SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name	CALIGULA
Product code (UVP)	84464864
UFI	6E80-S0DX-N00H-NC5Q (for Northern Ireland only)

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

Use	Fungicide

1.3 Details of the supplier of the safety data sheet

Supplier	Bayer CropScience Limited PO Box 1582 CB1 0FE Cambridge United Kingdom
Telephone	+44(0)1223 226500
FOR NORTHERN IRELAND:	Bayer CropScience Ltd Bayer Ltd 1st Floor, The Grange Offices The Grange, Brewery Road Stillorgan Co. Dublin A94 H2K7 Ireland
Telephone	+353 1 216 3300
Responsible Department	Email: gb-bcs-crop-regulatory-affairs@bayer.com

1.4 Emergency telephone no.

Emergency telephone no.	0330 678 3382 (24 hr) For Medical Professionals: You can also contact the relevant NPIS. For Members to the Public: You can contact NHS111 (for GB) or your local GP (for Northern Ireland) National Poisons Information Centre UK: 0344 892 0111 National Poisons Information Centre Dublin: +353 1 809 2166

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, as amended.

Short-term (acute) aquatic hazard: Category 1
H400 Very toxic to aquatic life.

Long-term (chronic) aquatic hazard: Category 2
H411 Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, as amended.

Hazard label for supply/use required.

Hazardous components which must be listed on the label:

- Fluopyram
- Prothioconazole

Signal word: Warning

Hazard statements

H410	Very toxic to aquatic life with long lasting effects.
EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
EUH208	Contains 1,2-benzisothiazolin-3-one, reaction mass of 5-chloro-2- methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1), 2-[2-(1-chlorocyclopropyl)-2-hydroxy-3-phenylpropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione. May produce an allergic reaction.

Precautionary statements

P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P410	Protect from sunlight.
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.

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).

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

Chemical nature

Suspo-emulsion (SE)
Fluopyram/Prothioconazole 125:125 g/l

Hazardous components

Hazard statements according to Regulation (EC) No. 1272/2008

Name	CAS-No. / EC-No. / REACH Reg. No.	Classification REGULATION (EC) No 1272/2008	Conc. [%]
Fluopyram	658066-35-4 619-797-7	Aquatic Chronic 2, H411	11.77
Prothioconazole	178928-70-6	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	11.77
1,2-Benzisothiazol-3(2H)-one	2634-33-5 01-2120761540-60-XXXX	Acute Tox. 4, H302 Acute Tox. 2, H330 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	> 0.005 – < 0.05
1,2-Propanediol	57-55-6 01-2119456809-23-0132	Not classified	> 1.00

Further information

1,2-Benzisothiazol-3(2H)-one	2634-33-5	SCL: Skin Sens. 1A; H317: SCL >= 0.036 %

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

Particle characteristics

This substance/ mixture does not contain nanoforms (according to REACH Regulation)

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General advice	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 center 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.
Ingestion	Do NOT induce vomiting. Call a physician or poison control center immediately. Rinse mouth.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms	No symptoms known or expected.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment	Treat symptomatically. 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

Suitable	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable	High volume water jet

5.3 Advice for firefighters

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

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Precautions	Avoid contact with spilled product or contaminated surfaces. Use personal protective equipment.

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).

6.3 Methods and materials for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

Information regarding safe handling, see section 7.
Information regarding personal protective equipment, see section 8.
Information regarding waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling

No specific precautions required when handling unopened packs/containers; follow relevant manual handling advice. Ensure adequate ventilation.

Hygiene measures

Avoid contact with skin, eyes and clothing. Keep working clothes separately. Wash hands before breaks and 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

Requirements for storage areas and containers

Keep containers tightly closed in a dry, cool and well-ventilated place. Store in original container. Store in a place accessible by authorized persons only. Protect from frost. Keep away from direct sunlight.

Advice on common storage

Keep away from food, drink and animal feedingstuffs.

