REGISTRATION REPORT

Part A

Risk Management

Product code: GLOB106 H

Product name: HARNIKO

Chemical active substance:

Aclonifen, 600 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Globachem NV

Date: 18/08/2025

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PART A

RISK MANAGEMENT

1 Details of the application

The company Globachem NV has requested a marketing authorisation in France for the product HARNIKO (product code: GLOB106 H), containing 600 g/L aclonifen[1] as an herbicide 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 NV's application submitted on 13/12/2023 to market HARNIKO (product code: GLOB106 H), 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 (2023-3151 and 2025-1077) 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 HARNIKO (product code: GLOB106 H), has been made using endpoints agreed in the EU peer review of aclonifen. It also includes assessment of data and information related to HARNIKO (product code: GLOB106 H), 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 HARNIKO (product code: GLOB106 H).

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1 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

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: "*Studies have been submitted to support the product authorisation of "Chanon" in relevant EU Member States.* " NB: CHANON is the former name of HARNIKO

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 3.

2 Details of the authorisation decision

2.1 Product identity

Product code	GLOB106 H
Product name in MS	HARNIKO
Authorisation number	2250282
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	GLOBACHM NV
Active substance(s) (incl. content)	aclonifen, 600 g/L
Formulation type	Suspension concentrate [SC]
Packaging	Containers in HDPE[5] (5L, 10L, 20L) Containers in HDPE/PA[6] (5L, 10L, 20L) Containers in f-HDPE[7] (5L, 10L, 20L) Containers in HDPE/EVOH[8] (5L, 10L, 20L) Packaging of 20L must be equipped with a device for homogenisation.
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

[5] High density polyethylene
[6] High density polyethylene / polyamide
[7] Fluorated-High density polyethylene
[8] High density polyethylene / ethylene alcohol vynilic

2.2 Conclusion

The evaluation of the application for HARNIKO (product code: GLOB106 H)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 sensitisation, category 1 Carcinogenicity, category 2 Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	 GHS08 GHS09
Signal word:	Warning
Hazard statement(s):	H317: May cause an allergic skin reaction H351: Suspected of causing cancer 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:	Contains 1,2-Benzisothiazol-3(2H)-one and 2-Methylisothiazol-3-2H)-one. May produce an allergic reaction.

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[9] 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[10] 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[11] 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[12] 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[13] 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:

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9 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/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

10 https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

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

12 https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734

13 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.

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	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 20 metres with a 20-metre permanent planted buffer strip to surface water bodies.
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 5 metres to non-agricultural land.
Other specific restrictions	
Re-entry period	48 hours.
Storage	-
SPa 1	-
Risk mitigation measures	The product must be stirred before using.
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: 18/08/2025

PPP (product name/code):	HARNIKO/ GLOB106 H	Formulation type:	SC [a, b]
Active substance 1:	aclonifen	Conc. of a.s. 1:	600 g/L [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	GLOBACHEM NV	Professional use:	☒
Zone(s):	Southern Zone [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Herbicide		

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: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		e.g. g safener/synergist per ha [f]
Zonal uses (field or outdoor uses, certain types of protected crops)													

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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: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	FR	Winter cereals Winter Wheat (TRZAW), Winter Barley (HORVW), Winter Rye (SECCW), Winter Triticale (TTLWI), Winter Durum Wheat (TRZDW)	F	Annual grassy weeds (GGGAN) Annual broadleaved weeds (BBBAN)	Downward spraying	BBCH 00-09	a) 1 b) 1	/	a) 1.35 b) 1.35	a) 810 b) 810	100-300	F	**Acceptable**
2	FR	Winter cereals Winter Wheat (TRZAW), Winter Barley (HORVW), Winter Rye (SECCW), Winter Triticale (TTLWI), Winter Durum Wheat (TRZDW)	F	Annual grassy weeds (GGGAN) Annual broadleaved weeds (BBBAN)	Downward spraying	BBCH 10-13	a) 1 b) 1	/	a) 1.35 b) 1.35	a) 810 b) 810	100-300	F	**Acceptable**

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.

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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)

Use rate proposed (according to GAP table): 0.45-1.35% v/v

The preparation is not the representative formulation for the inclusion of aclonifen.

The preparation does not contains more than 10% of compounds classified H304.

