

# SAFETY DATA SHEET



## Fluralaner / Moxidectin Liquid Formulation

Version 8.1      Revision Date: 02.10.2025      SDS Number: 656889-00026      Date of last issue: 14.11.2024  
Date of first issue: 02.05.2016

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### Section 1: Identification

**Product identifier** : 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)

### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive  
Singapore - Singapore 638408

Telephone : +1-908-740-4000

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

E-mail address : EHSDATASTEWARD@msd.com

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### Section 2: Hazard identification

#### Classification of the substance or mixture

Flammable liquids : Category 2

Serious eye damage/eye irritation : Category 2A

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

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### GHS Label elements, including precautionary statements

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.  
P202 Do not handle until all safety precautions have been read and understood.  
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/ hearing 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 disposal plant.

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### Other hazards which do not result in classification

Vapours may form explosive mixture with air.

### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
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
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

### Section 4: First-aid measures

#### Description of necessary 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

- Risks : 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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### Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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## Section 5: Fire-fighting measures

### Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : High volume water jet

### Special hazards arising from the substance or mixture

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

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

### Special protective actions for fire-fighters

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

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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## Section 6: Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Personal precautions : 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

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).

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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**

- Methods for cleaning up
- : Non-sparking tools should be used.  
Soak up with inert absorbent material.  
Suppress (knock down) gases/vapours/mists with a water spray jet.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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**Section 7: Handling and storage****Precautions for safe handling**

- Technical measures
- : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation
- : If sufficient ventilation is unavailable, use with local exhaust ventilation.  
Use explosion-proof electrical, ventilating and lighting equipment.
- Advice on safe handling
- : Do not get on skin or clothing.  
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.
- 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,

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appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### Conditions for safe storage, including any incompatibilities

- Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.  
Keep away from heat and sources of ignition.
- Materials to avoid : Do not store with the following product types:  
Self-reactive substances and mixtures  
Organic peroxides  
Oxidizing agents  
Flammable gases  
Pyrophoric liquids  
Pyrophoric solids  
Self-heating substances and mixtures  
Poisonous gases  
Explosives

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## Section 8: Exposure controls/personal protection

### Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	PEL (long term)	10 ppm 36 mg/m <sup>3</sup>	SG OEL
		TWA	10 ppm	ACGIH
Fluralaner	864731-61-3	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: Skin				
Acetone	67-64-1	PEL (long term)	1,000 µg/100 cm <sup>2</sup>	Internal
		PEL (short term)	750 ppm 1,780 mg/m <sup>3</sup>	SG OEL
		TWA	2,380 mg/m <sup>3</sup>	SG OEL
		STEL	250 ppm	ACGIH
Moxidectin	113507-06-5	TWA	500 ppm	ACGIH
		Wipe limit	10 µg/m <sup>3</sup> (OEB 3)	Internal
2,6-Di-tert-butyl-p-cresol	128-37-0	PEL (long term)	100 µg/100 cm <sup>2</sup>	Internal
		TWA (Inhal- able fraction and vapor)	10 mg/m <sup>3</sup>	SG OEL
			2 mg/m <sup>3</sup>	ACGIH

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**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

**Appropriate engineering control 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 containment devices). Minimize open handling. Use explosion-proof electrical, ventilating and lighting equipment.

**Individual protection measures, such as personal protective equipment (PPE)**

- |                        |  |
|------------------------|--|
| Eye/face protection    | : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Skin 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.                    |
| 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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**Section 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

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

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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.  
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

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

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
  
Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method  
  
Acute dermal toxicity : LD50 (Rat, male and female): > 2,000 mg/kg  
Method: OECD Test Guideline 402

#### 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

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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

**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

**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  
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 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.

**Product:**

- Species : Rabbit  
Assessment : No skin irritation  
Method : OECD Test Guideline 404

**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

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

- Species : Rabbit  
Result : No 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.

**Product:**

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

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

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

**Acetone:**

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

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**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.

**Respiratory sensitisation**

Not classified based on available information.

**Product:**

Test Type	:	Local lymph node assay (LLNA)
Method	:	OECD Test Guideline 429
Result	:	negative

**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

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Remarks : Based on data from similar materials

### **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)  
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

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**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

**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  
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)

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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  
NOAEL      : 4.5 mg/kg body weight  
Result      : negative

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

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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.

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

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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.

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

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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.

### 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 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:**

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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 : 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  
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

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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

#### 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.

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**Section 12: Ecological information****Toxicity****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  
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-:**

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- 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

**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

**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

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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

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

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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: Readily biodegradable.  
Biodegradation: 70 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C  
Remarks: The test was conducted equivalent or similar to guideline

**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

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

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 83.8 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**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

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

Partition coefficient: n-octanol/water : log Pow: < 4  
Remarks: Calculation

**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: 4.1

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

Results of PBT and vPvB assessment : Not persistent, bioaccumulative, 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  
UN proper shipping name : ACETONE SOLUTION  
Transport hazard class(es) : 3  
Packing group : II  
Labels : 3  
Environmental hazards : no

##### IATA-DGR

UN/ID No. : UN 1090  
UN proper shipping name : Acetone solution  
Transport hazard class(es) : 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)  
Transport hazard class(es) : 3  
Packing group : II  
Labels : 3  
EmS Code : F-E, S-D  
Marine pollutant : yes

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### 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 specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the 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:**

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AICS	: not determined
CA. 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/>

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 (General Provisions) Regulations - 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

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 Harmonised System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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 - Organisation for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006

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of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN