REGISTRATION REPORT

Part A

Risk Management

Product code: GLOB1296H

Product name: BRANDO

Chemical active substances:

napropamide, 500 g/L
quinmerac, 100 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: GLOBACHEM

Date: 15/04/2021

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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 BRANDO (product code: GLOB1296H), containing 500 g/L napropamide[1] and 100 g/L quinmerac[2], as a 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 11 February 2019 to market BRANDO (GLOB1296H) 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 (2019-1086) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[3], 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")[4]. 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 BRANDO (GLOB1296H) has been made using endpoints agreed in the EU peer reviews of napropamide and quinmerac. It also includes assessment of data and information related to BRANDO (GLOB1296H) 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[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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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 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011, as amended by Commission Implementing Regulation (EU) 2018/1260 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances pyridaben, quinmerac and zinc phosphide.

3 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

4 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

5 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

This document also describes the specific conditions of use and labelling required for France for the registration of BRANDO (GLOB1296H).

1.2 Letters of Access

The applicant has provided a letter of access for quinmerac active substance data. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: "*The application is for a new product that has never been authorised in the EU. 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 BRANDO (GLOB1296H), 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	GLOB1296H.
Product name in MS	BRANDO.
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use.
Low risk product (article 47)	No.
Function	Herbicide.
Applicant	GLOBACHEM NV.
Active substance(s) (incl. content)	napropamide, 500 g/L. quinmerac, 100 g/L.
Formulation type	Suspension concentrate [SC].
Packaging	N/A : no marketing authorisation granted
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 BRANDO (GLOB1296H) resulted in the decision **to refuse** 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:	Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statement(s):	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:	To avoid risks to man and the environment, comply with the instructions for use EUH401.
	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction EUH208.

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

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

N/A : no marketing authorisation granted.

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[6] 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 26 March 2014[7] 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[8] 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.

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

N/A : no marketing authorisation granted.

2.5.2 Specific restrictions linked to the intended uses

N/A : no marketing authorisation granted.

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6 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,

7 http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

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 26 March 2014 (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. 1.0, date: 2021-04-15

PPP (product name/code):	BRANDO/GLOB1296H	Formulation type:	SC [a, b]
Active substance 1:	napropamide	Conc. of a.s. 1:	500 g/L [c]
Active substance 2:	quinmerac	Conc. of a.s. 2:	100 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:** 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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Winter oilseed rape (BRSNW)	F	Weeds	Normal downward spraying	Pre-emergence	a) 1 b) 1 every 3 years	/	a) 2.5 b) 2.5	a) 1250 g napro-pamide/ha + 250 g quin-merac/ha b) 1250 g napropamide/ha + 250 g quinmerac/ha	100-400	F – the latest time of application must be growth stage BBCH 09 at the latest.	**Not acceptable** (groundwater)

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 acceptable.

The appearance of the product is that of a uniform white-coloured opaque liquid, with a faint sweet odour. It is not explosive, has no oxidising properties and is not highly flammable. It has a self-ignition temperature of more than 400 °C. In 1 % aqueous solution, it has a pH (1 % dilution) value around 3.87 at 20.1 °C. Its viscosity ranges from 854.4 mPa·s (20.2 s^{-1}) to 4063 mPa·s (2.6 s^{-1}). There was no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substances' content nor the technical properties were changed.

The surface tension of the diluted product (2.5 %) is 38.70 mN/m at 25 °C, which indicates that the product is surface-active. The pourability-rinsibility characteristics are consistent with this type of product. Only 0.0524 % of material remained on a 75 µm screen during a wet sieve test. After one minute, 2-4 mL of persistent foam remained, indicating that the formulation is not a foaming product. Suspensibility was investigated at the maximum and minimum application rates and was 100.9/100.9 % for quinmerac and 100.5/100.6 % for napropamide respectively, meaning effect/no effect of the concentration.

The technical characteristics are acceptable for a suspension concentrate (SC) formulation.

