

Fluazuron / Fipronil Formulation

Version 6.6 Revision Date: 30.09.2023 SDS Number: 557842-00017 Date of last issue: 04.04.2023
Date of first issue: 15.03.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Fluazuron / Fipronil Formulation

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 in accordance with ABNT NBR 14725 Standard

Flammable liquids : Category 3

Acute toxicity (Oral) : Category 5

Acute toxicity (Dermal) : Category 5

Skin irritation : Category 2

Eye irritation : Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity -
single exposure : Category 3

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





Short-term (acute) aquatic
hazard : Category 1

Long-term (chronic) aquatic
hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

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Hazard pictograms :    

Signal Word : Danger

Hazard Statements : H226 Flammable liquid and vapor.
 H303 + H313 May be harmful if swallowed or in contact with skin.
 H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H360D May damage the unborn child.
 H373 May cause damage to organs (Central nervous system, Kidney) 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/ sparks/ open flames/ hot surfaces. No smoking.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
 P312 Call a POISON CENTER/ doctor if you feel unwell.
 P391 Collect spillage.

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)
2-(2-Butoxyethoxy)ethanol	112-34-5	Acute toxicity (Oral), Category 5 Acute toxicity (Dermal), Category 5 Skin irritation, Category 3 Eye irritation, Category 2A	>= 50 -< 70
N-Methyl-2-pyrrolidone	872-50-4	Flammable liquids, Category 4 Acute toxicity (Oral), Category 5 Skin irritation, Category 2	>= 10 -< 20

SAFETY DATA SHEET



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		Eye irritation, Category 2A Reproductive toxicity, Category 1B Specific target organ toxicity - single exposure, Category 3	
Ethanol#	64-17-5	Flammable liquids, Category 2 Eye irritation, Category 2A	>= 10 -< 20
Fluazuron	86811-58-7	Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	>= 2,5 -< 5
Fipronil	120068-37-3	Acute toxicity (Oral), Category 3 Acute toxicity (Inhalation), Category 2 Acute toxicity (Dermal), Category 3 Specific target organ toxicity - repeated exposure (Central nervous system, Kidney), Category 1 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	>= 1 -< 2,5
2,6-Di-tert-butyl-p-cresol	128-37-0	Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	>= 0,1 -< 0,25
tert-Butyl-4-methoxyphenol	25013-16-5	Acute toxicity (Oral), Category 5 Skin irritation, Category 2 Eye irritation, Category 2A Carcinogenicity, Category 2 Reproductive toxicity, Category 2	>= 0,1 -< 0,25

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		Short-term (acute) aquatic hazard, Category 2 Long-term (chronic) aquatic hazard, Category 2	
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Voluntarily-disclosed substance

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May be harmful if swallowed or in contact with skin.
Causes skin irritation.
Causes serious eye irritation.
May cause respiratory irritation.
May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure.
There may be delayed neurological effects, including brain oedema.
- Protection of first-aiders : Must not be confused with organophosphorous compounds!
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

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

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- 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.
- Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Chlorine compounds
Fluorine compounds
Sulfur oxides
- 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

- Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.
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.
- 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.
 Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
 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

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
2-(2-Butoxyethoxy)ethanol	112-34-5	TWA (Inhalable fraction and vapor)	10 ppm	ACGIH
Ethanol	64-17-5	LT	780 ppm 1.480 mg/m ³	BR OEL
Further information: Degree of harmfulness: minimum				
		STEL	1.000 ppm	ACGIH
Fluazuron	86811-58-7	TWA	60 µg/m ³ (OEB 3)	Internal
		Wipe limit	600 µg/ 100cm ²	Internal
Fipronil	120068-37-3	TWA	2 µg/m ³ (OEB 4)	Internal
Further information: Skin				
		Wipe limit	20 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-Methyl-2-pyrrolidone	872-50-4	5-Hydroxy-N-methyl-2-pyrrolidone	Urine	End of workday	100 mg/l	BR BEI
		5-Hydroxy-N-methyl-2-pyrrolidone	Urine	End of shift (As soon as possible after exposure ceases)	100 mg/l	ACGIH BEI

Engineering measures

- : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
 Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
 Minimize open handling.
 Use explosion-proof electrical, ventilating and lighting

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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	:	Combined particulates and organic vapor type
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	light yellow
Odor	:	solvent
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	:	32 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available

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Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : 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.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

May be harmful if swallowed or in contact with skin.

