

**Fluralaner / Moxidectin Liquid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.12.2023	656888-00021	Date of first issue: 02.05.2016

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**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

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**Section 2: Hazard identification****GHS Classification**

Flammable liquids : Category 2

Serious eye damage/eye irritation : 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-furanyl)methyl]-.omega.-hydroxy-	31692-85-0	>= 20 -< 30
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 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 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 : 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 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).

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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 (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.  
Flash back possible over considerable distance.  
Vapours may form explosive mixtures with air.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Chlorine compounds  
Fluorine compounds  
Nitrogen oxides (NO<sub>x</sub>)

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.

Hazchem Code : 2YE

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### Section 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

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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.

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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.<br>Use explosion-proof electrical, ventilating and lighting equipment.   |
| Advice on safe handling     | : | Do not get on skin or clothing.<br>Do not breathe mist or vapours.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Non-sparking tools should be used.<br>Keep container tightly closed.<br>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures            | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.   |
| Conditions for safe storage | : | Keep in properly labelled containers.<br>Store locked up.<br>Keep tightly closed.<br>Keep in a cool, well-ventilated place.<br>Store in accordance with the particular national regulations.<br>Keep away from heat and sources of ignition.   |
| Materials to avoid          | : | Do not store with the following product types:<br>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	10 ppm 36 mg/m <sup>3</sup>	NZ OEL	
		TWA	10 ppm	ACGIH	
Fluralaner	864731-61-3	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal	
		Further information: Skin			
		Wipe limit	1000 µg/100 cm <sup>2</sup>	Internal	
Acetone	67-64-1	WES-TWA	500 ppm 1,185 mg/m <sup>3</sup>	NZ OEL	
		Further information: Exposure can also be estimated by biological monitoring			
		WES-STEL	1,000 ppm 2,375 mg/m <sup>3</sup>	NZ OEL	
		Further information: Exposure can also be estimated by biological monitoring			
		TWA	250 ppm	ACGIH	
		STEL	500 ppm	ACGIH	
Moxidectin	113507-06-5	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal	
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal	
2,6-Di-tert-butyl-p-cresol	128-37-0	WES-TWA	10 mg/m <sup>3</sup>	NZ OEL	
		Further information: Skin sensitiser			
		TWA (Inhalable fraction and vapor)	2 mg/m <sup>3</sup>	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

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

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
 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.  
 Use explosion-proof electrical, ventilating and lighting equipment.

**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.

**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.

**Section 9: Physical and chemical properties**

**Appearance** : liquid

**Colour** : Colorless to pale yellow

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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/cm <sup>3</sup>
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 <sup>2</sup> /s
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.



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Particle size : Not applicable

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### Section 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.

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### Section 11: Toxicological information

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye 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
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 national or regional regulation.

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### 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
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### 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): 1,950 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

### 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 (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

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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:**

Species : Rabbit

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|| 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 - Assessment	: No data available
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**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 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  
 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

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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.

**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

**N,N-Diethyl-m-toluamide:**

Effects on foetal development : 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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<p>Effects on foetal development</p>	<p>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.</p>
<p>Reproductive toxicity - Assessment</p>	<p>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.</p> <p>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</p> <p>Some evidence of adverse effects on development, based on animal experiments.</p>

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

<p>Effects on fertility</p>	<p>Test Type: Two-generation reproduction toxicity study          Species: Rat          Application Route: Ingestion          Result: negative</p>
<p>Effects on foetal development</p>	<p>Test Type: Embryo-foetal development          Species: Rat          Application Route: Ingestion          Result: negative</p>

### 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 concentrations of 100 mg/kg bw or less.

**Repeated dose toxicity****Components:****N,N-Dimethylacetamide:**

Species : Rat  
 NOAEL : 90 mg/m<sup>3</sup>  
 LOAEL : 360 mg/m<sup>3</sup>  
 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 : 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.

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### Components:

#### Fluralaner:

|| Not applicable

#### 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

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Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 0.015 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	:	NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity)	:	NOEC (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)): 0.0736 µg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1,000

**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 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

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)):  $\geq$  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

**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 (Chronic 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 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



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**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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**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
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**Acetone:**

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

**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-octanol/water** : log Pow: < 4  
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-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

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### Mobility in soil

#### Components:

##### Fluralaner:

|| Distribution among environmental compartments : log Koc: 4.1

#### 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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### 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 handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

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### Section 14: Transport information

#### International Regulations

##### UNRTDG

UN number : UN 1090  
 Proper shipping name : ACETONE SOLUTION  
 Class : 3  
 Packing group : II  
 Labels : 3  
 Environmentally hazardous : no

##### 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

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**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.

**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.

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**Section 15: Regulatory information****Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100757 Veterinary Medicines Limited Pack Size Finished Dose Group Standard

**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

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### Section 16: Other information

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#### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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 BEI : New Zealand. Biological Exposure Indices  
 NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric 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; KECl - 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; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Sub-

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stances 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.

NZ / EN