REGISTRATION REPORT

Part A

Risk Management

Product code: GLOB1907bH

Product name(s): BOKATOR

Chemical active substance(s):

Aclonifen, 600g/L
Diflufenican, 30 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: GLOBACHEM NV

Date: 15 september 2023

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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 BOKATOR (formulation code: GLOB1907bH), containing 600 g/L Aclonifen[1] and 30 g/L Diflufenican[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 02/02/2022 to market DIFLANIL ACE (GLOB1907bH) in France (product uses described under point 2.3). France acted as a zonal/interzonal 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 (2021-4630 and 2023-2174) 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 DIFLANIL ACE (GLOB1907bH) has been made using endpoints agreed in the EU peer reviews of Aclonifen and Diflufenican. It also includes assessment of data and information related to DIFLANIL ACE (GLOB1907bH) 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 DIFLANIL ACE (GLOB1907bH).

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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: actives substances data are not protected any more.

1.3 Justification for submission of tests and studies

According to the applicant: « The application is for a new product. It follows the data requirements for the active substance 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 DIFLANIL ACE (GLOB1907bH), 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	GLOB1907bH
Product name in MS	DIFLANIL ACE
Authorisation number	-
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	GLOBACHEM NV
Active substance(s) (incl. content)	Aclonifen, 600 g/L Diflufenican, 30 g/L
Formulation type	Suspension concentrate [SC]
Packaging	HDPE-f bottles (0.25, 0.5, 1L) and HDPE-f containers (5, 10, 20L) with a homogenisation system for 20 L packaging HDPE-EVOH bottles (0.25, 0.5, 1L) and HDPE-EVOH containers (5, 10, 20L) with a homogenisation system for 20 L packaging HDPE bottles (0.25, 0.5, 1L) and HDPE containers (5, 10, 20L) with a homogenisation system for 20 L packaging HDPE-PA bottles (0.25, 0.5, 1L) and HDPE-PA containers (5, 10, 20L) with a homogenisation system for 20 L packaging
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion DAMM

The evaluation of the application for DIFLANIL ACE 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

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.

Thus, 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 culture[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/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; 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 50 meters[10] with an unsprayed vegetated buffer zone of 20 meters to surface water bodies for the uses on potatoes.
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 5 metres to non-agricultural land for the uses on potatoes.
Other specific restrictions	
Re-entry period	48 hours
Storage	The formulation must be stored at a temperature below 40 °C.
	The product must be homogenised before use.
Risk mitigation measures	Do not plant a subsequent crop or replacement less than 120 days after application of the diflufenican substance.
Risk mitigation measures	none
Agricultural recommendations	- To avoid any risk of phytotoxicity, specify the optimum conditions of application in relation to adjacent crops. - To avoid any risk of phytotoxicity, specify the optimum conditions for planting subsequent or replacement crops.

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.

[10] in consistency with French Order of 4 May 2017 (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), modified by the French Order of 27 December 2019.

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: 15 09 2023

PPP (product name/code):	DIFLANIL ACE / GLOB1907bH	Formulation type:	SC [a, b]
Active substance 1:	Aclonifen	Conc. of a.s. 1:	600 g/L [c]
Active substance 2:	Diflufenican	Conc. of a.s. 2:	30 g/L [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)	kg or 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)	kg or 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	Potato (SOLTU)	F	annual grassy weeds (GGGAN) annual broadleaved weeds (BBBAN)	Downward spraying	BBCH 00-09	a) 1 b) 1	-	a) 1.9 b) 1.9	a) Aclonifen: 1.14 diflufenican: 0.057 b) Aclonifen: 1.14 diflufenican: 0.057	100 - 300	N/A	**Acceptable**
2	FR	Sunflower (HELAN)	F	annual grassy weeds (GGGAN) annual broadleaved weeds (BBBAN)	Downward spraying	BBCH 00-09	a) 1 b) 1	-	a) 1.9 b) 1.9	a) Aclonifen: 1.14 diflufenican: 0.057 b) Aclonifen: 1.14 diflufenican: 0.057	100 - 300	N/A	**Not acceptable** (selectivity, aquatic organisms)
3	FR,	Sunflower (HELAN)	F	annual grassy weeds (GGGAN) annual broadleaved weeds (BBBAN)	Downward spraying	BBCH 00-09	a) 1 b) 1	-	a) 1 b) 1	a) Aclonifen: 0.6 diflufenican: 0.03 b) Aclonifen: 0.6 diflufenican: 0.03	100-300	N/A	**Not acceptable** (aquatic organisms)

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.
** Possible application during the flowering period according to the order of 20 November 2021 on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products

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)

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 yellow uniform liquid, with an emulsion paint type odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature of more than 400 °C. It has no flash below 100 °C and is therefore not considered to be highly flammable. In aqueous solution (1% dilution), it has a pH value around 7.67. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at 40 °C in HDPE packaging (1L), neither the active ingredient content nor the technical properties were changed. The preparation should be stored at a temperature below 40°C. The commercial packaging is made of HDPE, HDPE-F, HDPE-EVOH and HDPE/PA. As HDPE packaging was tested (worst case), extrapolation to other packaging materials is acceptable due to the type of product (aqueous SC formulation).

