

# SAFETY DATA SHEET

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



## Fluralaner (Cattle Pour-On) Formulation

Version 5.2      Revision Date: 01.12.2023      SDS Number: 1699479-00019      Date of last issue: 30.09.2023  
Date of first issue: 21.05.2017

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### 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

Company : MSD  
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

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### 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)





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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	:	<b>Prevention:</b> 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. <b>Response:</b> 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
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	EC-No. Index-No. Registration number		(% w/w)
2-Pyrrolidone	616-45-5 210-483-1	Eye Irrit. 2; H319 Repr. 1B; H360FD  specific concentra- tion 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 concentra- tion 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.

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- 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.
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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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 (NO<sub>x</sub>)

### 5.3 Advice for firefighters

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

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- |                         |   |  |
|-------------------------|---|--|
| Technical measures      | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.<br>Use explosion-proof electrical, ventilating and lighting equipment.   |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Avoid breathing mist or vapours.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Non-sparking tools should be used.<br>Keep container tightly closed.<br>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br>Take precautionary measures against static discharges.<br>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.<br>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:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Flammable solids<br>Pyrophoric liquids<br>Pyrophoric solids<br>Self-heating substances and mixtures<br>Substances and mixtures, which in contact with water, emit flammable gases<br>Explosives<br>Gases<br>Very acutely toxic substances and mixtures |

### 7.3 Specific end use(s)

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

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### 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 245 mg/m <sup>3</sup>	FOR-2011-12-06-1358
Fluralaner	864731-61-3	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 µg/100 cm <sup>2</sup>	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/m <sup>3</sup>
	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/m <sup>3</sup>
	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
Workers		Skin contact	Long-term systemic effects	19 mg/kg bw/day
Consumers		Inhalation	Long-term systemic effects	33 mg/m <sup>3</sup>
Workers		Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
Consumers		Inhalation	Long-term local effects	1,7 mg/m <sup>3</sup>
Consumers		Skin contact	Long-term systemic effects	9,4 mg/kg bw/day
Propan-2-ol	Consumers	Ingestion	Long-term systemic effects	9,4 mg/kg bw/day
	Workers	Inhalation	Long-term systemic effects	500 mg/m <sup>3</sup>

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	Workers	Skin contact	Long-term systemic effects	888 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	89 mg/m <sup>3</sup>
	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
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.)
L-Menthol	Soil	0,0612 mg/kg dry weight (d.w.)
	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
Decanoic acid, mixed diesters with octanoic acid and propylene glycol	Fresh water sediment	289 µg/l
	Marine sediment	28,9 µg/l
	Soil	48,4 µg/l
	Soil	0,2638 mg/kg
	Propan-2-ol	Fresh water
	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.



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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.  
Equipment should conform to NS 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

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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

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## 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

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### 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.

#### 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

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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

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### 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

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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

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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

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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



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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

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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 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.

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### 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.

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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:

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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.

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### Components:

#### Fluralaner:

Assessment : This substance is not considered to be persistent, bioaccumulating 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

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## 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 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.

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## 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.

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(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
<b>ADN</b>	: 3	
<b>ADR</b>	: 3	
<b>RID</b>	: 3	
<b>IMDG</b>	: 3	
<b>IATA</b>	: 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

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### 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.

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## 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 75, 3

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

REACH - List of substances subject to authorisation : Not applicable



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(Annex XIV)

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

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

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : 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
E1	ENVIRONMENTAL HAZARDS	100 t	200 t
P5c	FLAMMABLE LIQUIDS	5.000 t	50.000 t

### 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

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

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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

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:

Flam. Liq. 3	H226
Eye Irrit. 2	H319
Repr. 1B	H360FD
STOT SE 3	H336

### Classification procedure:

Based on product data or assessment
Calculation method
Calculation method
Calculation method

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Aquatic Chronic 1

H410

Calculation method

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NO / EN