



**BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC
65+65+130 G/L**

Version 3 / IRL
102000027828

1/12
Revision Date: 23.10.2019
Print Date: 30.09.2020

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

1.1 Product identifier

Trade name BIXAFEN+FLUOPYRAM+PROTHIOCONAZOLE EC 65+65+130 G/L
Product code (UVP) 80513666, 86804662

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 Ltd
Bayer Ltd
The Atrium, Blackthorn Road
Sandyford
Dublin 18
Ireland

Telephone +353-1-2999313

Responsible Department Email: ukcropsupport@bayer.com

1.4 Emergency telephone no.

Emergency telephone no. 00800 1020 3333 (24 hr)

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.

Acute toxicity: Category 4

H302 Harmful if swallowed.

Skin sensitisation: Category 1B

H317 May cause an allergic skin reaction.

Serious eye damage: Category 1

H318 Causes serious eye damage.

Specific target organ toxicity - single exposure: Category 3

H335 May cause respiratory irritation.

Acute aquatic toxicity: Category 1

H400 Very toxic to aquatic life.

Chronic aquatic toxicity: Category 1

H410 Very 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



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packaging of substances and mixtures, as amended.

Hazard label for supply/use required.

Hazardous components which must be listed on the label:

- Bixafen
- Fluopyram
- Prothioconazole
- N,N-Dimethyl decanamide



Signal word: Danger

Hazard statements

- | | |
|--------|---|
| H302 | Harmful if swallowed. |
| H317 | May cause an allergic skin reaction. |
| H318 | Causes serious eye damage. |
| H335 | May cause respiratory irritation. |
| 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. |

Precautionary statements

- | | |
|--------------------|--|
| P280 | Wear protective gloves/ protective clothing/ eye protection/ face protection. |
| P305 + P351 + P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P310 | Immediately call a POISON CENTER/doctor/ physician. |
| P391 | Collect spillage. |
| P410 | Protect from sunlight. |
| P501 | Dispose of contents/container to a licensed hazardous waste disposal contractor or collection site, except for triple rinsed empty containers which can be disposed of as non-hazardous waste. |

2.3 Other hazards

No other hazards known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Chemical nature

Emulsifiable concentrate (EC)
Prothioconazole/Fluopyram/Bixafen 130:65:65 g/l

Hazardous components

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

Name	CAS-No. / EC-No. /	Classification	Conc. [%]
		REGULATION (EC) No	

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	REACH Reg. No.	1272/2008	
Bixafen	581809-46-3	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	6.37
Fluopyram	658066-35-4 619-797-7	Aquatic Chronic 2, H411	6.37
Prothioconazole	178928-70-6	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	12.7
2-Ethylhexanol propylene ethyleneglycol ether	64366-70-7	Aquatic Chronic 3, H412	> 1 – < 25
N,N-Dimethyl decanamide	14433-76-2 238-405-1 01-2119485027-36-XXXX	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Chronic 3, H412	> 25

Further information

Bixafen	581809-46-3	M-Factor: 10 (acute)
Prothioconazole	178928-70-6	M-Factor: 10 (acute), 1 (chronic)

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

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.
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.



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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

5.2 Special hazards arising from the substance or mixture In the event of fire the following may be released: Hydrogen cyanide (hydrocyanic acid), Carbon monoxide (CO), Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment for firefighters In the event of fire and/or explosion do not breathe fumes. In the event of fire, wear self-contained breathing apparatus.

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 If the product contaminates rivers and lakes or drains inform respective authorities.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up Clean contaminated floors and objects thoroughly, observing environmental regulations. Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

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 Use only in area provided with appropriate exhaust ventilation.

Advice on protection against fire and explosion Keep away from heat and sources of ignition.

Hygiene measures Avoid contact with skin, eyes and clothing. Keep working clothes separately. Wash hands before breaks and immediately after handling the product. Wash hands immediately after work, if necessary take a



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

Advice on common storage Keep away from food, drink and animal feedingstuffs.