Its technical characteristics are acceptable for a *suspension concentrate* formulation. Due to the type of formulation (SC) and size of packaging (up to 20L), sedimentation cannot be excluded. Therefore, it is recommended to shake the preparation before using.

The intended concentration of use is 0.633% (1.9 L in 300 L water) to 1.9 % (1.9 L in 100 L water).

3.2 Efficacy (Part B, Section 3)

Considering the data submitted,

- The efficacy level of the product Diflanil Ace (code: GLOB1907bH) applied in pre-emergence of the crop (targets: broad-leaved weeds and the grass weeed *Echinochloa crus-galli*), is considered satisfying on the claimed crops (potato and sunflower) at the dose of 1.9 L/ha.

- In addition, the applicant requests a reduced dose rate of 1 L/ha for the control of a more limited weed spectrum (including *Chenopodium album* which is difficult to control in sunflower). The reduced dose of 1 L/ha remains agronomically acceptable, because of it’s interest for the control of certain weeds, even if this dose does not guarantee an optimal efficiency.

- The selectivity level of the product Diflanil Ace (code: GLOB1907bH), and the risk of negative impact on the yield and quality of the harvest are considered acceptable for the intended use on potato crops. Regarding sunflower, the selectivity level of the product Diflanil Ace (code: GLOB1907bH), and the risk of negative impact on yield and quality of the harvest are considered not acceptable at the dose of 1,9 L/ha, as the product can cause strong and sometimes persistant symptoms on treated crops, associated with an impact on yield. At the dose of 1 L/ha on sunflower, the selectivity level of the product Diflanil Ace (code: GLOB1907bH) is considered acceptable at this reduced dose.

- The risks of negative impact on propagation are considered acceptable.

- The risk of negative impact on succeeding crops is considered acceptable. Nevertheless, specific attention should be paid to the conditions of implantation of succeeding and replacement crops (ploughing is necessary for susceptible crops). Please see part B of the document for specific recommendations.

- The risk of negative impact on adjacent crops is considered acceptable. Nevertheless, specific attention should be paid to the conditions of application of the product near susceptible adjacent crops. Please see part B of the document for specific recommendations.

- The risk of resistance to aclonifen and diflufenican does not require the set up of a survey on intended 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 substances 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/this dossier and validated for the determination of residues of aclonifen and diflufenican in plants (high water content and fatty commodities), food of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints		
Active substance	**Aclonifen**	**Diflufenican**
AOEL systemic	0.07 mg/kg bw/d	0.11 mg/kg bw/d
AAOEL	None	None
Oral absorption	100%	58%
Vapour pressure	$3{,}2.10^{-5}$ Pa at 25°C	4.25×10^{-6} Pa à 25 °C
Reference	EFSA Scientific Report (2008) 149, 1-80	EFSA Scientific Report (2007) 122, 1-84
Dermal absorption	Concentrate: 0.076% (600 g/L) Dilution: 2.3% (dilution rate 1:150) Dilution: 2.42% (using the pro-rata correction)	Concentrate: 50%* Dilution: 50% Default values (EFSA Journal 2017; 15(6):4873)

*Concentration in the formulation is below 50 g/L, so dermal absorption value of the dilution is also used for the concentrate (SANTE/2018/10591, implementation of the guidance of 2017)

3.4.1 Acute toxicity

DIFLANIL ACE (GLOB1907bH) containing 600 g/L Aclonifen and 30 g/L Diflufenican has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin and eye but is a skin sensitiser.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[11]:

Model data		Aclonifen	Diflufenican
	Level of PPE	**% AOEL**	**% AOEL**
Application : *Tractor mounted boom spray application outdoors to low crops* **Outdoor** **Potatoes and Sunflower (BBCH 09 - Bare soil)**			
Application rate: 1.9 L DIFLANIL ACE /ha		1.14 kg Aclonifen / ha	0.057 kg Diflufenican / ha
Spray ap-plication (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	0.98	2.90

According to the model calculations, it can be concluded that the risk for the operator using DIFLANIL ACE (GLOB1907bH) is acceptable with a working coverall and gloves 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

According to the EFSA Calculator and for "bare-soil" applications, no re-entry activities are foreseen for workers. As such, and since DIFLANIL ACE (GLOB1907bH) is a pre-emergence herbicide, a worker exposure assessment is not required.

