according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 28.09.2024 1699479-00023 Date of first issue: 21.05.2017 8.1

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name Fluralaner (Cattle Pour-On) Formulation

Other means of identification : EXZOLT POUR-ON FOR CATTLE (92557)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-

stance/Mixture

: Veterinary product

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

MSD Company

Kilsheelan

Clonmel Tipperary, IE

Telephone 353-51-601000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 3 H226: Flammable liquid and vapour. Eye irritation, Category 2 H319: Causes serious eye irritation.

Reproductive toxicity, Category 1B H360FD: May damage fertility. May damage the

unborn child.

Specific target organ toxicity - single ex-

posure, Category 3

H336: May cause drowsiness or dizziness.

Long-term (chronic) aquatic hazard, Cat-

H410: Very toxic to aquatic life with long lasting

egory 1

effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

Hazard pictograms :









Signal word : Danger

Hazard statements : H226 Flammable liquid and vapour.

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.

P210 Keep away from heat, hot surfaces, sparks, open

flames and other ignition sources. No smoking. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P391 Collect spillage.

Hazardous components which must be listed on the label:

2-Pyrrolidone Propan-2-ol

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name CAS-No. Classification	Concentration
--------------------------------------	---------------

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

	EC-No. Index-No. Registration number		(% w/w)
2-Pyrrolidone	616-45-5 210-483-1	Eye Irrit. 2; H319 Repr. 1B; H360FD	>= 30 - < 50
		specific concentra- tion limit Repr. 1B; H360FD > 3 %	
Propan-2-ol	67-63-0 200-661-7 603-117-00-0	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	>= 30 - < 50
L-Menthol	2216-51-5 218-690-9	Skin Irrit. 2; H315 Eye Irrit. 2; H319	>= 10 - < 20
		specific concentra- tion limit Skin Irrit. 2; H315 > 25 % Eye Irrit. 2; H319 > 25 %	
Fluralaner	864731-61-3	Repr. 2; H361d Aquatic Chronic 1; H410	>= 3 - < 10
		M-Factor (Chronic aquatic toxicity): 1.000	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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).

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes serious eye irritation.

May cause drowsiness or dizziness.

May damage fertility. May damage the unborn child.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

5.2 Special hazards arising from the substance or mixture

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 prod-

ucts

Carbon oxides

Chlorine compounds Fluorine compounds Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

for firefighters

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Remove all sources of ignition.

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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 absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

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 equip-

ment.

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 as-

sessment

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.

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 contami-

nated 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

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.

Advice on common storage : 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

7.3 Specific end use(s)

Specific use(s) : No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Propan-2-ol	67-63-0	TWA	100 ppm	FOR-2011-
			245 mg/m3	12-06-1358
Fluralaner	864731-61-	TWA	100 μg/m3 (OEB 2)	Internal
	3			
	Further information: Skin			
		Wipe limit	1000 μg/100 cm ²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health ef-	Value
			fects	
2-Pyrrolidone	Workers	Inhalation	Long-term systemic effects	57,8 mg/m3
	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	277 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	17,1 mg/m3
	Consumers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	167 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	5,2 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	33,3 mg/kg bw/day
L-Menthol	Workers	Inhalation	Long-term systemic effects	132 mg/m3
	Workers	Skin contact	Long-term systemic effects	19 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	33 mg/m3
	Workers	Inhalation	Long-term local ef- fects	10 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	1,7 mg/m3
	Consumers	Skin contact	Long-term systemic effects	9,4 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	9,4 mg/kg bw/day
Propan-2-ol	Workers	Inhalation	Long-term systemic effects	500 mg/m3

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 8.1 28.09.2024 1699479-00023 Date of first issue: 21.05.2017

Workers	Skin contact	Long-term systemic effects	888 mg/kg bw/day
Consumers	Inhalation	Long-term systemic effects	89 mg/m3
Consumers	Skin contact	Long-term systemic effects	319 mg/kg bw/day
Consumers	Ingestion	Long-term systemic effects	26 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Fluralaner	Water	7 ng/l
2-Pyrrolidone	Fresh water	0,5 mg/l
	Freshwater - intermittent	0,5 mg/l
	Marine water	0,05 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	0,4205 mg/kg dry
		weight (d.w.)
	Soil	0,0612 mg/kg dry
		weight (d.w.)
L-Menthol	Fresh water	15,6 μg/l
	Marine water	1,56 μg/l
	Intermittent use/release	156 µg/l
	Sewage treatment plant	2,37 mg/l
	Fresh water sediment	289 μg/l
	Marine sediment	28,9 μg/l
	Soil	48,4 μg/l
Decanoic acid, mixed diesters	Soil	0,2638 mg/kg
with octanoic acid and propylene glycol		
Propan-2-ol	Fresh water	140,9 mg/l
•	Marine water	140,9 mg/l
	Intermittent use/release	140,9 mg/l
	Sewage treatment plant	2251 mg/l
	Fresh water sediment	552 mg/kg dry
		weight (d.w.)
	Marine sediment	552 mg/kg dry
		weight (d.w.)
	Soil	28 mg/kg dry
		weight (d.w.)
	Oral (Secondary Poisoning)	160 mg/kg food

8.2 Exposure controls

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.07.2024 28.09.2024 1699479-00023 Date of first issue: 21.05.2017 8.1

Eye/face 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.

Hand protection

Material Chemical-resistant gloves

Remarks Take note that the product is flammable, which may impact

the selection of hand protection.

Skin and body protection

Work uniform or laboratory coat.

