

# REGISTRATION REPORT

## Part B

### Section 1: Identity

### Section 2: Physical and chemical properties

### Section 4: Further information

Detailed summary of the risk assessment

Product code: GLOB2111F

Product name(s): Starinta

Chemical active substance(s):

Bixafen, 125 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: December 2023

zRMS Assessment : 09/08/2024

Version after commenting : 15/11/2024

## Version history

When	What
August 2024	zRMS assessment
November 2024	zRMS: after first round of commenting

## Table of Contents

<b>1</b>	<b>Section 1: Identity of the plant protection product.....</b>	<b>4</b>
1.1	Applicant (KCP 1.1) .....	4
1.2	Producer of the plant protection product and of the active substances (KCP 1.2) .....	4
1.2.1	Producer(s) of the preparation .....	4
1.2.2	Producer(s) of the active substance(s) .....	4
1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s) .....	4
1.2.3.1	Bixafen .....	4
1.3	Trade names and producer's development code numbers for the preparation (KCP 1.3) .....	5
1.4	Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4) .....	5
1.4.1	Composition of the plant protection product (KCP 1.4.1) .....	5
1.4.2	Information on the active substance(s) (KCP 1.4.2) .....	5
1.4.3	Information on safeners, synergists and co-formulants (KCP 1.4.3) .....	5
1.5	Type and code of the plant protection product (KCP 1.5) .....	6
1.6	Function (KCP 1.6) .....	6
<b>2</b>	<b>Section 2: Physical, chemical and technical properties of the plant protection product .....</b>	<b>7</b>
<b>3</b>	<b>Section 3 is presented as a separate document .....</b>	<b>17</b>
<b>4</b>	<b>Section 4: Further information on the plant protection product .....</b>	<b>18</b>
4.1	Packaging and Compatibility with the Preparation (KCP 4.4) .....	18
4.2	Procedures for Cleaning Application Equipment .....	20
4.2.1	Procedures for cleaning application equipment and protective clothing .....	20
4.2.2	Effectiveness of the cleaning procedures (KCP 4.2) .....	20
4.3	Recommended methods and precautions (KCP 4.2) .....	21
4.3.1	Procedures for storage .....	21
4.3.2	Transport .....	21
4.3.3	Firefighting measures .....	21
4.3.4	Exposure control .....	21
4.3.5	Environmental precautions .....	21
4.4	Emergency measures (KCP 4.3) .....	22
4.4.1	Accidental release measures .....	22
4.4.2	First aid measures .....	22
4.5	Procedures for destruction and neutralisation (KCP 4.5) .....	22
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation .....</b>	<b>23</b>
<b>Appendix 2</b>	<b>Additional data on the physical, chemical and technical properties of the active substance .....</b>	<b>27</b>
A 2.1	Bixafen .....	27

State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

Sufficient data on identity, physical and chemical properties and other information are **not** available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- Missing storage stability study at ambient temperature – study is ongoing. It is required to set a shelf-life for the PPP from real time storage test at ambient temperature and may be evaluated in post-registration at national level.

## **1 Section 1: Identity of the plant protection product**

### **1.1 Applicant (KCP 1.1)**

Name: Globachem NV  
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Lichtenberglaan 2019  
3800 Sint-Truiden  
Belgium  
Contact :   
Telephone number: +32 11 26 34 20  
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E-mail:

### **1.2 Producer of the plant protection product and of the active substances (KCP 1.2)**

#### **1.2.1 Producer(s) of the preparation**

Confidential information or data are provided separately (Part C).

#### **1.2.2 Producer(s) of the active substance(s)**

Confidential information or data are provided separately (Part C).

#### **1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)**

##### **1.2.3.1 Bixafen**

Bixafen min. 980 g/kg

The source of the active ingredient has been confirmed to be equivalent to the annex I source by the RMS

Poland.

Further information relating to the impurities is confidential information – data is provided separately (Part C).

### 1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Please refer to Registration Report Part A for the relevant country

Company code number: GLOB2111F

### 1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

#### 1.4.1 Composition of the plant protection product (KCP 1.4.1)

GLOB2111F was not the representative formulation during the EU evaluation of bixafen.

**Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)**

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Bixafen	125	<del>112.5 – 137.5</del> 117.5 – 132.5	127.6	12.7

\* Based on the minimum purity of the active substance declared for registration in the active substance dossiers.

\*\* Based on the density of the formulation = 1.01 g/mL.

For bixafen there are no toxicologically, ecotoxicologically or environmentally relevant impurities present.