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Product:

Acute oral toxicity : Acute toxicity estimate: 2.242 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: 3.646 mg/kg
Method: Calculation method

Components:**2-(2-Butoxyethoxy)ethanol:**

Acute oral toxicity : LD50 (Mouse): 2.410 mg/kg

Acute dermal toxicity : LD50 (Rabbit): 2.764 mg/kg

N-Methyl-2-pyrrolidone:

Acute oral toxicity : LD50 (Rat): 4.150 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rat): > 5.000 mg/kg

Ethanol:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 124,7 mg/l
Exposure time: 4 h
Test atmosphere: vapor

Fluazuron:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 6,0 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402

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Acute oral toxicity : LD50 (Rat): 92 mg/kg

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Acute inhalation toxicity : LC50 (Rat): 0,36 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): 354 mg/kg

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

tert-Butyl-4-methoxyphenol:

Acute oral toxicity : LD50 (Rabbit): 2.100 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Causes skin irritation.

Components:**2-(2-Butoxyethoxy)ethanol:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : Mild skin irritation

N-Methyl-2-pyrrolidone:

Result : Skin irritation

Ethanol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Fluazuron:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Fipronil:

Species : Rabbit
Method : OECD Test Guideline 404

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Result : No 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

tert-Butyl-4-methoxyphenol:

Species : Rabbit
Result : Skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:**2-(2-Butoxyethoxy)ethanol:**

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

N-Methyl-2-pyrrolidone:

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

Ethanol:

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

Fluazuron:

Species : Rabbit
Result : Mild eye irritation
Method : OECD Test Guideline 405

Fipronil:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

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

tert-Butyl-4-methoxyphenol:

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

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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.

Components:**2-(2-Butoxyethoxy)ethanol:**

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

N-Methyl-2-pyrrolidone:

Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

Ethanol:

Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Result : negative

Fluazuron:

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

Fipronil:

Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

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

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

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tert-Butyl-4-methoxyphenol:

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

Germ cell mutagenicity

Not classified based on available information.

Components:**2-(2-Butoxyethoxy)ethanol:**

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: Mouse
 Application Route: Ingestion
 Result: negative

N-Methyl-2-pyrrolidone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
 Method: OECD Test Guideline 471
 Result: negative

Test Type: In vitro mammalian cell gene mutation test
 Method: OECD Test Guideline 476
 Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
 Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
 Species: Mouse
 Application Route: Ingestion
 Method: OECD Test Guideline 474
 Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
 Species: Hamster
 Application Route: Ingestion
 Method: OECD Test Guideline 475
 Result: negative

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Ethanol:

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

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: equivocal

Fluazuron:

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

Test Type: DNA Repair
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Cytogenetic assay
Species: Hamster
Result: equivocal

Fipronil:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 486
Result: negative

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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

tert-Butyl-4-methoxyphenol:

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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**N-Methyl-2-pyrrolidone:**

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Species : Rat
Application Route : inhalation (vapor)
Exposure time : 2 Years
Result : negative

Fluazuron:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Method : OECD Test Guideline 453
Result : negative

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Species : Mouse
 Application Route : Ingestion
 Exposure time : 2 Years
 Result : negative

Fipronil:

Species : Mouse
 Application Route : Ingestion
 Exposure time : 78 weeks
 Method : Directive 67/548/EEC, Annex V, B.32.
 Result : negative

Species : Rat
 Application Route : Ingestion
 Exposure time : 104 weeks
 Method : Directive 67/548/EEC, Annex V, B.33.
 Result : positive
 Remarks : The mechanism or mode of action is not relevant in humans.

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

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

tert-Butyl-4-methoxyphenol:

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

Species : Hamster, male
 Application Route : Ingestion
 Exposure time : 24 weeks
 Result : positive

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

Reproductive toxicity

May damage the unborn child.

