

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Fluazuron / Fipronil Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
7.1	14.04.2025	564222-00022	Date of first issue: 15.03.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Fluazuron / Fipronil Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Veterinary product

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 3	H226: Flammable liquid and vapour.
Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Reproductive toxicity, Category 1B	H360D: May damage the unborn child.
Specific target organ toxicity - single exposure, Category 3	H335: May cause respiratory irritation.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)





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Hazard pictograms	:	   
Signal word	:	Danger
Hazard statements	:	H226 Flammable liquid and vapour. 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 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. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention. P391 Collect spillage.

Hazardous components which must be listed on the label:

N-Methyl-2-pyrrolidone
Fipronil (ISO)

Restricted to professional users.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
2-(2-Butoxyethoxy)ethanol	112-34-5 203-961-6 603-096-00-8	Eye Irrit. 2; H319	>= 50 - < 70
Ethanol#	64-17-5 200-578-6 603-002-00-5	Flam. Liq. 2; H225 Eye Irrit. 2; H319 specific concentra- tion limit Eye Irrit. 2; H319 >= 50 %	>= 10 - < 20
N-Methyl-2-pyrrolidone	872-50-4 212-828-1 606-021-00-7	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 1B; H360D STOT SE 3; H335 specific concentra- tion limit STOT SE 3; H335 >= 10 %	>= 10 - < 20
Fluazuron	86811-58-7	Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1.000 M-Factor (Chronic aquatic toxicity): 1.000	>= 2,5 - < 10
Fipronil (ISO)	120068-37-3 424-610-5 608-055-00-8	Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 3; H311 STOT RE 1; H372 (Central nervous system, Kidney) Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 1 - < 2,5

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		<div>M-Factor (Acute aquatic toxicity): 1.000 M-Factor (Chronic aquatic toxicity): 10.000</div> <div>Acute toxicity estimate</div> <div>Acute oral toxicity: 92 mg/kg Acute inhalation toxicity (dust/mist): 0,36 mg/l Acute dermal toxicity: 354 mg/kg</div>	
2,6-Di-tert-butyl-p-cresol	128-37-0 204-881-4	<div>Aquatic Acute 1; H400 Aquatic Chronic 1; H410</div> <div>M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1</div>	$\geq 0,1 - < 0,25$
tert-Butyl-4-methoxyphenol	25013-16-5 246-563-8	<div>Skin Irrit. 2; H315 Eye Irrit. 2; H319 Carc. 2; H351 Repr. 2; H361d Aquatic Chronic 2; H411</div>	$\geq 0,1 - < 0,25$

For explanation of abbreviations see section 16.
#: Voluntarily-disclosed substance

SECTION 4: First aid measures

4.1 Description of 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.
- 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).
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.

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- | | |
|-------------------------|--|
| 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. |

4.2 Most important symptoms and effects, both acute and delayed

- | | |
|-------|--|
| Risks | : There may be delayed neurological effects, including brain oedema.
Must not be confused with organophosphorous compounds!

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. |
|-------|--|

4.3 Indication of any immediate medical attention and special treatment needed

- | | |
|-----------|---|
| Treatment | : Treat symptomatically and supportively. |
|-----------|---|

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | |
|--------------------------------|--|
| Suitable extinguishing media | : Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
| Unsuitable extinguishing media | : High volume water jet |

5.2 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. |
|---------------------------------------|--|

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Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Chlorine compounds
Fluorine compounds
Sulphur oxides

5.3 Advice for firefighters

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Remove all sources of ignition.
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 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).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material 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

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certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 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.
Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.
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. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|---|
| Requirements for storage areas and containers | : | 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. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents |

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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

