

Fluralaner / Moxidectin Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 13.04.2024 11.0 06.07.2024 656888-00024 Date of first issue: 02.05.2016

Section 1: Identification

Product name : Fluralaner / Moxidectin Liquid Formulation

Other means of identification : Bravecto Plus (A011446)

BRAVECTO PLUS FLEA, TICK AND WORM 112.5 MG FLURALANER AND 5.6 MG MOXIDECTIN SPOT-ON SOLUTION FOR KITTENS AND SMALL CATS (85418) BRAVECTO PLUS FLEA, TICK AND WORM 250 MG FLURALANER AND 12.5 MG MOXIDECTIN SPOT-ON

SOLUTION FOR MEDIUM CATS (85416)

BRAVECTO PLUS FLEA, TICK AND WORM 500 MG FLURALANER AND 25 MG MOXIDECTIN SPOT-ON

SOLUTION FOR LARGE CATS (85413)

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 2

Serious eye damage/eye irri-

tation

Category 2

Reproductive toxicity : Category 1

Specific target organ toxicity - :

repeated exposure

Category 2 (Central nervous system)

Hazardous to the aquatic

environment - acute hazard

Category 1



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Hazardous to the aquatic environment - chronic hazard

Category 1

GHS label elements

Hazard pictograms









Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation. H360D May damage the unborn child.

H373 May cause damage to organs (Central nervous system)

through prolonged or repeated exposure.

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 equipment.

P242 Use non-sparking tools.

P243 Take action to prevent static discharges.

P260 Do not breathe mist or vapours.

P264 Wash skin thoroughly after handling.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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

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.

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



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disposal plant.

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)
N,N-Dimethylacetamide	127-19-5	>= 30 -< 50
Fluralaner	864731-61-3	>= 25 -< 30
Poly(oxy-1,2-ethanediyl), .alpha[(tetrahydro-2-	31692-85-0	>= 20 -< 30
furanyl)methyl]omegahydroxy-		
Acetone	67-64-1	>= 10 -< 20
N,N-Diethyl-m-toluamide	134-62-3	>= 10 -< 20
Moxidectin	113507-06-5	>= 1 -< 2.5
2,6-Di-tert-butyl-p-cresol	128-37-0	>= 0.1 -< 0.25

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 soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed, DO NOT induce vomiting.

If vomiting occurs have person lean forward.

Call a physician or poison control centre immediately.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

Causes serious eye irritation.

May damage the unborn child.

delayed

May cause damage to organs through prolonged or repeated

exposure.

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.



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Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

High volume water jet

Dry chemical

Unsuitable extinguishing

media

Specific hazards during fire-

fighting

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

....

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 : 2YE

Section 6: Accidental release measures

Personal precautions, protective equipment and emer-

gency procedures

Remove all sources of ignition.

Ventilate the area.

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



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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.

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.

Do not breathe 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. Do not eat, drink or smoke when using this product.

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



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Organic peroxides Oxidizing agents Flammable gases Pyrophoric liquids Pyrophoric solids

Self-heating substances and mixtures

Poisonous gases Explosives

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
N,N-Dimethylacetamide	127-19-5	WES-TWA	5 ppm 18 mg/m3	NZ OEL		
	Further inform	Further information: Skin absorption				
		TWA	10 ppm	ACGIH		
Fluralaner	864731-61-3	TWA	100 μg/m3 (OEB 2)	Internal		
	Further information: Skin					
		Wipe limit	1000 µg/100 cm ²	Internal		
Acetone	67-64-1	WES-TWA	500 ppm 1,185 mg/m3	NZ OEL		
	Further information: Exposure can also be estimated by biological monitoring					
		WES-STEL	1,000 ppm 2,375 mg/m3	NZ OEL		
	Further information: Exposure can also be estimated by bio monitoring					
		TWA	250 ppm	ACGIH		
		STEL	500 ppm	ACGIH		
Moxidectin	113507-06-5	TWA	10 μg/m3 (OEB 3)	Internal		
		Wipe limit	100 μg/100 cm ²	Internal		
2,6-Di-tert-butyl-p-cresol	128-37-0	WES-TWA	10 mg/m3	NZ OEL		
	Further inform	Further information: Skin sensitiser				
		TWA (Inhal-	2 mg/m3	ACGIH		
		able fraction and vapor)				

