

Fluralaner Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 16.1 2024/09/28 401068-00029 Date of first issue: 2015/12/10

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.

Menuma 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

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 protec-

tion/ 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 ad-

vice 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.

Get medical attention if irritation develops and persists.

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

In case of eye contact

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 (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- : Carbon oxides



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ucts Chlorine compounds

Fluorine compounds Sulphur 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 firefighters

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

Use personal protective equipment.

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 pro-

tective 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 con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Handling

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 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 as-



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sessment

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.

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 / Concentration standard / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
Sucrose	57-50-1	TWA	10 mg/m3	ACGIH
Fluralaner	864731-61-3	TWA	100 μg/m3 (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 μg/100 cm ²	Internal
2,6-Di-tert-butyl-p-cresol	128-37-0	8h-OEL-M	10 mg/m3	JP ISHL OEL 577-2(2)
		TWA (Inhalable fraction and vapor)	2 mg/m3	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.



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Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

: Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Impermeable protective gloves

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

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



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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

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

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- :

tions

Can react with strong oxidizing agents.

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

Hazardous decomposition

products

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Skin contact

exposure Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg



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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

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



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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.

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



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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

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

Sucrose:

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

Result: negative

Fluralaner:

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

Result: negative

Test Type: Mouse Lymphoma

Result: negative

Test Type: Chromosomal aberration

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow Application Route: Oral

Result: negative



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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

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

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 - Assess- : No data available

ment

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



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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 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 develop-

ment were detected.

Remarks: No significant adverse effects were reported

Effects on foetal develop-

ment

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.

Sodium n-dodecyl sulfate:

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

Species: Rat

Application Route: Ingestion



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Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

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

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

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 concentra-

tions of 100 mg/kg bw or less.

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



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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
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



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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.

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

M-Factor (Chronic aquatic

toxicity)

1,000



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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 tox-

icity)

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

ma/l

Exposure time: 42 d

Toxicity to daphnia and other :

aquatic invertebrates (Chronic toxicity)

Toxicity to microorganisms

NOEC (Ceriodaphnia dubia (water flea)): 0.88 mg/l

Exposure time: 7 d

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

1

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.316 mg/l

Exposure time: 21 d



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M-Factor (Chronic aquatic

toxicity)

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.

: 1

Biodegradation: 95 % Exposure time: 28 d

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- : log Pow: > 4

octanol/water Re

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- : log Pow: 5.1



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octanol/water

Mobility in soil

Components:

Fluralaner:

Distribution among environ-

mental compartments

log Koc: 4.1

Hazardous to the ozone layer

Not applicable

Other adverse effects

Components:

Fluralaner:

Results of PBT and vPvB

assessment

Substance is not persistent, bioaccumulative, and toxic (PBT).

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

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)

956

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen: 956

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ger aircraft)

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.

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



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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
Dodecyl sodium sulfate	>=1 - <=5	From April 1st, 2025

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical n	name	Remarks
Dodecyl so	dium sulfate	From April 1st, 2025

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Chemical name	
Sodium dodecyl sulfate	

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



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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

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

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

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 Agen-

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

JP ISHL OEL 577-2(2) : Concentration standard (Value set by the Minister of Health,

Labour and Welfare stipulated under the Ministerial Ordinance

Article 577-2(2))

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

JP ISHL OEL 577-2(2) / 8h- : 8-hour Occupational Exposure Limit-Mean



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OEL-M

AIIC - Australian Inventory of Industrial Chemicals: ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals: OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance: PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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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