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



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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-: Veterinary product

stance/Mixture

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 ex-H335: May cause respiratory irritation.

posure, Category 3

Specific target organ toxicity - repeated H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure. H400: Very toxic to aquatic life.

Short-term (acute) aquatic hazard, Cate-

Long-term (chronic) aquatic hazard, Cat-H410: Very toxic to aquatic life with long lasting

egory 1 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)

Additional Labelling

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 concentration 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 concentration 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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			M-Factor (Acute aquatic toxicity): 1,000 M-Factor (Chronic aquatic toxicity): 10,000 Acute toxicity estimate Acute oral toxicity: 92 mg/kg Acute inhalation tox-	
2,6-D	i-tert-butyl-p-cresol	128-37-0 204-881-4	icity (dust/mist): 0.36 mg/l Acute dermal toxicity: 354 mg/kg Aquatic Acute 1; H400	>= 0.1 - < 0.2
			Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	
tert-B	utyl-4-methoxyphenol	25013-16-5 246-563-8	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Carc. 2; H351 Repr. 2; H361d Aquatic Chronic 2;	>= 0.1 - < 0.2

For explanation of abbreviations see section 16.

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 ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

H411

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.

[#] Voluntarily-disclosed substance

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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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : 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.

Must not be confused with organophosphorous compounds!

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 (CO2)

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.

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Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx) 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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 pro-

tective 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 absor-

bent.

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 deter-

mine which regulations are applicable.

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



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Sections 13 and 15 of this SDS provide information regarding

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 equip-

ment.

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 as-

sessment

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 respira-

tory 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 contami-

nated 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:

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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

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- Butoxyeth- oxy)ethanol	112-34-5	TWA	10 ppm 67.5 mg/m3	2006/15/EC
	Further inform	nation: Indicative		
		STEL	15 ppm 101.2 mg/m3	2006/15/EC
	Further inform	nation: Indicative	-	
		OELV - 8 hrs (TWA)	10 ppm 67.5 mg/m3	IE OEL
		OELV - 15 min (STEL)	12 ppm 101.2 mg/m3	IE OEL
N-Methyl-2- pyrrolidone	872-50-4	TWA	10 ppm 40 mg/m3	2009/161/EU
	Further inform skin, Indicativ	Further information: Identifies the possibility of significant uptake through the skin. Indicative		
		STEL	20 ppm 80 mg/m3	2009/161/EU
		Further information: Identifies the possibility of significant uptake through the skin, Indicative		
		TWA	10 ppm 40 mg/m3	2004/37/EC
	Further inform	Further information: Skin, Carcinogens or mutagens		
		STEL	20 ppm 80 mg/m3	2004/37/EC
	Further inform	nation: Skin, Carcino	gens or mutagens	
		OELV - 8 hrs (TWA)	10 ppm 40 mg/m3	IE OEL

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	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body			
		OELV - 15 min (STEL)	20 ppm 80 mg/m3	IE OEL
	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body			
Ethanol	64-17-5	OELV - 15 min (STEL)	1,000 ppm	IE OEL
Fluazuron	86811-58-7	TWA	60 μg/m3 (OEB 3)	Internal
		Wipe limit	600 μg/ 100cm2	Internal
Fipronil (ISO)	120068-37- 3	TWA	2 μg/m3 (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	20 μg/100 cm2	Internal
2,6-Di-tert-butyl-p- cresol	128-37-0	OELV - 8 hrs (TWA)	2 mg/m3	IE OEL

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/m3
	Workers	Inhalation	Long-term local ef- fects	40 mg/m3
	Workers	Skin contact	Long-term systemic effects	4.8 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	3.6 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	4.5 mg/m3
	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
Ethanol	Workers	Inhalation	Long-term systemic effects	380 mg/m3
	Workers	Skin contact	Long-term systemic effects	267 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	114 mg/m3
2-(2- Butoxyethoxy)ethanol	Workers	Inhalation	Long-term systemic effects	67.5 mg/m3
	Workers	Inhalation	Long-term local ef- fects	67.5 mg/m3
	Workers	Inhalation	Acute local effects	101.2 mg/m3
	Workers	Skin contact	Long-term systemic effects	83 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	40.5 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	40.5 mg/m3