The intended concentrations of use are 0.625 % (2.5 L in 400 L water) to 2.5 % (2.5 L in 100 L water).

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

The efficacy of the product BRANDO (GLOB1296H) applied pre-emergence is considered satisfactory to control annual broadleaved weeds and grasses in winter oilseed rape.

The level of selectivity of the product BRANDO (GLOB1296H) is considered acceptable for the requested use.

The risks of negative impact on yield, quality and multiplication are considered acceptable.

The risks of negative impact on succeeding and adjacent crops are considered acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops.

The risk of resistance developing or appearing to napropamide does not require monitoring for the requested use. There is a risk of resistance developing or appearing to quinmerac for *Papaver rhoeas*; this requires monitoring.

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 (toluene from technical napropamide) in the formulation are available and validated.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft/Renewal Assessment Reports (DAR/RAR) and validated for the determination of residues of napropamide and quinmerac in plants (oily crops), soil, water (surface and drinking) and air.

A validated method (including its ILV) for the determination of quinmerac and napropamide residues in foodstuffs of animal origin is required.

3.4 Mammalian toxicology (Part B, Section 6)

Active substance: **napropamide**			
ADI	0.3 mg/kg bw/d		EU 2017/Efsa 2010
ARfD	Not applicable		
AOEL	0.5 mg/kg bw/d		
AAOEL	-		
Dermal absorption	Based on or default values according to guidance on dermal absorption (Efsa 2017):		
		Concentrate (used in formulation) 500 g/L	Spray dilution (used in formulation) (1:160)
	Dermal absorption endpoints %	**10**	**50**
Oral absorption (%)	**> 90**		Efsa 2010

Active substance: **quinmerac**			
ADI	0.08 mg/kg bw/d		EU 2017/Efsa 2010/Anses (05/2013)
ARfD	0.3 mg/kg bw		
AOEL	0.08 mg/kg bw/d		
AAOEL	-		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2017):		
		Concentrate (used in formulation) 100 g/L	Spray dilution (used in formulation) (1:160)

	Dermal absorption endpoints %	10	50
Oral absorption (%)	**100**		Efsa 2010

3.4.1 Acute toxicity

BRANDO (GLOB1296H), containing 500 g/L napropamide and 100 g/L quinmerac, has no acute oral, dermal or inhalational toxicity, is not irritating to the skin, is not damaging to the eyes and is not a skin sensitiser.

3.4.2 Operator exposure

Considering the proposed use, operator systemic exposure was estimated using the EFSA model[9]:

Model data		**Napropamide**	**Quinmerac**
	Level of PPE	**% AOEL**	**% AOEL**
Application : Tractor (vehicle-mounted)/*down* **Outdoor** **Crops *winter oilseed rape (BRSNW)***			
Application rate: 2.5 L BRANDO/ha		1250 g napropamide/ha	250 g quinmerac/ha
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Working coverall during mix/loading and application and gloves during mix/loading	17.73	22.55

According to the model calculations, it may be concluded that the risk for the operator using BRANDO (GLOB1296H) is acceptable with a working coverall during mixing/loading and application, and gloves during mixing/loading.

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

3.4.3 Worker exposure

EFSA model: At the time of application (pre-emergence), the field is free from any crop or weed. Thus, no contact with treated leaf surfaces is expected. Nevertheless, contact with soil-borne residues may occur. Therefore, France as zRMS has reassessed the worker exposure, considering the crop scenario "oilseed" instead of "bare soil". According to the model calculations, it may be concluded that the risk for the worker using BRANDO (GLOB1296H) is acceptable with work-wear.

3.4.4 Bystander and resident exposure

Bystander - EFSA model (w/o AAOEL): 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.,

[9] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874).

no acute operator or bystander exposure assessments can be performed with the AOE model where no AAOEL has been set[10].

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 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*."

