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

Product name ZIGNAL®

Other means of identification

Product code 50000004

Unique Formula Identifier

(UFI)

: YCXW-226X-TN47-VM7F

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

Use of the Sub- : Fungicide

stance/Mixture

Recommended restrictions :

on use

Use as recommended by the label.

For professional users only.

1.3 Details of the supplier of the safety data sheet

Supplier Address FMC Chemicals Hellas MEPE

Syngrou Avenue 348 17674 Kallithea

Greece

Telephone: +30 211 1982768 Telefax: +30 211 1138614

E-mail address: SDS-Info@fmc.com .

1.4 Emergency telephone number

For leak, fire, spill or accident emergencies, call:

Greece: 30-2111768478 (CHEMTREC)

Medical emergency: Greece: 30 210 77 93 777

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

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



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Skin sensitisation, Sub-category 1B H317: May cause an allergic skin reaction.

Eye irritation, Category 2 H319: Causes serious eye irritation.

Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child.

Short-term (acute) aquatic hazard, Cate-

gory 1

H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms







Signal word Warning

Hazard statements H317 May cause an allergic skin reaction.

> Causes serious eye irritation. H319

H361d Suspected of damaging the unborn child.

Very toxic to aquatic life with long lasting effects. H410

P102 Keep out of reach of children. Precautionary statements

Prevention:

P262 Do not get in eyes, on skin, or on clothing.

P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/protective clothing, eye/face

protection.

Storage:

P405 Store locked up.

Disposal:

Dispose of contents/container as hazardous waste in

accordance with local regulations.

Hazardous components which must be listed on the label:

fluazinam (ISO)

1,2-benzisothiazol-3(2H)-one

Additional Labelling

EUH401 To avoid risks to human health and the environment, comply with the instruc-

tions for use.

For special phrases (SP) and safety intervals, consult the label.

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



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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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
fluazinam (ISO)	79622-59-6 612-287-00-5	Acute Tox. 4; H332 Eye Dam. 1; H318 Skin Sens. 1A; H317 Repr. 2; H361d Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 30 - < 50
		M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	
		Acute toxicity esti- mate	
		Acute inhalation toxicity (dust/mist): 1,32 mg/l	
Residues (petroleum), catalytic reformer fractionator, sulfonated, polymers with formaldehyde, sodium salts	68425-94-5	Eye Irrit. 2; H319 Aquatic Chronic 3; H412	>= 1 - < 2,5
Alcohols, C13-15, branched and linear, ethoxylated	157627-86-6	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 3; H412	>= 1 - < 2,5

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		Acute toxicity estimate Acute oral toxicity: 500 mg/kg	
1,2-benzisothiazol-3(2H)-one	2634-33-5 220-120-9 613-088-00-6	Acute Tox. 2; H330 Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Skin Sens. 1A; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 specific concentration limit Skin Sens. 1A; H317 >= 0,036 % Acute toxicity estimate Acute oral toxicity: 450 mg/kg Acute inhalation toxicity (dust/mist): 0,21 mg/l	>= 0,0025 - < 0,025

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Move out of dangerous area.

Consult a physician.

Show this safety data sheet to the doctor in attendance.

Do not leave the victim unattended.

Protection of first-aiders : Avoid inhalation, ingestion and contact with skin and eyes.

If inhaled : Remove to fresh air.

If unconscious, place in recovery position and seek medical

advice.

Consult a physician after significant exposure.

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



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In case of skin contact : If on clothes, remove clothes.

If on skin, rinse well with water.

Wash off with soap and plenty of water.

Get medical attention immediately if irritation develops and

persists.

In case of eye contact : Small amounts splashed into eyes can cause irreversible tis-

sue damage and blindness.

In the case of contact with eyes, rinse immediately with plenty

of water and seek medical advice.

Continue rinsing eyes during transport to hospital.

Remove contact lenses. Protect unharmed eye.

Keep eye wide open while rinsing.

If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.

Do NOT induce vomiting.