Suitable materials Coextruded containers with an internal barrier layer made of ethylene vinyl alcohol copolymer (EVOH)

7.3 Specific end use(s) Refer to the label and/or leaflet.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No known occupational limit values.

8.2 Exposure controls

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 Wear respirator with an organic vapours and gas filter mask (protection factor 10) conforming to EN140 type A or equivalent. 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 4 suit.

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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.

General protective measures If product is handled while not enclosed, and if contact may occur: Complete suit protecting against chemicals

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties**

Form	Liquid, clear to slightly turbid
Colour	brown
Odour	weak, characteristic
pH	4.0 - 6.0 (1 %) (23 °C) (deionized water)
Flash point	148 °C
Auto-ignition temperature	360 °C
Density	ca. 1.02 g/cm ³ (20 °C)
Partition coefficient: n-octanol/water	Bixafen: log Pow: 3.3 (40 °C) Fluopyram: log Pow: 3.3 Prothioconazole: log Pow: 3.82 (20 °C) (pH 7) N,N-Dimethyldecanamide: log Pow: 2.46
Impact sensitivity	Not impact sensitive.
Oxidizing properties	No oxidizing properties
Explosivity	Not explosive 92/69/EEC, A.14 / OECD 113

9.2 Other information Further safety related physical-chemical data are not known.

SECTION 10: STABILITY AND REACTIVITY**10.1 Reactivity**

Thermal decomposition 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.



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- 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 toxicological effects

- Acute oral toxicity** LD50 (Rat) > 300 - 2,000 mg/kg
- Acute inhalation toxicity** During intended and foreseen applications, no respirable aerosol is formed.
- Irritating to respiratory system.
The value mentioned relates to N,N-dimethylacetamide.
- Acute dermal toxicity** LD50 (Rat) > 2,000 mg/kg
- Skin corrosion/irritation** No skin irritation (Rabbit)
- Serious eye damage/eye irritation** Risk of serious damage to eyes. (Rabbit)
- Respiratory or skin sensitisation** Skin: Sensitising (Mouse)
OECD Test Guideline 429, local lymph node assay (LLNA)

Assessment STOT Specific target organ toxicity – single exposure

Bixafen: Based on available data, the classification criteria are not met.
Fluopyram: Based on available data, the classification criteria are not met.
Prothioconazole: Based on available data, the classification criteria are not met.
N,N-Dimethyldecan-1-amide: May cause respiratory irritation.

Assessment STOT Specific target organ toxicity – repeated exposure

Bixafen did not cause human relevant specific target organ toxicity in experimental animal studies.
Fluopyram did not cause specific target organ toxicity in experimental animal studies.
Prothioconazole did not cause specific target organ toxicity in experimental animal studies.
N,N-Dimethyldecanamide did not cause specific target organ toxicity in experimental animal studies.

Assessment mutagenicity

Bixafen was not mutagenic or genotoxic in a battery of in vitro and in vivo tests.
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.
N,N-Dimethyldecanamide was not genotoxic in a battery of in vitro tests.

Assessment carcinogenicity

Bixafen was not carcinogenic in lifetime feeding studies in rats and mice.
Fluopyram caused at high dose levels an increased incidence of tumours in rats in the following organ(s): Liver.


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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.

N,N-Dimethyldecanamide is not considered carcinogenic.

Assessment toxicity to reproduction

Bixafen did not cause reproductive toxicity in a two-generation study in rats.

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.

N,N-Dimethyldecanamide is not considered a reproductive toxicant at non-maternally toxic dose levels.

Assessment developmental toxicity

Bixafen did not cause developmental toxicity in rats and rabbits.

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.

N,N-Dimethyldecanamide did not cause developmental toxicity in rats and rabbits.

Aspiration hazard

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

Further information

No further toxicological information is available.

