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 / Abamectin 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.

Acute toxicity, Category 4 H332: Harmful if inhaled. Skin irritation, Category 2 H315: Causes skin irritation.

Eye irritation, Category 2 H319: Causes serious eye irritation. Skin sensitisation, Category 1 H317: May cause an allergic skin reaction. Germ cell mutagenicity, Category 2 H341: Suspected of causing genetic defects. Reproductive toxicity, Category 1B H360D: May damage the unborn child. Specific target organ toxicity - single ex-H336: May cause drowsiness or dizziness.

posure, Category 3

Specific target organ toxicity - single ex-

posure, Category 3

Specific target organ toxicity - repeated H373: May cause damage to organs through prolonged or repeated exposure.

exposure, Category 2

H400: Very toxic to aquatic life. Short-term (acute) aquatic hazard, Cate-

gory 1

H335: May cause respiratory irritation.

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Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

#### 2.2 Label elements

### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms









Signal word : Danger

Hazard statements : H226 Flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H341 Suspected of causing genetic defects.

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:

Propan-2-ol

N-Methyl-2-pyrrolidone

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate abamectin (combination of avermectin B1a and avermectin B1b) (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.

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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.

### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Propan-2-ol	67-63-0 200-661-7 603-117-00-0	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	>= 30 - < 50
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 %	>= 30 - < 50
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
abamectin (combination of aver- mectin B1a and avermectin B1b) (ISO)	71751-41-2 606-143-00-0	Acute Tox. 2; H300 Acute Tox. 1; H330 Acute Tox. 3; H311 Repr. 2; H361fd STOT RE 1; H372 (Central nervous system)	>= 1 - < 2.5

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ersion 3.0	Revision Date: 28.09.2024	SDS Number: 803734-00028	Date of last issue: 06.07.2024 Date of first issue: 12.07.2016	
			Aquatic Acute 1; H400 Aquatic Chronic 1; H410	
			M-Factor (Acute aquatic toxicity): 10,000 M-Factor (Chronic aquatic toxicity): 10,000	
			specific concentration limit STOT RE 1; H372 >= 5 % STOT RE 2; H373 0.5 - < 5 %	
ylmet oxabi	abicyclo[4.1.0]hept-3- hyl 7- cyclo[4.1.0]heptane-3- xylate	2386-87-0 219-207-4	Skin Sens. 1; H317 >= 1  Muta. 2; H341  STOT RE 2; H373  (nasal cavity)  Aquatic Chronic 3;  H412	- < 2.5
2,6-D	i-tert-butyl-p-cresol	128-37-0 204-881-4		- < 0.25

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

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.

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If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

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.

Never give anything by mouth to an unconscious person.

#### 4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes skin irritation.

May cause an allergic skin reaction.

Causes serious eye irritation.

Harmful if inhaled.

May cause respiratory irritation. May cause drowsiness or dizziness. Suspected of causing genetic defects.

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 (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire- : Do not use a solid water stream as it may scatter and spread

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fighting fire.

Flash back possible over considerable distance. Vapours may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Carbon oxides
Nitrogen oxides (NOx)

Chlorine compounds
Fluorine compounds

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

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employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

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. Contaminated work clothing should not be allowed out of the workplace.

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

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away from heat and sources of ignition.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides Flammable solids Pyrophoric liquids Pyrophoric solids