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	Consumers	Inhalation	Acute local effects	60.7 mg/m3
	Consumers	Skin contact	Long-term systemic effects	50 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	5 mg/kg bw/day
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	1.09 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

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	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.)
	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 guick 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

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



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Remarks : Consider double gloving. Take note that the product is flam-

mable, 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 being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to I.S. 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

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Viscosity, kinematic No data available

Solubility(ies)

No data available Water solubility

Partition coefficient: n-

octanol/water

No data available

Vapour pressure No data available

Relative density No data available

No data available Relative vapour density

Particle characteristics

No data available Particle size

9.2 Other information

Explosives Not explosive

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

No data available Evaporation rate

No data available Molecular weight

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.

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



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SECTION 11: Toxicological information

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

Information on likely routes of : Inhalation

exposure

Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

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

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

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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

Ethanol:

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



Fluazuron / Fipronil Formulation

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Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

N-Methyl-2-pyrrolidone:

Result : Skin irritation

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

Result : Irritation to eyes, reversing within 21 days

Fluazuron:

Species : Rabbit

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



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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:

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

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



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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

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

Ethanol:

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

Method: OECD Test Guideline 471

Result: negative

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



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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

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis 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

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

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



Fluazuron / Fipronil Formulation

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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

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

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



Fluazuron / Fipronil Formulation

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Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis 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 (vapour)

Exposure time : 2 Years
Result : negative

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

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.

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



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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

ment

Carcinogenicity - Assess- : 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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Ethanol:

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

Species: Mouse

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

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



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Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: positive

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: inhalation (vapour)

Result: positive

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Ingestion

Result: positive

Reproductive toxicity - As-

sessment

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 develop-

ment

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

Fipronil (ISO):

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

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

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



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Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

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 develop-

ment

Test Type: Fertility/early embryonic development

Species: Mouse

Application Route: Ingestion

Result: positive

Reproductive toxicity - As-

sessment

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.

Components:

Fipronil (ISO):

Exposure routes : Ingestion

Target Organs : Central nervous system, Kidney

Assessment : Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

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

Assessment : No significant health effects observed in animals at concentra-

tions of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

2-(2-Butoxyethoxy)ethanol:

Species : Rat

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



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NOAEL 250 mg/kg LOAEL 1,000 mg/kg Application Route Ingestion Exposure time 90 Days

OECD Test Guideline 408 Method

Species Rat

NOAEL >= 0.094 mg/lApplication Route : inhalation (vapour)

: Exposure time 90 Days

Method **OECD Test Guideline 413**

Species Rat

NOAEL >= 2,000 mg/kgApplication Route Skin contact Exposure time 90 Days

Ethanol:

Species Rat

NOAEL 1,730 mg/kg LOAEL : 3,200 mg/kg : Ingestion Application Route Exposure time 90 Days

N-Methyl-2-pyrrolidone:

Species Rat, male NOAEL 169 mg/kg LOAEL : 433 mg/kg Ingestion Application Route Exposure time 90 Days

Method **OECD Test Guideline 408**

Rat Species 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

Fluazuron:

Species Rat LOAEL 240 mg/kg Application Route Ingestion Exposure time 13 Weeks

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



Fluazuron / Fipronil Formulation

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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: RabbitNOAEL: 5 mg/kgLOAEL: 10 mg/kgApplication Route: Skin contactExposure 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

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: RatNOAEL: 50 mg/kgLOAEL: 250 mg/kgApplication Route: IngestionExposure time: 8 Months

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

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



Fluazuron / Fipronil Formulation

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Assessment The substance/mixture does not contain components consid-

> ered 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.

