

Section 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier

Product Name: DRAKIX®
Product Code: 162-01-02
UFI Code: N0VQ-9NDQ-K408-9F10

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

Product Use: Fungicide

1.3 Details of the supplier of the safety data sheet

Company: Life Scientific Ltd,
Block 4,
Belfield Office Park,
Beech Hill Road,
Dublin 4
Ireland
Telephone: +353 (0) 1 2832024
Email: info@lifescientific.com
Web: www.lifescientific.com

1.4 Emergency contact information

In case of Emergency: Tel. NHS 111

Section 2. HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EU) No. 1272/2008

Aquatic Acute	Category 1	H400
Aquatic Chronic	Category 2	H410

2.2 Label Elements

Labelling according to Regulation (EU) 1272/2008

Hazard Pictograms:



Hazardous components which must be listed on the label:

- Fluopyram
- Prothioconazole

Signal Word:

Warning

Hazard Phrases:

H410 Very toxic to aquatic life with long lasting effects.

EUH208 Contains 1,2-Benzisothiazolin-3-one and 2-[2-(1-chlorocyclopropyl)-2- hydroxy-3-phenylpropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione. May cause an allergic reaction.

EUH401 To avoid risks to human health and the environment, comply with the instructions for use.

Precautionary Phrases:

P102 Keep out of reach of children.
P280 Wear eye protection/face protection.
P391 Collect spillage.
P501 Dispose of contents/container to a licensed hazardous waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste.

Other Phrases:

EUH401 To avoid risks to human health and the environment, comply with the instructions for use.
EUH208 Contains 1,2-Benzisothiazolin-3-one and 2-[2-(1-chlorocyclopropyl)-2-hydroxy-3-phenylpropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione. May cause an allergic reaction.

2.3 Other Hazards

No additional hazards known beside those mentioned.

Fluopyram: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB).
Prothioconazole: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB).

The substance/mixture does not meet the criteria for vPvB according to regulation (EC) No 1907/2006, Annex III.

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

3.1 Substances

No substances fulfil the criteria set out in Annex II, Part A of the REACH Regulation (EC) No 1907/2006.

3.2 Mixtures

Chemical Name	CAS	EC	Classification (Regulation (EC) No 1272/2008)	Concentration (% w/w)
Fluopyram	658066-35-4	6149-797-7	Aquatic Chronic 2; H411	11.79
Prothioconazole	178928-70-6	-	Aquatic Acute 1; H400 Aquatic Chronic 3; H410	11.79
1,2-Benzisothiazol-3(2H)-one (20% w/w)	2634-33-5	220-120-9	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	>0.005 – <0.095
1,2-Propanediol	57-55-6		Not classified	>1

For the full text of the H-Statements mentioned in this Section, see Section 16.

Particle characteristics

This substance/ mixture does not contain nanoforms.

Section 4. FIRST AID MEASURES

4.1 Description of first aid measures

General information: Move out of dangerous area. Remove contaminated clothing immediately and dispose of safely. Place and transport victim in stable position (lying sideways).

Inhalation:	Move to fresh air. Keep patient warm and at rest. Call a physician or Poison Control Centre immediately.
Ingestion:	If swallowed, seek medical advice immediately and show this container or label. Rinse mouth. Do NOT induce vomiting. Call a physician or poison control centre immediately.
Skin contact:	Wash off thoroughly with plenty of soap and water, if available with polyethyleneglycol 400, subsequently rinse with water. If symptoms persist, call a physician.
Eye contact:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Get medical attention if irritation develops and persists.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: None known.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physicians: There is no specific antidote available. Treat symptomatically. In case of ingestion, gastric lavage is not normally required. However, if a significant amount (more than a mouthful) has been ingested, administer activated charcoal and sodium sulphate. There is no specific antidote

Section 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Do not use high volume water jet.

5.2 Advice for firefighters

In the event of fire and/or explosion do not breathe fumes. Wear self-contained breathing apparatus and protective suit. Contain the spread of the fire-fighting media. Do not allow run-off from firefighting to enter drains or water courses.

Section 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Do not breathe vapour/spray. Use personal protective clothing. Avoid contact with spilled product or contaminated surfaces. Prevent any contamination of the skin, eyes and clothing. Wear suitable personal protective equipment (refer to section 8).

6.2 Environmental precautions

Do not allow to get into surface water, drains and ground water. If spillage enters drains leading to sewage works inform local water company immediately. If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060), the Environment Agency (England & Wales), the Scottish Environmental Protection Agency (Scotland), or the Environment and Heritage Service (Northern Ireland) if it enters surface or ground waters. Keep people and animals away.