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

If symptoms persist, call a physician. Take victim immediately to hospital.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Exposure to skin may result in mild symptoms include itching,

hives or rash, and skin redness. More severe symptoms include sneezing, itchy watery eyes, and difficulty breathing.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

Immediate medical attention is required in case of ingestion.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Dry chemical, CO2, water spray or regular foam.

Unsuitable extinguishing

media

Do not spread spilled material with high-pressure water

streams.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Do not allow run-off from fire fighting to enter drains or water

courses.

Hazardous combustion prod: :

ucts

Fire may produce irritating, corrosive and/or toxic gases.

Halogenated compounds Nitrogen oxides (NOx)

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



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Carbon oxides Ammonia

5.3 Advice for firefighters

Special protective equipment:

for firefighters

Firefighters should wear protective clothing and self-contained

breathing apparatus.

Specific extinguishing meth-

ods

Remove undamaged containers from fire area if it is safe to do

SO.

Use a water spray to cool fully closed containers.

Further information : Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Collect contaminated fire extinguishing water separately. This

must not be discharged into drains.

Fire residues and contaminated fire extinguishing water must

be disposed of in accordance with local regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Evacuate personnel to safe areas.

Do not touch or walk through the spilled material.

If it can be safely done, stop the leak. Use personal protective equipment.

Never return spills in original containers for re-use.

Mark the contaminated area with signs and prevent access to

unauthorized personnel.

Only qualified personnel equipped with suitable protective

equipment may intervene.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

Prevent further leakage or spillage if safe to do so.

If the product contaminates rivers and lakes or drains inform

respective authorities.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Never return spills in original containers for re-use.

Collect as much of the spill as possible with a suitable absor-

bent material.

Pick up and transfer to properly labelled containers. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

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

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



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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid formation of aerosol.

Do not breathe vapours/dust.

Avoid exposure - obtain special instructions before use.

Avoid contact with skin and eyes. For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the ap-

plication area.

Provide sufficient air exchange and/or exhaust in work rooms. To avoid spills during handling keep bottle on a metal tray. Dispose of rinse water in accordance with local and national

regulations.

Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being

used.

Advice on protection against

fire and explosion

Normal measures for preventive fire protection.

Hygiene measures : Avoid contact with skin, eyes and clothing. Do not inhale aer-

osol. When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday. Remove and wash contaminated clothing and gloves, includ-

ing the inside, before re-use.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Observe label precautions. Electrical installations / working materials must

comply with the technological safety standards.

Further information on stor-

age conditions

The product is stable under normal conditions of warehouse storage. Protect from heat and direct sunlight. Store in closed, labelled containers. The storage room should be constructed of incombustible material, closed, dry, ventilated and with impermeable floor, without access of unauthorised persons or children. A warning sign reading "POISON" is recommended. The room should only be used for storage of chemicals. Food, drink, feed and seed should not be present. A hand wash

station should be available.

Recommended storage tem: :

perature

5 - 30 °C

Further information on stor-

age stability

No decomposition if stored and applied as directed.

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



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7.3 Specific end use(s)

Specific use(s) : Registered pesticide to be used in accordance with a label

approved by country-specific regulatory authorities.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

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

Substance name	End Use	Exposure routes	Potential health effects	Value
urea	Workers	Inhalation	Long-term systemic effects	292 mg/m3
	Workers	Inhalation	Acute systemic effects	292 mg/m3
	Workers	Dermal	Long-term systemic effects	580 mg/kg bw/day
	Workers	Dermal	Acute systemic ef- fects	580 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	125 mg/m3
	Consumers	Inhalation	Acute systemic effects	125 mg/m3
	Consumers	Dermal	Long-term systemic effects	580 mg/kg bw/day
	Consumers	Dermal	Acute systemic effects	580 mg/kg bw/day
	Consumers	Oral	Long-term systemic effects	42 mg/kg bw/day
	Consumers	Oral	Acute systemic effects	42 mg/kg bw/day
1,2-benzisothiazol- 3(2H)-one	Workers	Inhalation	Long-term systemic effects	6,81 mg/m3
	Workers	Dermal	Long-term systemic effects	0,966 mg/kg
	Consumers	Inhalation	Long-term systemic effects	1,2 mg/m3
	Consumers	Dermal	Long-term systemic effects	0,345 mg/kg