Suitable materials

HDPE - steel case
Coex HDPE/EVOH/HDPE - steel case

7.3 Specific end use(s)

Refer to the label and/or leaflet.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components	CAS-No.	Control parameters	Update	Basis
Fluopyram	658066-35-4	0.34 mg/m3 (TWA)		OES BCS*
Prothioconazole	178928-70-6	1.4 mg/m3 (SK-ABS)		OES BCS*
1,2-Propanediol	57-55-6	10 mg/m3	2007	EH40 WEL

(Particulate.)		(TWA)		
1,2-Propanediol (Total vapour and particulates.)	57-55-6	474 mg/m3/150 ppm (TWA)	2007	EH40 WEL

*OES BCS: Internal Bayer AG, Crop Science Division "Occupational Exposure Standard"

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.

Personal protective equipment
In normal use and handling conditions please refer to the label and/or leaflet. In all other cases the following recommendations would apply.

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.

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.

Eye protection

Wear goggles (conforming to EN166, Field of Use = 5 or equivalent).

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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form	Liquid
Colour	white to beige
Odour	weak, characteristic
Odour Threshold	No data available
Melting point/ range	No data available
Boiling Point	No data available
Flammability	No data available
Upper explosion limit	No data available
Lower explosion limit	No data available
Flash point	> 100 °C Not relevant; aqueous solution
Auto-ignition temperature	405 °C
Self-accelarating decomposition temperature (SADT)	No data available
pH	5.0 - 8.0 (100 %) (23 °C)
Viscosity, dynamic	No data available
Viscosity, kinematic	No data available
Water solubility	No data available
Partition coefficient: n-octanol/water	Fluopyram: log Pow: 3.3 Prothioconazole: log Pow: 3.82 (20 °C) (pH 7)
Surface tension	37 mN/m (25 °C)
Vapour pressure	No data available
Density	ca. 1.06 g/cm³ (20 °C)
Relative density	No data available
Relative vapour density	No data available
Assessment nano particles	This substance/ mixture does not contain nanoforms (according to REACH Regulation)
Particle size	No data available

9.2 Other information

Explosivity	Not explosive
Oxidizing properties	No oxidizing properties
Evaporation rate	No data available
Other physico-chemical properties	Further safety related physical-chemical data are not known.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	Stable under normal conditions.
10.2 Chemical stability	Stable under recommended storage conditions.
10.3 Possibility of hazardous reactions	No hazardous reactions when stored and handled according to prescribed instructions.
10.4 Conditions to avoid	Extremes of temperature and direct sunlight.
10.5 Incompatible materials	Store only in the original container.
10.6 Hazardous decomposition products	No decomposition products expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute oral toxicity	LD50 (Rat) > 2,000 mg/kg
Acute inhalation toxicity	LC50 (Rat) > 1,633 mg/l Exposure time: 4 h Highest attainable concentration.
Acute dermal toxicity	LD50 (Rat) > 2,000 mg/kg
Skin corrosion/irritation	No skin irritation (Rabbit)
Serious eye damage/eye irritation	No eye irritation (Rabbit)
Respiratory or skin sensitisation	Non-sensitizing. (Mouse) OECD Test Guideline 429, local lymph node assay (LLNA)

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.

Assessment 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.

Assessment 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.

Assessment 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

Endocrine disrupting properties

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

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish	LC50 (Oncorhynchus mykiss (rainbow trout)) 12.8 mg/l Exposure time: 96 h
Toxicity to aquatic invertebrates	EC50 (Daphnia magna (Water flea)) 30 mg/l Exposure time: 48 h
Toxicity to aquatic plants	ErC50 (Raphidocelis subcapitata (freshwater green alga)) 12.9 mg/l

Growth rate; Exposure time: 72 h

EC10 (Raphidocelis subcapitata (freshwater green alga)) 6.86 mg/l
Growth rate; Exposure time: 72 h

ErC50 (Skeletonema costatum) 0.03278 mg/l
Exposure time: 72 h
The value mentioned relates to the active ingredient prothioconazole.