6.3 Methods and materials for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Clean contaminated floors and objects thoroughly, observing environmental regulations. Collect and transfer the product into a properly labelled and tightly closed container. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Information regarding handling/storage can be found in section 7, exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

Section 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

No specific precautions required when handling unopened containers; follow relevant manual handling advice. No special measures necessary if stored and handled correctly. Ensure thorough ventilation of stores and work areas.

When using do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. Avoid contact with skin and eyes. Keep working clothes separately. Wash hands immediately after handling the product. Remove soiled clothing immediately and clean thoroughly before using again. Garments that cannot be cleaned must be destroyed (burnt).

7.2 Conditions for safe storage, including any incompatibilities

Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Segregate from foods and animal feeds. Store in a place accessible by authorized persons only. Keep out of reach of children. Protect from frost. Keep away from heat and direct sunlight.

Suitable materials: HDPE & Coex HDPE/EVOH/HDPE – steel case

7.3 Specific end use(s)

For the relevant identified use(s) listed in Section 1.2. Refer to the product label.

Section 8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 Control parameters

Component	CAS-No.	Control Parameters	Basis
Fluopyram	658066-35-4	0.34 mg/m ³ (TWA)	"Occupational Exposure Standard" of a similar formulation.
Prothioconazole	178928-70-6	1.4 mg/m ³ (SK-ABS)	"Occupational Exposure Standard" of a similar formulation.
1,2-Propanediol	57-55-6	10 mg/m ³ (TWA)	EH40 WEL
1,2-Propanediol (total vapour and particulates)	57-55-6	474 mg/m ³ / 150 ppm (TWA)	EH40 WEL

8.2 Exposure controls

Refer to COSHH assessment (Control of Substances Hazardous to Health (Amendment) Regulations 2004). Engineering controls should be used in preference to personal protective equipment wherever practicable. Refer also to COSHH Essentials.

Engineering control measures: Containment and/or segregation is the most reliable technical protection measure if exposure cannot be eliminated. The extent of these protection measures depends on the actual risks in use. If airborne mists or vapours are generated, use local exhaust ventilation controls. Where necessary, seek additional occupational hygiene advice.

Individual Protective measures: The use of technical measures should always have priority over the use of personal protective equipment. When selecting personal protective equipment, seek appropriate professional advice. Personal protective equipment should be certified to appropriate standards.

Personal protective equipment

In normal use and handling conditions please refer to the label. In all other cases the following recommendations would apply.

Eye protection and face: Wear goggles (conforming to EN166, Field of Use = 5 or equivalent).

Hand protection: Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time.

Wash gloves when contaminated. Dispose of when contaminated inside, when perforated or when contamination on the outside cannot be removed. Wash hands frequently and always before eating, drinking, smoking or using the toilet.

Material:	Nitrile rubber
Rate of permeability:	> 480 min
Glove thickness:	> 0.4 mm
Protective index:	Class 6
Directive:	Protective gloves complying with EN 374.

Skin and body protection: Wear standard coveralls and Category 3 Type 6 suit.
If there is a risk of significant exposure, consider a higher protective type suit.
Wear two layers of clothing wherever possible. Polyester/cotton or cotton overalls should be worn under chemical protection suit and should be professionally laundered frequently. If chemical protection suit is splashed, sprayed or significantly contaminated, decontaminate as far as possible, then carefully remove and dispose of as advised by manufacturer.

Respiratory protection: Respiratory protection is not required under anticipated circumstances of exposure.
Respiratory protection should only be used to control residual risk of short duration activities, when all reasonably practicable steps have been taken to reduce exposure at source (e.g. containment and/or local extract ventilation). Always follow respirator manufacturer's instructions regarding wearing and maintenance.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Form:	Liquid.
Colour:	Opaque white
Odour:	No noticeable odour.

Chemical properties

pH (at 20 °C):	3.63 – 4.75 (1 % dilution)
Boiling point (°C):	No data available
Melting point (°C):	No data available
Flash Point:	>105 °C.
Autoignition temperature:	413 °C.
Kinematic viscosity:	No data available.
Solubility in water:	No data available.
Relative Density (at 20 °C):	1.0476
Surface tension:	43.03 mN/m
Acidity (%w/w as H ₂ SO ₄):	0.034% w/w as H ₂ SO ₄
Assessment nano particles:	This substance/ mixture does not contain nanoforms

9.2 Other Information

9.2.1 Information with regard to physical hazard classes

Explosivity	No data available
Oxidizing properties	No data available.
Flammability	Not flammable.
Evaporation rate	No data available

9.2.2 Other safety characteristics

Other physico-chemical properties	No data available
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Section 10. STABILITY AND REACTIVITY

10.1 Reactivity

No information available.