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

Substance name	Environmental Compartment Value	
urea	Fresh water 0,47 mg/l	
	Marine water	0,047 mg/l
1,2-benzisothiazol-3(2H)-one	Fresh water	0,00403 mg/l
	Marine water 0,000403 r	
	Sewage treatment plant	1,03 mg/l
	Fresh water sediment	0,0499 mg/l

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



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Marine sediment 0,00499 mg/l

8.2 Exposure controls

Personal protective equipment

Eye/face protection : Eye wash bottle with pure water

Tightly fitting safety goggles

Face-shield

Hand protection

Material : Wear chemical resistant gloves, such as barrier laminate,

butyl rubber or nitrile rubber.

Remarks : The suitability for a specific workplace should be discussed

with the producers of the protective gloves.

Skin and body protection : Impervious clothing

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Respiratory protection : In case of mist, spray or aerosol exposure wear suitable per-

sonal respiratory protection and protective suit.

Protective measures : Plan first aid action before beginning work with this product.

Always have on hand a first-aid kit, together with proper in-

structions.

Wear suitable protective equipment. When using do not eat, drink or smoke.

In the context of professional plant protection use as recommended, the end user must refer to the label and the instruc-

tions for use.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : light yellow, yellowish-brown

Odour : odourless

Odour Threshold : No data available

Melting point/range : not determined

Boiling point/boiling range : No data available

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



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Upper explosion limit / Upper

flammability limit

: not determined

Lower explosion limit / Lower

flammability limit

not determined

Flash point : $> 103 \, ^{\circ}\text{C}$

Method: Pensky-Martens closed cup - PMCC

Auto-ignition temperature : No data available

Decomposition temperature : not determined

pH : 7,5 - 8,3

Concentration: 1 %

Viscosity

Viscosity, dynamic : 15,5 mPa,s (20 °C)

Viscosity, kinematic : 1094 - 1406 mm2/s

Solubility(ies)

Water solubility : Miscible

Partition coefficient: n-

octanol/water

Not available for this mixture.

Vapour pressure : 0,0011 Pa (20 °C)

Relative density : 1,2547 (20 °C)

Density : 1,2547 g/cm3

Relative vapour density : not determined

Particle characteristics

Particle size : Not applicable

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Particle Size Distribution : Not applicable

Shape : Not applicable

9.2 Other information

Explosives : Not explosive

Oxidizing properties : Non-oxidizing

Flammability (liquids) : The product may be combustible., Based on available infor-

mation, the classification criteria for flammability hazard are

not met.

Self-ignition : > 400 °C

Evaporation rate : No data available

Molecular weight : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

No decomposition if stored and applied as directed.

10.2 Chemical stability

No decomposition if stored and applied as directed.

10.3 Possibility of hazardous reactions

Hazardous reactions : No decomposition if stored and applied as directed.

10.4 Conditions to avoid

Conditions to avoid : Avoid extreme temperatures

Avoid formation of aerosol. Heat, flames and sparks.

Heating of the mixture may evolve harmful and irritant va-

pours.

10.5 Incompatible materials

Materials to avoid : Avoid strong acids, bases, and oxidizers

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10.6 Hazardous decomposition products

Stable under recommended storage conditions.