Experience with human exposure

Components:

N-Methyl-2-pyrrolidone:

Skin contact Symptoms: Skin irritation

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

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

Exposure time: 96 h

Method: OECD Test Guideline 201

EC10 : > 1,995 mg/lToxicity to microorganisms

Exposure time: 30 min

Ethanol:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : 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

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



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Toxicity to microorganisms : EC50 (Protozoa): 5,800 mg/l

Exposure time: 4 h

Toxicity to fish (Chronic tox-

icity)

: NOEC: >= 79 mg/l Exposure time: 100 d

Species: Oryzias latipes (Japanese medaka)

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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

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 : > 600 mg/l

Exposure time: 30 min Method: ISO 8192

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 12.5 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

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 tox- :

icity)

1,000

M-Factor (Chronic aquatic

toxicity)

: 1,000

Fipronil (ISO):

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



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Toxicity to fish LC50 (Lepomis macrochirus (Bluegill sunfish)): 85.2 μg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : 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 tox- :

icity)

1,000

EC50: > 1,000 mg/l Toxicity to microorganisms

Exposure time: 3 h

Toxicity to fish (Chronic tox-

icity)

NOEC: 2.9 µg/l

Exposure time: 35 d

Species: Cyprinodon variegatus (sheepshead minnow)

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.0077 µg/l Exposure time: 28 d

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

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 tox- : 1

city)

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



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Toxicity to microorganisms : EC50 : > 10,000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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

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:

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



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Biodegradability : Result: Readily biodegradable.

Biodegradation: 73 % Exposure time: 28 d

Method: OECD Test Guideline 301C

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- : log Pow: 1

octanol/water

Ethanol:

Partition coefficient: n- : log Pow: -0.35

octanol/water

N-Methyl-2-pyrrolidone:

Partition coefficient: n- : log Pow: -0.46

octanol/water Method: OECD Test Guideline 107

Fluazuron:

Partition coefficient: n- : log Pow: 5.1

octanol/water

Fipronil (ISO):

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 321

Partition coefficient: n- : log Pow: 4

octanol/water

Bioaccumulation : Species: Cyprinus carpio (Carp)

Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n- : log Pow: 5.1

octanol/water

tert-Butyl-4-methoxyphenol:

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

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



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Bioaccumulation : Species: Oryzias latipes (Orange-red killifish)

Bioconcentration factor (BCF): 16 - 21

Partition coefficient: n- : log Pow: 2.82

octanol/water 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 consid-

ered 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.

12.7 Other adverse effects

No data available

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 han-

dling 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

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



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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
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

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IATA (Cargo)

Packing instruction (cargo 366

aircraft)

Packing instruction (LQ) Y344 Packing group Ш

Labels Flammable Liquids

IATA (Passenger)

Packing instruction (passen-355

ger aircraft)

Packing instruction (LQ) Y344 Packing group Ш

Labels Flammable Liquids

14.5 Environmental hazards

ADN

Environmentally hazardous yes

Environmentally hazardous yes

Environmentally hazardous yes

IMDG

Marine pollutant yes

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)

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-2pyrrolidone

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

Number on list 71: N-Methyl-2pyrrolidone

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



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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) Number on list 72: N-Methyl-2pyrrolidone

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

N-Methyl-2-pyrrolidone

Not applicable

Not applicable

Fipronil (ISO)

not

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone

layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

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 PLAMMABLE LIQUIDS 5,000 t Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

HAZARDS

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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.

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



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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

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 or mutagens

at work

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

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

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

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

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



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IE OEL / OELV - 15 min : Occupational exposure limit value (15-minute reference peri-

(STEL) o

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; 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; 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:

Classification procedure:

H226	Based on product data or assessment
H315	Calculation method
H319	Calculation method
H360D	Calculation method
H335	Calculation method
H373	Calculation method
H400	Calculation method
	H315 H319 H360D H335 H373

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Aquatic Chronic 1 H410 Calculation method

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