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	N- Methyla- cetamide	Urine	End of shift at end of work-	30 mg/g creatinine	ACGIH BEI



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				week		
Acetone	67-64-1	Acetone	Urine	End of shift	50 mg/l	NZ BEI
		Acetone	Urine	End of shift (As	25 mg/l	ACGIH BEI
				soon as possible after		
				exposure ceases)		

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.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face con-

tainment devices). Minimize open handling.

Use explosion-proof electrical, ventilating and lighting equip-

ment.

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.

Filter type Hand protection Self-contained breathing apparatus

Material : Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is flam-

mable, 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,

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.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Section 9: Physical and chemical properties

Appearance : liquid



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Colour : Colorless to pale yellow

Odour : No data available

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 : 2 °C

Method: closed cup

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 : 1.06

Density : 1.08 g/cm³

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 : 7.5 mm2/s

Explosive properties : Not explosive



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

Particle characteristics

Particle size Not applicable

Section 10: Stability and reactivity

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Highly 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.

Oxidizing agents Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes Inhalation

Skin contact Ingestion Eve contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Acute dermal toxicity Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

N,N-Dimethylacetamide:

Acute oral toxicity : LD50 (Rat): 4,800 mg/kg

: LC50 (Rat): 2.2 mg/l Acute inhalation toxicity

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity Acute toxicity estimate: 1,100 mg/kg

Method: Expert judgement



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Remarks: Based on national or regional regulation.

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

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

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

Method: OECD Test Guideline 423

Remarks: Based on data from similar materials

Acetone:

Acute oral toxicity : LD50 (Rat): 5,800 mg/kg

Acute inhalation toxicity : LC50 (Rat): 76 mg/l

Exposure time: 4 h

Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): 7,426 mg/kg

N,N-Diethyl-m-toluamide:

Acute oral toxicity : LD50 (Rat): 1,892 mg/kg

Acute inhalation toxicity : LC50 (Rat): 5.95 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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

Moxidectin:

Acute oral toxicity : LD50 (Rat): 106 mg/kg

LD50 (Mouse): 42 - 84 mg/kg

Acute inhalation toxicity : LC50 (Rat): 3.28 mg/l

Exposure time: 5 h

Test atmosphere: dust/mist

LC50 (Rat): 2.87 - 4.06 mg/l Test atmosphere: dust/mist

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

Remarks: No significant adverse effects were reported

Acute toxicity (other routes of : LD50 (Rat): 394 mg/kg



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administration) Application Route: Intraperitoneal

LD50 (Mouse): 84 mg/kg

Application Route: Intraperitoneal

LD50 (Rat): > 640 mg/kg

Application Route: Subcutaneous

LD50 (Mouse): 263 mg/kg

Application Route: Subcutaneous

2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity : LD50 (Rat): > 6,000 mg/kg

Method: OECD Test Guideline 401

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

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

N,N-Dimethylacetamide:

Species : Rabbit

Result : No skin irritation

Fluralaner:

Species : Rabbit

Result : No skin irritation

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 439

Remarks : Based on data from similar materials

Result : No skin irritation

Acetone:

Assessment : Repeated exposure may cause skin dryness or cracking.

