-methylphenol	64

#### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

#### Substances Prevented From Impairment of Health

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

#### Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
sodium dodecyl sulphate	>=1 - <=5	From April 1st, 2025

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**Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
sodium dodecyl sulphate	From April 1st, 2025

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof****Class I Designated Chemical Substances**

Chemical name	Administration number	Concentration (%)
Sodium dodecyl sulfate	275	2.0

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

**Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

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**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

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

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect

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Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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

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.

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