#### 1.4.2 Information on the active substance(s) (KCP 1.4.2)

**Table 1.4-4: Information on bixafen**

Type	Name/Code Number
ISO common name	Bixafen
CAS No.	581809-46-3
EC No.	Not allocated (642-423-9: List number assigned by ECHA)
CIPAC No.	819

#### 1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

There are no safeners or synergists in the formulation. Information regarding the co-formulants is confidential.

CONFIDENTIAL information is provided separately (Part C).

### **1.5 Type and code of the plant protection product (KCP 1.5)**

Type: Emulsifiable concentrate

[Code: EC]

### **1.6 Function (KCP 1.6)**

Fungicide.

## 2                    **Section 2: Physical, chemical and technical properties of the plant protection product**

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a brownish yellow liquid, with a mild aromatic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 361.1 °C. In aqueous solution, it has a pH value around 5.76 at 25 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE/PA*, *HDPE/F*. Its technical characteristics are acceptable for a *emulsifiable concentrate* formulation.

The intended concentration of use is 0.33% to 1.0%.

### **zRMS comments**

A shelf-life of at least 2 years was evaluated based on the low and high temperature stability tests. Storage stability study at ambient temperature is ongoing. It is required to set a shelf-life for the PPP from real time storage test at ambient temperature and may be evaluated in post-registration at national level.

### **Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only**

No implications for labelling from physical chemical part.

### **Notifier Proposals for Risk and Safety Phrases (KCP 12)**

None.

### **Compliance with FAO specifications:**

The product GLOB2111F complies with FAO specifications.

### **Formulation used for tests**

The product used in the tests has the same composition as the one cited in Part C. It contains 125 g/L bixafen and all other co-formulants were the same and had the same concentration.

**Table 2-1: Physical, chemical and technical properties of the plant protection product**

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual observation	GLOB2111F Batch: KS160222-02	Color: Brownish yellow Odor: Mild aromatic Physical state: liquid	Y	Kishora, K. S., 2023a	<b>Accepted</b>
Explosive properties (KCP 2.2.1)	Theoretical certificate	/	No explosive properties	N	Kishora, K. S., 2023b	<b>Accepted</b> Based on the information of ingredients of PPP. The ingredients of test item are not classified as explosive.
Oxidizing properties (KCP 2.2.2)	Theoretical certificate	/	No oxidising properties	N	Kishora, K. S., 2023b	<b>Accepted</b> Based on the information of ingredients of PPP. The ingredients of test item are not classified as oxidising.
Flash point (KCP 2.3.1)	EEC A.9	GLOB2111F Batch: KS160222-02	The sample flashed at $113.1 \pm 0.3$ °C	Y	Kishora, K. S., 2023c	<b>Accepted</b> The determination of flash point of test item was carried out using Pensky-Martens Flash Point apparatus in accordance with CIPAC Method MT 12 and EEC A.9 method. The flash point of test item is 113°C. The test item is not

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						classified, according to CLP Regulation, as flammable.
Flammability (KCP 2.3.2)	-	-	-			
Self-heating (KCP 2.3.3)	EEC A.15	GLOB2111F Batch: KS160222-02	The sample auto-ignited at $361.1 \pm 0.2$ °C	Y	Kishora, K. S., 2023d	<b>Accepted</b> Auto-ignition temperature of test item is 361°C.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	GLOB2111F Batch: KS160222-02	pH neat formulation: $4.11 \pm 0.01$ at 25°C. Acidity or alkalinity not required as the pH was found to be between 4 and 10	Y	Kishora, K. S., 2023a	<b>Accepted</b> The pH was not less than 4 and also not higher than 10, the acidity/alkalinity was not tested.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	GLOB2111F Batch: KS160222-02	pH of 1% w/v aqueous solution: $5.76 \pm 0.06$ at 25°C.	Y	Kishora, K. S., 2023a	<b>Accepted</b>
Viscosity (KCP 2.5.1)	CIPAC MT 192	GLOB2111F Batch: KS160222-02	At $20 \pm 0.2$ °C: from 167.0 to 180.0 mPa.s At $40 \pm 0.2$ °C: from 130.4 to 152.0 mPa.s	Y	Kishora, K. S., 2023e	<b>Accepted</b> Determination of viscosity of test item was measured using rotational viscometer. The viscosity was measured using a single spindle at 3 different speeds (40, 60 and 80 rpm).
Surface tension (KCP 2.5.2)	EEC A.5	GLOB2111F Batch: KS160222-	At the highest in use concentration (1.0% v/v) $41.766 \pm 0.117$ dynes/cm at 20.3 °C Neat formulation	Y	Kishora, K. S., 2023f	<b>Accepted</b> The surface tension of test item was measured

