DRAFT REGISTRATION REPORT

Part A

Risk Management

Product code: Napropamide 450 SC

Product name: NAPRAMID 450

Active Substance:

Napropamide, 450 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: GLOBACHEM NV

Date: 05/12/2017

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PART A – Risk Management

The company GLOBACHEM NV has requested marketing authorisation in France for the product NAPRAMID 450 (formulation code: Napropamide 450 SC), containing 450 g/L napropamide for use as a herbicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to NAPRAMID 450 (Napropamide 450 SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of NAPRAMID 450 (Napropamide 450 SC) have been made using endpoints agreed in the EU peer review of napropamide.

This document describes the specific conditions of use and labelling required for France for the registration of NAPRAMID 450 (Napropamide 450 SC).

Appendix 1 of this document provides a copy of the French Decision.

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

Appendix 3 of this document is a copy of the letter(s) of access.

1 DETAILS OF THE APPLICATION

1.1 Application Background

The present registration report concerns the evaluation of GLOBACHEM NV's application to market NAPRAMID 450 (Napropamide 450 SC) in France as a herbicide (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 renewal of authorisation after approval of the active substance of this product in France and in other MSs of the Southern zone[1].

1.2 Active substance approval

Napropamide

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.
Specific provisions of regulation were as follows : PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on napropamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — operator safety: conditions of use shall prescribe the use of adequate personal protective equipment, where necessary, — protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones,

[1] France is the only named country in the GAP table, cf. Section 2.3

— consumer safety as regards the occurrence in groundwater of the metabolite 2-(1-naphthyloxy)propionic acid, hereinafter 'NOPA'. The Member States concerned shall ensure that the applicant presents to the Commission, by 31 December 2012 at the latest, information confirming the surface water exposure assessment as regards the photolysis metabolites and the metabolite NOPA and information for the risk assessment of aquatic plants.
An EFSA conclusion is available (EFSA Journal 2010; 8(4):1565 (*this version replaces that in EFSA Scientific Report (2008) 140, 1-74, Conclusion on the peer review of napropamide, dated 26 March 2008*)) A Review Report is available (SANCO/12647/2010 final, 28 October 2010).

1.3 Regulatory Approach

The present application (2013-0283) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[2] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[5], implementing regulations, Commission Directive 2010/83/EU of 30 November 2010 amending Council Directive 91/414/EEC to include napropamide as active substance and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. 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 conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[6], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[7] provides that:

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

[2] French Food Safety Agency, Afssa, before 1 July 2010
[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] 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 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte
[5] 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
[6] 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
[7] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" 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.

1.4 Data Protection Claims

Where protection for data is being claimed for information supporting registration of NAPRAMID 450 (Napropamide 450 SC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter of access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product Identity

Product name (code)	NAPRAMID 450 (Napropamide 450 SC)
Authorisation number	2100244
Function	Herbicide
Applicant	GLOBACHEM NV
Composition	450 g/L napropamide
Formulation type (code)	Suspension concentrate (SC)
Packaging	Bottles HDPE (1 L) Canisters HDPE (5 L)

2.2 Classification and Labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

2.2.2 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-

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

Health hazards	-	
Environmental hazards	Aquatic Chronic 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H410	Very toxic to aquatic life with long lasting effects
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	

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

2.2.3 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for professional uses only to the following conditions:

SP1	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.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres[9] with permanent untreated vegetative buffer strip of 5 metres to surface water bodies

2.2.4 Other phrases linked to the product

Wear suitable personal protective equipment[10]: refer to the Decision in Appendix 1 for the details
Re-entry period[11]: 6 hours
Pre-harvest interval[12]: Application must be made at growth stage BBCH 09 at the latest
Other mitigation measures: It is recommended that the formulation be stored at a temperature below 40 °C The following intervals after application must be respected before re-sowing or replanting: • 180 days for root crops; • 60 days for all other crops
The label may include the following recommendations: - The label must reflect the conditions of authorisation.

[9] The legal basis for this is **Titre III Article 11** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[10] If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

[11] The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[12] According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and Decision.