SECTION 11: Toxicological information

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

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : LD50 Oral (Rat, female): > 2.000 mg/kg

Method: OECD Test Guideline 425

Symptoms: Diarrhoea

GLP: yes

Assessment: The component/mixture is minimally toxic after

single ingestion. Remarks: no mortality

Acute inhalation toxicity : Acute toxicity estimate: 4,48 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Acute dermal toxicity : LD50 Dermal (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 402

GLP: yes

Assessment: The component/mixture is minimally toxic after

single contact with skin. Remarks: no mortality

Components:

fluazinam (ISO):

Acute oral toxicity : LD50 (Rat, female): > 2.000 mg/kg

Method: OECD Test Guideline 425

Symptoms: Diarrhoea

GLP: yes

Assessment: The component/mixture is minimally toxic after

single ingestion. Remarks: no mortality

Acute inhalation toxicity : LC50 (Rat, male): 1,32 - 2,13 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Symptoms: Fatality, Breathing difficulties, ataxia

GLP: yes

Acute dermal toxicity : LD50 (Rat, male and female): > 2.000 mg/kg

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Method: OECD Test Guideline 402

GLP: yes

Assessment: The component/mixture is minimally toxic after

single contact with skin. Remarks: no mortality

Residues (petroleum), catalytic reformer fractionator, sulfonated, polymers with formalde-

hyde, sodium salts:

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

Alcohols, C13-15, branched and linear, ethoxylated:

Acute oral toxicity : LD50 (Rat): 500 - 2.000 mg/kg

1,2-benzisothiazol-3(2H)-one:

Acute oral toxicity : LD50 (Rat, male and female): 490 mg/kg

Method: OECD Test Guideline 401

Acute toxicity estimate: 450 mg/kg

Method: Acute toxicity estimate according to Regulation (EC)

No. 1272/2008

Remarks: Based on EU Harmonised classification - Annex VI

of Regulation (EC) No 1272/2008 (CLP Regulation)

Acute inhalation toxicity : Acute toxicity estimate: 0,21 mg/l

Test atmosphere: dust/mist

Method: Acute toxicity estimate according to Regulation (EC)

No. 1272/2008

Remarks: Based on EU Harmonised classification - Annex VI

of Regulation (EC) No 1272/2008 (CLP Regulation)

Acute dermal toxicity : LD50 (Rat, male and female): > 2.000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Skin corrosion/irritation

Not classified based on available information.

Product:

Species : Rabbit

Assessment : Not classified as irritant
Method : OECD Test Guideline 404

GLP : yes

Remarks : Minimal effects that do not meet the threshold for classifica-

tion.

Remarks : Extremely corrosive and destructive to tissue.

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



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Components:

fluazinam (ISO):

Species : Rabbit

Assessment : No skin irritation

Method : OECD Test Guideline 404

GLP : yes

Remarks : Minimal effects that do not meet the threshold for classifica-

tion.

Residues (petroleum), catalytic reformer fractionator, sulfonated, polymers with formalde-

hyde, sodium salts:

Remarks : No data available

Alcohols, C13-15, branched and linear, ethoxylated:

Result : No skin irritation

1,2-benzisothiazol-3(2H)-one:

Species : Rabbit Exposure time : 72 h

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Species : Rabbit

Assessment : No eye irritation

Method : OECD Test Guideline 405

Remarks : Minimal effects that do not meet the threshold for classifica-

tion.

Components:

fluazinam (ISO):

Assessment : Risk of serious damage to eyes.

Remarks : Based on EU Harmonised classification - Annex VI of Regula-

tion (EC) No 1272/2008 (CLP Regulation)

Species : Rabbit

Assessment : Irritating to eyes.

Method : OECD Test Guideline 405

GLP : yes

Residues (petroleum), catalytic reformer fractionator, sulfonated, polymers with formalde-

hyde, sodium salts:

Result : Eye irritation

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Alcohols, C13-15, branched and linear, ethoxylated:

Result : Irreversible effects on the eye

1,2-benzisothiazol-3(2H)-one:

Species : Bovine cornea

Method : OECD Test Guideline 437

Result : No eye irritation

Species : Rabbit

Method : EPA OPP 81-4

Result : Irreversible effects on the eye

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Product:

Test Type : Local lymph node assay (LLNA)

Assessment : The product is a skin sensitiser, sub-category 1B.

Method : OECD Test Guideline 429
Result : Causes skin sensitization.

