

Fluralaner (Cattle Pour-On) Formulation

Version 9.0 Revision Date: 2023/12/01 SDS Number: 1688451-00019 Date of last issue: 2023/09/30
Date of first issue: 2017/05/21

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Fluralaner (Cattle Pour-On) Formulation
Other means of identification : EXZOLT POUR-ON FOR CATTLE (92557)

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Flammable liquids : Category 3
Serious eye damage/eye irritation : Category 2
Reproductive toxicity : Category 1B
Specific target organ toxicity - single exposure : Category 3
Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms : 

Signal word : Danger

Hazard statements : H226 Flammable liquid and vapour.

Fluralaner (Cattle Pour-On) Formulation

Version 9.0	Revision Date: 2023/12/01	SDS Number: 1688451-00019	Date of last issue: 2023/09/30 Date of first issue: 2017/05/21
----------------	------------------------------	------------------------------	---

H319 Causes serious eye irritation.
 H336 May cause drowsiness or dizziness.
 H360FD May damage fertility. May damage 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.
 P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P233 Keep container tightly closed.
 P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
 P242 Use non-sparking tools.
 P243 Take action to prevent static discharges.
 P261 Avoid breathing mist or vapours.
 P264 Wash skin thoroughly after handling.
 P271 Use only outdoors or in a well-ventilated area.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
 P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P337 + P313 If eye irritation persists: Get medical advice/ attention.
 P391 Collect spillage.

Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.
 P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

Important symptoms and out- : Vapours may form explosive mixture with air.
 lines of the emergency as-
 sumed

Fluralaner (Cattle Pour-On) Formulation

Version 9.0 Revision Date: 2023/12/01 SDS Number: 1688451-00019 Date of last issue: 2023/09/30
 Date of first issue: 2017/05/21

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
2-Pyrrolidone	616-45-5	>= 30 - < 40	5-112
Propan-2-ol	67-63-0	>= 30 - < 40	2-207
L-Menthol	2216-51-5	>= 10 - < 20	3-2333
Fluralaner	864731-61-3	>= 3 - < 10	

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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
 If easy to do, remove contact lens, if worn.
 Get medical attention.
- 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 : Causes serious eye irritation.
 May cause drowsiness or dizziness.
 May damage fertility. May damage 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 (CO₂)
 Dry chemical
- Unsuitable extinguishing media : High volume water jet

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

- Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Chlorine compounds
Fluorine compounds
Nitrogen oxides (NOx)
- 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.
-

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.
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.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
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 : Non-sparking tools should be used.
Soak up with inert absorbent material.
Suppress (knock down) gases/vapours/mists with a water spray jet.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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.

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

7. HANDLING AND STORAGE

Handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.
- Advice on safe handling : Do not get on skin or clothing.
Avoid breathing mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
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.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.
Keep away from heat and sources of ignition.
- Materials to avoid : Do not store with the following product types:
Oxidizing solids
Oxidizing liquids
- Packaging material : Unsuitable material: None known.

Fluralaner (Cattle Pour-On) Formulation

Version 9.0 Revision Date: 2023/12/01 SDS Number: 1688451-00019 Date of last issue: 2023/09/30
 Date of first issue: 2017/05/21

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
Propan-2-ol	67-63-0	ACL	200 ppm	JP OEL ISHL
		OEL-C	400 ppm 980 mg/m ³	JP OEL JSOH
		TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
Fluralaner	864731-61-3	TWA	100 µg/m ³ (OEB 2)	Internal
Further information: Skin				
		Wipe limit	1000 µg/100 cm ²	Internal

Biological occupational exposure limits

Components	CAS-No.	Target substance	Biological specimen	Sampling time	Permissible concentration	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of shift at end of work-week	40 mg/l	ACGIH BEI

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
 Laboratory operations do not require special containment.
 Use explosion-proof electrical, ventilating and lighting equipment.

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
 Remarks : Take note that the product is flammable, which may impact the selection of hand protection.