SECTION 12: ECOLOGICAL INFORMATION
12.1 Toxicity

Toxicity to fish	LC50 (Oncorhynchus mykiss (rainbow trout)) 1.77 mg/l static test; Exposure time: 96 h
Toxicity to aquatic invertebrates	EC50 (Daphnia magna (Water flea)) 3.39 mg/l Exposure time: 48 h
Toxicity to aquatic plants	EC50 (Raphidocelis subcapitata (freshwater green alga)) 2.97 mg/l Growth rate; Exposure time: 72 h
	EC10 (Skeletonema costatum) 0.01427 mg/l Growth rate; Exposure time: 72 h The value mentioned relates to the active ingredient prothioconazole.
	ErC50 (Skeletonema costatum) 0.03278 mg/l Exposure time: 72 h The value mentioned relates to the active ingredient prothioconazole.

12.2 Persistence and degradability

Biodegradability	Bixafen: Not rapidly biodegradable
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Fluopyram:
Not rapidly biodegradable
Prothioconazole:
Not rapidly biodegradable
N,N-Dimethyldecanamide:
rapidly biodegradable

Koc
Bixafen: Koc: 3869
Fluopyram: Koc: 279
Prothioconazole: Koc: 1765

12.3 Bioaccumulative potential

Bioaccumulation
Bixafen: Bioconcentration factor (BCF) 695
Does not bioaccumulate.
Fluopyram: Bioconcentration factor (BCF) 18
Does not bioaccumulate.
Prothioconazole: Bioconcentration factor (BCF) 19
Does not bioaccumulate.
N,N-Dimethyldecanamide:
Does not bioaccumulate.

12.4 Mobility in soil

Mobility in soil
Bixafen: Slightly mobile in soils
Fluopyram: Moderately mobile in soils
Prothioconazole: Slightly mobile in soils
N,N-Dimethyldecanamide: Slightly mobile in soils

12.5 Results of PBT and vPvB assessment

PBT and vPvB assessment
Bixafen: 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).
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).
N,N-Dimethyldecanamide: 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 Other adverse effects

Additional ecological information
No other effects to be mentioned.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product
It is best to use all of the product in accordance with label directions. If it is necessary to dispose of unused product, please follow container label instructions and applicable local guidelines.



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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.
Contaminated packaging	Not completely emptied packagings should be disposed of as hazardous waste.
Waste key for the unused product	02 01 08* agrochemical waste containing hazardous substances

SECTION 14: TRANSPORT INFORMATION

ADR/RID/ADN

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

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. (BIXAFEN 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. (BIXAFEN SOLUTION)
14.3 Transport hazard class(es)	9
14.4 Packaging Group	III
14.5 Environm. Hazardous Mark	YES

14.6 Special precautions for user

See sections 6 to 8 of this Safety Data Sheet.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

No transport in bulk according to the IBC Code.



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SECTION 15: REGULATORY INFORMATION

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

Republic of Ireland Regulations

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.

Supply and Use

European Communities (Prohibition of Certain Active Substances in Plant Protection Products) Regulations 1981 (SI No 320/1981)

European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations 2003 (SI No 83/2003)

European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations 2001 (SI No 624/2001)

2010 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001 (SI No 619/2001)

Waste Treatment

Landfill Directive

Regulation on Substances That Deplete the Ozone Layer 1994 (EEC/3093/94)

Further information

WHO-classification: II (Moderately hazardous)

15.2 Chemical safety assessment

A chemical safety assessment is not required.

SECTION 16: OTHER INFORMATION

Text of the hazard statements mentioned in Section 3

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
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.

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


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Conc.	Concentration
EC-No.	European community number
ECx	Effective concentration to x %
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELV	Exposure Limit Value
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 information contained within this Safety Data Sheet is in accordance with the guidelines established by Regulation (EU) 1907/2006 and Regulation (EU) 2015/830 amending Regulation (EU) No 1907/2006 and any subsequent amendments. This data sheet complements the user's instructions, but does not replace them. The information it contains is based on the knowledge available about the product concerned at the time it was compiled. Users are further reminded of the possible risks of using a product for purposes other than those for which it was intended. The required information complies with current EEC legislation. Addressees are requested to observe any additional national requirements.

Reason for Revision: Reviewed and updated for general editorial purposes. Section 2: Hazards Identification. Section 3: Composition / Information on Ingredients. Section 12. Ecological information.

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