

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
4.0	15.10.2020	656889-00012	Date of first issue: 02.05.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fluralaner / Moxidectin Liquid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive
Singapore - Singapore 638408

Telephone : 908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION**GHS Classification**

Flammable liquids : Category 2

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 2 (Central nervous system)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.

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H315 Causes skin irritation.
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.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
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/ shower.
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.
P332 + P313 If skin irritation occurs: 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 disposal plant.

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 20 %

Other hazards which do not result in classification

Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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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
N,N-Diethyl-m-toluamide	134-62-3	>= 10 -< 20
Acetone	67-64-1	>= 10 -< 20
Moxidectin	113507-06-5	>= 1 -< 2.5
2,6-Di-tert-butyl-p-cresol	128-37-0	>= 0.1 -< 0.25

4. 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.
- 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 for at least 15 minutes while removing 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.
 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 delayed : Causes skin irritation.
 Causes serious eye irritation.
 May damage the unborn child.
 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.

5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray
 Alcohol-resistant foam
 Carbon dioxide (CO₂)
 Dry chemical
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire- : Do not use a solid water stream as it may scatter and spread

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective 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 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.

7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE
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		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. 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 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. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.	
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	

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	PEL (long term)	10 ppm 36 mg/m ³	SG OEL
		TWA	10 ppm	ACGIH
Fluralaner	864731-61-3	TWA	100 µg/m ³ (OEB 2)	Internal
Further information: Skin				
		Wipe limit	1000 µg/100 cm ²	Internal
Acetone	67-64-1	PEL (long term)	750 ppm 1,780 mg/m ³	SG OEL

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		PEL (short term)	1,000 ppm 2,380 mg/m ³	SG OEL
		TWA	250 ppm	ACGIH
		STEL	500 ppm	ACGIH
Moxidectin	113507-06-5	TWA	10 µg/m ³ (OEB 3)	Internal
		Wipe limit	100 µg/100 cm ²	Internal
2,6-Di-tert-butyl-p-cresol	128-37-0	PEL (long term)	10 mg/m ³	SG OEL
		TWA (Inhalable fraction and vapor)	2 mg/m ³	ACGIH

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	N-Methylacetamide	Urine	End of shift at end of work-week	30 mg/g Creatinine	ACGIH BEI
Acetone	67-64-1	Acetone	Urine	End of shift (As soon as possible after exposure ceases)	25 mg/l	ACGIH BEI

Engineering measures : Use explosion-proof electrical, ventilating and lighting equipment.

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.

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 containment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Self-contained breathing apparatus

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

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| 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, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing. |
| 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|--|---|----------------------------|
| Appearance | : | liquid |
| 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 |

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Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	1.06
Density	:	1.08 g/cm ³
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 mm ² /s
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle size	:	Not applicable

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Highly flammable liquid and vapour. 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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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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
Acute inhalation toxicity : LC50 (Rat): 2.2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : Acute toxicity estimate: 1,100 mg/kg
Method: Expert judgement
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

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

N,N-Diethyl-m-toluamide:

Acute oral toxicity : LD50 (Rat): 1,950 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

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

Moxidectin:

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

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	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 (Rat): > 2,000 mg/kg Remarks: No significant adverse effects were reported
Acute toxicity (other routes of administration)	: LD50 (Rat): 394 mg/kg 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

Causes skin irritation.

Components:

N,N-Dimethylacetamide:

Species	: Rabbit
Result	: No skin irritation

Fluralaner:

Species	: Rabbit
Result	: No skin irritation

N,N-Diethyl-m-toluamide:

Species	: Rabbit
Result	: Skin irritation

Acetone:

Assessment	: Repeated exposure may cause skin dryness or cracking.
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Moxidectin:

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

N,N-Diethyl-m-toluamide:

Species	: Rabbit
Result	: Irritation to eyes, reversing within 21 days

Acetone:

Species	: Rabbit
Result	: Irritation to eyes, reversing within 21 days
Method	: OECD Test Guideline 405

Moxidectin:

Species	: Rabbit
Result	: Moderate eye irritation

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.

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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.

