

Fluralaner / Moxidectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.11.2024
10.2	02.10.2025	656874-00027	Date of first issue: 02.05.2016

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)

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification of the substance or mixture in accordance with ABNT NBR 14725 Standard**

Flammable liquids : Category 2

Acute toxicity (Oral) : Category 5

Acute toxicity (Inhalation) : Category 5

Acute toxicity (Dermal) : Category 5

Eye irritation : Category 2A

Reproductive toxicity : Category 1B

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

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Aspiration hazard : Category 2

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :    

Signal Word : Danger

Hazard Statements : H225 Highly flammable liquid and vapor.
H303 + H313 + H333 May be harmful if swallowed, in contact with skin or if inhaled.
H305 May be harmful if swallowed and enters airways.
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.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P302 + P312 IF ON SKIN: Call a POISON CENTER/ doctor if you feel unwell.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304 + P312 IF INHALED: Call a POISON CENTER/ doctor if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P331 Do NOT induce vomiting.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

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P391 Collect spillage.

Storage:

P405 Store locked up.

Other hazards which do not result in classification

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
N,N-Dimethylacetamide	127-19-5	Flam. Liq., 4 Acute Tox. (Oral), 5 Acute Tox. (Inhalation), 4 Acute Tox. (Dermal), 4 Eye Irrit., 2A Repr., 1B	≥ 30 -< 50
Fluralaner	864731-61-3	Repr., 2 Aquatic Chronic, 1	≥ 25 -< 30
Poly(oxy-1,2-ethanediyl), α -[(tetrahydro-2-furanyl)methyl]- ω -hydroxy-	31692-85-0	Eye Irrit., 2A	≥ 20 -< 30
N,N-Diethyl-m-toluamide	134-62-3	Acute Tox. (Oral), 4 Acute Tox. (Inhalation), 5 Acute Tox. (Dermal), 5 Eye Irrit., 2A Aquatic Acute, 3	≥ 10 -< 20
Acetone	67-64-1	Flam. Liq., 2 Eye Irrit., 2A STOT SE, 3 Asp. Tox., 2	≥ 10 -< 20
Moxidectin	113507-06-5	Acute Tox. (Oral), 3 Acute Tox. (Inhalation), 4 Acute Tox. (Dermal), 5 Eye Irrit., 2B Repr., 2 STOT RE, (Central nervous system), 1 Aquatic Acute, 1 Aquatic Chronic, 1	≥ 1 -< 2,5
2,6-Di-tert-butyl-p-cresol	128-37-0	Aquatic Acute, 1 Aquatic Chronic, 1	$\geq 0,1$ -< 0,25

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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 center immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : May be harmful if swallowed, in contact with skin or if inhaled.
May be harmful if swallowed and enters airways.
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).

Indication of any immediate medical attention and special treatment needed

- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : High volume water jet
- 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.
Vapors may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

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| Hazardous combustion products | : Carbon oxides
Chlorine compounds
Fluorine compounds
Nitrogen oxides (NO _x) |
| Specific extinguishing methods | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area. |
| Special protective equipment for fire-fighters | : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment. |
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SECTION 6. ACCIDENTAL RELEASE MEASURES

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| 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/vapors/mists with a water spray jet.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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

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| Technical measures | : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
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| 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 vapors.
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, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |
| Conditions for safe storage | : | Keep in properly labeled 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:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures which in contact with water emit flammable gases
Explosives
Gases
Very acutely toxic substances and mixtures |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

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Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	LT	8 ppm 28 mg/m ³	BR OEL
Further information: Absorption through the skin, Degree of harmfulness: maximum				
		TWA	10 ppm	ACGIH
Fluralaner	864731-61-3	TWA	100 µg/m ³ (OEB 2)	Internal
Further information: Skin				
		Wipe limit	1000 µg/100 cm ²	Internal
Acetone	67-64-1	LT	780 ppm 1.870 mg/m ³	BR OEL
Further information: Degree of harmfulness: minimum				
		TWA	250 ppm	ACGIH
		STEL	500 ppm	ACGIH
Moxidectin	113507-06-5	TWA	10 µg/m ³ (OEB 3)	Internal
		Wipe limit	100 µg/100 cm ²	Internal
2,6-Di-tert-butyl-p-cresol	128-37-0	TWA (Inhalable fraction and vapor)	2 mg/m ³	ACGIH

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	N-methylacetamide	Urine	End of workday at end of work-week	30 mg/g creatinine	BR BEI
		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 workday	25 mg/l	BR 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.

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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

Physical state	:	liquid
Color	:	Colorless to pale yellow
Odor	:	No data available
Odor 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

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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
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	1,06
Density	:	1,08 g/cm ³
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	7,5 mm ² /s
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle 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 vapor. Vapors 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

May be harmful if swallowed, in contact with skin or if inhaled.