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

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 : liquid

Colour : blue green, clear

Odour : mint-like

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 applicable

Flammability (liquids) : Not applicable

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : 25 °C

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

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

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 : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Flammable liquid and vapour.
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:**2-Pyrrolidone:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

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

Fluralaner (Cattle Pour-On) Formulation

Version 9.0 Revision Date: 2023/12/01 SDS Number: 1688451-00019 Date of last issue: 2023/09/30
 Date of first issue: 2017/05/21

Method: OECD Test Guideline 402
 Assessment: The substance or mixture has no acute dermal toxicity

Propan-2-ol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
 Acute inhalation toxicity : LC50 (Rat): > 25 mg/l
 Exposure time: 6 h
 Test atmosphere: vapour
 Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

L-Menthol:

Acute inhalation toxicity : LC50 (Rat): 5.289 mg/l
 Exposure time: 4 h
 Test atmosphere: dust/mist
 Method: OECD Test Guideline 403
 Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg
 Method: OECD Test Guideline 402

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:

2-Pyrrolidone:

Species : Rabbit
 Method : OECD Test Guideline 404
 Result : No skin irritation

Propan-2-ol:

Species : Rabbit
 Result : No skin irritation

L-Menthol:

Species : Rabbit
 Method : OECD Test Guideline 404
 Result : Skin irritation

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

Fluralaner:

Species	: Rabbit
Result	: No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

2-Pyrrolidone:

Species	: Rabbit
Result	: Irritation to eyes, reversing within 7 days

Propan-2-ol:

Species	: Rabbit
Result	: Irritation to eyes, reversing within 21 days

L-Menthol:

Species	: Rabbit
Result	: Irritation to eyes, reversing within 7 days
Method	: OECD Test Guideline 405

Fluralaner:

Species	: Rabbit
Result	: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

2-Pyrrolidone:

Test Type	: Local lymph node assay (LLNA)
Exposure routes	: Skin contact
Species	: Mouse
Method	: OECD Test Guideline 429
Result	: negative
Remarks	: Based on data from similar materials

Propan-2-ol:

Test Type	: Buehler Test
Exposure routes	: Skin contact

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative

L-Menthol:

Test Type	: Local lymph node assay (LLNA)
Exposure routes	: Skin contact
Species	: Mouse
Method	: OECD Test Guideline 429
Result	: negative

Fluralaner:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

2-Pyrrolidone:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative Remarks: Based on data from similar materials
	Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: negative

Propan-2-ol:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo)

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

cytogenetic assay)
 Species: Mouse
 Application Route: Intraperitoneal injection
 Result: negative

L-Menthol:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
 Result: negative
 Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
 cytogenetic assay)
 Species: Mouse
 Application Route: Intraperitoneal injection
 Method: OECD Test Guideline 474
 Result: negative
 Remarks: Based on data from similar materials

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:

2-Pyrrolidone:

Species : Mouse
 Application Route : Ingestion
 Exposure time : 18 month(s)
 Result : negative
 Remarks : Based on data from similar materials

Propan-2-ol:

Species : Rat
 Application Route : inhalation (vapour)
 Exposure time : 104 weeks

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

Method	: OECD Test Guideline 451
Result	: negative

L-Menthol:

Species	: Mouse
Application Route	: Ingestion
Exposure time	: 103 weeks
Method	: OECD Test Guideline 453
Result	: negative
Remarks	: Based on data from similar materials

Fluralaner:

Carcinogenicity - Assessment	: No data available
------------------------------	---------------------

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

2-Pyrrolidone:

Effects on fertility	: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: positive Remarks: Based on data from similar materials
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: positive
Reproductive toxicity - Assessment	: Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

Propan-2-ol:

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

L-Menthol:

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

Fluralaner (Cattle Pour-On) Formulation

Version 9.0 Revision Date: 2023/12/01 SDS Number: 1688451-00019 Date of last issue: 2023/09/30
 Date of first issue: 2017/05/21

||ment

Species: Rat
 Application Route: Ingestion
 Result: negative

Fluralaner:

||Effects on fertility

: Test Type: Two-generation study
 Species: Rat
 Application Route: Oral
 General Toxicity - Parent: NOAEL: 50 mg/kg body weight
 General Toxicity F1: LOAEL: 100 mg/kg body weight
 Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects.

Test Type: One-generation reproduction toxicity study
 Species: Dog
 Application Route: Oral
 Fertility: NOAEL: 75 mg/kg body weight
 Result: No effects on fertility and early embryonic development were detected.
 Remarks: No significant adverse effects were reported

||Effects on 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.

STOT - single exposure

May cause drowsiness or dizziness.

Components:

Propan-2-ol:

||Assessment

: May cause drowsiness or dizziness.

