REGISTRATION REPORT

Part A

Risk Management

Product code: GLOB2111F

Product name: STARINTA

Chemical active substance:

Bixafen, 125 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Globachem NV

Date: 03/11/2025

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PART A

RISK MANAGEMENT

1 Details of the application

The company Globachem N.V. has requested a marketing authorisation in France for the product STARINTA (product code: GLOB2111F), containing 125 g/L bixafen[1] as a fungicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of Globachem N.V.'s application submitted on 22/12/2023 to market STARINTA in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2024-0467) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of STARINTA has been made using endpoints agreed in the EU peer review of bixafen. It also includes assessment of data and information related to STARINTA where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of STARINTA.

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1 Commission Implementing Regulation (EU) No 350/2013 of 17 April 2013 approving the active substance bixafen, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

2 REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

3 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

4 COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

1.2 Letters of Access

Not necessary: active substance data are not protected any more.

1.3 Justification for submission of tests and studies

According to the applicant: “This application was made in accordance with the article 33 of the Regulation 1107/2009. It follows the data requirements for the active substances laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013”.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of STARINTA, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	GLOB2111F
Product name in MS	STARINTA
Authorisation number	2250545
Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	GLOBACHM NV
Active substance(s) (incl. content)	Bixafen, 125 g/L
Formulation type	Emulsifiable Concentrate [EC]
Packaging	Bottles in HDPE/PA (0.25 L, 0.5 L, 1 L, 2 L) Bottles in HDPE /F (0.5 L, 1 L, 2 L) Containers in HDPE/PA (3 L, 5 L, 10 L, 15 L, 20 L) Containers in HDPE/F (3 L, 5 L, 10 L, 15 L, 20 L)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for STARINTA resulted in the decision to **grant** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin irritation, category 2 Serious eye damage, category 1 Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	 GHS05 GHS07 GHS09
Signal word:	Danger
Hazard statement(s):	H315: Causes skin irritation. H318: Causes serious eye damage. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	-

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[5] provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 April 2021[6] provides that:

- an authorisation granted for a "reference" crop applies also for "related" crops, unless formally stated in the Decision
- the "reference" and "related" crops are defined in Appendix 1 of that French Order.

Moreover, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Finally, the French Order of 20 November 2021[8] on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop[9] when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	

[5] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

[6] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

[7] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

[8] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734

[9] List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres to surface water bodies.
Other specific restrictions	
Re-entry period	24 hours.
Storage	None
SPa 1	To prevent the development of resistance of cereal pathogens to bixafen, the number of applications of the product is limited to a maximum of 1 per crop cycle on wheat, triticale, and barley. In order to best manage the risks of resistance, it is recommended to follow the restrictions on use by chemical group recommended by the "Note Commune INRAE, ANSES, ARVALIS - Institut du végétal pour la gestion de la résistance aux fongicides utilisés pour lutter contre les maladies des céréales à paille".
Risk mitigation measures	Bystander and resident protection : - Respect an unsprayed zone of 3 meters from the extremity of the boom and : • areas where bystanders are present during treatment • areas where residents could be present
Agricultural recommendations	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 03/11/2025

PPP (product name/code):	STARINTA / GLOB2111F	Formulation type:	EC [a, b]
Active substance 1:	Bixafen	Conc. of a.s. 1:	125 g/L [c]
Applicant:	GLOBACHEM NV	Professional use:	☒
Zone(s):	Southern Zone [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Fungicide		

GLOB2111F / STARINTA
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/syner-gist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea-son	Min. inter-val between applications (days)	L product / ha a) max. rate per appl. b) max. to-tal rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Winter wheat *Triticum aestivum winter / Triticum durum winter* (TRZAW/TRZDW)	F	*Puccinia striiformis* (PUCCST) *Puccinia recondita* (PUCCRE)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Acceptable**
1	FR	Winter wheat *Triticum aestivum winter / Triticum durum winter* (TRZAW/TRZDW)	F	*Parastagonospora nodor*um (LEPTNO)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
1	FR	Winter wheat *Triticum aestivum winter / Triticum durum winter* (TRZAW/TRZDW)	F	*Zymoseptoria tritici* (SEPTTR) *Blumeria graminis* (ERYSGR)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
2	FR	Winter wheat *Triticum aestivum winter / Triticum durum winter* (TRZAW/TRZDW)	F	*Fusarium sp.* (FUSASP)	Normal down-ward spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
3	FR	Winter barley *Hordeum vulgare winter* (HORVW)	F	*Blumeria graminis* (ERYSGR)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
3	FR	Winter barley *Hordeum vulgare winter* (HORVW)	F	*Puccinia hordei* (PUCCHD) *Rhynchosporium secalis* (RHYNSE)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Acceptable**
3	FR	Winter barley *Hordeum vulgare winter*	F	*Pyrenophora teres* (PYRNTE) *Ramularia collo-cygni*	Normal down-ward	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**