Resident - EFSA model: Residential exposure was assessed according to the EFSA model. An acceptable risk was determined for residents (adult and child) when mitigation measures such as a buffer zone of 2-3 metres are taken:

Model (AOEM) - All pathways (mean)	**% AOEL napropamide**	**% AOEL quinmerac**
Resident (children)	37.01	47.33
Resident (adults)	13.83	17.52

3.4.5 Combined exposure

Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first-tier assessment.

A cumulative assessment for operators and bystanders/residents has been performed, but not for workers, assuming estimation of worker exposure was not calculated. At the first tier, combined exposure is 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 active substance and the HI (sum of hazard quotients) are:

Population groups and PPE		**Active substance**	**Estimated exposure / AOEL (HQ)**
Operators	Working coverall during mixing/loading and application; gloves during mixing/loading	**Napropamide**	0.1773
		Quinmerac	0.2255
	Cumulative risk operators (HI)		**0.4028**
Bystanders/Residents	Children - All pathways (mean)	**Napropamide**	0.3701
		Quinmerac	0.4733

[10] 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)

	Cumulative risk bystanders/residents (child) (HI)		**0.8434**
	Adults - All pathways (mean)	**Napropamide**	0.1383
		Quinmerac	0.1752
	Cumulative risk bystanders/residents (adult) (HI)		**0.3135**
Worker	Working coverall and gloves	**Napropamide**	NA
		Quinmerac	NA
	Cumulative risk workers (HI)		**NA**

The Hazard Index is < 1. Thus combined exposure to both active substances in BRANDO (GLOB1296H) is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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

The data available are considered sufficient for risk assessment. No exceedence of the current MRL of 0.1 mg/kg mg/kg for napropamide as laid down in Reg. (EU) 396/2005 is expected.

The chronic and short-term intakes of napropamide and quinmerac residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern. For quinmerac, risks for the consumer cannot be evaluated, due to the lack of residue data.

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

According to the available data, the following specific mitigation measures (related to napropamide) are recommended:

- For root and tuber crops, a waiting period of 180 days after treatment with BRANDO (GLOB1296H) is required before planting or sowing.
- For other crops, a waiting period of 60 days after treatment with BRANDO (GLOB1296H) is required before planting or sowing.

Noticed data gaps: none.

Information on BRANDO (GLOB1296H)

Crop	**PHI for BRANDO requested by applicant**	**PHI/withholding period* sufficiently supported for**		**PHI for BRANDO proposed by zRMS**	**zRMS Comments (if different PHI proposed)**
		Napropamide	**Quinmerac**		
Winter oilseed rape	N/A	Yes	Yes	F (BBCH 09)	

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

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for BRANDO
Crop group	**Led by napropamide**	**Led by quinmerac**	
Root/tuber crops	180	-	180
Other crops	60	-	60

NR: 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. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (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 values of napropamide, quinmerac and their 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 or agreed in the assessment based on new data provided.

PECsoil and PECsw values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

The PECgw values calculated for napropamide and its metabolite and for quinmerac metabolites (for an application every third year for quinmerac metabolites) are below the threshold values defined in the guidance document SANCO 221/2000, after the use of BRANDO (GLOB1296H).

The PECgw values calculated for quinmerac (for an application every third year) are above the threshold value of 0.1 µg/L for one FOCUS scenario (maximum PECgw value of 0.309 µg/L), after the use of BRANDO (GLOB1296H). Therefore the risk of groundwater contamination by quinmerac cannot be finalised by France as zRMS for the use of this product on oilseed rape.

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 substances and 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, bees and other non-target arthropods, earthworms, other soil macro- and micro-organisms and terrestrial plants are acceptable for the intended uses. Risk mitigations are required for aquatic organisms.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to point 3.6 for conclusions on the risk of groundwater contamination.

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

Neither active substance is approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

N/A : no marketing authorisation granted.

5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted.