Self-heating substances and mixtures

Substances and mixtures, which in contact with water, emit

flammable gases

Explosives Gases

Very acutely toxic substances and mixtures

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
Propan-2-ol	67-63-0	OELV - 8 hrs (TWA)	200 ppm	IE OEL
	Further inform	nation: Substances w	hich have the capacity to pe	netrate intact
			th it, and be absorbed into th	
		OELV - 15 min (STEL)	400 ppm	IE OEL
			which have the capacity to pe th it, and be absorbed into the	
N-Methyl-2-	872-50-4	TWA	10 ppm	2009/161/EU
pyrrolidone			40 mg/m3	
	Further inform skin, Indicative	Further information: Identifies the possibility of significant uptake through the		
		STEL	20 ppm 80 mg/m3	2009/161/EU
	Further inform	ation: Identifies the	possibility of significant uptak	e through the
	skin, Indicative			J
		TWA	10 ppm 40 mg/m3	2004/37/EC
	Further information: Skin, Carcinogens or mutagens		•	
		STEL	20 ppm 80 mg/m3	2004/37/EC
	Further inform	ı nation: Skin, Carcino		I .
		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		
Fluazuron	86811-58-7	TWA	60 μg/m3 (OEB 3)	Internal
		Wipe limit	600 μg/ 100cm2	Internal
abamectin (combination of avermectin B1a and avermectin B1b) (ISO)	71751-41-2	TWA	15 μg/m3 (OEB 3)	Internal
		Wipe limit	150 μg/100 cm <sup>2</sup>	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
7- Oxabicy- clo[4.1.0]hept-3- ylmethyl 7- oxabicy- clo[4.1.0]heptane-3- carboxylate	Workers	Inhalation	Long-term systemic effects	0.18 mg/m3
	Workers	Inhalation	Long-term local ef- fects	0.18 mg/m3
	Workers	Skin contact	Long-term systemic effects	0.05 mg/kg bw/day
Propan-2-ol	Workers	Inhalation	Long-term systemic effects	500 mg/m3
	Workers	Skin contact	Long-term systemic effects	888 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	89 mg/m3
	Consumers	Skin contact	Long-term systemic	319 mg/kg

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l			effects	bw/day
	Consumers	Ingestion	Long-term systemic effects	26 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

### 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.)
7-Oxabicyclo[4.1.0]hept-3-	Fresh water	0.024 mg/l
ylmethyl 7-		
oxabicyclo[4.1.0]heptane-3-		
carboxylate		
	Freshwater - intermittent	0.24 mg/l
	Marine water	0.0024 mg/l
	Sewage treatment plant	19.5 mg/l
	Fresh water sediment	0.211 mg/kg dry
		weight (d.w.)
	Marine sediment	0.0211 mg/kg dry
		weight (d.w.)
	Soil	0.0282 mg/kg dry
		weight (d.w.)
Propan-2-ol	Fresh water	140.9 mg/l
	Marine water	140.9 mg/l
	Intermittent use/release	140.9 mg/l
	Sewage treatment plant	2251 mg/l
	Fresh water sediment	552 mg/kg dry
		weight (d.w.)
	Marine sediment	552 mg/kg dry
		weight (d.w.)
	Soil	28 mg/kg dry
		weight (d.w.)
	Oral (Secondary Poisoning)	160 mg/kg food
2,6-Di-tert-butyl-p-cresol	Fresh water	0.199 µg/l
	Intermittent use/release	0.02 μg/l

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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

#### 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 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

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Colour : No data available

Odour : No data available

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 : 28 °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

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

#### 9.2 Other information

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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 : Inhalation exposure Skin contact

Ingestion
Eye contact

Acute toxicity

Harmful if inhaled.

**Product:** 

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

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 2.06 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

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

Method: Calculation method

**Components:** 

Propan-2-ol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 25 mg/l

Exposure time: 6 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 5,000 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

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

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Acute oral toxicity : LD50 (Rat): 24 mg/kg

LD50 (Mouse): 10 mg/kg

LDLo (Monkey): 24 mg/kg

Symptoms: Dilatation of the pupil

Acute inhalation toxicity : LC50 (Rat): 0.023 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): 330 mg/kg

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LD50 (Rabbit): 2,000 mg/kg

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Acute oral toxicity : LD50 (Rat, male): > 2,959 - 5,000 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): >= 5.19 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 436

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

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

Acute oral toxicity : LD50 (Rat): > 6,000 mg/kg

Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Skin corrosion/irritation

Causes skin irritation.

**Components:** 

Propan-2-ol:

Species : Rabbit

Result : No skin irritation

N-Methyl-2-pyrrolidone:

Result : Skin irritation

Fluazuron:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Species : Rabbit

Result : No skin irritation

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



### Fluazuron / Abamectin Formulation

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#### 7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

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

#### Serious eye damage/eye irritation

Causes serious eye irritation.