10.2 Chemical Stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

None known. No hazardous reactions when stored and handled according to recommended instructions.

10.4 Conditions to avoid

Extremes of temperature and direct sunlight.

10.5 Incompatible material

Store only in the original container

10.6 Hazardous decomposition products

No decomposition products expected under normal conditions of use and storage.

Section 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

LD₅₀ oral (rat): >2000 mg/kg.
LD₅₀ dermal (rat): >2000 mg/kg.
Tests conducted with a similar formulation.

Acute inhalation toxicity

LC50 (Rat) > 1,633 mg/l
Exposure time: 4 h
Highest attainable concentration
Test conducted with a similar formulation.

Skin corrosion/irritation

No skin irritation (Rabbit)
Test conducted with a similar formulation.

Serious eye damage/irritation

No eye irritation (Rabbit)
Test conducted with a similar formulation.

Respiratory or skin sensitisation

Non-sensitizing. (Mouse)
OECD Test Guideline 429, local lymph node assay (LLNA)
Test conducted with a similar formulation.

Assessment STOT Specific target organ toxicity – single exposure

Fluopyram: Based on available data, the classification criteria are not met.
Prothioconazole: Based on available data, the classification criteria are not met.

Assessment STOT Specific target organ toxicity – repeated exposure

Fluopyram did not cause specific target organ toxicity in experimental animal studies.
Prothioconazole did not cause specific target organ toxicity in experimental animal studies.

Mutagenicity:

Fluopyram was not mutagenic or genotoxic in a battery of in vitro and in vivo tests.
Prothioconazole was not mutagenic or genotoxic based on the overall weight of evidence in a battery of in vitro and in vivo tests.

Carcinogenicity:

Fluopyram caused at high dose levels an increased incidence of tumours in rats in the following organ(s): Liver.
Fluopyram caused at high dose levels an increased incidence of tumours in mice in the following organ(s): Thyroid.
The tumours seen with Fluopyram were caused through a non-genotoxic mechanism, which is not relevant at low doses. The mechanism that triggers these tumours is not relevant to humans.
Prothioconazole was not carcinogenic in lifetime feeding studies in rats and mice.

Toxicity to reproduction

Fluopyram caused reproduction toxicity in a two-generation study in rats only at dose levels also toxic to the parent animals. The reproduction toxicity seen with Fluopyram is related to parental toxicity.
Prothioconazole caused reproduction toxicity in a two-generation study in rats only at dose levels also toxic to the parent animals. The reproduction toxicity seen with Prothioconazole is related to parental toxicity.

Assessment developmental toxicity

Fluopyram caused developmental toxicity only at dose levels toxic to the dams. The developmental effects seen with Fluopyram are related to maternal toxicity.
Prothioconazole caused developmental toxicity only at dose levels toxic to the dams. The developmental effects seen with Prothioconazole are related to maternal toxicity.

Aspiration hazard

Based on available data, the classification criteria are not met.

Further information

No further toxicological information is available.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

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.

11.2.2 Other information

No further toxicological information is available.

Section 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish	LC ₅₀ (<i>Oncorhynchus mykiss</i> (rainbow trout)) 12.8 mg/l Exposure time: 96 h
Toxicity to aquatic invertebrates	EC ₅₀ (<i>Daphnia magna</i> (Water flea)) 30 mg/l Exposure time: 48 h
Toxicity to aquatic plants	E _r C ₅₀ (<i>Raphidocelis subcapitata</i> (freshwater green alga)) 12.9 mg/l Growth rate; Exposure time: 72 h EC ₁₀ (<i>Raphidocelis subcapitata</i> (freshwater green alga)) 6.86 mg/l Growth rate; Exposure time: 72 h E _r C ₅₀ (<i>Skeletonema costatum</i>) 0.03278 mg/l Exposure time: 72 h The value mentioned relates to the active ingredient prothioconazole. EC ₁₀ (<i>Skeletonema costatum</i>) 0.01427 mg/l Growth rate; Exposure time: 72 h The value mentioned relates to the active ingredient prothioconazole

12.2 Persistence and degradability

Biodegradability	
Fluopyram:	Not rapidly biodegradable
Prothioconazole:	Not rapidly biodegradable.
Koc	
Fluopyram: Koc: 279	
Prothioconazole: Koc: 1765	

12.3 Bioaccumulative potential

Bioaccumulation	
Fluopyram:	Does not bioaccumulate.
Bioconcentration factor (BCF) 18	
Prothioconazole:	Does not bioaccumulate.
Bioconcentration factor (BCF) 19.	