Components:**2-(2-Butoxyethoxy)ethanol:**

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 415
 Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

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Species: Rat
Application Route: Ingestion
Result: negative

N-Methyl-2-pyrrolidone:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: positive

Test Type: Fertility/early embryonic development
Species: Rat
Application Route: inhalation (vapor)
Result: positive

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Ingestion
Result: positive

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

Ethanol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Fluazuron:

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
Result: negative

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

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Fipronil:

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: Rabbit
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

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
Result: negative

tert-Butyl-4-methoxyphenol:

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

Effects on fetal development : Test Type: Fertility/early embryonic development
Species: Mouse
Application Route: Ingestion
Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

May cause respiratory irritation.

Components:**N-Methyl-2-pyrrolidone:**

Assessment : May cause respiratory irritation.

STOT-repeated exposure

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

Components:**Fipronil:**

Routes of exposure : Ingestion

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Target Organs : Central nervous system, Kidney
 Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

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:****2-(2-Butoxyethoxy)ethanol:**

Species : Rat
 NOAEL : 250 mg/kg
 LOAEL : 1.000 mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days
 Method : OECD Test Guideline 408

Species : Rat
 NOAEL : $\geq 0,094$ mg/l
 Application Route : inhalation (vapor)
 Exposure time : 90 Days
 Method : OECD Test Guideline 413

Species : Rat
 NOAEL : ≥ 2.000 mg/kg
 Application Route : Skin contact
 Exposure time : 90 Days

N-Methyl-2-pyrrolidone:

Species : Rat, male
 NOAEL : 169 mg/kg
 LOAEL : 433 mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days
 Method : OECD Test Guideline 408

Species : Rat
 NOAEL : 0,5 mg/l
 LOAEL : 1 mg/l
 Application Route : inhalation (dust/mist/fume)
 Exposure time : 96 Days
 Method : OECD Test Guideline 413

Species : Rabbit
 NOAEL : 826 mg/kg
 LOAEL : 1.653 mg/kg
 Application Route : Skin contact
 Exposure time : 20 Days

Ethanol:

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Species : Rat
NOAEL : 1.280 mg/kg
LOAEL : 3.156 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Fluazuron:

Species : Rat
NOAEL : 240 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks
Target Organs : Liver, Thyroid, Pituitary gland

Species : Rat
NOAEL : 10 mg/kg
LOAEL : 100 mg/kg
Application Route : Skin contact
Exposure time : 3 Weeks

Species : Dog
NOAEL : 7,5 mg/kg
LOAEL : 110 mg/kg
Application Route : Ingestion
Exposure time : 52 Weeks
Target Organs : Liver

Fipronil:

Species : Rabbit
NOAEL : 5 mg/kg
LOAEL : 10 mg/kg
Application Route : Skin contact
Exposure time : 21 Days
Method : OECD Test Guideline 410

Species : Rat, male
NOAEL : 0,059 mg/kg
LOAEL : 0,019 mg/kg
Application Route : Ingestion
Exposure time : 89 Weeks
Method : Directive 67/548/EEC, Annex V, B.33.

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

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

tert-Butyl-4-methoxyphenol:

Species : Rat
NOAEL : 50 mg/kg
LOAEL : 250 mg/kg
Application Route : Ingestion

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Exposure time : 8 Months

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****N-Methyl-2-pyrrolidone:**

Skin contact : Symptoms: Skin irritation

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****2-(2-Butoxyethoxy)ethanol:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 1.300 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): >= 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10: > 1.995 mg/l
Exposure time: 30 min

N-Methyl-2-pyrrolidone:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 500 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1.000 mg/l
Exposure time: 24 h
Method: DIN 38412

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 600,5 mg/l
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 92,6 mg/l
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chron- : NOEC (Daphnia magna (Water flea)): 12,5 mg/l
Exposure time: 21 d

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ic toxicity) Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 600 mg/l
Exposure time: 30 min
Method: ISO 8192

Ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1.000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Ceriodaphnia (water flea)): > 1.000 mg/l
aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
plants Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11,5 mg/l
Exposure time: 72 h

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 9,6 mg/l
aquatic invertebrates (Chronic toxicity) Exposure time: 9 d

Toxicity to microorganisms : EC50 (Pseudomonas putida): 6.500 mg/l
Exposure time: 16 h