Acetone:

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

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

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)
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		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
N,N-Diethyl-m-toluamide:		
Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES)
		Result: negative
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
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

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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
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 - Assessment : No data available

N,N-Diethyl-m-toluamide:

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

Acetone:

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

Moxidectin:

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

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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
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 development	: Test Type: Embryo-foetal development Species: Rat Application Route: Inhalation Result: positive
Reproductive toxicity - Assessment	: 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

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		Result: No effects on fertility and early embryonic development were detected. Remarks: No significant adverse effects were reported
Effects on foetal development	:	Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: Skeletal malformations, Visceral malformations Remarks: Maternal toxicity observed. Test Type: Development Species: Rabbit Application Route: Dermal Developmental Toxicity: NOAEL: 100 mg/kg body weight Result: Skeletal malformations
Reproductive toxicity - Assessment	:	Suspected of damaging the unborn child.
N,N-Diethyl-m-toluamide:		
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative
Acetone:		
Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: inhalation (vapour) 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.

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	Test Type: Three-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.
Effects on foetal development	: 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 doses.
	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 - Assessment	: 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 development	: 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.
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STOT - repeated exposure

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

Components:**Moxidectin:**

Target Organs	: Central nervous system
Assessment	: Causes damage to organs through prolonged or repeated

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|| exposure.

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

|| Assessment : No significant health effects observed in animals at concentrations 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
 || Exposure time : 90 Days

|| Species : Rat

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NOAEL	: 45 mg/l
Application Route	: inhalation (vapour)
Exposure time	: 8 Weeks

Moxidectin:

Species	: Mouse
NOAEL	: 3.9 mg/kg
LOAEL	: 15.4 mg/kg
Application Route	: Oral
Exposure time	: 4 Weeks
Symptoms	: 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	: 0.3 mg/kg
LOAEL	: 0.87 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.

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 Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	:	NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l

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Exposure time: 72 h
 Method: OECD Test Guideline 201
 Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : 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 (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.000047 mg/l
 Exposure time: 21 d
 Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1,000

N,N-Diethyl-m-toluamide:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 110 mg/l
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 75 mg/l
 Exposure time: 48 h

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 (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): ≥ 79 mg/l
 Exposure time: 21 d
 Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: 61,150 mg/l
 Exposure time: 30 min
 Method: ISO 8192

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

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Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 0.087 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 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.

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 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l
 Exposure time: 30 d
 Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.316 mg/l
 Exposure time: 21 d

M-Factor (Chronic aquatic toxicity) : 1

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.
 Biodegradation: 70 %
 Exposure time: 28 d
 Remarks: The 10 day time window criterion is not fulfilled.

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N,N-Diethyl-m-toluamide:

Biodegradability : Result: Not readily biodegradable.

Acetone:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 91 %
Exposure time: 28 d

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

N,N-Diethyl-m-toluamide:

Partition coefficient: n-octanol/water : log Pow: 2.02

Acetone:

Partition coefficient: n-octanol/water : log Pow: -0.27 - -0.23

Moxidectin:

Partition coefficient: n-octanol/water : log Pow: 4.7

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:**

Distribution among environmental compartments : log Koc: 3.4

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Other adverse effects**Components:****Fluralaner:**

Results of PBT and vPvB assessment	:	This substance is not considered to be persistent, bioaccumulating and toxic (PBT).
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13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	:	Dispose of in accordance with local regulations.
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.

14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number	:	UN 1090
Proper shipping name	:	ACETONE SOLUTION
Class	:	3
Packing group	:	II
Labels	:	3

IATA-DGR

UN/ID No.	:	UN 1090
Proper shipping name	:	Acetone solution
Class	:	3
Packing group	:	II
Labels	:	Flammable Liquids
Packing instruction (cargo aircraft)	:	364
Packing instruction (passenger aircraft)	:	353

IMDG-Code

UN number	:	UN 1090
Proper shipping name	:	ACETONE SOLUTION (Fluralaner, Moxidectin)
Class	:	3
Packing group	:	II
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.

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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.

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Acetone
Regulations

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

AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION**Further information**

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD
compile the Safety Data eChem Portal search results and European Chemicals Agen-
Sheet 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)
SG OEL : Singapore. Workplace Safety and Health Act - First Schedule
Permissible Exposure Limits of Toxic Substances

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term
SG OEL / PEL (short term) : Permissible Exposure Level (PEL) Short Term

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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; 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.

SG / EN