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[12].
According to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): *"No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. 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."*
No AAOEL has been set for substances Aclonifen and Diflufenican. Thus, for these active substances, resident exposure assessment covers bystander exposure.

3.4.5 Resident exposure

Resident exposure was assessed according to EFSA model without mitigation measures, a distance of 3 metres from the spray boom and no drift reduction technology was considered.

[11] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)
[12] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

Model data		Aclonifen	Diflufenican
		% AOEL	**% AOEL**
Scenario: *Tractor mounted boom spray application outdoors to low crops (Bare soil)* Buffer zone: 2-3 (m) Drift reduction technology: no Number of applications : 1 Interval between treatments: 365 days			
DT_{50}		30 days	30 days
DFR		3 µg/cm²/kg a.s./ha	3 µg/cm²/kg a.s./ha
Resident (children) Body weight: 10 kg	Spray drift (75th percentile)	10.93	6.96
	Vapour (75th percentile)	1.53	0.97
	Surface deposits (75th percentile)	1.90	0.40
	Entry into treated crops (75th percentile)	6.65	4.37
	All pathways (mean)	14.31	8.59
Resident (adults) Body weight: 60 kg	Spray drift (75th percentile)	2.56	1.67
	Vapour (75th percentile)	0.33	0.21
	Surface deposits (75th percentile)	0.27	0.18
	Entry into treated crops (75th percentile)	3.69	2.43
	All pathways (mean)	4.70	3.07

An acceptable risk was determined for resident (adult and child).

3.4.6 Combined exposure

A cumulative assessment for operators, residents and bystander (adult and child) was performed. At the first tier, combined exposure was calculated as the sum of the component exposures, without regard to the mode of action or mechanism/target of toxicity.
Hazard quotients (HQ) for each substance and the hazard index (HI: sum of hazard quotients) are detailed in the table below.

Risk assessment from combined exposure (longer term exposure)

Population groups and PPE		Aclonifen Estimated exposure / AOEL (HQ)	Diflufenican Estimated exposure / AOEL (HQ)	Cumulative Exposure – Hazard Index
Operators Bare soil	Working coverall and gloves during mixing/loading and application	0.98	2.90	0.04
Worker Bare soil	Working coverall and gloves	NA	NA	NA
Resident - child Bare soil	Drift	10.93	6.96	0.18
	Vapour	1.53	0.97	0.03
	Deposits	1.90	0.40	0.02
	Re-entry	6.65	4.37	0.11

	Sum of all pathways	14.31	8.59	0.23
Resident – adult Bare soil	Drift	2.56	1.67	0.04
	Vapour	0.33	0.21	0.005
	Deposits	0.27	0.18	0.005
	Re-entry	3.69	2.43	0.06
	Sum of all pathways	4.70	3.07	0.08

The Hazard Index is < 1. Thus combined exposure to all substances in DIFLANIL ACE is not expected to present a risk for operators, workers, bystanders and residents (adult and child).

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

3.5.1 Residues

The preparation DIFLANIL ACE (GLOB1907bH) is composed of aclonifen and diflufenican.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.02 mg/kg on potatoes and sunflower for aclonifen as laid down in Reg. (EU) 396/2005 is not expected. Moreover, an exceedance of the current MRL of 0.01 mg/kg on potato and sunflower seeds for diflufenican as laid down in Reg. (EU) 396/2005 is not expected.

According to SANTE/11956/2016 rev. 9 (14 September 2018), sunflower is considered a melliferous crop. Considering that the active substance aclonifen is systemic, in the absence of residue trials with honey, an exceedance of the current MRLs of 0.05 mg/kg for aclonifen in honey, as laid down in Reg. (EU) 396/2005, cannot be excluded for sunflower.

3.5.2 Consumer exposure

The chronic and the short-term intakes of aclonifen residues are unlikely to present a public health concern. Moreover, the chronic and the short-term intakes of diflufenican residues are unlikely to present a public health concern. Since the setting of an ARfD was not deemed necessary, no acute risk assessment was performed in the framework of this dossier.

As far as consumer health protection is concerned, France zRMS agrees with the authorization of the intended use on potato and disagrees with authorization of the intended use on sunflower.

According to available data, the following specific mitigation measure is recommended:
waiting period of 120 days before planting succeeding crops.

