

Fluralaner (Cattle Pour-On) Formulation

Version 6.1 Revision Date: 01.12.2023 SDS Number: 1688411-00019 Date of last issue: 30.09.2023
Date of first issue: 21.05.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

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

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 : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification in accordance with ABNT NBR 14725 Standard**

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

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H226 Flammable liquid and vapor.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

Fluralaner (Cattle Pour-On) Formulation

Version 6.1 Revision Date: 01.12.2023 SDS Number: 1688411-00019 Date of last issue: 30.09.2023
 Date of first issue: 21.05.2017

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.
 P210 Keep away from heat/ sparks/ open flames/ hot surfaces.
 No smoking.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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

Other hazards which do not result in classification

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
2-Pyrrolidone	616-45-5	Eye irritation, Category 2B Reproductive toxicity, Category 1B	>= 30 -< 50
Propan-2-ol	67-63-0	Flammable liquids, Category 2 Eye irritation, Category 2A Specific target organ toxicity - single exposure, Category 3	>= 30 -< 50
L-Menthol	2216-51-5	Acute toxicity (Inhalation), Category 5 Skin irritation, Category 2 Eye irritation, Category 2B Short-term (acute) aquatic hazard, Category 3	>= 10 -< 20
Fluralaner	864731-61-3	Reproductive toxicity, Category 2 Long-term (chronic) aquatic hazard, Category 1	>= 5 -< 10

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.1	01.12.2023	1688411-00019	Date of first issue: 21.05.2017

SECTION 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. |
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SECTION 5. FIRE-FIGHTING MEASURES

- | | | |
|---------------------------------------|---|---|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
| Unsuitable extinguishing media | : | High volume water jet |
| 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.
Vapors 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 (NO _x) |
| 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. |

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.1	01.12.2023	1688411-00019	Date of first issue: 21.05.2017

Special protective equipment for fire-fighters : Evacuate area.
 In the event of fire, wear self-contained breathing apparatus.
 Use personal protective equipment.

SECTION 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/vapors/mists with a water spray jet.
 For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

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 vapors.
 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.

Fluralaner (Cattle Pour-On) Formulation

Version 6.1 Revision Date: 01.12.2023 SDS Number: 1688411-00019 Date of last issue: 30.09.2023
 Date of first issue: 21.05.2017

- 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.
- 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.
 Keep tightly closed.
 Keep in a cool, well-ventilated place.
 Store in accordance with the particular national regulations.
- Materials to avoid** : Do not store with the following product types:
 Strong oxidizing agents
 Self-reactive substances and mixtures
 Organic peroxides
 Flammable solids
 Pyrophoric liquids
 Pyrophoric solids
 Self-heating substances and mixtures
 Substances and mixtures which in contact with water emit flammable gases
 Explosives
 Gases
 Very acutely toxic substances and mixtures

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propan-2-ol	67-63-0	LT	310 ppm 765 mg/m ³	BR OEL
	Further information: Absorption through the skin, Degree of harmfulness: medium			
		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

Fluralaner (Cattle Pour-On) Formulation

Version 6.1 Revision Date: 01.12.2023 SDS Number: 1688411-00019 Date of last issue: 30.09.2023
 Date of first issue: 21.05.2017

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of workday at end of work-week	40 mg/l	BR BEI
		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 vapor type

Hand protection

Material : Chemical-resistant gloves

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

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

Appearance : liquid

Color : blue green, clear

Odor : mint-like

Odor Threshold : No data available

pH : No data available

Fluralaner (Cattle Pour-On) Formulation

Version 6.1 Revision Date: 01.12.2023 SDS Number: 1688411-00019 Date of last issue: 30.09.2023
Date of first issue: 21.05.2017

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : 25 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Flammable liquid and vapor.

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.1	01.12.2023	1688411-00019	Date of first issue: 21.05.2017

tions	Vapors 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure :

- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

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
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: vapor

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 (Cattle Pour-On) Formulation

Version 6.1 Revision Date: 01.12.2023 SDS Number: 1688411-00019 Date of last issue: 30.09.2023
Date of first issue: 21.05.2017

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:

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 (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.1	01.12.2023	1688411-00019	Date of first issue: 21.05.2017

Fluralaner:

Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

2-Pyrrolidone:

Test Type : Local lymph node assay (LLNA)
Routes of exposure : 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
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

L-Menthol:

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

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:

2-Pyrrolidone:

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

Test Type: In vitro mammalian cell gene mutation test

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.1	01.12.2023	1688411-00019	Date of first issue: 21.05.2017

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 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

Fluralaner (Cattle Pour-On) Formulation

Version 6.1 Revision Date: 01.12.2023 SDS Number: 1688411-00019 Date of last issue: 30.09.2023
Date of first issue: 21.05.2017

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 (vapor)
Exposure time : 104 weeks
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 fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: positive

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.1	01.12.2023	1688411-00019	Date of first issue: 21.05.2017

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 fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

L-Menthol:

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

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.1	01.12.2023	1688411-00019	Date of first issue: 21.05.2017

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.

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 (vapor)
 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

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.1	01.12.2023	1688411-00019	Date of first issue: 21.05.2017

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

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:

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

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.1	01.12.2023	1688411-00019	Date of first issue: 21.05.2017

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

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

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.1	01.12.2023	1688411-00019	Date of first issue: 21.05.2017

Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity) : NOEC (Zebrafish): $\geq 0,049$ mg/l
 Exposure time: 21 d
 Method: OECD Test Guideline 204
 Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): $0,0736$ $\mu\text{g/l}$
 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- : log Pow: 3,15

Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.1	01.12.2023	1688411-00019	Date of first issue: 21.05.2017

octanol/water

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 environmental compartments : log Koc: 4,1

Other adverse effects

Components:

Fluralaner:

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

SECTION 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

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

Domestic regulation

ANTT

UN number : UN 1993

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

Class : 3

Packing group : III

Labels : 3

Hazard Identification Number : 30

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Propan-2-ol

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

AICS : not determined

DSL : not determined

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IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 01.12.2023
Date format : dd.mm.yyyy

Further information

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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
BR BEI : Brazil. NR7. Parameters for Biological Control of Occupational Exposure to Some Chemical Agents
BR OEL : Brazil. NR 15 - Unhealthy activities and operations

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
BR OEL / LT : Up to 48 hours /week

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 Recom-

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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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