		(HORVW)		(RAMUCC)	spraying								
4	FR	Winter barley *Hordeum vulgare winter* (HORVW)	F	*Fusarium sp.* (FUSASP)	Normal down-ward spraying	BBCH 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
5	FR	Winter rye *Secale cereale winter* (SECCW)	F	*Rhynchosporium secalis* (RHYNSE) *Puccinia recondita* (PUCCRE)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Acceptable**
5	FR	Winter rye *Secale cereale winter* (SECCW)	F	*Blumeria graminis* (ERYSGR)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
6	FR	Winter rye *Secale cereale winter* (SECCW)	F	*Fusarium sp.* (FUSASP)	Normal down-ward spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
9	FR	Spring wheat *Triticum aestivum spring/Triticum durum spring* (TRZAS/TRZDS)	F	*Puccinia striiformis* (PUCCST) *Puccinia recondita* (PUCCRE)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Acceptable**
9	FR	Spring wheat *Triticum aestivum spring/Triticum durum spring* (TRZAS/TRZDS)	F	*Parastagonospora nodor*um (LEPTNO)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
9	FR	Spring wheat *Triticum aestivum spring/Triticum durum spring* (TRZAS/TRZDS)	F	*Zymoseptoria tritici* (SEPTTR) *Blumeria graminis* (ERYSGR)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
10	FR	Spring wheat *Triticum aestivum spring/Triticum durum spring.* (TRZAS/TRZDS)	F	*Fusarium sp.* (FUSASP)	Normal down-ward spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
11	FR	Winter barley *Hordeum vulgare winter* (HORVW)	F	*Blumeria graminis* (ERYSGR)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
11	FR	Winter barley *Hordeum vulgare*	F	*Puccinia hordei* (PUCCHD)	Normal down-	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Acceptable**

		winter (HORVW)		*Rhynchosporium secalis* (RHYNSE)	ward spraying								
11	FR	Winter barley *Hordeum vulgare winter* (HORVW)	F	*Pyrenophora teres* (PYRNTE) *Ramularia collo-cygni* (RAMUCC)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**
12	FR	Spring barley *Hordeum vulgare spring* (HORVS)	F	*Fusarium sp.* (FUSASP)	Normal down-ward spraying	BBCH 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
13	FR	Spring rye *Secale cereale spring* (SECCS)	F	*Rhynchosporium secalis* (RHYNSE) *Puccinia recondita* (PUCCRE)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Acceptable**
13	FR	Spring rye *Secale cereale spring* (SECCS)	F	*Blumeria graminis* (ERYSGR)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
14	FR	Spring rye *Secale cereale spring* (SECCS)	F	*Fusarium sp.* *(FUSASP)*	Normal down-ward spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
Minor uses according to Article 51 (zonal uses)													
19	FR	Triticale winter *Triticale sp. winter* (TTLWI)	F	*Puccinia striiformis* (PUCCST) *Rhynchosporium secalis* (RHYNSE)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Acceptable**
19	FR	Triticale winter *Triticale sp. winter* (TTLWI)	F	*Parastagonospora nodor*um (LEPTNO)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
19	FR	Triticale winter *Triticale sp. winter* (TTLWI)	F	*Zymoseptoria tritici* (SEPTTR) *Blumeria graminis* (ERYSGR)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
20	FR	Triticale winter *Triticale sp. winter* (TTLWI)	F	*Fusarium sp.* (FUSASP)	Normal down-ward	BBCH 61 – 69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)

					spraying								
23	FR	Spelt *Triticum spelta* (TRZSP)	F	*Puccinia striiformis* (PUCCST) *Puccinia recondita* (PUCCRE) *Puccinia triticina* *(*PUCCRT) *Rhynchosporium secalis* (RHYNSE)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Acceptable**
23	FR	Spelt *Triticum spelta* (TRZSP)	F	*Zymoseptoria tritici* (SEPTTR) *Blumeria graminis* (ERYSGR)	Normal down-ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)
24	FR	Spelt *Triticum spelta* (TRZSP)	F	*Fusarium sp.* (FUSASP)	Normal down-ward spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	**Not acceptable** (efficacy)