2.3 Product uses

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, date: 2017-12-05**

PPP (product name/code):	NAPRAMID 450/Napropamide 450 SC	Formulation type:	SC
Active substance 1:	napropamide	Conc. of a.s. 1:	450 g/L
Applicant:	GLOBACHEM NV	Professional use:	☒
Zone(s):	southern	Non-professional use:	☐
Verified by MS:	yes		

Field of use: herbicide

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	France	Oilseed rape (winter)	F	Annual grasses and broadleaved weeds.	Normal downward spraying. Has to be incorporated with a harrow at a depth of 3 to 4 cm within 48 hours after the treatment.	Before sowing of the crop at a well cultivated soil. BBCH 01-09	a) 1 b) 1			200 - 400	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 authorization 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 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

The formulation NAPRAMID 450 (Napropamide 450 SC) is a suspension concentrate. All studies have been performed in accordance with the current requirements. The appearance of the formulation is a uniform creamy-coloured liquid with an odour like sweet emulsion paint. It is not explosive and has no oxidising properties. It has a self-ignition temperature of 400 °C and no flash point below 82 °C. In aqueous solution (1 %), its pH is 6.72 at 20 °C. Stability data indicate a shelf life of at least 2 years at ambient temperature (HDPE). Its technical characteristics are acceptable for a suspension concentrate formulation.
The formulation must be stored at a temperature below 40°C.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

An analytical method for the determination of active substance in the formulation is available and validated.

As the relevant impurity (toluene) is a by-product of the manufacturing process for napropamide and as such cannot be formed by storage of the formulation, an analytical method for the determination of this impurity in the formulation is not necessary.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the monograph [Draft Assessment Report] and in this dossier and validated for the determination of residues of napropamide in plants (high-oil-content commodities), soil, water (surface and drinking) and air. Analytical methods for the determination of residues of napropamide in foodstuffs of animal origin are not necessary.

To update the dossier, **a confirmatory method for the determination of napropamide residues in soil and water is required.**

The active substance is neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

NAPRAMID 450 (Napropamide 450 SC) has a low acute oral, dermal and inhalational toxicity. It is not irritant to skin and eyes and does not cause skin sensitisation.

3.1.3.2 Operator Exposure

Exposure assessments
NAPRAMID 450 (Napropamide 450 SC) is a suspension concentrate containing 450 g/L napropamide, intended to be used on winter oilseed rape for pre- and post-emergent weed control. Use pattern pertinent to operator exposure is summarised below.

Summary of critical use pattern in the Southern Zone (i.e. worst case)

Crop	Application rate (L product/ha)	Spray dilution (L/ha)	Application equipment	Number of applications
Winter oilseed rape	2.8[#]	200 - 400	Tractor-mounted hydraulic boom sprayer	1

[#] 1260 g napropamide per hectare

The estimations were compared to following data from the Annex I inclusion [approval] for napropamide and agreed end points provided in this dossier:

End-Point	Active Substance
Dermal penetration	Concentrate: 0.3 % Spray dilutions: 3 %
AOEL	0.5 mg/kg bw/d

Operator exposure:

The following personal protective equipment is recommended by the applicant

During mixing/loading

- Nitrile gloves certified EN 374-3;
- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Long-sleeved aprons, Category III Type PB3 worn over the coverall proposed above;

During application

- *If application with tractor with cab*
- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Disposable nitrile gloves certified EN 374-2 in the case of an intervention on application equipment, but not inside the cab. In the case of an intervention on application equipment, it should be noted that gloves should be worn only outside the tractor cab and stored after use outside the cab

If application with tractor without cab

- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Disposable nitrile gloves certified EN 374-2 in the case of an intervention on application equipment;

For equipment cleaning

- Nitrile gloves certified EN 374-3;
- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Long-sleeved aprons, Category III Type PB3 worn over the coverall proposed above.

Estimations of potential operator exposure have been undertaken using BBA model and an adaptation to French specifications. According to the model calculations, it can be concluded that the risk for the operator using NAPRAMID 450 (Napropamide 450 SC) is acceptable with the use of gloves and a coverall (90 % protection factor).

3.1.3.3 Bystander Exposure

Bystander exposures were estimated using EUROPOEM 2[13]. Based on this estimation it can be concluded that there is no undue risk to any bystander after accidental short-term exposure to NAPRAMID 450 (Napropamide 450 SC).