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments																			
		02	38.786 ± 0.113 dynes/cm at 20.1 °C					at maximum recommended in use concentration and for neat formulation. The surface tension is below 60 mN/m, the product is surface active.																			
Relative density (KCP 2.6.1)	EEC A.3	GLOB2111F Batch: KS160222-02	1.006 ± 0.001 g/mL at 20.2 °C			Y	Kishora, K. S., 2023g	Accepted																			
Bulk density (KCP 2.6.2)	-	-	Not necessary for an EC formulation					Accepted																			
Storage Stability after 14 days at 54° C (KCP 2.7.1)		GLOB2111F Batch: KS160222-02	<table><tr><td></td><td>Before storage</td><td>After storage</td></tr><tr><td>Appearance</td><td>Color: Brownish yellow Odor: Mild aromatic Physical state: liquid</td><td>Color: Brownish yellow Odor: Mild aromatic Physical state: liquid</td></tr><tr><td>A.I. content</td><td>124.6 ± 1.2 g/L</td><td>124.4 ± 1.2 g/L</td></tr><tr><td>pH 1 % dilution (CIPAC MT 75.3)</td><td>5.76 ± 0.06</td><td>5.73 ± 0.03</td></tr><tr><td>pH neat (CIPAC MT 75.3)</td><td>4.11 ± 0.02</td><td>4.12 ± 0.02</td></tr><tr><td>Emulsion stability (MT 36.3)</td><td colspan="2">No formation of froth, free oil, cream or solid matter was observed for both dose rates (0.25% and 1.0 % v/v)) with standard CIPAC water D and A</td></tr><tr><td>Stability of packaging HDPE/PA and</td><td colspan="2">No perforations, leakage, discoloration or darkening. There was no significant change in weight</td></tr></table>		Before storage	After storage	Appearance	Color: Brownish yellow Odor: Mild aromatic Physical state: liquid	Color: Brownish yellow Odor: Mild aromatic Physical state: liquid	A.I. content	124.6 ± 1.2 g/L	124.4 ± 1.2 g/L	pH 1 % dilution (CIPAC MT 75.3)	5.76 ± 0.06	5.73 ± 0.03	pH neat (CIPAC MT 75.3)	4.11 ± 0.02	4.12 ± 0.02	Emulsion stability (MT 36.3)	No formation of froth, free oil, cream or solid matter was observed for both dose rates (0.25% and 1.0 % v/v)) with standard CIPAC water D and A		Stability of packaging HDPE/PA and	No perforations, leakage, discoloration or darkening. There was no significant change in weight		Y	Kishora, K. S., 2023a	Accepted Based on the result of accelerated storage stability study, PPP was concluded to be stable when stored at the elevated temperature of 54°C±2°C for 14 days.  The PPP stored at both ambient temperature and elevated temperature 54°C±2°C (aged dample) was analysed for ist active ingredient content, appearance, pH, emulsion stability and stability of packaging
	Before storage	After storage																									
Appearance	Color: Brownish yellow Odor: Mild aromatic Physical state: liquid	Color: Brownish yellow Odor: Mild aromatic Physical state: liquid																									
A.I. content	124.6 ± 1.2 g/L	124.4 ± 1.2 g/L																									
pH 1 % dilution (CIPAC MT 75.3)	5.76 ± 0.06	5.73 ± 0.03																									
pH neat (CIPAC MT 75.3)	4.11 ± 0.02	4.12 ± 0.02																									
Emulsion stability (MT 36.3)	No formation of froth, free oil, cream or solid matter was observed for both dose rates (0.25% and 1.0 % v/v)) with standard CIPAC water D and A																										
Stability of packaging HDPE/PA and	No perforations, leakage, discoloration or darkening. There was no significant change in weight																										