N,N-Diethyl-m-toluamide:

Species : Rabbit

Result : No skin irritation

Moxidectin:



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Species : Rabbit

Result : Mild skin irritation

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

N,N-Dimethylacetamide:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Fluralaner:

Species : Rabbit

Result : Mild eye irritation

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Species : Tissue Culture

Method : OECD Test Guideline 492

Remarks : Based on data from similar materials

Species : Bovine cornea

Method : OECD Test Guideline 437

Remarks : Based on data from similar materials

Result : Irritation to eyes, reversing within 21 days

Acetone:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

N,N-Diethyl-m-toluamide:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days Remarks : Based on national or regional regulation.

Moxidectin:

Species : Rabbit

Result : Moderate eye irritation



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2,6-Di-tert-butyl-p-cresol:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

N,N-Dimethylacetamide:

Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Fluralaner:

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Test Type : KeratinoSens assay

Method : OECD Test Guideline 442D

Result : negative

Remarks : Based on data from similar materials

Test Type : Direct Peptide Reactivity Assay (DPRA)

Method : OECD Test Guideline 442C

Result : positive

Remarks : Based on data from similar materials

Test Type : Dendritic cell activation test Method : OECD Test Guideline 442E

Result : negative

Remarks : Based on data from similar materials

Acetone:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative



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Moxidectin:

Test Type : Buehler Test Exposure routes : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

2,6-Di-tert-butyl-p-cresol:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact Species : Humans Result : negative

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Components:

N,N-Dimethylacetamide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)

Species: Rat

Application Route: Inhalation Method: OECD Test Guideline 478

Result: negative

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

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials



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Acetone:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

N,N-Diethyl-m-toluamide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Moxidectin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster ovary cells

Result: negative

Test Type: in vitro assay Test system: Escherichia coli

Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: Rat

Cell type: Bone marrow

Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with

mammalian liver cells in vivo

Species: Rat Cell type: Liver cells Result: negative

2,6-Di-tert-butyl-p-cresol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test



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Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

N,N-Dimethylacetamide:

Species : Rat

Application Route : inhalation (vapour)

Exposure time : 18 month(s)
Result : negative

Fluralaner:

Carcinogenicity - Assess-

ment

No data available

Acetone:

Species : Mouse
Application Route : Skin contact
Exposure time : 424 days
Result : negative

N,N-Diethyl-m-toluamide:

Species : Rat
Application Route : Ingestion
Exposure time : 104 weeks
Result : negative

Moxidectin:

Species : Mouse Application Route : Oral Exposure time : 2 Years

NOAEL : 4.5 mg/kg body weight

Result : negative

Species : Rat
Application Route : Oral
Exposure time : 2 Years

NOAEL : 4.5 mg/kg body weight



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Result : negative

Species : Dog Application Route : Oral Exposure time : 1 Years

NOAEL : 0.5 mg/kg body weight

Result : negative

2,6-Di-tert-butyl-p-cresol:

Species : Rat
Application Route : Ingestion
Exposure time : 22 Months
Result : negative

Reproductive toxicity

May damage the unborn child.

Components:

N,N-Dimethylacetamide:

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

Species: Rat

Application Route: Inhalation

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Inhalation

Result: positive

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

Fluralaner:

Effects on fertility : Test Type: Two-generation study

Species: Rat

Application Route: Oral

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

neonatal effects.

Test Type: One-generation reproduction toxicity study

Species: Dog

Application Route: Oral

Fertility: NOAEL: 75 mg/kg body weight

Result: No effects on fertility and early embryonic develop-

ment were detected.

Remarks: No significant adverse effects were reported

Effects on foetal develop- : Test Type: Development



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ment 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.

Acetone:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: inhalation (vapour)

Result: negative

N,N-Diethyl-m-toluamide:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Moxidectin:

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

Species: Rat

Application Route: Oral

General Toxicity F1: LOAEL: 0.8 mg/kg body weight Symptoms: Reduced foetal weight, foetal mortality

Result: No effects on fertility, Some evidence of adverse effects on development, based on animal experiments.