Product:

Acute oral toxicity	: LD50 (Rat, female): > 2.000 mg/kg Method: OECD Test Guideline 423
Acute inhalation toxicity	: Acute toxicity estimate: 5,3 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 judgment 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), α -[(tetrahydro-2-furanyl)methyl]- ω -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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N,N-Diethyl-m-toluamide:

Acute oral toxicity	: LD50 (Rat): 1.892 mg/kg
Acute inhalation toxicity	: LC50 (Rat): 5,95 mg/l

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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: vapor

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

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.

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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), α -[(tetrahydro-2-furanyl)methyl]- ω -hydroxy-:

Species	:	reconstructed human epidermis (RhE)
Method	:	OECD Test Guideline 439
Remarks	:	Based on data from similar materials

Result	:	No skin irritation
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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

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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), α -[(tetrahydro-2-furanyl)methyl]- ω -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

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 sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

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Product:

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

Components:**N,N-Dimethylacetamide:**

Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative

Fluralaner:

Test Type	: Maximization Test
Routes of exposure	: Dermal
Species	: Guinea pig
Result	: Not a skin sensitizer.

Poly(oxy-1,2-ethanediyl), α -[(tetrahydro-2-furanyl)methyl]- ω -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	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative

Moxidectin:

Test Type	: Buehler Test
Routes of exposure	: Dermal
Species	: Guinea pig
Result	: Not a skin sensitizer.

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

Test Type	: Human repeat insult patch test (HRIPT)
Routes of exposure	: Skin contact
Species	: Humans

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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

Poly(oxy-1,2-ethanediyl), α -[(tetrahydro-2-furanyl)methyl]- ω -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

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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 test
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
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

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Application Route : inhalation (vapor)
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
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:**

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Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Inhalation
Result: negative

Effects on fetal development : Test Type: Embryo-fetal 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 fetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects.

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: Skeletal malformations., Visceral malformations.
Remarks: Maternal toxicity observed.

Test Type: Development
Species: Rabbit
Application Route: Dermal
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Skeletal malformations.

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

N,N-Diethyl-m-toluamide:

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

Acetone:

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

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Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: inhalation (vapor)
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 fetal weight., Fetal 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 fetal weight., Fetal mortality.
Result: No effects on fertility., Some evidence of adverse effects on development, based on animal experiments.

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 10 mg/kg body weight
Embryo-fetal toxicity.: LOAEL: 10 mg/kg body weight
Result: Skeletal malformations.
Remarks: The effects were seen only at maternally toxic doses.

Test Type: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion

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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:**

Species	: Rat
NOAEL	: 90 mg/m ³
LOAEL	: 360 mg/m ³
Application Route	: inhalation (vapor)
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

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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 (vapor)
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 : 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

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Aspiration toxicity

May be harmful if swallowed and enters airways.

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
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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), α-[(tetrahydro-2-furanyl)methyl]-ω-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

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

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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)): \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

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.

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Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0,48 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0,24 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 0,24 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: Readily biodegradable. Biodegradation: 70 % Exposure time: 28 d Method: OECD Test Guideline 301C Remarks: The test was conducted equivalent or similar to guideline
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Poly(oxy-1,2-ethanediyl), α -[(tetrahydro-2-furanyl)methyl]- ω -hydroxy-:

Biodegradability	:	Result: Not readily biodegradable. Method: OECD Test Guideline 301F Remarks: Based on data from similar materials
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N,N-Diethyl-m-toluamide:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 83,8 % Exposure time: 28 d Method: OECD Test Guideline 301B
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Acetone:

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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

Poly(oxy-1,2-ethanediyl), α -[(tetrahydro-2-furanyl)methyl]- ω -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

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

Results of PBT and vPvB assessment : Not persistent, bioaccumulative, and toxic (PBT).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	: Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	: Empty containers should be taken to an approved waste 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.

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

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

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

Not applicable for product as supplied.

Domestic regulation**ANTT**

UN number	:	UN 1090
Proper shipping name	:	ACETONE, SOLUTION
Class	:	3
Packing group	:	II
Labels	:	3
Hazard Identification Number	:	33

Special precautions for user

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

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

National List of Carcinogenic Agents for Humans - (LINACH)	:	Not applicable
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Brazil. List of chemicals controlled by the Federal Police	:	Not applicable
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The ingredients of this product are reported in the following inventories:

AICS	:	not determined
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CA. DSL	:	not determined
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IECSC	:	not determined
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SECTION 16. OTHER INFORMATION

Revision Date	:	02.10.2025
Date format	:	dd.mm.yyyy

Further information

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

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
BR BEI	:	Brazil. NR7. Parameters for Biological Control of Occupational Exposure to Some Chemical Agents

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BR OEL	:	Brazil. NR 15 - Unhealthy activities and operations
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
BR OEL / LT	:	Up to 48 hours /week

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 Standardization; 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 Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; 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 - 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, Authorization 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.

BR / Z8