Aclonifen contains phenol as relevant impurity. However it is not expected to be formed on storage as it is a process impurity. Determination of phenol in the preparation after storage was performed and content for this impurity remains below maximum limit (2.56 g/kg in the preparation).

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 an opaque bright yellow uniform liquid, with an almond type odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature of more than 400 °C. In aqueous solution (1%), it has a pH value around 7. 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 canisters (250ml and 1L). Its technical characteristics are acceptable for a suspension concentrate formulation. However, phase separation was not after storage and it is recommended to shake/stir the preparation before dilution in tanks.

Due to the type of formulation (SC), sedimentation of the product cannot be excluded. In addition, phase separation was noted after storage. Then, for packaging with a size of 20L, a mitigation measure is proposed: packaging of 20L must be equipped with a device for homogenization and the product must be stirred before using

Dilutions tested in the physchem study include 0.25 L in 100L (2.5 mL/L), 3.3 L in 100L (33 mL/L) and 4 L in 100L (40mL/L) depending on the study.

Dilutions of the current dossier range from 0.45 % (1.35 L in 300 L water) to 1.35 % (1.35 L in 100 L water).

3.2 Efficacy (Part B, Section 3)

The level of effectiveness of product HARNIKO (product code: GLOB106 H) applied in pre- or post-emergence is considered satisfactory for the control of broadleaf weeds and grasses for all the claimed uses.

The level of selectivity of product HARNIKO (product code: GLOB106 H) applied in pre- or post-emergence is considered acceptable on wheat, barley and rye. **Nevertheless, severe transient phytotoxicity symptoms may appear on rye with pre-emergence application.**

Given the absence of data on oats, the assessment of the selectivity level of product HARNIKO (product code: GLOB106 H) in pre- or post-emergence for this use cannot be finalised.

The risks of negative impact on yield, quality, the bread-making and malting-brewing and propagation are considered acceptable.

Given the absence of data on oats, the assessment of the risk of negative impact on yield, quality and propagation for this use cannot be finalised.

The risk of negative impact on succeeding crops is considered acceptable. Nevertheless, particular attention should be paid to the conditions under which replacement crops are planted after the application of product HARNIKO (product code: GLOB106 H).

The risk of negative impact on adjacent crops is considered acceptable.

The risk of resistance to aclonifen does not require the set-up of a monitoring for the claimed uses.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substance and the relevant impurity (phenol) in the formulation are available and validated.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report and validated for the determination of residues of aclonifen in plants (dry commodities), food of animal origin, soil, water (surface and drinking) and air. Methods for pre registration (residues trials and ecotoxicological studies) are considered fit for purpose.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active substance	**Aclonifen**
AOEL systemic	0.07 mg/kg bw/d
AAOEL	-
Oral absorption	80 %
Vapour pressure	1.6 x 10^{-5} Pa (20°C)
Reference	EFSA Scientific Report (2008) 149, 1-80 SANCO/161/08-rev.2
Dermal absorption	Concentrate: 0.19 % Dilution (24 g/L): 0.64 % Dilution (1.8 g/L): 4.2 %

3.4.1 Acute toxicity

HARNIKO (product code: GLOB106 H) has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to skin or eye. It is a skin sensitizer and is suspected of causing cancer.

3.4.2 Operator exposure

Considering proposed uses, the operator systemic exposure was estimated using the EFSA model (2022)[14]:

Long term exposure

		Aclonifen	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Critical use: Field crops (cereals)			
e.g. Tractor mounted boom spray application outdoors to low crops			
Application rate		0.81 kg a.s./ha pure / 0.826 kg a.s./ha tech	
Spray application (EFSA Model; 75th percentile) Body weight: 60 kg	Potential exposure	0.01	20.1
	Work wear (arms, body and legs covered) M/L and A	0.009	13.1

According to the exposure assessment using the EFSA model, the operator exposure to HARNIKO (product code: GLOB106 H) is below the AOEL value of aclonifen, 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

The workers may have to enter into treated areas after treatment for crop inspection/irrigation activities. Therefore, the worker systemic exposure was estimated using the EFSA model (2022)[9].

		Aclonifen	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Critical use: Field crops (cereals) e.g. inspection, irrigation Outdoor Work rate: 2 hours/day, DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.81 kg a.s./ha (tech 0.826)	
Body weight: 60 kg	Potential TC: 12500 cm^2/person/h	0.06	82.6
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.006	9.3

According to the exposure assessment using EFSA model, worker exposure to HARNIKO (product code: GLOB106 H) is below the AOEL value of aclonifen, with a working coverall.