#### **Components:**

#### Propan-2-ol:

Species : Rabbit

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

Method : OECD Test Guideline 405

Result : Mild eye irritation

### abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Species : Rabbit

Result : Mild eye irritation

### 7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

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

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



### Fluazuron / Abamectin Formulation

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#### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

### **Respiratory sensitisation**

Not classified based on available information.

#### **Components:**

#### Propan-2-ol:

Test Type : Buehler Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

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

#### Fluazuron:

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

#### abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Test Type : Maximisation Test Exposure routes : Skin contact

Result : Not a skin sensitizer.

#### 7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

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

Assessment : Probability or evidence of skin sensitisation in humans

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

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact
Species : Humans
Result : negative

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



### Fluazuron / Abamectin Formulation

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#### Germ cell mutagenicity

Suspected of causing genetic defects.

#### **Components:**

Propan-2-ol:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

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

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

Result: negative

Genotoxicity in vivo : Test Type: Cytogenetic assay

Species: Hamster Result: equivocal

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster lung cells

Result: negative

Test Type: Alkaline elution assay

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

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

Method: OECD Test Guideline 471

Result: positive

Test Type: In vitro mammalian cell gene mutation test

Result: positive

Test Type: In vitro sister chromatid exchange assay in mam-

malian cells Result: positive

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

thesis in mammalian cells (in vitro)

Result: positive

Genotoxicity in vivo : 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

Test Type: Micronucleus test

Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

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



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Test Type: Transgenic rodent somatic cell gene mutation as-

say

Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 488

Result: positive

Germ cell mutagenicity- As-

sessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity tests.

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

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

#### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### Propan-2-ol:

Species : Rat

Application Route : inhalation (vapour)

Exposure time : 104 weeks

Method : OECD Test Guideline 451

Result : negative

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

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



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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

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Species : Rat
Application Route : Oral
Exposure time : 105 weeks
Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 93 weeks
Result : negative

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Species : Mouse
Application Route : Skin contact
Exposure time : 29 Months
Result : negative

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

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

Reproductive toxicity

May damage the unborn child.

**Components:** 

Propan-2-ol:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop- : Test Type: Embryo-foetal development

ment Species: Rat

**Application Route: Ingestion** 

Result: negative

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



### Fluazuron / Abamectin Formulation

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II

N-Methyl-2-pyrrolidone:

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Effects on 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

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Effects on fertility : Test Type: Fertility

Species: Rat, male Application Route: Oral Result: Effects on fertility

Test Type: Two-generation reproduction toxicity study

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



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Species: Rat

Application Route: Oral

Early Embryonic Development: NOAEL: 0.12 mg/kg body

weight

Result: Fetotoxicity

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse Application Route: Oral

General Toxicity Maternal: NOAEL: 0.05 mg/kg body weight Developmental Toxicity: NOAEL: 0.2 mg/kg body weight

Result: Cleft palate

Remarks: Adverse developmental effects were observed

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 2 mg/kg body weight

Result: Cleft palate, Teratogenic effects, Reduced embryonic

survival

Remarks: Adverse developmental effects were observed

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 1.6 mg/kg body weight

Result: Teratogenic effects

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of

adverse effects on development, based on animal experi-

ments.

#### 7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

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



### Fluazuron / Abamectin Formulation

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#### STOT - single exposure

May cause respiratory irritation. May cause drowsiness or dizziness.

#### Components:

#### Propan-2-ol:

Assessment May cause drowsiness or dizziness.

#### N-Methyl-2-pyrrolidone:

Assessment : May cause respiratory irritation.

#### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

#### **Components:**

#### abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Exposure routes Ingestion

Target Organs Central nervous system

Assessment Causes damage to organs through prolonged or repeated

exposure.

### 7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Exposure routes Ingestion Target Organs nasal cavity

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

centrations of >10 to 100 mg/kg bw.