3.1.3.4 Worker Exposure

NAPRAMID 450 (Napropamide 450 SC) is intended to be used as a herbicide pre-crop emergence or at an early stage of development of the vegetation, and no specific tasks are expected to be performed. Therefore it can be assumed that the worker exposure to NAPRAMID 450 (Napropamide 450 SC) is negligible.

[13] Bystander exposure to pesticides – Report of the bystander working group, Europoem II Project, Fair3 CT96-1406, December 2002, 1-43.

If the worker has to intervene in the treated plot, the applicant recommends to wear:

- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Primary crop metabolisms were sufficiently investigated to define residue of napropamide for enforcement and risk assessment purposes in the crop under consideration.

Regarding the magnitude of residues in oilseed rape, a sufficient number of residue trials is available to support the intended GAPs in France. These data allow it to be considered that no quantifiable residues of napropamide will be present in grains, and to confirm that no MRL exceedance will result from the intended uses.

As residues of napropamide do not exceed the trigger value of 0.1 mg/kg in oilseed rape, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated. The following mitigation measures have been considered:

There is potential for low but measurable residues of napropamide to be taken up into rotational crops, particularly root crops. Therefore, for root crops, a waiting period of 180 days after treatment with napropamide before planting or sowing rotational or replacement crops is recommended. For all other crops, a waiting period of 60 days after treatment with napropamide before planting or sowing rotational or replacement crops is proposed for this product.

The residue data on oilseed rape for napropamide do not modify the dietary burden for beef, dairy cattle and pig. According to animal metabolism study, no significant residue levels of napropamide are expected in ruminants or pig commodities when crops are treated according to the intended GAPs. Therefore, it can be concluded there is no need to propose a residue definition for foods of animal origin as well as an MRL.

3.1.4.2 Consumer exposure

The toxicological profile of napropamide was evaluated at EU level, which resulted in the proposal of an ADI (0.30 mg/kg bw/d for napropamide) that was considered in the framework of this evaluation. During the European assessment, an ARfD was not deemed necessary.

Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated for the active substance. Based on EFSA PRIMo (rev2), chronic exposure was considered acceptable for all groups of consumers.

According to available data, specific mitigation measures are recommended: a waiting period (i.e., interval) of 180 days for root crops and of 60 days for all other crops after treatment, before planting or sowing rotational or replacement crops.

According to the implementing Regulation, "*Member States shall pay particular attention to* [inter alia] *consumer safety as regards the occurrence in groundwater of the metabolite 2-(1-naphthyloxy)propionic acid, hereinafter 'NOPA'*.

The maximum concentration of the metabolite NOPA in groundwater is 3.4 µg/L: it exceeds the threshold of 0.75 µg/L. An evaluation of the risk to consumers was therefore necessary.

Based on the European assessment, NOPA was considered "not relevant" in the context of guidance document SANCO/221/2000 on the relevance of metabolites groundwater[14].

The estimate of the risk to consumers was based on a 60 kg adult consuming 2 L of water per day. The theoretical maximum consumption of metabolite NOPA was less than 0.1 % of the ADI of napropamide (0.3 mg/kg bw/d), applicable to the metabolite. Therefore, the metabolite NOPA should not represent a hazard for consumer health.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substance and its 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 napropamide in soil, surface water and groundwater has 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 review or agreed in the assessment based on new data provided.

PEC soil and PECsw derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for napropamide do not exceed the trigger of 0.1 µg/L. PECgw of the non-relevant metabolite NOPA (metabolite of napropamide) do not exceed the trigger of 10 µg/L. 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 DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

Implications for labelling resulting from environmental fate assessment: None.

3.1.6 Ecotoxicology

Screening level dietary TERa and TERlt assessment according to the EFSA Bird and Mammal Guidance Document (2009) based on the proposed use of NAPRAMID 450 (Napropamide 450 SC) demonstrate that acute and long-term risks to birds and mammals feeding in treated fields are acceptable. Exposure to terrestrial vertebrates via contaminated puddles is also acceptable at the screening level. Assessments of secondary poisoning via intake of earthworms and fish demonstrate acceptable long-term risks.