Test Type: Three-generation reproduction toxicity study

Species: Rat



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Application Route: Oral

General Toxicity F1: LOAEL: 0.8 mg/kg body weight Symptoms: Reduced foetal weight, foetal mortality Result: No effects on fertility, Some evidence of adverse effects on development, based on animal experiments.

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

General Toxicity Maternal: LOAEL: 10 mg/kg body weight Embryo-foetal toxicity: LOAEL: 10 mg/kg body weight

Result: Skeletal malformations

Remarks: The effects were seen only at maternally toxic dos-

es.

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

General Toxicity Maternal: LOAEL: 5 mg/kg body weight Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: No teratogenic effects, No embryotoxic effects

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

2,6-Di-tert-butyl-p-cresol:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

STOT - single exposure

Not classified based on available information.

Components:

Acetone:

Assessment : May cause drowsiness or dizziness.

STOT - repeated exposure

May cause damage to organs (Central nervous system) through prolonged or repeated exposure.

Components:

Moxidectin:

Target Organs : Central nervous system



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Assessment : Causes damage to organs through prolonged or repeated

exposure.

2,6-Di-tert-butyl-p-cresol:

Assessment : No significant health effects observed in animals at concentra-

tions of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

N,N-Dimethylacetamide:

 Species
 : Rat

 NOAEL
 : 90 mg/m3

 LOAEL
 : 360 mg/m3

Application Route : inhalation (vapour)

Exposure time : 24 Months

Fluralaner:

Species : Dog
NOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 52 Weeks
Target Organs : Liver

Remarks : No significant adverse effects were reported

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

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

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

Target Organs : Liver, thymus gland

Species : Rat
NOAEL : 500 mg/kg
Application Route : Dermal
Exposure time : 90 Days
Target Organs : Liver

Remarks : No significant adverse effects were reported

Acetone:

Species : Rat
NOAEL : 900 mg/kg
LOAEL : 1,700 mg/kg
Application Route : Ingestion



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Exposure time : 90 Days

Species : Rat NOAEL : 45 mg/l

Application Route : inhalation (vapour)

Exposure time : 8 Weeks

Moxidectin:

Species: MouseNOAEL: 3.9 mg/kgLOAEL: 15.4 mg/kgApplication Route: OralExposure time: 4 WeeksSymptoms: Tremors

Species : Rat
NOAEL : 3.9 mg/kg
LOAEL : 7.9 mg/kg
Application Route : Oral
Exposure time : 13 Weeks

Target Organs : Central nervous system Symptoms : Tremors, Salivation

Species : Dog
NOAEL : 0.3 mg/kg
LOAEL : 0.9 mg/kg
Application Route : Oral
Exposure time : 90 Days

Target Organs : Central nervous system

Symptoms : Tremors, Lachrymation, Salivation

Species : Dog
NOAEL : 1.15 mg/kg
Application Route : Oral
Exposure time : 52 Weeks

Target Organs : Central nervous system Symptoms : Tremors, Lachrymation

2,6-Di-tert-butyl-p-cresol:

Species : Rat
NOAEL : 25 mg/kg
Application Route : Ingestion
Exposure time : 22 Months

Aspiration toxicity

Not classified based on available information.

Components:

Fluralaner:

Not applicable



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Acetone:

The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

Experience with human exposure

Components:

Fluralaner:

Skin contact : Remarks: May irritate skin.

Eye contact : Remarks: May cause eye irritation.

Moxidectin:

Inhalation : Remarks: No human information is available. Skin contact : Remarks: No human information is available. Eye contact : Remarks: No human information is available. Ingestion : Remarks: No human information is available.