#### 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:**

#### Propan-2-ol:

Species Rat NOAEL 12.5 mg/l

Application Route : inhalation (vapour)

Exposure time 104 Weeks

#### 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

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



### Fluazuron / Abamectin Formulation

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**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** 

NOAEL LOAEL Application Route Exposure time Rabbit 826 mg/kg : 1,653 mg/kg : Skin contact Exposure time 20 Days

Fluazuron:

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

Target Organs Liver, Thyroid, Pituitary gland

Rat Species 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 Inaestion Exposure time 52 Weeks Target Organs Liver

#### abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Species Rat NOAEL 1.5 mg/kg Application Route Oral : 24 Months Exposure time

Target Organs Central nervous system

Symptoms Tremors, ataxia

Species Mouse NOAEL 4.0 mg/kg Application Route : Oral Exposure time : 24 Months

Target Organs Central nervous system

**Symptoms** Tremors, ataxia

Species Dog NOAEL 0.25 mg/kg LOAEL 0.5 mg/kg

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



### Fluazuron / Abamectin Formulation

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Application Route : Oral Exposure time : 53 Weeks

Target Organs : Central nervous system
Symptoms : Tremors, weight loss
Remarks : mortality observed

Species : Monkey
NOAEL : 1.0 mg/kg
Application Route : Oral
Exposure time : 14 Weeks

Target Organs : Central nervous system

#### 7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Species: RatNOAEL: 5 mg/kgLOAEL: 50 mg/kgApplication Route: IngestionExposure time: 90 Days

Method : OECD Test Guideline 408

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

Species : Rat

NOAEL : 25 mg/kg

Application Route : Ingestion

Exposure time : 22 Months

#### **Aspiration toxicity**

Not classified based on available information.

#### 11.2 Information on other hazards

#### **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.

#### Experience with human exposure

#### **Components:**

### N-Methyl-2-pyrrolidone:

Skin contact : Symptoms: Skin irritation

#### abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Ingestion : Symptoms: May cause, Tremors, Diarrhoea, central nervous

system effects, Salivation, tearing

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



### Fluazuron / Abamectin Formulation

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#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### Components:

Propan-2-ol:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l

Exposure time: 24 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 1,050 mg/l

Exposure time: 16 h

N-Methyl-2-pyrrolidone:

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

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : 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:

LC50 (Cyprinus carpio (Carp)): > 9.1 mg/l Toxicity to fish

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia sp. (water flea)): 0.0006 mg/l

Toxicity to algae/aquatic

plants

Exposure time: 48 h

NOEC (Raphidocelis subcapitata (freshwater green alga)):

27.9 ma/l

Exposure time: 72 h

M-Factor (Acute aquatic tox- : 1,000

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



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icity)

M-Factor (Chronic aquatic

toxicity)

: 1,000

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 3.2 μg/l

Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.6 μg/l

Exposure time: 96 h

LC50 (Ictalurus punctatus (channel catfish)): 24 µg/l

Exposure time: 96 h

LC50 (Cyprinus carpio (Carp)): 42 µg/l

Exposure time: 96 h

LC50 (Cyprinodon variegatus (sheepshead minnow)): 15 µg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Americamysis): 0.022 µg/l

Exposure time: 96 h

EC50 (Daphnia magna (Water flea)): 0.34 μg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 100

mg/l

Exposure time: 72 h

M-Factor (Acute aquatic tox- :

icity)

10,000

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

Exposure time: 3 h

Test Type: Respiration inhibition

Toxicity to fish (Chronic tox-

icity)

: NOEC: 0.52 µg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other : aguatic invertebrates (Chron-

ic toxicity)

NOEC: 0.03 µg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

NOEC:  $0.0035 \mu g/l$  Exposure time: 28 d

Species: Mysidopsis bahia (opossum shrimp)

M-Factor (Chronic aquatic

toxicity)

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

: 10,000

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



### Fluazuron / Abamectin Formulation

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LC50 (Oncorhynchus mykiss (rainbow trout)): 24 mg/l Toxicity to fish

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 40 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Raphidocelis subcapitata (freshwater green alga)): >

110 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Raphidocelis subcapitata (freshwater green alga)): 30

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (activated sludge): 409 mg/l Toxicity to microorganisms