An aquatic risk assessment has been conducted. The risks for aquatic organisms are acceptable with a 5 m vegetated no-spray drift buffer and a 5 m vegetative strip. The risk to rooted macrophytes was also assessed for exposure via the sediment and was found to be acceptable.

For napropamide, photolysis metabolites have to be considered in the risk assessment (confirmatory data). As these confirmatory data and then their assessment by the RMS were not available at the time of the current assessment, data on these metabolites could not be included in the risk assessment. Therefore, a worst-case assumption of a 10 x increase in toxicity for the metabolites was used. **The risk is considered acceptable with a 5 m no spray buffer including 5 m vegetative strip**.

[14] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev4, 25 February 2003.

The HQc and HQo values for honey bees vulnerable to direct exposure via contact and oral routes, respectively, are below the relevant trigger values and demonstrate acceptable risks to bees for the proposed use of NAPRAMID 450 (Napropamide 450 SC).

Data on the formulated product NAPRAMID 450 (Napropamide 450 SC) have been generated for non-target arthropods other than bees. The Tier 1 HQ values for the sensitive non-target indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* were calculated. The values are below the ESCORT trigger value of 2 demonstrate acceptable risks to in-field and off-field populations of non-target arthropods.

Based on TERa and TERlt values for napropamide and NAPRAMID 450 (Napropamide 450 SC), the latter presents acceptable acute and long-term toxicity risks to earthworms. In the EFSA review it was concluded that no metabolites required assessment for soil organisms.

The proposed use of NAPRAMID 450 (Napropamide 450 SC) is not expected to result in adverse effects on the activity of soil microflora.

The risk from potential off-field spray drift of NAPRAMID 450 (Napropamide 450 SC) applied to winter oilseed rape at pre-emergence and growth stage BBCH 00-09 to non-target terrestrial plants is demonstrated to be acceptable, without mitigation measures.

3.1.7 Efficacy

Table: Conclusion of France for efficacy section

Crops	Maximum application rate per treatment	Maximum number of applications per use	Maximum number of applications per crop	Conclusion of France for efficacy section	Remarks
Winter Oilseed brassicas weed control (grass and broad-leaved weeds)	2.8 L/ha	1	1	Acceptable	Efficacy and selectivity tested only on winter oilseed rape

The product complies with the Uniform Principles.

Considering the data submitted:

- ✓ Considering the efficacy data provided and the practical knowledge on the active substance in France (national re-registration) for the requested use, the efficacy of NAPRAMID 450 (Napropamide 450 SC) can be always considered satisfactory.

- ✓ The selectivity of NAPRAMID 450 (Napropamide 450 SC) is considered acceptable on winter oilseed rape. The selectivity was not assessed on spring oilseed rape.

- ✓ The risk of negative impact (yield, quality, transformation processes, propagation, succeeding crops, adjacent crops) is considered acceptable.

- ✓ Napropamide belongs to the acetamide chemical family, HRAC (Herbicide Resistance Action Committee) group K3. Currently, no cases of resistance to napropamide have been identified worldwide. Given this information and considering the fact that the product was used once per crop or in programme with herbicides with a different mode of action, the possible occurrence or the development of resistance can be considered low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

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

- Confirmatory method for the determination of napropamide residues in water and soil.

3.4.3 Label amendments (see label in Appendix 2):

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.
The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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Décision relative à une demande de renouvellement de l'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 règlementaire,

Vu la demande de renouvellement de l'autorisation de mise sur le marché du produit phytopharmaceutique ***NAPRAMID 450***

de la société *GLOBACHEM NV*

enregistrée sous le *n°2013-0283*

Vu les conclusions de l'évaluation de l'Anses du 28 septembre 2017,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **est renouvelée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

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.

NAPRAMID 450
AMM n°2100244

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Informations générales sur le produit	
Noms du produit	NAPRAMID 450 NAPROL 450 NAPROP 450
Type de produit	Produit de référence
Titulaire	GLOBACHEM NV Brustem Industriepark Lichtenberglaan 2019 3800 SINT-TRUIDEN BELGIQUE
Formulation	Suspension concentrée (SC)
Contenant	450 g/L - napropamide
Numéro d'intrant	2100049
Numéro d'AMM	2100244
Fonction	Herbicide
Gamme d'usages	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. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2021.