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387

Combined particulates and organic vapour type (A-P) Filter type

SECTION 9: Physical and chemical properties

9.1 Information on basic 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

Initial boiling point and boiling

range

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

Flash point 25 °C

Auto-ignition temperature No data available

Decomposition temperature No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Flammable liquid and vapour.

Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure 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 tox-

icity

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: 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

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

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 7 days

Fluralaner:

Species : Rabbit

Result : Mild eye irritation

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

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 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

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

Cell type: Bone marrow

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

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

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 - Assess-

No data available

ment

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: positive

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

Reproductive toxicity - As-

sessment

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

L-Menthol:

Effects on foetal develop-

ment

Test Type: Embryo-foetal 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 develop-

ment were detected.

Remarks: No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No

teratogenic effects

Test Type: Development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 10 mg/kg body weight

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

Result: Skeletal malformations, Visceral malformations

Remarks: Maternal toxicity observed.

Test Type: Development

Species: Rabbit

Application Route: Dermal

Developmental Toxicity: NOAEL: 100 mg/kg body weight

Result: Skeletal malformations

Reproductive toxicity - As-

sessment

Suspected of damaging the unborn child.

STOT - single exposure

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 (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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

Application Route : Oral
Exposure time : 52 Weeks
Target Organs : Liver

Remarks : No significant adverse effects were reported

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

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

Species : Rat
LOAEL : 400 mg/kg
Application Route : Oral
Exposure time : 90 Days

Target Organs : Liver, thymus gland

Species : Rat NOAEL : 500 mg/kg

Application Route : Dermal Exposure time : 90 Days Target Organs : Liver

Remarks : No significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

Components:

Fluralaner:

Not applicable

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

Experience with human exposure

Components:

Fluralaner:

Skin contact : Remarks: May irritate skin.

Eye contact : Remarks: May cause eye irritation.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

SECTION 12: Ecological information

12.1 Toxicity

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

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

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 tox-

icity)

NOEC: >= 0,049 mg/l Exposure time: 21 d

Species: Zebrafish

Method: OECD Test Guideline 204

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0,0736 μg/l

Exposure time: 21 d Species: Daphnia magna (Water flea)

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

1.000

12.2 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:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

Biodegradability : Result: Readily biodegradable.

Biodegradation: 64 % Exposure time: 28 d

Method: OECD Test Guideline 301D

12.3 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)

Exposure time: 6 Weeks

Bioconcentration factor (BCF): 0,5 - 15 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

12.4 Mobility in soil

Components:

Fluralaner:

Distribution among environ-

mental compartments

: log Koc: 4,1

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

Components:

Fluralaner:

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

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

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

14.1 UN number or ID number

ADN : UN 1993
ADR : UN 1993
RID : UN 1993
IMDG : UN 1993
IATA : UN 1993

14.2 UN proper shipping name

ADN : FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

ADR : FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol)

RID : FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol)

IMDG : FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol, Fluralaner)

IATA : Flammable liquid, n.o.s.

(Propan-2-ol)

14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 3
ADR : 3
RID : 3
IMDG : 3
IATA : 3

14.4 Packing group

ADN

Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3

ADR

Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3
Tunnel restriction code : (D/E)

RID

Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3

IMDG

Packing group : III Labels : 3

EmS Code : F-E, <u>S-E</u>

IATA (Cargo)

Packing instruction (cargo : 366

aircraft)

Packing instruction (LQ) : Y344
Packing group : III

Labels : Flammable Liquids

IATA (Passenger)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

Packing instruction (passen: 355

ger aircraft)

Packing instruction (LQ) : Y344
Packing group : III

Labels : Flammable Liquids

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) Conditions of restriction for the following entries should be considered: Number on list 3

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not.

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

Not applicable

: Not applicable

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 8.1 28.09.2024 1699479-00023 Date of first issue: 21.05.2017

(Annex XIV)

Regulation (EC) on substances that deplete the ozone : Not applicable

laver

P5c

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia: Not applicable

ment and the Council concerning the export and import

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2
FLAMMABLE LIQUIDS 5.000 t 50.000 t

E1 ENVIRONMENTAL 100 t 200 t

HAZARDS

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

Full text of H-Statements

H225 : Highly flammable liquid and vapour.

H315 : Causes skin irritation.

H319 : Causes serious eye irritation. H336 : May cause drowsiness or dizziness.

H360FD : May damage fertility. May damage the unborn child.

H361d : Suspected of damaging the unborn child.

H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 28.09.2024 1699479-00023 Date of first issue: 21.05.2017 8.1

Flam. Liq. Flammable liquids Repr. Reproductive toxicity

Skin Irrit. Skin irritation

STOT SE Specific target organ toxicity - single exposure

FOR-2011-12-06-1358 Norway. Occupational Exposure limits

Long term exposure limit FOR-2011-12-06-1358 /

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways: ADR - Agreement concerning the International Carriage of Dangerous Goods by Road: AIIC - Australian Inventory of Industrial Chemicals: ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

compile the Safety Data

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

H226

Classification of the mixture:

Classification procedure:

Flam. Liq. 3 Based on product data or assessment Eye Irrit. 2 H319 Calculation method Repr. 1B H360FD Calculation method STOT SE 3 H336 Calculation method

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Fluralaner (Cattle Pour-On) Formulation

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

 8.1
 28.09.2024
 1699479-00023
 Date of first issue: 21.05.2017

Aquatic Chronic 1 H410 Calculation method

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.

NO / EN