Exposure time: 3 h

Method: OECD Test Guideline 209

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 tox- :

icity)

1

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

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



### Fluazuron / Abamectin Formulation

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Toxicity to daphnia and other : NOEC: 0.316 mg/l aquatic invertebrates (Chron- Exposure time: 21 d

ic toxicity) Species: Daphnia magna (Water flea)

o toxioity) Opooleo. Daprinia magna (water nea

M-Factor (Chronic aquatic : 1

toxicity)

### 12.2 Persistence and degradability

#### **Components:**

Propan-2-ol:

Biodegradability : Result: rapidly degradable

BOD/COD : BOD: 1,19 (BOD5)

COD: 2,23 BOD/COD: 53 %

N-Methyl-2-pyrrolidone:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 73 % Exposure time: 28 d

Method: OECD Test Guideline 301C

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Stability in water : Hydrolysis: 50 %(< 12 h)

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 71 % 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:

Propan-2-ol:

Partition coefficient: n-

log Pow: 0.05

octanol/water

N-Methyl-2-pyrrolidone:

Partition coefficient: n- : log Pow: -0.46

octanol/water Method: OECD Test Guideline 107

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



### Fluazuron / Abamectin Formulation

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П

Fluazuron:

Partition coefficient: n-

octanol/water

log Pow: 5.1

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

: Bioconcentration factor (BCF): 52 Bioaccumulation

Partition coefficient: n-

octanol/water

: log Pow: 4

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:

: log Pow: 1.34 Partition coefficient: n-

Method: OECD Test Guideline 107 octanol/water

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

12.4 Mobility in soil

**Components:** 

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Distribution among environ: log Koc: > 3.6

mental compartments

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

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#### **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

ADN : UN 1993
ADR : UN 1993
RID : UN 1993
IMDG : UN 1993
IATA : UN 1993

#### 14.2 UN proper shipping name

**ADN** : FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol)

ADR : FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol)

RID : FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol)

**IMDG** : FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol, Fluazuron, abamectin (combination of avermec-

tin B1a and avermectin B1b) (ISO))

IATA : Flammable liquid, n.o.s.

(Propan-2-ol)

#### 14.3 Transport hazard class(es)

Class Subsidiary risks

 ADN
 : 3

 ADR
 : 3

 RID
 : 3

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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, <u>S-E</u>

IATA (Cargo)

Packing instruction (cargo : 366

aircraft)

Packing instruction (LQ) : Y344
Packing group : III

Labels : Flammable Liquids

IATA (Passenger)

Packing instruction (passen: 355

ger aircraft)

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

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



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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)

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 71: N-Methyl-2pyrrolidone

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

on

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

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

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 pollutants (recast)

Regulation (ÉU) 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

N-Methyl-2-pyrrolidone

Not applicable

Not applicable

Not applicable

: Not applicable

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



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(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.

Quantity 1 Quantity 2
P5c FLAMMABLE LIQUIDS 5,000 t 50,000 t

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.

#### **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.

H300 : Fatal if swallowed.

H311 : Toxic in contact with skin. H315 : Causes skin irritation.

H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.

H330 : Fatal if inhaled.

H335 : May cause respiratory irritation.
H336 : May cause drowsiness or dizziness.
H341 : Suspected of causing genetic defects.

H360D : May damage the unborn child.

H361fd : Suspected of damaging fertility. Suspected of damaging the

unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

H373 : May cause damage to organs through prolonged or repeated

exposure.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.

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



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H412 : Harmful 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

Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Muta. : Germ cell mutagenicity
Repr. : Reproductive toxicity

Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation

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

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

(STEL) od

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

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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**

compile the Safety Data

Sheet

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

#### Classification of the mixture: Classification procedure:

Flam. Liq. 3	H226	Based on product data or assessment
Acute Tox. 4	H332	Calculation method
Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method
Skin Sens. 1	H317	Calculation method
Muta. 2	H341	Calculation method
Repr. 1B	H360D	Calculation method
STOT SE 3	H336	Calculation method
STOT SE 3	H335	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

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

IE / EN