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

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

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

The resident exposure was assessed according to the EFSA model (2022).

		Aclonifen	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
e.g. Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3(m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.81 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.01	18.1
	Vapour (75th perc.)	0.0008	1.1
	Deposits (75th perc.)	0.001	1.7
	Re-entry (75th perc.)	0.008	11.2
	Sum (mean)	0.01	21.2
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.003	4.3
	Vapour (75th perc.)	0.0003	0.4
	Deposits (75th perc.)	0.0003	0.5
	Re-entry (75th perc.)	0.004	6.2
	Sum (mean)	0.005	7.7

According to the resident exposure assessment performed by the EFSA model, the resident exposure to Aclonifen is below the AOEL value of aclonifen without mitigation measures.

3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

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

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs in winter cereals for aclonifen as laid down in Reg. (EU) 2021/1531 is not expected.

The chronic and the short-term intakes of aclonifen residues are unlikely to present a public health concern.

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

Information on HARNIKO (product code: GLOB106 H)(KCA 6.8)

Crop	PHI for Aclonifen 600 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Aclonifen 600 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		aclonifen		
Cereals	NR	F**	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 relevant.

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 aclonifen 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 PECsw derived for the active substance are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for aclonifen do not occur at levels exceeding those mentioned in regulation EU No 546/2011. 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 and its 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)

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)

HARNIKO (product code: GLOB106 H) contains aclonifen approved as a candidate for substitution because two of the criteria for PBT are met (bio accumulative and toxic).

Conclusion of the comparative assessment
Step 1 (French guidance document 27 July 2015):
- Taking into account the management of resistance in accordance with Articles 50(1)(c) of Regulation (EC) No 1107/2009:
As the diversity of available modes of action is not sufficient, product substitution is not considered for the following crops:
- Oats
- Wheat
- Cereals (with straw)
- Barley
- Rye

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

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation

HARNIKO_PAMM_2023-3151_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.

CHANON® SC

HERBICIDE utilisable sur céréales d'hiver contre les adventices.

Contient 600 g/l (49.73% p/p) d'**aclonifen** sous forme de suspension concentrée (SC)

Autorisation de Mise sur le Marché n°xxxx
Date de fabrication et numéro de lot : voir emballage

GROUPE	F3	HERBICIDE

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL
Consulter le livret avant toute utilisation

Conserver le produit dans son emballage d'origine. Le stocker dans un local réservé à cet usage, frais, sec, bien ventilé et fermant à clé, à l'abri du gel et de la chaleur.

Contenu: 5 / 10 / 20 litres

Distribué par :
A remplir

Détenteur d'AMM (EMB) et de la marque CHANON:
GLOBACHEM NV
Brustem Industriepark – Lichtenberglaan 2019
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REEMPLOI DE L'EMBALLAGE INTERDIT.

CHANON® SC – AMM n° xxxxx
Contient 600 g/l (49.73% p/p) d'aclonifen sous forme de suspension concentrée (SC)
UFI : xxxxx

ATTENTION

H317 : Peut provoquer une allergie cutanée.
H351 - Susceptible de provoquer le cancer
H410 : Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

P201 – Se procurer les instructions avant utilisation.
P261 - Éviter de respirer les aérosols.
P302+P352 - EN CAS DE CONTACT AVEC LA PEAU : Laver abondamment à l'eau.
P308 + P313 – EN CAS d'exposition prouvée ou suspectée : consulter un médecin.
P333+P313 - En cas d'irritation ou d'éruption cutanée : consulter un médecin.
P363 - Laver les vêtements contaminés avant réutilisation.
P391 - Recueillir le produit répandu.
P501 - Éliminer le contenu/récipient dans un centre de collecte des déchets dangereux ou spéciaux.

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

SP1: Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter 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 en bordure des 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 adjacente pour tous les usages ou utiliser des buses antidérives de 75%.

Délai de rentrée : 48 Heures

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

PREMIERS 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

CHANON SC est un herbicide contenant de l'aclonifen, utilisé en pré-émergence et en post-émergence précoce sur céréales d'hiver. L'aclonifen est un herbicide à large spectre appartenant à la famille des herbicides Diphenyl ether (HRAC Group F3). C'est un herbicide résiduel sélectif utilisé pour des applications en pré et post—levée qui est absorbée par l'hypocotyle/coléoptile et les cotylédons des adventices émergentes et est transféré vers les méristèmes.

