SAFETY DATA SHEET

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: 26.11.2024
9.0	14.04.2025	1699475-00025	Date of first issue: 21.05.2017

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 Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Piercetown
A86 HD21 Dunboyne, Ireland

Telephone : 908-740-4000

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 exposure, Category 3	H336: May cause drowsiness or dizziness.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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 protection/ 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. EC-No.	Classification	Concentration (% w/w)

	Index-No. Registration number		
2-Pyrrolidone	616-45-5 210-483-1	Eye Irrit. 2; H319 Repr. 1B; H360FD --- specific concentration limit Repr. 1B; H360FD > 3 %	>= 30 - < 50
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 --- specific concentration limit Skin Irrit. 2; H315 > 25 % Eye Irrit. 2; H319 > 25 %	>= 10 - < 20
Fluralaner	864731-61-3	Repr. 2; H361d Aquatic Chronic 1; H410 --- M-Factor (Chronic aquatic toxicity): 1,000	>= 3 - < 10

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 advice 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.

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.

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 products : Carbon oxides
Chlorine compounds
Fluorine compounds
Nitrogen oxides (NOx)

5.3 Advice for firefighters

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

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.

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 protective 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 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.

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

Technical measures	:	See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling : Do not get on skin or clothing.
Avoid breathing mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

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.

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

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	OELV - 8 hrs (TWA)	200 ppm	IE OEL
	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body			
		OELV - 15 min (STEL)	400 ppm	IE OEL
	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body			
Fluralaner	864731-61-3	TWA	100 µg/m3 (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 µg/100 cm²	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
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 effects	10 mg/m3
	Consumers	Inhalation	Long-term local effects	1.7 mg/m3
	Consumers	Skin contact	Long-term systemic	9.4 mg/kg

			effects	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
	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 with octanoic acid and propylene glycol	Soil	0.2638 mg/kg
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

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.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter should conform to I.S. EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

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
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

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 exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg
Method: OECD Test Guideline 423

Acute dermal toxicity : LD50 (Rat, female): > 2,000 mg/kg
Method: OECD Test Guideline 402

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: vapour

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

L-Menthol:

Acute inhalation toxicity : LC50 (Rat): 5.289 mg/l

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

Fluralaner:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Remarks: No mortality observed at this dose. No significant adverse effects were reported
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Remarks: No significant adverse effects were reported

Skin corrosion/irritation

Not classified based on available information.

Product:

Method	:	OECD Test Guideline 431
Result	:	Not corrosive

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

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

Test Type : Local lymph node assay (LLNA)
Method : OECD Test Guideline 429

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 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 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 - Assessment : No data available

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

2-Pyrrolidone:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: positive
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: positive

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

Propan-2-ol:

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

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

L-Menthol:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Fluralaner:

Effects on fertility : Test Type: Two-generation study
Species: Rat
Application Route: Oral
General Toxicity - Parent: NOAEL: 50 mg/kg body weight
General Toxicity F1: LOAEL: 100 mg/kg body weight

		Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects. Test Type: One-generation reproduction toxicity study Species: Dog Application Route: Oral Fertility: NOAEL: 75 mg/kg body weight Result: No effects on fertility and early embryonic development were detected. Remarks: No significant adverse effects were reported
Effects on foetal development	:	Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: Skeletal malformations, Visceral malformations Remarks: Maternal toxicity observed. Test Type: Development Species: Rabbit Application Route: Dermal Developmental Toxicity: NOAEL: 100 mg/kg body weight Result: Skeletal malformations
Reproductive toxicity - Assessment	:	Suspected of damaging the unborn child.

STOT - single exposure

May cause drowsiness or dizziness.

Components:

Propan-2-ol:

Assessment	:	May cause drowsiness or dizziness.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

2-Pyrrolidone:

Species	:	Rat
NOAEL	:	207 mg/kg
Application Route	:	Ingestion

Exposure time	:	3 Months
Method	:	OECD Test Guideline 408

Propan-2-ol:

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

L-Menthol:

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

Fluralaner:

Species	:	Dog
NOAEL	:	1 mg/kg
Application Route	:	Oral
Exposure time	:	52 Weeks
Target Organs	:	Liver
Remarks	:	No significant adverse effects were reported

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

Species	:	Rat
LOAEL	:	400 mg/kg
Application Route	:	Oral
Exposure time	:	90 Days
Target Organs	:	Liver, thymus gland

Species	:	Rat
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
Not classified based on available information.

Product:

Assessment : 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.

Experience with human exposure

Components:

Fluralaner:

Skin contact : Remarks: May irritate skin.
Eye contact : Remarks: May cause eye irritation.

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

Fluralaner:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.0488 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 0.015 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	:	NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity)	:	NOEC: >= 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 (Chronic 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:

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 environmental 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.

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 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.

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)
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, S-E

IATA (Cargo)

Packing instruction (cargo aircraft)	:	366
Packing instruction (LQ)	:	Y344
Packing group	:	III
Labels	:	Flammable Liquids

IATA (Passenger)

Packing instruction (passenger aircraft)	:	355
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). : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

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
P5c	FLAMMABLE LIQUIDS	5,000 t	50,000 t
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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
Flam. Liq.	:	Flammable liquids
Repr.	:	Reproductive toxicity
Skin Irrit.	:	Skin irritation
STOT SE	:	Specific target organ toxicity - single exposure
IE OEL	:	Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA)	:	Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL)	:	Occupational exposure limit value (15-minute reference period)

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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:		**Classification procedure:**
Flam. Liq. 3	H226	Based on product data or assessment
Eye Irrit. 2	H319	Calculation method
Repr. 1B	H360FD	Calculation method
STOT SE 3	H336	Calculation method
Aquatic Chronic 1	H410	Calculation method

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.

IE / EN