GLP : yes

Remarks : Causes sensitisation.

Components:

fluazinam (ISO):

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

Assessment : The product is a skin sensitiser, sub-category 1A.

Method : OECD Test Guideline 429

Result : May cause sensitisation by skin contact.

GLP : yes

1,2-benzisothiazol-3(2H)-one:

Test Type : Maximisation Test

Species : Guinea pig

Method : OECD Test Guideline 406

Result : May cause sensitisation by skin contact.

Species : Guinea pig Method : FIFRA 81.06

Result : May cause sensitisation by skin contact.

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Germ cell mutagenicity

Not classified based on available information.

Product:

Genotoxicity in vitro : Test Type: Ames test

Method: OECD Test Guideline 471

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Result: negative

Germ cell mutagenicity- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

Components:

fluazinam (ISO):

Genotoxicity in vitro : Test Type: Ames test

Metabolic activation: with and without metabolic activation

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Result: negative

Germ cell mutagenicity- As-

sessment

No genotoxic potential

1,2-benzisothiazol-3(2H)-one:

Genotoxicity in vitro : Test Type: gene mutation test

Test system: mouse lymphoma cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 476

Result: negative

Test Type: Ames test

Method: OECD Test Guideline 471

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: positive

Genotoxicity in vivo : Test Type: unscheduled DNA synthesis assay

Species: Rat (male) Cell type: Liver cells Application Route: Ingestion

Exposure time: 4 h

Method: OECD Test Guideline 486

Result: negative

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



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Test Type: Micronucleus test

Species: Mouse Application Route: Oral

Method: OECD Test Guideline 474

Result: negative

Germ cell mutagenicity- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

Carcinogenicity

Not classified based on available information.

Product:

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

Components:

fluazinam (ISO):

Carcinogenicity - Assess-

ment

Did not show carcinogenic effects in animal experiments.

Reproductive toxicity

Suspected of damaging the unborn child.

Product:

Reproductive toxicity - As-

sessment

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

Components:

fluazinam (ISO):

Effects on foetal develop-

ment

Species: Rat

Symptoms: Fetal effects, placental abnormalities, fused or incompletely ossified sternebrae, abnormalities of the head bones, not developed renal papillae and distended ureter Result: Embryotoxic effects and adverse effects on the off-

spring were detected.

Species: Rat

Symptoms: Fetal effects, Skeletal and visceral variations Result: Embryotoxic effects and adverse effects on the off-

spring were detected.

Reproductive toxicity - As-

sessment

: Animal testing did not show any effects on fertility., Some evidence of adverse effects on development, based on animal

experiments.

1,2-benzisothiazol-3(2H)-one:

Effects on fertility : Species: Rat, male

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



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Application Route: Ingestion

General Toxicity - Parent: NOAEL: 18,5 mg/kg body weight

General Toxicity F1: NOAEL: 48 mg/kg body weight

Fertility: NOAEL: 112 mg/kg bw/day

Symptoms: No effects on reproduction parameters

Method: OPPTS 870.3800

Result: negative

Reproductive toxicity - As-

sessment

Weight of evidence does not support classification for repro-

ductive toxicity

STOT - single exposure

Not classified based on available information.

Product:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

Components:

fluazinam (ISO):

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

STOT - repeated exposure

Not classified based on available information.

Product:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Components:

1,2-benzisothiazol-3(2H)-one:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

fluazinam (ISO):

Species : Rat

LOAEL : 41 mg/kg, 500 ppm

Application Route : Ingestion Exposure time : 90 days Target Organs : Liver

Symptoms : Reduced body weight, increased liver weight

1,2-benzisothiazol-3(2H)-one:

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



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Species : Rat, male and female

NOAEL : 15 mg/kg Application Route : Ingestion Exposure time : 28 d

Method : OECD Test Guideline 407

Symptoms : Irritation

Species : Rat, male and female

NOAEL : 69 mg/kg Application Route : Ingestion Exposure time : 90 d

Symptoms : Irritation, Reduced body weight

Aspiration toxicity

Not classified based on available information.