**** Withdrawl of the use by the applicant.**

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

Packaging claimed (France, national data and in RR 1,2&4):
- Bottles made of HDPE/PA or HDPE-F (0.25, 0.5, 1, 2L)
- Containers made of HDPE/PA or HDPE-F (3, 5, 10, 15, 20L)

Packaging authorised:
- Bottles made of HDPE/PA (0.25, 0.5, 1, 2L) or HDPE-F (0.5, 1, 2L)
- Containers made of HDPE/PA or HDPE-F (3, 5, 10, 15, 20L)

The preparation is not the representative formulation of the inclusion of bixafen. Physico-chemical properties were provided for this new formulation.

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 in HDPE/PA (0.25L) and HDPE-F (0.5L) bottles, 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* In all the requested containers except for the 250 mL HDPE/F, since the interactions between the formulation and the packaging are more significant with smaller volumes, and therefore the tested 500mL HDPE/F does not cover the claimed 250mL HDPE/F. Its technical characteristics are acceptable for a *emulsifiable concentrate* formulation. **Long term storage stability study is still on going and should be provided in post registration.**

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

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

The efficacy level of STARINTA is considered acceptable for uses targeting cereal rusts (different *Puccinia* species) and *Rhynchosporium secalis*.
However, given the SDHI resistance of *Puccinia recondita*, the product's efficacy is partial for the control of this disease, but remains acceptable when used as part of a control program.

Regarding use on wheat septoria *Zymoseptoria tritici*, the trials conducted mostly in Eastern European countries do not reflect the conditions encountered in France, where resistance of *Z. tritici* to SDHI strongly affects the effectiveness of SDHI. Besides, the provided trials do not include, as reference product, a similar bixafen straight product that is registered in France. Therefore, the efficacy assessment cannot be finalized for this use.
Regarding uses on cereal powdery mildews (*Erysiphe graminis*), due to an insufficient number of trials representative of French conditions and due to variable efficacy, the efficacy assessment cannot be finalized.

Regarding uses on *Fusarium* ear blight, the trials conducted do not allow to conclude against the fusarium species predominantly present in France, *Fusarium graminearum*. Therefore, the efficacy assessment cannot be finalized.

For the use on *Parastagonospora nodorum*, due to the lack of data, the efficacy assessment cannot be conducted.

The phytotoxicity level of the STARINTA product is considered negligible for the claimed uses.

The risks of negative impacts on yield, quality, breadmaking and propagation are considered negligible.

Regarding the risk of negative impacts on the brewing process, given the lack of data and a risk identified, a risk of negative impact of the product cannot be excluded.

The risks of negative impact on subsequent and adjacent crops are considered negligible.

There is a risk of resistance requiring the set up of a resistance monitoring to bixafen, for the following pathogens:

- *Zymoseptoria tritici, Puccinia recondita*, and *Puccinia striiformis* on wheat,
- *Puccinia hordei* on barley.

Efficacy trials should also be conducted in situations of resistance to bixafen for *Zymoseptoria tritici* on wheat.

To prevent the development of resistance of cereal pathogens to bixafen, the number of applications of the product is limited to a maximum of 1 per crop cycle on wheat, triticale, and barley.
To manage the risk of resistance to substances with the same mode of action (SDHI[10]), it is recommended to follow the use restrictions by chemical group recommended in the technical note on fungicides resistance management, for cereal pathogens[11].

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical method for the determination of bixafen content in the formulation STARINTA is available and validated.

3.3.2 Analytical methods for residues

Analytical methods for monitoring are available in the Draft Assessment Report and validated for determination of residues of Bixafen compounds in plants, soil, water (surface and drinking),air and for Bixafen and its metabolit (desmethyl-bixafen) in food of animal origin.

[10] SDHI : Succinate deshydrogenase inhibitors.
[11] Document: Note commune Résistances aux fongicides, Céréales à paille.

3.4 Mammalian toxicology (Part B, Section 6)

Agreed EU endpoints	
Active substance	**Bixafen**
AOEL systemic	0,13
AAOEL	-
Oral absorption	85%
Vapour pressure	$4{,}6.10^{-8}$ (20°C)
Reference	EFSA 2012: EFSA Journal 2012;10(11):2917 EU 2013 : SANCO/10357/2013 rev 3
Dermal absorption	Valeurs par défaut -Concentrate : 25% -Dilution : 70%

3.4.1 Acute toxicity

STARINTA has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is irritating to skin and corrosive to eyes and is not a skin sensitiser.