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 05 DEC. 2017

Françoise WEBER
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 : 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	1 L
Bidons en polyéthylène haute densité	5 L

Classification du produit		
La classification retenue est la suivante :		
Catégorie de danger		**Mention de danger**
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 règlementation 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 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
15205901 Crucifères oléagineuses* Désherbage	**2,8 L/ha**	**1/an**	entre les stades BBCH 00 et BBCH 09	F (BBCH 09)	5 (dont DVP 5)	-	-	-
	Uniquement sur colza d'hiver.							

DVP : Dispositif Végétalisé Permanent.

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 40°C.

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 pneumatique

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

• pendant l'application - pulvérisation vers le bas

Si application avec tracteur avec cabine :

- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 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 :

- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 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 EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

Pour le travailleur, porter

- Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant.

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

- 6 heures.

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.

NAPRAMID 450
AMM n°2100244

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Les délais d'implantation (rotation) ou de remplacement (échec cultural) suivants devront être respectés après l'application :
- 180 jours pour les cultures racines,
- 60 jours pour toutes les autres cultures.

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 5 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.

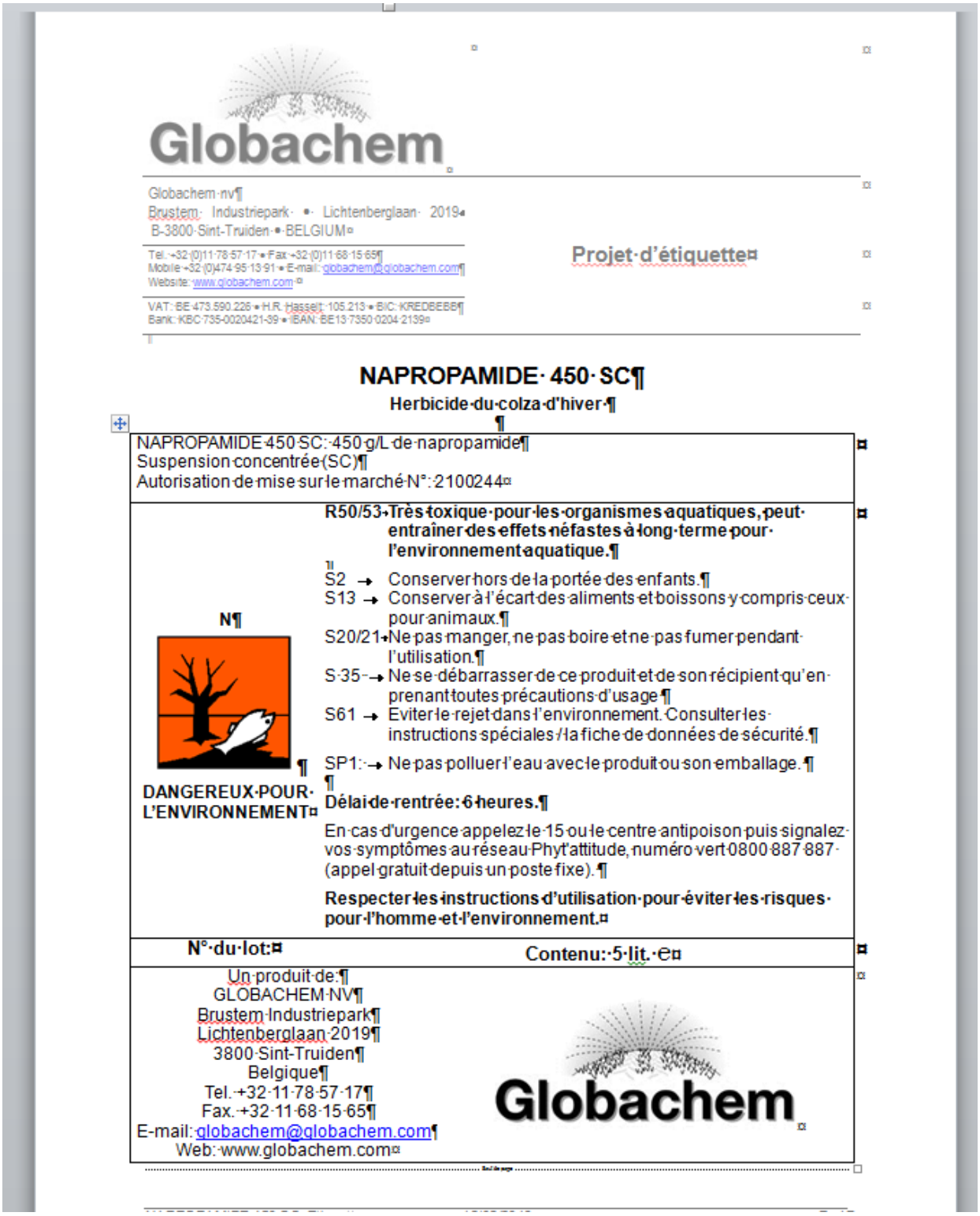
Le produit peut être utilisé sur les usages autorisés, y compris sur les cultures qui seraient exclues de la portée par la présente décision, conformément aux conditions d'emploi antérieures pendant une période de 6 mois.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir une méthode de confirmation pour la détermination des résidus de napropamide dans l'eau et dans le sol.	24	-