Tableau des usages autorisés

Cultures	Cibles	Dose maximale d'emploi	Nbre maximum d'applications par an	Stade d'application	Délai avant récolte (DAR)	Zone non traitée aquatique (ZNT)
Cultures d'hiver de blé, triticale, orge, seigle, et d'avoine	Désherbage des adventices	1,35 L/ha	1	BBCH 00-09 BBCH 10-13	F (BBCH 13)	5 mètres

L'utilisation de CHANON® SC sur ses usages autorisés n'est recommandée que sur les cultures mentionnées dans le tableau ci-dessus. Globachem N.V. décline en conséquence toute responsabilité en cas d'utilisation du produit sur des cultures ou pour des cibles non recommandées.

Les limites maximales de résidus sont consultables à l'adresse suivante : http://ec.europa.eu/food/plant/protection/pesticides/index_fr.htm

INFORMATION RELATIVE A L'EMPLOI

Spectre d'efficacité :

STEME – Fortement sensible
PAPRH – Fortement sensible
MATIN – Fortement sensible pre-em) / Sensible (post-em)
APESV – Fortement sensible (pre-em) / Modérément tolérant (post-em)
POAAN – Sensible (pre-em) / Fortement sensible (post-em)
LOLMU – Modérément tolérant (pre-em) / Sensible (post-em)
VERPE – Modérément tolérant (pre-em) / Sensible (post-em)
VIOAR – Modérement sensible (pre-em) / Sensible (post-em)
ALOMY – Modérément tolérant (pre-em) / Modérement sensible (post-em)

CHANON SC peut augmenter l'efficacité des partenaires de mélanfe utilisés pour contrôler ALOMY

Cultures suivantes et Cultures de remplacement :

Toute culture de remplacement peut être semée sans délai d'attente si le sol est travaillé.

Conditions d'application

Précautions d'emploi

Distance de Sécurité Riverains :
Conformément à la réglementation en vigueur et aux chartes d'engagements des utilisateurs, respecter une distance de sécurité au voisinage des zones d'habitation et des zones accueillant des groupes de personnes vulnérables.

Autres précautions
• La mise en place de haies pour protéger les zones vulnérables avoisinantes (point d'eau, bâtiments) est également très efficace pour limiter la dérive.
• Ne pas pulvériser à proximité des points d'eau (mares, cours d'eau, fossés...).
• Utiliser un volume de bouillie variant de 200 à 300 L d'eau par hectare et une pression de 2 à 3 bars.
• Eviter les redoublements de passage de rampes de pulvérisation.
• 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. Veiller à éviter tout retour de bouillie vers la source d'eau en utilisant une cuve intermédiaire, et/ou un clapet anti-retour et/ou une vanne programmable.
• Ne pas souffler dans les buses pour tenter de les déboucher.
• Ne pas respirer les vapeurs, ni le brouillard de pulvérisation.
• 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.
Nous attirons votre attention sur la nécessité de faire un test de compatibilité physique et biologique en procédant à une pulvérisation sur une surface significative de la culture.

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 le pulvérisateur sur une aire étanche sur laquelle les écoulements accidentels peuvent être récupérés.
Remplir à 50% du volume requis le réservoir du pulvérisateur avec de l'eau propre.
Mettre en marche le système d'agitation ou d'incorporation puis ajouter progressivement le produit. Ajouter enfin le reste du volume d'eau requis. Rincer le bidon de produit vide trois fois et ajouter le produit ainsi dilué au reste de la bouillie de pulvérisation.
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.

PREVENTION ET GESTION DE LA RÉSISTANCE

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 l'herbicide 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 préconisateur 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 l'emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur et fermé à clé, à l'abri de l'humidité, du gel, dans un endroit frais, aéré et ventilé, 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 individuelles.
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.F 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. Pulvériser le fond de cuve préalablement dilué 5 fois et les eaux de rinçage sur une parcelle déjà traitée. Il est

recommandé de nettoyer le pulvérisateur sur la parcelle ou sur une zone spécialement équipée pour recueillir les eaux de lavage.

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 du pulvérisateur. 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 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 préconisateur 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.