3.4.2 Operator exposure

Considering the proposed uses, the operator exposure was estimated using the EFSA model[12].

		Bixafen	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Application rate		1 x 0,1276 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0,1	96

According to the exposure assessment using the EFSA model 2022, the operator exposure to STARINTA is below the AOEL of bixafen, with a working coverall during mixing/loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop inspection/irrigation activities. Therefore, estimation of worker exposure was calculated according to AOEM model.

[12] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2022;20(1):7032)

		Bixafen	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Inspection, irrigation /outdoor Work rate: 2 hours/day DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha			
Application rate		1 x 0,1276 kg a.s./ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves TC: 1250 cm²/h	0,01	8,6

According to the exposure assessment using the EFSA model 2022, the worker exposure to STARINTA is below the AOEL of bixafen, with a working coverall and gloves during mixing/loading and application.

3.4.4 Bystander exposure

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2022;20(1):7032):
"When an acute risk assessment is not triggered (i.e. for PPPs containing active substances that are not acutely toxic, and for which the setting of an AAOEL was not necessary), no bystander risk assessment is required. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure."

3.4.5 Resident exposure

		Bixafen	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Fields crops			
Tractor mounted, downward application Buffer zone: 2-3 m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Number of applications: 1 Interval between treatments: 365 days Volume min: 100 L/ha			
Number of applications and application rate		1 x 0,1276 kg a.s./ha	
Resident child Body weight:	Drift (75th perc.)	0,02	18,6
	Vapour (75th perc.)	6.10^{-6}	0,005

10 kg	Deposits (75th perc.)	0,001	1,1
	Re-entry (75th perc.)	0,02	11,6
	Sum (mean)	0,03	20,2
Resident adult Body weight: 60 kg	Drift (75th perc.)	0,006	4,4
	Vapour (75th perc.)	2.10^{-6}	0,002
	Deposits (75th perc.)	0,0006	0,5
	Re-entry (75th perc.)	0,008	6,4
	Sum (mean)	0,01	7,5

According to the exposure assessment performed by EFSA model 2022, resident exposure to STARINTA is below the AOEL value of bixafen, with a buffer zone of 3 meters and without mitigation measures.

3.4.6 Combined exposure

Not applicable

3.5 Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment.
An exceedance of the current MRL of 1.5 mg/kg in barley, 0.3 mg/kg in wheat and 0.05 mg/kg in rye for bixafen as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of bixafen residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France, zRMS agrees with the authorization of the intended uses.

Information on GLOB 2111F

Crop group	**PHI for GLOB 2111F proposed by applicant**	**PHI/ Withholding period* sufficiently supported for**	**PHI for GLOB 2111F proposed by zRMS**	**zRMS Comments (if different PHI proposed)**
		bixafen		
Wheat (rye, triticale, spelt)	NR	NR	F	
Barley (oat)	NR	NR	F	

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Not necessary

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009.

The PEC of bixafen and its metabolite in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC_{SOIL} and PEC_{SW} derived for the active substance are used for the ecotoxicological risk assessment.

PEC_{GW} for bixafen and its metabolite do not occur at levels exceeding those mentioned in regulation EU No 546/2011 and guidance document SANCO 221/2000[13]. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(s) and its/their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses in the conditions of uses described under 2.5.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance bixafen is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

[13] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev11-final, 21 October 2021.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is "Not acceptable", please refer to relevant summary under point 3, "Background of authorisation decision and risk management".

5.1.1 Post-authorisation monitoring

A resistance monitoring[14] to bixafen should be set up for the following pathogens:

- *Zymoseptoria tritici*, *Puccinia recondita*, and *Puccinia striiformis* on wheat.
- *Puccinia hordei* on barley.

In addition, efficacy trials should also be conducted in situations of resistance[15] to bixafen, for *Zymoseptoria tritici* on wheat.

A report on the results of this survey should be provided at the time of the demand of renewal of the product or at any moment in case the applicant has any information available relating to the development of resistance (Article 56 point 4 of regulation 1107/2009).

5.1.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- The long term stability study of the preparation in commercial packaging or equivalent.

[14] Refer to the technical document n°23 (DT23): « Recommandations pour une surveillance (monitoring) de la résistance aux fongicides », de la Commission des Essais Biologiques (CEB, Végéphyl).

