

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

SECTION 1. IDENTIFICATION

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

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.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 the Hazardous Products Regulations

Flammable liquids : Category 3
Eye irritation : Category 2A
Reproductive toxicity : Category 1B
Specific target organ toxicity : Category 3
- single exposure

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H226 Flammable liquid and vapor.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H360FD May damage fertility. May damage the unborn child.

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.
P261 Avoid breathing mist or vapors.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version 6.0 Revision Date: 07/06/2024 SDS Number: 1688442-00021 Date of last issue: 04/06/2024
Date of first issue: 05/21/2017

P264 Wash skin thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves, protective clothing, eye protection and 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 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 attention.
P337 + P313 If eye irritation persists: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
2-Pyrrolidone	No data available	616-45-5	$\geq 30 - < 60$ *
Propan-2-ol	Isopropyl alcohol	67-63-0	$\geq 30 - < 60$ *
L-Menthol	Cyclohexanol, 5-methyl-2-(1-methylethyl)-, (1R,2S,5R)-	2216-51-5	$\geq 10 - < 25$ *
Fluralaner	No data available	864731-61-3	$\geq 5 - < 10$ *

* Actual concentration or concentration range is withheld as a trade secret

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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

In case of skin contact	: Get medical attention. 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.

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. 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 emergency procedures	: Remove all sources of ignition. Use personal protective equipment. Follow safe handling advice (see section 7) and personal
---	---

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

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.
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.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version 6.0 Revision Date: 07/06/2024 SDS Number: 1688442-00021 Date of last issue: 04/06/2024
Date of first issue: 05/21/2017

Materials to avoid : 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.
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	STEL	400 ppm 984 mg/m ³	CA AB OEL
		TWA	200 ppm 492 mg/m ³	CA AB OEL
		TWA	200 ppm	CA BC OEL
		STEL	400 ppm	CA BC OEL
		TWAEV	200 ppm	CA QC OEL
		STEV	400 ppm	CA QC OEL
		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.	Control parameters	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-

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

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. |
| 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. |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|---|---|-------------------|
| Appearance | : | liquid |
| Color | : | blue green, clear |
| Odor | : | mint-like |
| Odor Threshold | : | No data available |
| pH | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

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 characteristics	:	
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 reactions	:	Flammable liquid and vapor. Vapors may form explosive mixture with air. Can react with strong oxidizing agents.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

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: > 5 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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

II

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

		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 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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

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 (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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

	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 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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

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.

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

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

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

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
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.
------------------	---

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 0.015 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility.
Toxicity to algae/aquatic plants	: NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility.
Toxicity to fish (Chronic toxicity)	: NOEC (Zebrafish): >= 0.049 mg/l Exposure time: 21 d Method: OECD Test Guideline 204 Remarks: No toxicity at the limit of solubility.
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0.0736 µg/l Exposure time: 21 d Method: OECD Test Guideline 211

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: 2,23 BOD/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-	: log Pow: 0.05
---------------------------	-----------------

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

|| octanol/water

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

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

UN number : UN 1993
Proper shipping name : FLAMMABLE LIQUID, N.O.S.
II (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.
II (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
II 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

TDG

UN number : UN 1993
II Proper shipping name : FLAMMABLE LIQUID, N.O.S.
(Propan-2-ol)
Class : 3
Packing group : III
Labels : 3
ERG Code : 128
II Marine pollutant : yes(Fluralaner)

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

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

AICS : not determined

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	: ACGIH - Biological Exposure Indices (BEI)
CA AB OEL	: Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	: Canada. British Columbia OEL
CA QC OEL	: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	: 8-hour, time-weighted average
ACGIH / STEL	: Short-term exposure limit
CA AB OEL / TWA	: 8-hour Occupational exposure limit
CA AB OEL / STEL	: 15-minute occupational exposure limit
CA BC OEL / TWA	: 8-hour time weighted average
CA BC OEL / STEL	: short-term exposure limit
CA QC OEL / TWAEV	: Time-weighted average exposure value
CA QC OEL / STEV	: Short-term exposure value

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-

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fluralaner (Cattle Pour-On) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	1688442-00021	Date of first issue: 05/21/2017

tion 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

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/>

Revision Date : 07/06/2024
Date format : mm/dd/yyyy

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

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.

CA / Z8