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

2-Pyrrolidone:

Species	: Rat
NOAEL	: 207 mg/kg
Application Route	: Ingestion
Exposure time	: 3 Months
Method	: OECD Test Guideline 408

Propan-2-ol:

Species	: Rat
NOAEL	: 12.5 mg/l
Application Route	: inhalation (vapour)
Exposure time	: 104 Weeks

L-Menthol:

Species	: Mouse
NOAEL	: 1,250 mg/kg
Application Route	: Ingestion
Exposure time	: 91 Days
Method	: OECD Test Guideline 408
Remarks	: Based on data from similar materials

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
---------	-------

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

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.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

2-Pyrrolidone:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 500 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l Exposure time: 72 h EC10 (Desmodesmus subspicatus (green algae)): 22.2 mg/l Exposure time: 72 h
Toxicity to microorganisms	:	EC50: > 1,000 mg/l Exposure time: 30 min Method: OECD Test Guideline 209

Propan-2-ol:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l Exposure time: 96 h
------------------	---	--

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 24 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 1,050 mg/l
Exposure time: 16 h

L-Menthol:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 15.6 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)): 26.6 mg/l
Exposure time: 48 h
Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): 21.4 mg/l
Exposure time: 72 h
Method: Directive 67/548/EEC, Annex V, C.3.

NOEC (Desmodesmus subspicatus (green algae)): 9.65 mg/l
Exposure time: 72 h
Method: Directive 67/548/EEC, Annex V, C.3.

Toxicity to microorganisms : EC50: 237 mg/l
Exposure time: 96 h
Test Type: Respiration inhibition of activated sludge
Method: OECD Test Guideline 209

Fluralaner:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.0488 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0.015 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : NOEC (Zebrafish): >= 0.049 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 204
Remarks: No toxicity at the limit of solubility

Fluralaner (Cattle Pour-On) Formulation

Version 9.0 Revision Date: 2023/12/01 SDS Number: 1688451-00019 Date of last issue: 2023/09/30
Date of first issue: 2017/05/21

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

Persistence and degradability**Components:****2-Pyrrolidone:**

Biodegradability : Result: Readily biodegradable.
Remarks: Based on data from similar materials

Propan-2-ol:

Biodegradability : Result: rapidly degradable
BOD/COD : BOD: 1.19 (BOD5)COD: 2.23BOD/COD: 53 %

L-Menthol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 64 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

Bioaccumulative potential**Components:****2-Pyrrolidone:**

Partition coefficient: n-octanol/water : log Pow: -0.71
Method: OECD Test Guideline 107

Propan-2-ol:

Partition coefficient: n-octanol/water : log Pow: 0.05

L-Menthol:

Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 0.5 - 15
Exposure time: 6 Weeks
Method: OECD Test Guideline 305
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: 3.15

Fluralaner:

Bioaccumulation : Species: Zebrafish
Bioconcentration factor (BCF): 79.4

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4.5

Mobility in soil

Components:

Fluralaner:

Distribution among environmental compartments : log Koc: 4.1

Hazardous to the ozone layer

Not applicable

Other adverse effects

Components:

Fluralaner:

Results of PBT and vPvB assessment : This substance is not considered to be persistent, bioaccumulating 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 handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 1993

Proper shipping name : FLAMMABLE LIQUID, N.O.S. (Propan-2-ol)

Class : 3

Packing group : III

Labels : 3

Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 1993

Proper shipping name : Flammable liquid, n.o.s.

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

(Propan-2-ol)

Class : 3
Packing group : III
Labels : Flammable Liquids
Packing instruction (cargo aircraft) : 366
Packing instruction (passenger aircraft) : 355

IMDG-Code

UN number : UN 1993
Proper shipping name : FLAMMABLE LIQUID, N.O.S.
(Propan-2-ol, Fluralaner)

Class : 3
Packing group : III
Labels : 3
EmS Code : F-E, S-E
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 : 128

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Group 4, Type 2 petroleums, Water insoluble liquid, (1000 litre), Hazardous rank III

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Isopropyl alcohol	102

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Fluralaner (Cattle Pour-On) Formulation

Version 9.0 Revision Date: 2023/12/01 SDS Number: 1688451-00019 Date of last issue: 2023/09/30
 Date of first issue: 2017/05/21

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
Propyl alcohol	>=30 - <40	-
L-menthol	>=10 - <20	From April 1st, 2026

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Propyl alcohol	-
L-menthol	From April 1st, 2026

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

Organic Solvents Class 2

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

Inflammable Substance

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

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

Vessel Safety Law

Flammable liquids (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Flammable liquid (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

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

Specially Controlled 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

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 BEI : ACGIH - Biological Exposure Indices (BEI)

JP OEL ISHL : Japan. Administrative Control Levels

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

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

ACGIH / STEL : Short-term exposure limit

JP OEL ISHL / ACL : Administrative Control level

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
9.0	2023/12/01	1688451-00019	Date of first issue: 2017/05/21

JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

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; TECl - 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.

JP / EN