12.4 Mobility in soil

Fluopyram:	Moderately mobile in soils
Prothioconazole:	Slightly mobile in soils

12.5 Results of PBT and vPvB assessment

Fluopyram: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB).

Prothioconazole: This substance is not considered to be persistent, bioaccumulative and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulative (vPvB).

12.6 Endocrine disrupting properties

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.

12.7 Other adverse effects

None.

Section 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste disposal procedures: Do not contaminate ponds, waterways or ditches with chemical or used container. Do not dispose of waste into sewer. In accordance with current regulations and after consultation with the site operator and with the responsible authority, the product may be taken to a waste disposal site or incineration plant. Advice may be obtained from the local waste regulation authority (part of the Environment Agency in the UK).

Contaminated packaging: Small empty containers (< 10 L) should be manually rinsed three times or rinsed thoroughly using an integrated pressure rinsing device. Add the water from the washings to sprayer at time of filling. Empty containers should be taken for local recycling or waste disposal. Do not re-use empty containers. Dispose of empty and cleaned packaging safely. Follow advice on product label and/or leaflet.

Section 14. TRANSPORT INFORMATION

Transport the product in accordance with the provisions of ADR for road, RID for rail, IMDG for the sea, and ICAO / IATA for air transport

14.1 UN Number

3082.

14.2 UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S., (PROTHIOCONAZOLE, FLUOPYRAM SOLUTION)

14.3 Transport hazard class(es)

9.

14.4 Packing group

III.

14.5 Environmental hazards

Marine pollutant	YES
Hazard No. (ADR/RID/ADN)	90
Tunnel Code	-

UK 'Carriage' Regulations

UN number	3082
UN Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PROTHIOCONAZOLE, FLUOPYRAM SOLUTION)
Transport hazard class(es)	9
Packaging Group	III

Environm. Hazardous Mark YES
Emergency action code 3Z

14.6 Special precautions for user

Please refer to section 6 to 8 of this MSDS.

14.7 Transport in bulk according to Annex II of Marpol 73/78 and the IBC code

No transport in bulk according to the IBC Code.

Section 15. REGULATORY INFORMATION

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

UK and Northern Ireland Regulatory References

This material may be subject to some or all of the following regulations (and any subsequent amendments). Users must ensure that any uses and restrictions as indicated on the label and/or leaflet are followed.

Transport

Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (SI 2009 No 1348)
Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997 (SI 1997 No 2367)
Air Navigation Dangerous Goods Regulations 2002 (SI 2002 No 2786)

Supply and Use

Chemical (Hazard Information and Packaging for Supply) Regulations 2009 (SI 2009 No 716)
Chemical (Hazard Information and Packaging for Supply) (Northern Ireland) Regulations 2009
Control of Substances Hazardous to Health Regulations 2002 (SI 2002 No 2677)
EH40 Occupational Exposure Limits - Table 1 List of approved workplace exposure limits
Control of Pesticide Regulations 1986
Dangerous Substances and Explosive Atmospheres Regulations 2002

Waste Treatment

Environmental Protection Act 1990, Part II
Environmental Protection (Duty of Care) Regulations 1991
The Waste Management Licensing Regulations 1994 (as amended)
Hazardous Waste Regulations 2005 (Replacing Special Waste Regulations 1996 as amended)
Landfill Directive
Regulation on Substances That Deplete the Ozone Layer 1994 (EEC/3093/94)
Water Resources Act 1991
Anti-Pollution Works Regulations 1999

Further Information

WHO-classification: III (Slightly hazardous)

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out on this mixture by the supplier.

Section 16. OTHER INFORMATION

Full list of relevant hazard and precautionary statements that were not given in full in sections 2 and 3.

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

H412	Harmful to aquatic life with long lasting effects.
EUH208	Contains 1,2-Benzisothiazolin-3-one and 2-[2-(1-chlorocyclopropyl)-2- hydroxy-3-phenylpropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione. May cause an allergic reaction.
EUH401	To avoid risks to human health and the environment, comply with the instructions for use.

The information presented in this document is accurate to the best of our knowledge at the date of its publication. However, the information given is designed only as a guide for the methods of handling, storage, use, transportation and disposal of the product and is not considered a warranty or quality specification. Life Scientific Limited cannot be held responsible for any loss or damage resulting from the handling, storage, use or disposal of the product. The information contained in this document relates only to this specific product.

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