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
			HDPE-F (visual assessment)				<p>(HDPE/PA and HDPE-F) at the end of the 14 days of storage period. Based on the results of the study, it was concluded that the active ingredient content, color, odor, physical state, pH, emulsion stability for sample stored at elevated temperature of 54°C±2°C for 14 days were well compared with that of the results obtained for the test item stored at ambient temperature.</p> <p>The test item found to be non-corrosive for HDPE/PA and HDPE-F commercial containers as there was no significant change in the weight of commercial containers and there was not any perforations, leakage, discolorations and darkening found after storage at elevated temperature for 14 days.</p> <p>Accepted The content of active</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>substance – Bixafen - in PPP was determined by High Performance Liquid Chromatography (HPLC) equipped with DAD and PC based data system at wavelength measuring 238 nm. The method was developed and validated in GLP laboratory (the method was validated according to SANCO 3030/99 rev. 5). The loss of active substance after 14 days storage of test item at 54±2°C was almost negligible. It is recognised that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the preparation.</p>
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required as GLOB2111F is stable after storage for 14 days at 54 °C.			<b>Accepted</b>
Minimum content after heat stability testing	In house method	GLOB2111F Batch:	Pre-storage: 124.6 ± 1.2 g/L equivalent to 99.68 % of the declared	Y	Kishora, K. S., 2023a	<b>Accepted</b> The content of active

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.3)		KS160222-02	amount. Storage for 2 weeks at 54°C: 124.4 g/L equivalent to 99.52 % of the declared amount.			substance – Bixafen - in PPP was determined by High Performance Liquid Chromatography (HPLC) equipped with DAD and PC based data system at wavelength measuring 238 nm. The method was developed and validated in GLP laboratory (the method was validated according to SANCO 3030/99 rev. 5). The loss of active substance after 14 days storage of test item at 54±2°C was almost negligible. It is recognised that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the preparation.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 CIPAC MT 36.3	GLOB2111F Batch: KS160222-02	Apperance: Test item was homogeneous and there was no any separated materials.  Emulsion stability: No formation of froth, free oil, cream or solid matter was observed for both dose rates (high and low) with standard CIPAC water D and A.	Y	Kishora, K. S., 2023h	<b>Accepted</b> The test item GLOB2111F was observed to be homogenous and with no separated materials at the time of storage

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						and after 7 days of storage at 0±2°C.  Emulsion stability and Re-Emulsification It was observed that there was no formation of froth, free oil, cream and solid matter for both doses (the lowest and the highest in use concentration) with standard CIPAC water A and D for low temperature stability samples.
Ambient temperature shelf life (KCP 2.7.5)			Study is ongoing. GLOB2111F is expected to be stable for 2 years based on the available accelerated storage data.			<b>Data gap</b> Missing storage stability study at ambient temperature - study is ongoing. It is required to set a shelf-life for the PPP from real time storage test at ambient temperature and may be evaluated in post-registration at national level.
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Not necessary since GLOB2111F is expected to be stable for 2 years based on the available accelerated storage data.			See comments above
Wettability (KCP 2.8.1)	-	-	Not necessary for an EC formulation			<b>Accepted</b>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	GLOB2111F Batch: KS160222-02	<u>Minimum application rate (0.25% v/v):</u> After 1 min: 12 mL After 12 min: 8 mL <u>Maximum application rate (1.0% v/v):</u> After 1 min: 16 mL After 12 min: 10 mL	Y	Kishora, K. S., 2023i	<b>Accepted</b> Persistent foam is determined to measure the amount of foam likely to be present in a spray tank or other application equipment following dilution of the preparation. Acceptable limits: max 60 mL foam after 1 minute. The above mentioned criteria were met.
Suspensibility (KCP 2.8.3.1)	-	-	Not necessary for an EC formulation			<b>Accepted</b>
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not necessary for an EC formulation			<b>Accepted</b>
Dispersion stability (KCP 2.8.3.3)	-	-	Not necessary for an EC formulation			<b>Accepted</b>
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not necessary for an EC formulation			<b>Accepted</b>
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not necessary for an EC formulation			<b>Accepted</b>
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not necessary for an EC formulation			<b>Accepted</b>
Dust content (KCP 2.8.5.2.1)	-	-	Not necessary for an EC formulation			<b>Accepted</b>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not necessary for an EC formulation			Accepted
Attrition (KCP 2.8.5.3)	-	-	Not necessary for an EC formulation			Accepted
Hardness and integrity (KCP 2.8.5.4)	-	-	Not necessary for an EC formulation			Accepted
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	GLOB2111F Batch: KS160222-02	No formation of froth, free oil, cream or solid matter was observed for both dose rates (0.25% and 1.0 % v/v) with standard CIPAC water D and A.	Y	Kishora, K. S., 2023a	<b>Accepted</b> Emulsion stability and Re-Emulsification It was observed that there was no formation of froth, free oil, cream and solid matter for both doses (the lowest and the highest in use concentration) with standard CIPAC water A and D.
Emulsion stability (KCP 2.8.6.2)	-	-	-			
Re-emulsifiability (KCP 2.8.6.3)	-	-	-			
Flowability (KCP 2.8.7.1)	-	-	Not necessary for an EC formulation			Accepted
Pourability (KCP 2.8.7.2)	-	-	Not necessary for an EC formulation			Accepted
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not necessary for an EC formulation			Accepted
Physical compatibility of tank mixes	-	-	Not relevant – no tank mix on the label			<b>Accepted</b> No tank mix on the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.9.1)						label.
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant – no tank mix on the label			<b>Accepted</b> No tank mix on the label.
Adhesion to seeds (KCP 2.10.1)	-	-	Not applicable as GLOB2111F is not used for seed treatment.			<b>Accepted</b>
Distribution to seed (KCP 2.10.2)	-	-	Not applicable as GLOB2111F is not used for seed treatment.			<b>Accepted</b>
Other/special studies (KCP 2.11)	-	-	Not necessary			<b>Accepted</b>