Section 12: Ecological information

Ecotoxicity

Components:

N,N-Dimethylacetamide:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 500 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)): > 500 mg/l

Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC10: > 1,995 mg/l

Exposure time: 30 min

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



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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 : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.0736 μg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

: 1,000

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Acetone:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia pulex (Water flea)): 8,800 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000

mg/l

Exposure time: 96 h

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): >= 79 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211



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Toxicity to microorganisms EC50: 61,150 mg/l

> Exposure time: 30 min Method: ISO 8192

N,N-Diethyl-m-toluamide:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 97 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 75 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Selenastrum capricornutum (green algae)): 41 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Selenastrum capricornutum (green algae)): 7.6 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 3.7 mg/l

Exposure time: 21 d

Moxidectin:

Toxicity to fish LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0006 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 0.0002 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.00003 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 0.087

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

10,000

M-Factor (Chronic aquatic

toxicity)

10,000

2,6-Di-tert-butyl-p-cresol:

Toxicity to fish LC50 (Danio rerio (zebra fish)): > 0.57 mg/l

Exposure time: 96 h

Method: Directive 67/548/EEC, Annex V, C.1.



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Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.48 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

Toxicity to fish (Chronic tox-

icity)

NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l

NOEC (Daphnia magna (Water flea)): 0.316 mg/l

Exposure time: 30 d

Exposure time: 21 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other

aquatic invertebrates (Chron-

ic toxicity)

M-Factor (Chronic aquatic

toxicity) Toxicity to microorganisms

EC50: > 10,000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Persistence and degradability

Components:

N,N-Dimethylacetamide:

Biodegradability Result: Not readily biodegradable.

1

Biodegradation: 70 % Exposure time: 28 d

Remarks: The 10 day time window criterion is not fulfilled.

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Biodegradability Result: Not readily biodegradable.

Method: OECD Test Guideline 301F

Remarks: Based on data from similar materials

Acetone:

Biodegradability Result: Readily biodegradable.

> Biodegradation: 91 % Exposure time: 28 d



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N,N-Diethyl-m-toluamide:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 83.8 % Exposure time: 28 d

Method: OECD Test Guideline 301B

2,6-Di-tert-butyl-p-cresol:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 4.5 % Exposure time: 28 d

Method: OECD Test Guideline 301C

Bioaccumulative potential

Components:

Fluralaner:

Bioaccumulation : Species: Zebrafish

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

Partition coefficient: n-

octanol/water

log Pow: 4.5

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Partition coefficient: n- : log Pow: < 4

octanol/water Remarks: Calculation

Acetone:

Partition coefficient: n-

octanol/water

log Pow: -0.27 - -0.23

N,N-Diethyl-m-toluamide:

Partition coefficient: n-

octanol/water

log Pow: 2.02

Moxidectin:

Partition coefficient: n-

log Pow: 4.7

octanol/water

2,6-Di-tert-butyl-p-cresol:

Bioaccumulation : Species: Cyprinus carpio (Carp)

Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n-

octanol/water

log Pow: 5.1

Mobility in soil

Components:

Fluralaner:



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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 1090

Proper shipping name **ACETONE SOLUTION**

Class 3 Ш Packing group Labels 3 Environmentally hazardous no

IATA-DGR

UN/ID No. UN 1090

Proper shipping name Acetone solution

Class 3 Packing group Ш

Flammable Liquids Labels

Packing instruction (cargo

aircraft)

364

Packing instruction (passen-

ger aircraft)

353

IMDG-Code

UN 1090 UN number

ACETONE SOLUTION Proper shipping name

(Fluralaner, Moxidectin)

Class 3 Ш Packing group



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Labels : 3

EmS Code : F-E, S-D 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 1090

Proper shipping name : ACETONE SOLUTION

Class : 3
Packing group : II
Labels : 3
Hazchem Code : 2YE
Marine pollutant : no

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

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



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Further information

Sources of key data used to compile the Safety Data

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Sheet

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

: Internal technical data, data from raw material SDSs, OECD

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 BEI New Zealand. Biological Exposure Indices

NZ OEL New Zealand. Workplace Exposure Standards for Atmospher-

ic Contaminants

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

Workplace Exposure Standard - Time Weighted average NZ OEL / WES-TWA 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 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; 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 Recom-



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mendations 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.

NZ / EN