

Fluralaner (Cattle Pour-On) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 9.0 06.07.2024 1688455-00021 Date of first issue: 21.05.2017

Section 1: Identification

Product name : Fluralaner (Cattle Pour-On) Formulation

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

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908

Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800

CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

Section 2: Hazard identification

GHS Classification

Flammable liquids : Category 3

Serious eye damage/eye irri-

tation

Category 2

Reproductive toxicity : Category 1

Specific target organ toxicity - :

single exposure

Category 3

Aspiration hazard : Category 1

Hazardous to the aquatic environment - chronic hazard

Category 1

GHS label elements

Hazard pictograms :









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Signal word : Danger

Hazard statements : H226 Flammable liquid and vapour.

H304 May be fatal if swallowed and enters airways.

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. P233 Keep container tightly closed.

P241 Use explosion-proof electrical/ ventilating/ lighting equip-

ment.

P242 Use non-sparking tools.

P243 Take action to prevent static discharges.

P261 Avoid breathing mist or vapours. P264 Wash skin thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P331 Do NOT induce vomiting.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P391 Collect spillage.

Storage:

P403 + P235 Store in a well-ventilated place. Keep cool. P405 Store locked up.

Disposal:

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



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Other hazards which do not result in classification

Vapours may form explosive mixture with air.

Section 3: Composition/information on ingredients

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
2-Pyrrolidone	616-45-5	>= 30 -< 50
Propan-2-ol	67-63-0	>= 30 -< 50
L-Menthol	2216-51-5	>= 10 -< 20
Fluralaner	864731-61-3	>= 2.5 -< 10

Section 4: First-aid measures

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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.

May be fatal if swallowed and enters airways.

Get medical attention.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

Causes serious eve irritation.

May cause drowsiness or dizziness.

May damage fertility. May damage the unborn child.

Protection of first-aiders First Aid responders should pay attention to self-protection,

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet



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Specific hazards during fire-

fighting

Do not use a solid water stream as it may scatter and spread

fire.

Flash back possible over considerable distance. Vapours may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Chlorine compounds Fluorine compounds Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

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

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

so.

Evacuate area.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Hazchem Code : 3Y

Section 6: Accidental release measures

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Remove all sources of ignition.

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Non-sparking tools should be used.

Soak up with inert absorbent material.

Suppress (knock down) gases/vapours/mists with a water

spray jet.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.



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Section 7: Handling and storage

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Use explosion-proof electrical, ventilating and lighting equip-

ment.

Advice on safe handling : Do not get on skin or clothing.

Avoid breathing mist or vapours.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Non-sparking tools should be used. Keep container tightly closed.

Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke. Wash 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.

Conditions for safe storage : 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.

Materials to avoid : Do not store with the following product types:

Self-reactive substances and mixtures

Organic peroxides
Oxidizing agents
Flammable gases
Pyrophoric liquids
Pyrophoric solids

Self-heating substances and mixtures

Poisonous gases Explosives



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Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
Propan-2-ol	67-63-0	WES-TWA	400 ppm 983 mg/m3	NZ OEL		
		WES-STEL	500 ppm 1,230 mg/m3	NZ OEL		
		TWA	200 ppm	ACGIH		
		STEL	400 ppm	ACGIH		
Fluralaner	864731-61-3	TWA	100 µg/m3 (OEB Internal 2)			
	Further information: Skin					
		Wipe limit	1000 μg/100 cm ²	Internal		

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentration	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of shift at end of work- week	40 mg/l	ACGIH BEI

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Combined particulates and organic vapour type

Filter type Hand protection

Material : Chemical-resistant gloves

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

the selection of hand protection.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,



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mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Section 9: 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

flammability limit

No data available

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

n- : Not applicable

Auto-ignition temperature

: No data available



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Decomposition temperature No data available

Viscosity

Viscosity, kinematic No data available

Explosive properties Not explosive

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

Particle characteristics

Not applicable Particle size

Section 10: Stability and reactivity

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Flammable liquid and vapour.

Possibility of hazardous reac-

tions

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

Conditions to avoid Heat, flames and sparks.

Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes 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 tox-

icity

Acute dermal toxicity LD50 (Rabbit): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Propan-2-ol:

Acute oral toxicity LD50 (Rat): > 5,000 mg/kg



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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

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Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Remarks: No mortality observed at this dose. No significant adverse effects were reported

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Remarks: No significant adverse effects were reported

Skin corrosion/irritation

Not classified based on available information.

Components:

2-Pyrrolidone:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Propan-2-ol:

Species : Rabbit

Result : No skin irritation

L-Menthol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : Skin irritation

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Species : Rabbit

Result : No skin irritation



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Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

2-Pyrrolidone:

Species : Rabbit

Result : Irritation to eyes, reversing within 7 days

Propan-2-ol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

L-Menthol:

Species : Rabbit

Result : Irritation to eyes, reversing within 7 days

Method : OECD Test Guideline 405

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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.

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)



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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.

Chronic toxicity

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



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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



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Application Route : Ingestion Exposure time : 103 weeks

Method : OECD Test Guideline 453

Result : negative

Remarks : Based on data from similar materials

Fluralaner:

Carcinogenicity - Assess- : No data available

ment

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

2-Pyrrolidone:

Effects on fertility: Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: positive

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on sexual function and fertil-

ity, based on animal experiments., Clear evidence of adverse

effects on development, based on animal experiments.