Fluazuron:

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 9,1 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia sp. (Water flea)): 0,0006 mg/l
aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : NOEC (Raphidocelis subcapitata (freshwater green alga)): 27,9 mg/l
plants Exposure time: 72 h

M-Factor (Acute aquatic tox- : 1.000
icity)

M-Factor (Chronic aquatic : 1.000
toxicity)

Fipronil:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 85,2 µg/l
Exposure time: 96 h

Toxicity to daphnia and other : LC50 (Mysidopsis bahia (opossum shrimp)): 0,14 µg/l
aquatic invertebrates Exposure time: 96 h

Toxicity to algae/aquatic : EC50 (Desmodesmus subspicatus (green algae)): 68 µg/l
plants Exposure time: 96 h
Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): 40 µg/l
Exposure time: 96 h

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Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1.000
 Toxicity to fish (Chronic toxicity) : NOEC (Cyprinodon variegatus (sheepshead minnow)): 2,9 µg/l
 Exposure time: 35 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Mysidopsis bahia (opossum shrimp)): 0,0077 µg/l
 Exposure time: 28 d

M-Factor (Chronic aquatic toxicity) : 10.000

Toxicity to microorganisms : EC50: > 1.000 mg/l
 Exposure time: 3 h

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

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 0,57 mg/l
 Exposure time: 96 h
 Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,48 mg/l
 Exposure time: 48 h
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0,24 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,24 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Japanese medaka)): 0,053 mg/l
 Exposure time: 30 d
 Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0,316 mg/l
 Exposure time: 21 d

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC50: > 10.000 mg/l
 Exposure time: 3 h
 Method: OECD Test Guideline 209

tert-Butyl-4-methoxyphenol:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 1,56 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 203

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Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2,3 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 1,9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,25 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Persistence and degradability**Components:****2-(2-Butoxyethoxy)ethanol:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 85 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

N-Methyl-2-pyrrolidone:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 73 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Ethanol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

Fipronil:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 47 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

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

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 4,5 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

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Bioaccumulative potential**Components:****2-(2-Butoxyethoxy)ethanol:**

Partition coefficient: n-octanol/water : log Pow: 1

N-Methyl-2-pyrrolidone:

Partition coefficient: n-octanol/water : log Pow: -0,46
Method: OECD Test Guideline 107

Ethanol:

Partition coefficient: n-octanol/water : log Pow: -0,35

Fluazuron:

Partition coefficient: n-octanol/water : log Pow: 5,1

Fipronil:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 321

Partition coefficient: n-octanol/water : log Pow: 4

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

tert-Butyl-4-methoxyphenol:

Bioaccumulation : Species: Oryzias latipes (Orange-red killifish)
Bioconcentration factor (BCF): 16 - 21

Partition coefficient: n-octanol/water : log Pow: 2,82
Method: OECD Test Guideline 117

Mobility in soil

No data available

Other adverse effects

No data available

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.

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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 1170
 Proper shipping name : ETHANOL SOLUTION
 Class : 3
 Packing group : III
 Labels : 3
 Environmentally hazardous : no

IATA-DGR

UN/ID No. : UN 1170
 Proper shipping name : Ethanol solution
 Class : 3
 Packing group : III
 Labels : Flammable Liquids
 Packing instruction (cargo aircraft) : 366
 Packing instruction (passenger aircraft) : 355

IMDG-Code

UN number : UN 1170
 Proper shipping name : ETHANOL SOLUTION
 (Fluazuron, Fipronil)
 Class : 3
 Packing group : III
 Labels : 3
 EmS Code : F-E, S-D
 Marine pollutant : yes

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

Not applicable for product as supplied.

Domestic regulation**ANTT**

UN number : UN 1170
 Proper shipping name : ETHANOL SOLUTION
 Class : 3
 Packing group : III
 Labels : 3
 Hazard Identification Number : 30

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

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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)

Group 2B: Possibly carcinogenic to humans
tert-Butyl-4-methoxyphenol 25013-16-5

Brazil. List of chemicals controlled by the Federal Police : Ethanol

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023
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/>

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
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 Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA

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- International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - 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.

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