Components:

fluazinam (ISO):

The substance does not have properties associated with aspiration hazard potential.

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:

fluazinam (ISO):

Skin contact : Symptoms: irritant effects, sensitising effects

Further information

Product:

Remarks : No data available

SECTION 12: Ecological information

12.1 Toxicity

Product:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0,16 mg/l

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



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Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0,23 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Desmodesmus subspicatus (green algae)): 0,13 mg/l

Exposure time: 96 h

ErC50 (Lemna gibba (duckweed)): 0,57 mg/l

Exposure time: 7 d

NOEC (Lemna gibba (duckweed)): 0,094 mg/l

Exposure time: 7 d

Toxicity to soil dwelling or-

ganisms

LC50: > 1.000 mg/kg

Exposure time: 14 d

Species: Eisenia fetida (earthworms)

Toxicity to terrestrial organ-

isms

LD50: > 100 µg/bee Exposure time: 48 h

End point: Acute oral toxicity Species: Apis mellifera (bees)

LD50: > 100 μg/bee Exposure time: 48 h

End point: Acute contact toxicity Species: Apis mellifera (bees)

LD50: > 2.000 mg/kg

Species: Coturnix japonica (Japanese quail)

Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

Components:

fluazinam (ISO):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0,11 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0,19 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

IC50 (Selenastrum capricornutum (green algae)): > 0,2 mg/l

Exposure time: 96 h

M-Factor (Acute aquatic tox-

icity)

10

Toxicity to microorganisms : EC50 (activated sludge): 75 mg/l

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



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Exposure time: 3 h

Toxicity to fish (Chronic tox-

icity)

NOEC: 0,012 mg/l Exposure time: 28 d

Species: Oncorhynchus mykiss (rainbow trout)

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: < 0,0125 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic

toxicity)

10

Toxicity to soil dwelling or-

ganisms

LC50: > 1.000 mg/kgExposure time: 28 d

Species: Eisenia fetida (earthworms)

Toxicity to terrestrial organ-

isms

LD50: > 4.190 mg/kg

Species: Anas platyrhynchos (Mallard duck)

LD50: 1.782 mg/kg

Species: Colinus virginianus (Bobwhite quail)

Residues (petroleum), catalytic reformer fractionator, sulfonated, polymers with formaldehyde, sodium salts:

Toxicity to fish LC50 (Zebra fish): > 10 - 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

EC10: > 10 - 100 mg/lExposure time: 21 d

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

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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Alcohols, C13-15, branched and linear, ethoxylated:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 1 - 10 mg/l

Exposure time: 48 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Scenedesmus subspicatus): > 1 - 10 mg/l

Exposure time: 72 h

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: > 0,1 - 1 mg/l

1,2-benzisothiazol-3(2H)-one:

Toxicity to fish : LC50 (Cyprinodon variegatus (sheepshead minnow)): 16,7

mg/l

Exposure time: 96 h Test Type: static test

LC50 (Oncorhynchus mykiss (rainbow trout)): 2,15 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 2,9 mg/l

Exposure time: 48 h Test Type: static test

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 0,070

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,04

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

: 1

Toxicity to microorganisms : EC50 (activated sludge): 24 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

EC50 (activated sludge): 12,8 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

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



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M-Factor (Chronic aquatic : 1

toxicity)

Product:

12.2 Persistence and degradability

Biodegradability Remarks: Product contains minor amounts of not readily bio-

degradable components, which may not be degradable in

waste water treatment plants.

Components:

fluazinam (ISO):

Biodegradability : Result: Not readily biodegradable.

Residues (petroleum), catalytic reformer fractionator, sulfonated, polymers with formalde-

hyde, sodium salts:

Biodegradability Result: Not readily biodegradable.

Remarks: Based on data from similar materials

Alcohols, C13-15, branched and linear, ethoxylated:

Biodegradability Result: Readily biodegradable.