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
2-(2-Butoxyethoxy)ethanol	112-34-5	TWA	10 ppm 68 mg/m ³	FOR-2011-12-06-1358
		TWA	10 ppm 67,5 mg/m ³	2006/15/EC
	Further information: Indicative			
		STEL	15 ppm 101,2 mg/m ³	2006/15/EC
	Further information: Indicative			
N-Methyl-2-pyrrolidone	872-50-4	TWA	14,4 mg/m ³	FOR-2011-12-06-1358
	Further information: Substances considered to be reprotoxic, Chemicals that can be absorbed through the skin.			
		STEL	20 ppm 80 mg/m ³	FOR-2011-12-06-1358
	Further information: Substances considered to be reprotoxic, Chemicals that can be absorbed through the skin.			
		TWA	10 ppm 40 mg/m ³	2009/161/EU
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	20 ppm 80 mg/m ³	2009/161/EU
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		TWA	10 ppm 40 mg/m ³	2004/37/EC
	Further information: Skin, Carcinogens or mutagens			

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		STEL	20 ppm 80 mg/m ³	2004/37/EC
	Further information: Skin, Carcinogens or mutagens			
Ethanol	64-17-5	TWA	500 ppm 950 mg/m ³	FOR-2011- 12-06-1358
Fluazuron	86811-58-7	TWA	60 µg/m ³ (OEB 3)	Internal
		Wipe limit	600 µg/ 100cm ²	Internal
Fipronil (ISO)	120068-37-3	TWA	2 µg/m ³ (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	20 µg/100 cm ²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
N-Methyl-2-pyrrolidone	Workers	Inhalation	Long-term systemic effects	14,4 mg/m ³
	Workers	Inhalation	Long-term local effects	40 mg/m ³
	Workers	Skin contact	Long-term systemic effects	4,8 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	3,6 mg/m ³
	Consumers	Inhalation	Long-term local effects	4,5 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	2,4 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,85 mg/kg bw/day
	Workers	Inhalation	Long-term systemic effects	380 mg/m ³
	Workers	Skin contact	Long-term systemic effects	267 mg/kg bw/day
2-(2-Butoxyethoxy)ethanol	Consumers	Inhalation	Long-term systemic effects	114 mg/m ³
	Workers	Inhalation	Long-term systemic effects	67,5 mg/m ³
	Workers	Inhalation	Long-term local effects	67,5 mg/m ³
	Workers	Inhalation	Acute local effects	101,2 mg/m ³
	Workers	Skin contact	Long-term systemic effects	83 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	40,5 mg/m ³
	Consumers	Inhalation	Long-term local effects	40,5 mg/m ³
	Consumers	Inhalation	Acute local effects	60,7 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	50 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	5 mg/kg bw/day

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2,6-Di-tert-butyl-p-cresol	Workers	Inhalation	Long-term systemic effects	3,5 mg/m3
	Workers	Dermal	Long-term systemic effects	0,5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,86 mg/m3
	Consumers	Dermal	Long-term systemic effects	0,25 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,25 mg/kg bw/day
tert-Butyl-4-methoxyphenol	Workers	Inhalation	Long-term systemic effects	4,93 mg/m3
	Workers	Skin contact	Long-term systemic effects	1,4 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,87 mg/m3
	Consumers	Skin contact	Long-term systemic effects	0,5 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,5 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
N-Methyl-2-pyrrolidone	Fresh water	0,25 mg/l
	Freshwater - intermittent	5 mg/l
	Marine water	0,025 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	1,09 mg/kg dry weight (d.w.)
	Marine sediment	0,109 mg/kg dry weight (d.w.)
	Soil	0,07 mg/kg dry weight (d.w.)
Ethanol	Fresh water	0,96 mg/l
	Freshwater - intermittent	2,75 mg/l
	Marine water	0,79 mg/l
	Sewage treatment plant	580 mg/l
	Fresh water sediment	3,6 mg/kg dry weight (d.w.)
	Marine sediment	2,9 mg/kg dry weight (d.w.)
	Soil	0,63 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	380 mg/kg food
2-(2-Butoxyethoxy)ethanol	Fresh water	1,1 mg/l
	Freshwater - intermittent	11 mg/l
	Marine water	0,11 mg/l
	Sewage treatment plant	200 mg/l
	Fresh water sediment	4,4 mg/kg dry weight (d.w.)
	Marine sediment	0,44 mg/kg dry weight (d.w.)