### 3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

## 4 Section 4: Further information on the plant protection product

### 4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

#### zRMS comments

The HDPE/PA and HDPE-F bottles were used in accelerated storage study (14 days at 54±2°C). The HDPE/PA and HDPE-F bottles were stable in accelerated storage study.

**Table 4.1-1: Packaging information for 250 mL bottle**

Type	Description
Material:	HDPE/PA, HDPE/F
Shape/size:	cylindrical / approx. 60 mm diameter x 125 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-2: Packaging information for 500 mL bottle**

Type	Description
Material:	HDPE/PA, HDPE/F
Shape/size:	cylindrical / approx. 60 mm diameter x 185 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-3: Packaging information for 1L bottle**

Type	Description
Material:	HDPE/PA, HDPE/F
Shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-4: Packaging information for 2L container**

Type	Description
Material:	HDPE/PA, HDPE/F
Shape/size:	rectangular / approx. 106 mm width x 155 mm length x 189 mm height
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-5: Packaging information for 3L container**

Type	Description
Material:	HDPE/PA, HDPE/F
Shape/size:	rectangular / approx. 160 mm width x 262 mm length x 115 mm height
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-6: Packaging information for 5 litre container**

Type	Description
Material:	HDPE/PA, HDPE/F
Shape/size:	rectangular / approx. 140 mm x 190 mm x 313 mm
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-7: Packaging information for 10 litre container**

Type	Description
Material:	HDPE/PA, HDPE/F
Shape/size:	rectangular / approx. 179 mm x 240 mm x 375 mm
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-8: Packaging information for 15 litre container**

Type	Description
Material:	HDPE/PA, HDPE/F
Shape/size:	Height: 311 mm, Width: 245 mm, Length: 294 mm
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant
Content product in the bottle	10 kg

**Table 4.1-9: Packaging information for 20 litre container**

Type	Description
Material:	HDPE/PA, HDPE/F
Shape/size:	rectangular / approx. 263 mm width x 292 mm length x 372 mm height
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal
Manner of construction	extruded
UN/ADR	compliant

## 4.2 Procedures for Cleaning Application Equipment

### 4.2.1 Procedures for cleaning application equipment and protective clothing

Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, boom and nozzles three times with clean water until the foam and all traces of product have been removed.

### 4.2.2 Effectiveness of the cleaning procedures (KCP 4.2)

The effectiveness of tank cleaning was assessed in the study of Kishora, 2023j. Tank mix is prepared at the highest recommended concentration of the test item and it is transferred into polyethylene bottles and stored overnight. The bottles were then single, double and triple rinsed with 10 mL tap water and the remaining residue was collected with 10 mL acetonitrile. The collected residue was then assayed by HPLC-UV.

It was concluded that the active ingredient removed from the bottles was 99.997% of the initially added amount. This demonstrates that only a very limited amount of residue would remain in the spray tank after cleaning.

#### zRMS comment

##### Accepted

The study in order to assess the effectiveness of cleaning of PPP (GLOB2111F) was performed. The

effectiveness of cleaning test of GLOB2111F was carried out in accordance with PSD Efficacy Guideline 305 EPPO PP1/292.

Analytical method of determination of residue of Bixafen has been validated by establishing linearity range, limit of detection (LOD), limit of quantitation (LOQ), specificity, accuracy and precision.

The samples were analyzed for the active ingredient content using HPLC method.

The percentage of active ingredients content removed for the test item GLOB2111F was found to be 99.997%.

