

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Fluralaner (Cattle Pour-On) Formulation

Version
8.1

Revision Date:
02.10.2025

SDS Number:
9373320-00015

Date of last issue: 14.04.2025
Date of first issue: 27.08.2021

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
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom
Telephone : +1-908-740-4000
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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

| | |
|--|---|
| 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. |

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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.

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------|---|----------------|--------------------------|
| | | | |

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| | | | |
|---------------|--------------------------------------|---|--------------|
| 2-Pyrrolidone | 616-45-5 210-483-1 | Eye Irrit. 2; H319 Repr. 1B; H360FD specific concentration limit Repr. 1B; H360FD > 3 % 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 % 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.

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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 (NO_x)

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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. If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

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.

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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 |

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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 | STEL | 500 ppm 1,250 mg/m ³ | GB EH40 |
| | | TWA | 400 ppm 999 mg/m ³ | GB EH40 |
| Fluralaner | 864731-61-3 | TWA | 100 µg/m ³ (OEB 2) | Internal |
| Further information: Skin | | Wipe limit | 1000 µg/100 cm ² | Internal |

Derived No Effect Level (DNEL)

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------|-----------|-----------------|----------------------------|------------------------|
| 2-Pyrrolidone | Workers | Inhalation | Long-term systemic effects | 57.8 mg/m ³ |
| | 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 ³ |
| | 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/m ³ |
| | Workers | Skin contact | Long-term systemic effects | 19 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 33 mg/m ³ |
| | Workers | Inhalation | Long-term local effects | 10 mg/m ³ |
| | Consumers | Inhalation | Long-term local ef- | 1.7 mg/m ³ |

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| | | | fects | |
|-------------|-----------|--------------|----------------------------|------------------|
| | 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 |
| | 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)

| 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 |

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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 BS 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

Appearance : liquid

Colour : blue green, clear

Odour : mint-like

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : 25 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Upper explosion limit / Upper : No data available

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flammability limit

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

9.2 Other information

Particle size : Not applicable

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 toxicological effects

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

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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

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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

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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

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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 - Assess- : No data available

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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 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.

Effects on foetal development : Test Type: Development
Species: Rat

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Application Route: Oral
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the off-spring 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

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

Species : Rat
NOAEL : 500 mg/kg
Application Route : Dermal
Exposure time : 90 Days
Target Organs : Liver
Remarks : No significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

Components:

Fluralaner:

Not applicable

Experience with human exposure

Components:

Fluralaner:

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

SECTION 12: Ecological information

12.1 Toxicity

Components:

2-Pyrrolidone:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l

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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

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| | |
|--|---|
| | 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

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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 : Not persistent, bioaccumulative, and toxic (PBT).

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12.6 Other adverse effects

Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f) at levels of 0.1% or higher.

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. |

SECTION 14: Transport information

14.1 UN 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) |

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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 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 | |

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Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

| | |
|---------|------------------|
| AICS | : not determined |
| CA. 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 |
| GB EH40 | : UK. EH40 WEL - Workplace Exposure Limits |
| GB EH40 / TWA | : Long-term exposure limit (8-hour TWA reference period) |
| GB EH40 / STEL | : Short-term exposure limit (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 -

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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 Harmonised 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 Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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 - Organisation 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 |
| Aquatic Chronic 1 | H410 |

Classification procedure:

| |
|-------------------------------------|
| Based on product data or assessment |
| Calculation method |
| Calculation method |
| Calculation method |
| 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.

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