EC10 (Skeletonema costatum) 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: Bioconcentration factor (BCF) 18
Does not bioaccumulate.
Prothioconazole: Bioconcentration factor (BCF) 19
Does not bioaccumulate.

12.4 Mobility in soil

Mobility in soil Fluopyram: mobile in soil
Prothioconazole: criterion of mobility not fulfilled

12.5 Results of PBT and vPvB assessment

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

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

12.7 Other adverse effects

Additional ecological information No other effects to be mentioned.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product	In accordance with current regulations and, if necessary, after consultation with the site operator and/or 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 containers (< 10 l or < 10 kg) should be rinsed thoroughly using an integrated pressure rinsing device, or, by manually rinsing three times. Add washings to sprayer at time of filling. Dispose of empty and cleaned packaging safely. Follow advice on product label and/or leaflet.

SECTION 14: TRANSPORT INFORMATION

ADR/RID/ADN

14.1 UN number	**3082**
14.2 Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PROTHIOCONAZOLE, FLUOPYRAM SOLUTION)
14.3 Transport hazard class(es)	9
14.4 Packaging Group	III
14.5 Environm. Hazardous Mark	YES
Hazard no.	90
Tunnel Code	-

This classification is in principle not valid for carriage by tank vessel on inland waterways. Please refer to the manufacturer for further information.

IMDG

14.1 UN number	**3082**
14.2 Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PROTHIOCONAZOLE, FLUOPYRAM SOLUTION)
14.3 Transport hazard class(es)	9
14.4 Packaging Group	III
14.5 Marine pollutant	YES

IATA

14.1 UN number	**3082**
14.2 Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PROTHIOCONAZOLE, FLUOPYRAM SOLUTION)
14.3 Transport hazard class(es)	9
14.4 Packaging Group	III
14.5 Environm. Hazardous Mark	YES

UK 'Carriage' Regulations

14.1 UN number	**3082**
14.2 Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PROTHIOCONAZOLE, FLUOPYRAM SOLUTION)
14.3 Transport hazard class(es)	9

14.4 Packaging Group	III
14.5 Environm. Hazardous Mark	YES
Emergency action code	3Z

14.6 Special precautions for user
See sections 6 to 8 of this Safety Data Sheet.

14.7 Transport in bulk according to IMO instruments
No transport in bulk according to the IBC Code.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/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)

SECTION 16: OTHER INFORMATION

Text of the hazard statements mentioned in Section 3

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.

Abbreviations and acronyms

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute toxicity estimate
CAS-Nr.	Chemical Abstracts Service number
Conc.	Concentration
EC-No.	European community number
ECx	Effective concentration to x %
EH40 WEL	Worker Exposure Limit
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
EN	European Standard
EU	European Union
IATA	International Air Transport Association
IBC	International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (IBC Code)
ICx	Inhibition concentration to x %
IMDG	International Maritime Dangerous Goods
LCx	Lethal concentration to x %
LDx	Lethal dose to x %
LOEC/LOEL	Lowest observed effect concentration/level
MARPOL	MARPOL: International Convention for the prevention of marine pollution from ships
N.O.S.	Not otherwise specified
NOEC/NOEL	No observed effect concentration/level
OECD	Organization for Economic Co-operation and Development
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SI	Statutory Instrument
TWA	Time weighted average
UN	United Nations
WHO	World health organisation

The above information is intended to give general health and safety guidance on the storage and transport of the product.
It is not intended to apply to the use of the product for which purposes the product label and any appropriate technical usage literature available should be consulted and any relevant licenses, consents or approvals complied with.
The requirements or recommendations of any relevant site or working procedure, system or policy in force or arising from any risk assessment involving the substance or product should take precedence

over any of the guidance contained in this safety data sheet where there is a difference in the information given.
The information provided in this safety data sheet is accurate at the date of publication and will be updated as and when appropriate.
No liability will be accepted for any injury, loss or damage resulting from any failure to take account of information or advice contained in this safety data sheet.

Reason for Revision: The following sections have been revised: Section 3: Composition / Information on Ingredients.

Changes since the last version are highlighted in the margin. This version replaces all previous versions.