Propan-2-ol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

Test Type: Embryo-foetal development Species: Rat

ment

Application Route: Ingestion

Result: negative

L-Menthol:

Effects on foetal development Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Fluralaner:



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Effects on fertility : Test Type: Two-generation study

Species: Rat

Application Route: Oral

General Toxicity - Parent: NOAEL: 50 mg/kg body weight General Toxicity F1: LOAEL: 100 mg/kg body weight Result: No effects on fertility, Postimplantation loss., Adverse

neonatal effects.

Test Type: One-generation reproduction toxicity study

Species: Dog

Application Route: Oral

Fertility: NOAEL: 75 mg/kg body weight

Result: No effects on fertility and early embryonic develop-

ment were detected.

Remarks: No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

Application Route: Oral

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

teratogenic effects

Test Type: Development

Species: Rabbit

Application Route: Oral

Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: Skeletal malformations, Visceral malformations

Remarks: Maternal toxicity observed.

Test Type: Development

Species: Rabbit

Application Route: Dermal

Developmental Toxicity: NOAEL: 100 mg/kg body weight

Result: Skeletal malformations

Reproductive toxicity - As-

sessment

: Suspected of damaging the unborn child.

STOT - single exposure

May cause drowsiness or dizziness.

Components:

Propan-2-ol:

Assessment : May cause drowsiness or dizziness.

STOT - repeated exposure

Not classified based on available information.



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Repeated dose toxicity

Components:

2-Pyrrolidone:

Species : Rat NOAEL : 207 mg/kg : Ingestion : 3 Months Application Route

Exposure time

Method : OECD Test Guideline 408

Propan-2-ol:

Species : Rat NOAEL : 12.5 mg/l

: inhalation (vapour) Application Route

Exposure time : 104 Weeks

L-Menthol:

Species : Mouse NOAEL : 1,250 mg/kg Application Route Exposure time : Ingestion : 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 Target Organs : 52 Weeks : Liver

Remarks : No significant adverse effects were reported

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

Application Route : Oral Exposure time 24 Weeks Symptoms : Diarrhoea

Species Rat LÖAEL 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



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Remarks : No significant adverse effects were reported

Aspiration toxicity

May be fatal if swallowed and enters airways.

Components:

Propan-2-ol:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

Fluralaner:

Not applicable

Experience with human exposure

Components:

Fluralaner:

Skin contact : Remarks: May irritate skin.

Eye contact : Remarks: May cause eye irritation.

Section 12: Ecological information

Ecotoxicity

Components:

2-Pyrrolidone:

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

Exposure time: 96 h

Method: OECD Test Guideline 203

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



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aquatic invertebrates

Toxicity to daphnia and other : 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.

: EC50: 237 mg/l Toxicity to microorganisms

Exposure time: 96 h

Test Type: Respiration inhibition of activated sludge

Method: OECD Test Guideline 209

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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 ma/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic tox-

icity)

NOEC (Zebrafish): >= 0.049 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 204

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 0.0736 µg/l



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aquatic invertebrates (Chron-

Exposure time: 21 d

ic toxicity)

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

: 1.000

Persistence and degradability

Components:

2-Pyrrolidone:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Propan-2-ol:

Biodegradability : Result: rapidly degradable

BOD/COD : BOD: 1,19 (BOD5)

COD: 2,23 BOD/COD: 53 %

L-Menthol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 64 % Exposure time: 28 d

Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:

2-Pyrrolidone:

Partition coefficient: n- : log Pow: -0.71

octanol/water Method: OECD Test Guideline 107

Propan-2-ol:

Partition coefficient: n-

octanol/water

: log Pow: 0.05

L-Menthol:

Bioaccumulation : Species: Cyprinus carpio (Carp)

Bioconcentration factor (BCF): 0.5 - 15

Exposure time: 6 Weeks

Method: OECD Test Guideline 305

Remarks: Based on data from similar materials

Partition coefficient: n-

octanol/water

: log Pow: 3.15

Fluralaner:

Bioaccumulation : Species: Zebrafish



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> Bioconcentration factor (BCF): 79.4 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 4.5

Mobility in soil

Components:

Fluralaner:

Distribution among environ-

mental compartments

: log Koc: 4.1

Other adverse effects

Components:

Fluralaner:

Results of PBT and vPvB

assessment

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

Section 13: Disposal considerations

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

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

International Regulations

UNRTDG

UN number : UN 1993

Proper shipping name : FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol)

Class : 3
Packing group : III
Labels : 3
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 1993

Proper shipping name : Flammable liquid, n.o.s.

(Propan-2-ol)

Class : 3



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Packing group : III

Labels : Flammable Liquids

Packing instruction (cargo:

aircraft)

Packing instruction (passen: 355

ger aircraft)

IMDG-Code

UN number : UN 1993

Proper shipping name : FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol, Fluralaner)

Class : 3
Packing group : III
Labels : 3
EmS Code : F-E, S-E
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

NZS 5433

UN number : UN 1993

Proper shipping name : FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol)

Class : 3
Packing group : III
Labels : 3
Hazchem Code : 3Y
Marine pollutant : yes

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

Section 15: Regulatory information

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

HSNO Approval Number

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable



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HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 06.07.2024

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 Agentus http://acha.gov/acha.gov/

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

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospher-

ic Contaminants

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average NZ OEL / WES-STEL : Workplace Exposure Standard - Short-Term Exposure Limit

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Con-



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centration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified: Nch - Chilean Norm: NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate: NOM - Official Mexican Norm: NTP - National Toxicology Program: NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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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