[15] Refer to the technical document n°29 (DT29): « Recommandations pour l'étude au champ de l'efficacité de produits fongicides vis-à-vis des maladies des céréales à paille en situation de résistance », de la Commission des Essais Biologiques (CEB, Végéphyl).

Appendix 1 Copy of the product authorisation

STARINTA_PAMM_2024-0467_D.pdf

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

STARINTA®

FONGICIDE CEREALES

Contient 125 g/L (12.5% p/p) de Bixafen sous forme de concentré émulsionnable (EC)

Autorisation de Mise sur le Marche n° xxx

Date de fabrication / Numéro de lot : voir emballage

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

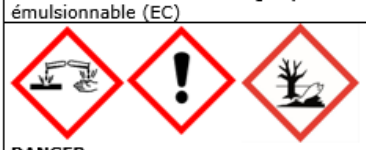
Contenu : 0,1 ; 0,25 ; 0,5 ; 1 ; 2 ; 3 ; 5 ; 10 ; 15 ; 20 L e

Distribué par :
A compléter

Détenteur d'AMM:
GLOBACHEM NV
Brustem Industriepark – Lichtenberglaan 2019
3800 Sint-Truiden
Belgique
Tel. +32 11 78 57 17
Fax. +32 11 68 15 65

Détenteur de la marque STARINTA: société du groupe Globachem

STARINTA®
AMM n° xxx – Contient 125 g/L (12.5 % p/p) de bixafen sous forme de concentré émulsionnable (EC)



DANGER

H315 – Provoque une irritation cutanée.
H318 – Provoque de graves lésions des yeux.
H410 – Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

Conseils de prudence
P273 – Eviter le rejet dans l'environnement
P280 – Porter des gants de protection/ des vêtements de protection/ un équipement de protection des yeux/du visage.
P302+P352 – EN CAS DE CONTACT AVEC LA PEAU : Laver abondamment à l'eau
P391 – Recueillir le produit répandu.
P501 – Eliminer le contenu/ récipient conformément à la réglementation locale/régionale/nationale/internationale.

Délai de rentrée des travailleurs dans la zone traitée: 48 heures

SP1: Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surfaces. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.
SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

SPe3 Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacent.

EUH401: Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

Distribué par :
A compléter

EN CAS D'URGENCE
Composer le 15 ou le 112 ou contacter le centre anti poison le plus proche

puis signalez vos symptômes au réseau Phyt'Attitude. N° vert : 0 800 887 887 (Appel gratuit depuis un poste fixe).

Ppremiers soins
S'éloigner de la zone dangereuse.
En cas de contact cutané : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.

En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Consulter un spécialiste.
En cas d'inhalation : Emmener la victime à l'air frais. En cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre antipoison.
En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours : le 15, le 112 ou un centre antipoison.
Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.
En cas d'intoxication animale : contactez votre vétérinaire.
Fiche de données de sécurité disponible sur le site www.quickfds.com

DESCRIPTIF DU PRODUIT

STARINTA® est un fongicide contenant du bixafen permettant de contrôler les maladies foliaires et des épis sur céréales d'hiver et de printemps. La substance active Bixafen est un inhibiteur de la succinate déshydrogenase (SDHIs) qui appartient à la famille des pyrazole-carboxamide (code FRAC : F7). Il est appliqué par voie foliaire et présente une systémie pénétrante, locale et acropétale. Il a une action protectrice et curative et contrôle une large gamme de maladies fongiques.

Tableau des usages autorisés

Cultures	Cible	Dose maximale d'emploi	Nombre maximum d'applications par an	Stade d'application	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)
Blé d'hiver, Blé de printemps, Seigle d'hiver, Seigle de printemps, Triticale d'hiver, Triticale de printemps et épeautre	Septoriose(s) Helminthosporiose(s) Rouille(s) Ramulariose(s) Oïdium(s) Rynchosporiose(s)	1 L/ha	1	BBCH 30 - 61	-	5 m
	Fusariose			BBCH 61-69		
Orge d'hiver, Orge de printemps,	Septoriose(s) Helminthosporiose(s) Rouille(s) Ramulariose(s) Oïdium(s) Rynchosporiose(s)			BBCH 30 - 61		
	Fusariose			BBCH 61		

Globachem NV ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées ci-dessus et, à ce titre, décline toute responsabilité concernant son utilisation aux autres usages prévus par le catalogue des usages en vigueur.

Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database

INFORMATIONS RELATIVES A L'EMPLOI

Champ d'activité et conditions d'application

Précautions d'emploi

- Vérifier régulièrement et maintenir le bon état et le réglage du matériel d'application, en conformité avec la législation.

- Surveiller le remplissage de la cuve du pulvérisateur et ajuster le volume de bouillie (clapet anti-retour, dispositif de surverse).
- Ne pas souffler dans les buses pour tenter de les déboucher.
- Ne pas respirer les vapeurs, ni le brouillard de pulvérisation.
- Ne pas pulvériser à proximité des points d'eau (mares, cours d'eau, fossés...).
- Attention aux dérives d'embruns de la pulvérisation sur les cultures voisines. Ne pas traiter en présence de vent, même faible (selon la réglementation en vigueur)
- Ne pas conserver la bouillie de pulvérisation dans la cuve plus de 48 heures.

Mélanges extemporanés
Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur.

Préparation de la bouillie
Avant de débuter le remplissage de la cuve du pulvérisateur pour préparer la bouillie de pulvérisation, s'assurer que celle-ci ne contient aucun résidu liquide ou solide d'un traitement précédent. Remplir au ¾ d'eau la cuve du pulvérisateur. Agiter le bidon de STARINTA® et verser dans la cuve la dose de produit nécessaire. Ajouter enfin le reste du volume d'eau requis. Maintenir la bouillie en état d'agitation jusqu'à la fin de la pulvérisation. Ne préparez jamais plus de bouillie qu'il n'en est nécessaire. Ne pas laisser la bouillie dans la cuve du pulvérisateur pendant de longues périodes (par exemple pendant le temps des repas).

PREVENTION ET GESTION DE LA RÉSISTANCE

Dans le but d'éviter des phénomènes de résistances face aux produits de la famille des SDHI's, le nombre d'applications avec STARINTA est limité à une application par saison. Pour maximiser la stratégie sur la gestion de la résistance, suivre les recommandations générales FRAC, incluant l'utilisation alterner de fongicides à différents modes d'actions dans les itinéraires culturaux.
L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants.
Pour réduire ce risque, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit. Il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.
En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de cette préparation liée à ces phénomènes de résistance. De ce fait, GLOBACHEM NV décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.
Consultez votre distributeur pour connaître les cas avérés de résistance au niveau de votre région.

MISE EN ŒUVRE REGLEMENTAIRE ET BONNES PRATIQUES
Stockage du produit
Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées.

Protection de l'opérateur et du travailleur
Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée.
Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.
L'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections complémentaires comme les protections individuelles.

En tout état de cause, le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage). Les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Porter un vêtement de travail et les Équipements de Protection Individuelle (EPI) suivants:

CF 1.F1 EPI

Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide, à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination de produits dangereux.
Immédiatement après l'application, nettoyer les équipements de protection, se laver les mains à l'eau savonneuse, prendre une douche et changer de vêtements.

Nettoyage du pulvérisateur et gestion des fonds de cuve
À la fin de la période d'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses…) doit être nettoyée très soigneusement avec un produit adapté (type Phytnet) puis rincée à l'eau claire. Le rinçage du pulvérisateur, l'épandage ou la vidange du fond de cuve et l'élimination des effluents doivent être réalisés conformément à la réglementation en vigueur.

Élimination du produit, de l'emballage


Réemploi de l'emballage interdit.
Lors de l'utilisation du produit, bien vider et rincer le bidon à l'eau claire (rinçage manuel à 3 reprises en agitant le bidon rempli au 1/3 ou rinçage mécanique d'une durée minimale de 30 secondes) en veillant à verser l'eau de rinçage dans la cuve de l'appareil. Apporter les emballages ouverts, rincés et égouttés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique.
Pour les fûts, apporter les emballages vidés et fermés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique.
Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I.VALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

En cas de déversement accidentel
Se protéger (EPI) et sécuriser la zone. Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens. Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse. Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.

AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite.
Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases, la culture et les traitements selon la bonne pratique agricole et les recommandations de votre distributeur en tenant compte, sous la responsabilité de l'utilisateur, de tous les facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...
Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les Autorités Compétentes françaises. Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.

GARANTIE

Le fabricant ne donne aucune garantie, explicite ou implicite, relative à l'utilisation du produit d'une autre manière que celle indiquée sur l'étiquette. L'utilisateur sera responsable des risques liés à l'utilisation et/ou la manipulation et/ou l'entreposage de ce produit en cas de non-respect des recommandations de l'étiquette.