It demonstrates that only a very limited amount of residue remains in the spray tank after cleaning.

### 4.3 Recommended methods and precautions (KCP 4.2)

Reference is made to the submitted SDS where all the required and detailed information can be found.  
A summary is given below

#### 4.3.1 Procedures for storage

Storage conditions:	Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.
Incompatible products:	Strong bases. Strong acids.
Incompatible materials:	Sources of ignition. Direct sunlight

#### 4.3.2 Transport

In accordance with ADN / ADR / IATA / IMDG / RID

- UN number is 3082.
- UN Proper shipping name is "ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
- Transport hazard class is 9.
- Packaging group is III

#### 4.3.3 Firefighting measures

Suitable extinguishing media:	Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media :	Do not use a heavy water stream.
Firefighting instructions :	Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent firefighting water from entering the environment.
Protection during firefighting:	Do not enter fire area without proper protective equipment, including respiratory protection.

#### 4.3.4 Exposure control

All unnecessary exposure should be avoided. For personal protection measures reference is made to dRR Part B Section 6.

#### 4.3.5 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.  
Avoid release to the environment.

#### **4.4 Emergency measures (KCP 4.3)**

Reference is made to the submitted SDS for KCP 4.3 where all the required and detailed information can be found.

A short summary is given below:

##### **4.4.1 Accidental release measures**

Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Avoid release to the environment.

Evacuate unnecessary personnel. Equip clean-up crew with proper protection. Ventilate area.

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

##### **4.4.2 First aid measures**

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: Allow affected person to breathe fresh air. Allow the victim to rest.

First-aid measures after skin contact: Wash with plenty of water/.... Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention. Specific treatment (see supplemental first aid instruction on this label).

First-aid measures after eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.

First-aid measures after ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

#### **4.5 Procedures for destruction and neutralisation (KCP 4.5)**

In the event of accidental spillages the neutralisation procedures are as follows: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials (reference is also made to 4.4.1 above).

## Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1, KCP 2.4.1, KCP 2.4.2, KCP 2.7.1, KCP 2.8.6.1	Kishora, K. S.	2023a	Accelerated storage stability test of GLOB2111F AG-G0103 Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished	N	Globachem NV
KCP 2.2.1, KCP 2.2.2  (Filed in Part C)	Kishora, K. S.	2023b	Theoretical certificate of explosive and oxidizing properties for an EC formulation containing 125 g/L Bixafen Eurofins Advinus Agrosiences Services India Private Limited Non-GLP Unpublished	N	Globachem NV
KCP 2.3.1	Kishora, K. S.	2023c	Determination of flash point of GLOB2111F AG-G0106 Eurofins Advinus Agrosiences Services India Private Limited Non-GLP Unpublished	N	Globachem NV
KCP 2.3.3	Kishora, K. S.	2023d	Determination of auto ignition temperature of GLOB2111F AG-G0113 Eurofins Advinus Agrosiences Services India Private Limited	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Non-GLP Unpublished		
KCP 2.5.1	Kishora, K. S.	2023e	Determination of viscosity of GLOB2111F AG-G0107 Eurofins Advinus Agrosciences Services India Private Limited GLP Unpublished	N	Globachem NV
KCP 2.5.2	Kishora, K. S.	2023f	Determination of surface tension of GLOB2111F AG-G0108 Eurofins Advinus Agrosciences Services India Private Limited GLP Unpublished	N	Globachem NV
KCP 2.6.1	Kishora, K. S.	2023g	Determination of relative density of GLOB2111F AG-G0109 Eurofins Advinus Agrosciences Services India Private Limited GLP Unpublished	N	Globachem NV
KCP 2.7.4	Kishora, K. S.	2023h	Low temperature stability of GLOB2111F AG-G0110 Eurofins Advinus Agrosciences Services India Private Limited GLP Unpublished	N	Globachem NV
KCP 2.8.2	Kishora, K. S.	2023i	Determination of presintence foam of GLOB2111F AG-G0111 Eurofins Advinus Agrosciences Services India Private Limited GLP Unpublished	N	Globachem NV
KCP 4.2	Kishora, K. S.	2023j	Determination of the effectiveness of cleaning for GLOB2111F AG-G0112	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished		

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

The following tables are to be completed by MS.

**List of data submitted by the applicant and not relied on**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

**List of data relied on and not submitted by the applicant but necessary for evaluation**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

## **Appendix 2    Additional data on the physical, chemical and technical properties of the active substance**

### **A 2.1            Bixafen**

Not required.