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	Soil	0,32 mg/kg dry weight (d.w.)
	Secondary Poisoning	56 mg/kg food
2,6-Di-tert-butyl-p-cresol	Fresh water	0,199 µg/l
	Intermittent use/release	0,02 µg/l
	Marine water	0,02 µg/l
	Sewage treatment plant	0,17 mg/l
	Fresh water sediment	0,0996 mg/kg dry weight (d.w.)
	Marine sediment	0,00996 mg/kg dry weight (d.w.)
	Soil	0,04769 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	8,33 mg/kg food
tert-Butyl-4-methoxyphenol	Fresh water	0,0124 mg/l
	Freshwater - intermittent	0,0156 mg/l
	Marine water	0,00124 mg/l
	Marine water - intermittent	0,00156 mg/l
	Fresh water sediment	1,78 mg/kg dry weight (d.w.)
	Marine sediment	0,178 mg/kg dry weight (d.w.)
	Soil	0,348 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

- 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.
- 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.
- Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task

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Respiratory protection	:	being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing. If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter should conform to NS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	light yellow
Odour	:	solvent-like
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	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
Flash point	:	32 °C
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available

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

Vapour pressure : No data available

Relative density : No data available

Relative vapour density : No data available

Particle characteristics
Particle size : No data available

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Flammable liquid and vapour.
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure : Inhalation
Skin contact

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Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

2-(2-Butoxyethoxy)ethanol:

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

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

Ethanol:

Acute oral toxicity : LD50 (Rat): 10.470 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat, male): 116,9 mg/l
Exposure time: 4 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 15.800 mg/kg

N-Methyl-2-pyrrolidone:

Acute oral toxicity : LD50 (Rat): 4.150 mg/kg
Method: OECD Test Guideline 401
Remarks: The test was conducted equivalent or similar to guideline

Acute inhalation toxicity : LC50 (Rat): > 5,1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: The test was conducted according to guideline

Acute dermal toxicity : LD50 (Rat): > 5.000 mg/kg
Method: OECD Test Guideline 402
Remarks: The test was conducted equivalent or similar to guideline

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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

Fipronil (ISO):

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

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

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Ethanol:

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

N-Methyl-2-pyrrolidone:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	Skin irritation
Remarks	:	The test was conducted equivalent or similar to guideline

Fluazuron:

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

Fipronil (ISO):

Species	:	Rabbit
Method	:	OECD Test Guideline 404
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

Ethanol:

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

N-Methyl-2-pyrrolidone:

Species	:	Rabbit
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Method	:	OECD Test Guideline 405
Result	:	Irritation to eyes, reversing within 21 days
Remarks	:	The test was conducted equivalent or similar to guideline

Fluazuron:

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

Fipronil (ISO):

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

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

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	No eye irritation
Remarks	:	Based on data from similar materials

tert-Butyl-4-methoxyphenol:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days
Remarks	:	Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

2-(2-Butoxyethoxy)ethanol:

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

Ethanol:

Test Type	:	Mouse ear swelling test (MEST)
Exposure routes	:	Skin contact
Species	:	Mouse
Result	:	negative

N-Methyl-2-pyrrolidone:

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

Fluazuron:

Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative

Fipronil (ISO):

Test Type	: Buehler Test
Exposure routes	: 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)
Exposure routes	: Skin contact
Species	: Humans
Result	: negative

tert-Butyl-4-methoxyphenol:

Test Type	: Human repeat insult patch test (HRIPT)
Exposure routes	: 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
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	: 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
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Ethanol:

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
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Rat
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
Remarks: The test was conducted according to guideline

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: The test was conducted according to guideline

Test Type: DNA damage and repair, unscheduled DNA syn-
thesis in mammalian cells (in vitro)
Method: OECD Test Guideline 482
Result: negative
Remarks: The test was conducted equivalent or similar to
guideline

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
Remarks: The test was conducted according to guideline

Fluazuron:

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

Test Type: DNA Repair
Result: negative

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		Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	:	Test Type: Cytogenetic assay Species: Hamster Result: equivocal
Fipronil (ISO):		
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
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

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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
Method : OECD Test Guideline 451
Result : negative
Remarks : The test was conducted according to guideline

Species : Rat
Application Route : Inhalation
Exposure time : 2 Years
Method : OECD Test Guideline 453
Result : negative
Remarks : The test was conducted equivalent or similar to guideline

Fluazuron:

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

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

Fipronil (ISO):

Species : Mouse
Application Route : Ingestion
Exposure time : 78 weeks

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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, 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
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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
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Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative
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Ethanol:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion
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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
Remarks: The test was conducted according to guideline

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: positive
Remarks: The test was conducted according to guideline

Test Type: Fertility/early embryonic development
Species: Rat
Application Route: inhalation (vapour)
Method: OECD Test Guideline 414
Result: positive
Remarks: The test was conducted equivalent or similar to guideline

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: positive
Remarks: The test was conducted equivalent or similar to guideline

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

Fluazuron:

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

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

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Fipronil (ISO):

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: 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 foetal development : Test Type: Embryo-foetal 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 foetal 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 through prolonged or repeated exposure.

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Components:

Fipronil (ISO):

Exposure routes	: Ingestion
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.
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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 (vapour)
Exposure time	: 90 Days
Method	: OECD Test Guideline 413

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

Ethanol:

Species	: Rat
NOAEL	: 1.730 mg/kg
LOAEL	: 3.200 mg/kg
Application Route	: Ingestion
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

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Remarks : The test was conducted according to guideline

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
Remarks : The test was conducted according to guideline

Species : Rabbit, male
NOAEL : 826 mg/kg
LOAEL : 1.653 mg/kg
Application Route : Skin contact
Exposure time : 20 Days
Method : OECD Test Guideline 410
Remarks : The test was conducted equivalent or similar to guideline

Fluazuron:

Species : Rat
LOAEL : 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 (ISO):

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, B.33

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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
Exposure time	:	8 Months

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

Assessment	:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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Experience with human exposure

Components:

N-Methyl-2-pyrrolidone:

Skin contact	:	Symptoms: Skin irritation
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SECTION 12: Ecological information

12.1 Toxicity

Components:

2-(2-Butoxyethoxy)ethanol:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 1.300 mg/l Exposure time: 96 h
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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
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Toxicity to algae/aquatic	:	ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
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plants

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

Ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14.200 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 5.012 mg/l
Exposure time: 48 h

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

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

Toxicity to microorganisms : EC50 (Protozoa): 5.800 mg/l
Exposure time: 4 h

Toxicity to fish (Chronic toxicity) : NOEC: ≥ 79 mg/l
Exposure time: 100 d
Species: Oryzias latipes (Japanese medaka)

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

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
Remarks: The test was conducted according to guideline

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 microorganisms : EC50 (activated sludge): > 600 mg/l
Exposure time: 30 min

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Method: ISO 8192

Remarks: The test was conducted according to guideline

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 12,5 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: The test was conducted according to guideline

Fluazuron:

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

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

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

M-Factor (Acute aquatic toxicity) : 1.000

M-Factor (Chronic aquatic toxicity) : 1.000

Fipronil (ISO):

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

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

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

NOEC (Desmodesmus subspicatus (green algae)): 40 µg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1.000

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

Toxicity to fish (Chronic toxicity) : NOEC: 2,9 µg/l
Exposure time: 35 d
Species: Cyprinodon variegatus (sheepshead minnow)

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

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ic toxicity)	Species: Mysidopsis bahia (opossum shrimp)
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 microorganisms	: EC50 : > 10.000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	: NOEC: 0,053 mg/l Exposure time: 30 d Species: Oryzias latipes (Japanese medaka) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 0,316 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)
M-Factor (Chronic aquatic toxicity)	: 1
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
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

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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

12.2 Persistence and degradability

Components:

2-(2-Butoxyethoxy)ethanol:

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

Ethanol:

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

N-Methyl-2-pyrrolidone:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 73 %
Exposure time: 28 d
Method: OECD Test Guideline 301C
Remarks: The test was conducted according to guideline

Fipronil (ISO):

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

12.3 Bioaccumulative potential

Components:

2-(2-Butoxyethoxy)ethanol:

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

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Ethanol:

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

N-Methyl-2-pyrrolidone:

Partition coefficient: n-octanol/water : log Pow: -0,46
Method: OECD Test Guideline 107
Remarks: The test was conducted according to guideline

Fluazuron:

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

Fipronil (ISO):

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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

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levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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

14.1 UN number or ID number

ADN	:	UN 1170
ADR	:	UN 1170
RID	:	UN 1170
IMDG	:	UN 1170
IATA	:	UN 1170

14.2 UN proper shipping name

ADN	:	ETHANOL SOLUTION
ADR	:	ETHANOL SOLUTION
RID	:	ETHANOL SOLUTION
IMDG	:	ETHANOL SOLUTION (Fluazuron, Fipronil (ISO))
IATA	:	Ethanol solution

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	:	3
ADR	:	3
RID	:	3
IMDG	:	3

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IATA : 3

14.4 Packing group

ADN

Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3

ADR

Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3
Tunnel restriction code : (D/E)

RID

Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3

IMDG

Packing group : III
Labels : 3
EmS Code : F-E, S-D

IATA (Cargo)

Packing instruction (cargo aircraft) : 366
Packing instruction (LQ) : Y344
Packing group : III
Labels : Flammable Liquids

IATA (Passenger)

Packing instruction (passenger aircraft) : 355
Packing instruction (LQ) : Y344
Packing group : III
Labels : Flammable Liquids

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

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14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3

Number on list 30: N-Methyl-2-pyrrolidone

Number on list 55: 2-(2-Butoxyethoxy)ethanol

Number on list 71: N-Methyl-2-pyrrolidone

Number on list 72: N-Methyl-2-pyrrolidone

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : N-Methyl-2-pyrrolidone

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

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Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Fipronil (ISO)
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

P5c	FLAMMABLE LIQUIDS	Quantity 1 5.000 t	Quantity 2 50.000 t
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H225	: Highly flammable liquid and vapour.
H301	: Toxic if swallowed.
H311	: Toxic in contact with skin.
H315	: Causes skin irritation.
H319	: Causes serious eye irritation.
H330	: Fatal if inhaled.
H335	: May cause respiratory irritation.
H351	: Suspected of causing cancer.
H360D	: May damage the unborn child.
H361d	: Suspected of damaging the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.
H411	: Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

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Acute Tox.	: Acute toxicity
Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Carc.	: Carcinogenicity
Eye Irrit.	: Eye irritation
Flam. Liq.	: Flammable liquids
Repr.	: Reproductive toxicity
Skin Irrit.	: Skin irritation
STOT RE	: Specific target organ toxicity - repeated exposure
STOT SE	: Specific target organ toxicity - single exposure
2004/37/EC	: Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work - Annex III
2006/15/EC	: Europe. Indicative occupational exposure limit values
2009/161/EU	: Europe. COMMISSION DIRECTIVE 2009/161/EU establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC
FOR-2011-12-06-1358	: Norway. Occupational Exposure limits
2004/37/EC / STEL	: Short term exposure limit
2004/37/EC / TWA	: Long term exposure limit
2006/15/EC / TWA	: Limit Value - eight hours
2006/15/EC / STEL	: Short term exposure limit
2009/161/EU / TWA	: Limit Value - eight hours
2009/161/EU / STEL	: Short term exposure limit
FOR-2011-12-06-1358 / TWA	: Long term exposure limit
FOR-2011-12-06-1358 / STEL	: Short term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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

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tative) 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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/>

Classification of the mixture:

Flam. Liq. 3	H226
Skin Irrit. 2	H315
Eye Irrit. 2	H319
Repr. 1B	H360D
STOT SE 3	H335
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Based on product data or assessment
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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NO / EN