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. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substances and their metabolites 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.

The PEC of aclonifen and diflufenican and its metabolites 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.
PECsoil and PECsw derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.
PECgw for aclonifen and diflufenican and its metabolites 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.
Based on vapour pressure, information on volatilisation from plants and soil, and DT50 calculation, no significant contamination of the air compartment 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, mammals and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses.

The chronic risk assessment for pollinators, adult and larvae, no safe uses is demonstrated according to the EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (2013). No reliable data are available to refine the risk assessment.

Risk mitigations are required for aquatic organisms for intended uses on potatoes. However, intended uses on uses on sunlfowers in considered as not acceptable since no safe uses is demonstrated with the proposed approach and mitigation measures.

Risk mitigations are required for non-target plants.

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)

DIFLANIL ACE (GLOB1907bH) contains diflufenican and aclonifen which are approved as candidates for substitution because they meet two of PBT criteria (bioaccumulative and toxic for aclonifen, persistent and toxic for diflufenican).

<u>Step 1 (French guidance document 27 July 2015):</u>

- Taking into account the management of resistance:

In accordance with Articles 50(1)(c) of Regulation (EC) No 1107/2009, in the frame of resistance emergence prevention, as the a.s. candidates for substitution are an important part of the resistance

management strategy and as there are too few modes of action available, **substitution is not considered for all uses.**

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

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) n° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,

Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique ***BOKATOR***

de la société *GLOBACHEM NV*

enregistrées sous les *n° 2021-4630 et 2023-2174*

Vu les conclusions de l'évaluation de l'Anses du 20 juillet 2023,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

DIFLANIL ACE
AMM n° 2230589

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Informations générales sur le produit	
Nom du produit	BOKATOR
Type de produit	Produit de référence
Titulaire	GLOBACHEM NV Lichtenberglaan 2019 Brustem Industriepark 3800 SINT-TRUIDEN Belgique
Formulation	Suspension concentrée (SC)
Contenant	600 g/L - aclonifène 30 g/L - diflufénican
Numéro d'intrant	1053-2021.01
Numéro d'AMM	2230589
Fonction	Herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2024.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 15/09/2023

DocuSigned by:
Charlotte Grastilleur

Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Bouteilles en polyéthylène haute densité	250 mL ; 500 mL ; 1 L
Bouteilles en polyéthylène haute densité / éthylène alcool vinylique	250 mL ; 500 mL ; 1 L
Bouteilles en polyéthylène haute densité / polyamide	250 mL ; 500 mL ; 1 L
Bouteilles en polyéthylène haute densité fluoré	250 mL ; 500 mL ; 1 L
Bidons en polyéthylène haute densité	5 L ; 10 L ; 20 L
Bidons en polyéthylène haute densité / éthylène alcool vinylique	5 L ; 10 L ; 20 L
Bidons en polyéthylène haute densité / polyamide	5 L ; 10 L ; 20 L
Bidons en polyéthylène haute densité fluoré	5 L ; 10 L ; 20 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Sensibilisants cutanés - Catégorie 1	H317 : Peut provoquer une allergie cutanée
Cancérogénicité - Catégorie 2	H351 : Susceptible de provoquer le cancer
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
Pour les phrases P se référer à la réglementation en vigueur. **Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.**	

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15655901 Pomme de terre*Désherbage	1,9 L/ha	1/an	Jusqu'au stade BBCH 09	F (BBCH 09)	50 (dont DVP 20)	-	5	Non concerné
	-							

DVP : Dispositif Végétalisé Permanent.

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15905901 Tournesol*Désherbage	1 L/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques.		

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Stocker le produit à une température inférieure à 40°C.

- Agiter le produit dans son emballage avant utilisation.

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- 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.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

• pendant l'application

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

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Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 48 heures

Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et :

- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Respect des limites maximales de résidus (LMR)

- Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.
- Afin d'éviter la présence de résidus de diflufenican dans les cultures suivantes, ne pas implanter de cultures moins de 120 jours après traitement.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : 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.

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau.
- SPe 8 : Pour protéger les abeilles et autres insectes pollinisateurs, ne pas utiliser en présence d'abeilles et autres insectes pollinisateurs.

Protection de la flore

- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Contient de la 1,2-benzisothiazol-3-one.

- Pour prévenir tout risque éventuel de phytotoxicité, préciser les conditions optimales d'application par rapport aux cultures adjacentes.

- Pour prévenir tout risque éventuel de phytotoxicité, préciser les conditions optimales d'implantation des cultures suivantes ou de remplacement.

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.

1G.1 DIFLANIL ACE
Projet d'étiquette - I