1,2-benzisothiazol-3(2H)-one:

Result: rapidly biodegradable Biodegradability

Method: OECD Test Guideline 301C

12.3 Bioaccumulative potential

Product:

Bioaccumulation Remarks: No data is available on the product itself.

Remarks: No data available

Components:

fluazinam (ISO):

Bioaccumulation Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 500 - 800 Remarks: Low potential for bioaccumulation

Partition coefficient: n-

octanol/water

log Pow: 4,67 (21 °C)

pH: 7

log Pow: 3,34 (22 °C)

pH: 9

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



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Alcohols, C13-15, branched and linear, ethoxylated:

Bioaccumulation Remarks: Bioaccumulation is unlikely.

1,2-benzisothiazol-3(2H)-one:

Bioaccumulation Species: Lepomis macrochirus (Bluegill sunfish)

Exposure time: 56 d

Bioconcentration factor (BCF): 6,62 Method: OECD Test Guideline 305

Remarks: Substance is not persistent, bioaccumulative, and

toxic (PBT).

Partition coefficient: n-

octanol/water

log Pow: 0,7 (20 °C)

pH: 7

log Pow: 0,99 (20 °C)

pH: 5

12.4 Mobility in soil

Product:

Distribution among environ-

mental compartments

: Remarks: No data is available on the product itself.

Components:

fluazinam (ISO):

Distribution among environ-

mental compartments

Remarks: Low mobility in soil

1,2-benzisothiazol-3(2H)-one:

Distribution among environmental compartments

Koc: 9,33 ml/g, log Koc: 0,97 Method: OECD Test Guideline 121 Remarks: Highly mobile in soils

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

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



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levels of 0.1% or higher.

12.7 Other adverse effects

Product:

Additional ecological infor-

mation

: An environmental hazard cannot be excluded in the event of

unprofessional handling or disposal.

Very toxic to aquatic life with long lasting effects.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : The product should not be allowed to enter drains, water

courses or the soil.

Do not contaminate ponds, waterways or ditches with chemi-

cal or used container.

Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.

Do not re-use empty containers.

Packaging that is not properly emptied must be disposed of as

the unused product.

Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number or ID number

ADN : UN 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (Fluazinam)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (Fluazinam)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (Fluazinam)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

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



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N.O.S. (Fluazinam)

IATA : Environmentally hazardous substance, liquid, n.o.s.

(Fluazinam)

14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

ADR

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 964

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 964

ger aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

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14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

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

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) Conditions of restriction for the following entries should be considered: Number on list 75, 3

If you intend to use this product as tattoo ink, please contact your vendor.

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Not applicable

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

Not applicable

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

tants (recast)

Not applicable

Not applicable

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

ort

REACH - List of substances subject to authorisation

(Annex XIV)

Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the

E1

ENVIRONMENTAL HAZARDS

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



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control of major-accident hazards involving dangerous substances.

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:

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

fluazinam (ISO)

mixture of polyorganosiloxanes and fillers

Alcohols, C13-15, branched and linear, ethoxylated

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

TECI: Not in compliance with the inventory

15.2 Chemical safety assessment

A chemical safety assessment is not required for this product (mixture).

SECTION 16: Other information

Full text of H-Statements

H302 : Harmful if swallowed. H315 : Causes skin irritation.

H317 : May cause an allergic skin reaction. H318 : Causes serious eye damage.

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



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H319 H330 H332 H361c H400 H410 H412	ľ	: Fatal if inhale : Harmful if inh : Suspected of : Very toxic to : Very toxic to	naled. f damaging the unborn child.

Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Dam. : Serious eye damage

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

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

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

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



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Classification of the mixture:		Classification procedure:	
Skin Sens. 1B	H317	Based on product data or assessment	
Eye Irrit. 2	H319	Based on product data or assessment	
Repr. 2	H361d	Based on product data or assessment	
Aquatic Acute 1	H400	Based on product data or assessment	
Aquatic Chronic 1	H410	Based on product data or assessment	

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