



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 7.1
 28.09.2024
 186539-00033
 Date of first issue: 17.06.2015

SECTION 1. IDENTIFICATION

Product identifier : Fluralaner

Product code : Fluralaner,Fluralaner

Other means of identification : BRAVECTO QUANTUM FLURALANER 150 mg/mL

INJECTABLE SUSPENSION FOR DOGS (91883)

Bravecto Quantum (powder vial) (A011993)

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530

Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Reproductive toxicity : Category 2

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

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. P273 Avoid release to the environment.





Version **Revision Date:** SDS Number: Date of last issue: 06.07.2024 28.09.2024 186539-00033 Date of first issue: 17.06.2015 7.1

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.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form combustible dust concentrations in air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Substance Substance name Fluralaner

CAS-No. 864731-61-3

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Fluralaner	864731-61-3	Repr., 2 Aquatic Chronic, 1	>= 90 -<= 100

SECTION 4. FIRST AID MEASURES

In the case of accident or if you feel unwell, seek medical General advice

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 soap and 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 If in eyes, rinse well with water.

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.

Contact with dust can cause mechanical irritation or drying of

Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders First Aid responders should pay attention to self-protection,





Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 186539-00033 Date of first issue: 17.06.2015

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

High volume water jet

Specific hazards during fire

fighting

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Do not use a solid water stream as it may scatter and spread

tire.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Chlorine compounds Fluorine compounds

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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective 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.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are



Fluralaner

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 7.1
 28.09.2024
 186539-00033
 Date of first issue: 17.06.2015

released into the atmosphere in sufficient concentration. 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 : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the

environment.

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.

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 (Form of exposure)	Control parameters / Permissible concentration	Basis
Fluralaner	864731-61-3	TWA	100 μg/m3 (OEB 2)	Internal



Fluralaner

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 7.1
 28.09.2024
 186539-00033
 Date of first issue: 17.06.2015

Further information: Skin
Wipe limit 1000 μg/100 cm² Internal

Engineering measures : Use feasible engineering controls to minimize exposure to

compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Personal protective equipment

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

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Take note that the product is flammable, which may impact the selection of hand

protection. Wash hands before breaks and at the end of

workday.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Color : white to off-white

Odor : odorless

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : 173,3 - 175,5 °C

Initial boiling point and boiling :

range

No data available

Flash point : 236 °C



Fluralaner

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 7.1
 28.09.2024
 186539-00033
 Date of first issue: 17.06.2015

Evaporation rate : No data available

Flammability (solid, gas) : May form combustible dust concentrations in air.

Flammability (liquids) : Not applicable

Burning number : 2 (25 °C)

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : < 0,0000001 hPa (20 °C)

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : 0,082 mg/l

Partition coefficient: n-

octanol/water

log Pow: 4,5

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : 556,29 g/mol

Dust deflagration index (Kst) : 170 m.b_/s

Minimum ignition energy : > 30 - < 100 mJ

Method: With inductance

> 30 - < 100 mJ

Method: Without inductance

Particle characteristics

Particle size : 1,97 mm

SECTION 10. STABILITY AND REACTIVITY



Fluralaner

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 28.09.2024 186539-00033 Date of first issue: 17.06.2015 7.1

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

Possibility of hazardous reac-

tions

May form combustible dust concentrations in air.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Avoid dust formation.

Oxidizing agents Incompatible materials

Hazardous decomposition No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of: Inhalation

exposure Skin contact Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Components:

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

Skin corrosion/irritation

Not classified based on available information.

Components:

Fluralaner:

Species Rabbit

No skin irritation Result

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Fluralaner:

Species Rabbit

Result Mild eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.



Fluralaner

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 7.1
 28.09.2024
 186539-00033
 Date of first issue: 17.06.2015

Respiratory sensitization

Not classified based on available information.

Components:

Fluralaner:

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

Germ cell mutagenicity

Not classified based on available information.

Components:

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

Carcinogenicity

Not classified based on available information.

Components:

Fluralaner:

Carcinogenicity - Assess-

: No data available

ment

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.



Fluralaner

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 186539-00033 Date of first issue: 17.06.2015

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 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.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Fluralaner:

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

Remarks : No significant adverse effects were reported

Species : Juvenile dog LOAEL : 56 - 280 mg/kg

Application Route : Oral
Exposure time : 24 Weeks
Symptoms : Diarrhea



Fluralaner

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 7.1
 28.09.2024
 186539-00033
 Date of first issue: 17.06.2015

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

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.

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- : NOEC (Zebrafish): >= 0,049 mg/l



Fluralaner

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 7.1
 28.09.2024
 186539-00033
 Date of first issue: 17.06.2015

icity) 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

Persistence and degradability

No data available

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

Mobility in soil

Components:

Fluralaner:

Distribution among environ-

mental compartments

log Koc: 4,1

Other adverse effects

Components:

Fluralaner:

Results of PBT and vPvB

assessment

Substance is 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



Fluralaner

Version **Revision Date:** SDS Number: Date of last issue: 06.07.2024 28.09.2024 186539-00033 Date of first issue: 17.06.2015 7.1

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

(Fluralaner)

Class 9 Ш Packing group 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

IMDG-Code

UN number **UN 3077**

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Fluralaner)

Class 9 Packing group Ш Labels 9 F-A, S-F **EmS Code** Marine pollutant yes

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

Not applicable for product as supplied.

Domestic regulation

ANTT

UN number **UN 3077**

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Fluralaner)

9 Class Ш Packing group Labels 9 Hazard Identification Number 90

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

Safety, health and environmental regulations/legislation specific for the substance or mixture



Fluralaner

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 186539-00033 Date of first issue: 17.06.2015

National List of Carcinogenic Agents for Humans -

(LINACH)

Brazil. List of chemicals controlled by the Federal : Not applicable

Police

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

Further information

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-

Not applicable

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

Full text of other abbreviations

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 - Transporta-



Fluralaner

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 7.1
 28.09.2024
 186539-00033
 Date of first issue: 17.06.2015

tion 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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