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 du produit phytopharmaceutique ***BRANDO***

de la société *GLOBACHEM NV*

enregistrée sous le *n°2019-1086*

Vu les conclusions de l'évaluation de l'Anses du 28 janvier 2021,

Considérant qu'un risque inacceptable de contamination des eaux souterraines par le quinmérac et ses métabolites, lié à l'utilisation du produit, ne peut être exclu,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

BRANDO
AMM n°-

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Informations générales sur le produit	
Nom du produit	BRANDO
Type de produit	Produit de référence
Titulaire	GLOBACHEM NV Brustem Industriepark Lichtenberglaan 2019 3800 Sint-Truiden Belgique
Formulation	Suspension concentrée (SC)
Contenant	500 g/L - napropamide 100 g/L - quinmérac
Numéro d'intrant	095-2019.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 15 AVR. 2021

Caroline SEMAILLE
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 I : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
15205901 Crucifères oléagineuses*Désherbage	2,5 L/ha	1/an	F (BBCH 09)
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque inacceptable de contamination des eaux souterraines par le quinmérac et ses métabolites.		

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.

BRANDO®

HERBICIDE COLZA

Contient 500 g/L (45.16% p/p) de **napropamide** et 100 g/L (9.03% p/p) de **napropamide** sous forme de Suspension concentrée (SC)

Autorisation de Mise sur le Marche n° xxx

Date de fabrication / Numéro de lot : voir emballage

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Contenu : 1 ; 2 ; 3 ; 5 ; 10 ; 20 L e

Distribué par :
A compléter

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

BRANDO®
AMM n° xxx – Contient 500 g/L (45.16% p/p) de napropamide et 100 g/L (9.03% p/p) de napropamide sous forme de Suspension concentrée (SC)

Délai de rentrée des travailleurs dans la zone traitée: 6 heures

SP1: Ne pas polluer l'eau avec le produit ou son emballage.
SPe2: Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur sols artificiellement drainés ayant une teneur en argile supérieure ou égale à 45 %.

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

Conserver à l'abri du gel.

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).

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

BRANDO® est un herbicide de post-semis prélevée du colza d'hiver. Il se compose de quinmérac, matière active de la famille des acides quinoléine-carboxyliques (code HRAC O) et de napropamide matière active de la famille des acétamides (code HRAC K3). Il présente une efficacité sur dicotylédones et sur graminées.

Tableau des usages autorisés

Cultures	Cible	Dose maximale d'emploi (L/ha)	Nombre maximum d'applications par an	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)
Colza d'hiver	Adventices	2,5	1	-	5 m

Globachem NV ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées ci-dessus et, à ce titre, déclinent 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

RECOMMANDATIONS D'EMPLOI

Champ d'activité
BRANDO® s'utilise en prélevée post-semis de la culture de colza d'hiver. Il est particulièrement efficace à la dose de 2.5 L/ha pour lutter contre les coquelicot, pâturin annuel, camomille inodore, gaillet gratteron et les véroniques.

Conditions d'application
BRANDO® s'utilise en un seul passage, dans les 3 jours après le semis.
Appliquer BRANDO® sur un sol finement préparé et non motteux. Veiller à ce que le semis soit effectué à une profondeur régulière et suffisante (2 à 3 cm). Ne pas rouler la culture après traitement. Ne pas traiter en conditions météorologiques défavorables: vent, pluie, forte chaleur supérieure à 25 °C à l'ombre. Traiter par temps calme afin de protéger les cultures voisines. Afin d'éviter tout risque de manque de sélectivité pouvant entraîner des retards de croissance, toute irrigation dans les 3 semaines qui suivent l'application de BRANDO® est à proscrire; de plus, ne pas effectuer de traitement si des précipitations importantes (20 mm ou plus) sont à craindre dans les jours qui suivent l'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.

Cultures suivantes dans la rotation
Aucune restriction dans le cadre normal de la rotation.

Cultures de remplacement
En cas de remplacement, seules les cultures choux, cultures racines, cultures fourragères et le colza peuvent être semées endéans les 7 mois suivant l'application de BRANDO®. Le maïs peut être semé après 9 mois. Pour les autres cultures, attendre 12 mois avant la plantation / le semis. Un labour à une profondeur de minimum 20 cm permet de réduire les effets.

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

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.