Appendix 2 – Copy of the draft product label as proposed by the applicant



Globachem

Globachem nv
Brustem Industriepark • Lichtenberglaan 2019
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Website: www.globachem.com

VAT: BE 473.590.226 • H.R. Hasselt: 105.213 • BIC: KREDBEBB
Bank: KBC 735-0020421-59 • IBAN: BE13 7350 0204 2139

Projet d'étiquette

NAPROPAMIDE 450 SC

Herbicide du colza d'hiver

NAPROPAMIDE 450 SC: 450 g/L de napropamide
Suspension concentrée (SC)
Autorisation de mise sur le marché N°: 2100244

R50/53 Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.

S2 → Conserver hors de la portée des enfants.
S13 → Conserver à l'écart des aliments et boissons y compris ceux pour animaux.
S20/21 Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.
S 35 → Ne se débarrasser de ce produit et de son récipient qu'en prenant toutes précautions d'usage.
S61 → Eviter le rejet dans l'environnement. Consulter les instructions spéciales / la fiche de données de sécurité.

SP1: → Ne pas polluer l'eau avec le produit ou son emballage.

N

DANGEREUX POUR L'ENVIRONNEMENT

Délai de rentrée: 6 heures.

En cas d'urgence appelez le 15 ou le centre antipoison puis signalez vos symptômes au réseau Phyt'attitude, numéro vert 0800 887 887 (appel gratuit depuis un poste fixe).

Respecter les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

N° du lot:

Contenu: 5 lit. e

Un produit de:
GLOBACHEM NV
Brustem Industriepark
Lichtenberglaan 2019
3800 Sint-Truiden
Belgique
Tel. +32 11 78 57 17
Fax. +32 11 68 15 65
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CARACTERISTIQUES DU PRODUIT

NAPROPAMIDE 450 SC agit sur les adventices au moment de leur germination et limite leur développement par action racinaire. Pour obtenir une bonne efficacité, il est préférable de traiter sur un sol humide.

Le champ d'activité consiste de:

- *graminées:* vulpin, pâturin, agrostis, panic, sétaire, digitaire
- *dicotylédones:* arabette, bleuet, chénopode, amaranthe, séneçon, stellaire, matricaire, coquelicot, gaillet, géranium disséqué, alchémille, laiteron, mouron des oiseaux, véroniques

DOSES HOMOLOGUEES

Colza d'hiver: 2,8 L/ha, 1 traitement/an.

Les limites maximales de résidus sont consultables à l'adresse suivante:
http://ec.europa.eu/sanco_pesticides/public/index.cfm

RECOMMANDATIONS D'EMPLOI

Ne pas utiliser sur colza de printemps. Eviter tout risque de surdosage (recroisement de jets, fourrières). NAPROPAMIDE 450 SC doit être incorporé à une profondeur de 3 à 4 cm pour se situer au niveau de la germination des adventices. L'incorporation doit être réalisée dans les 48 heures suivant le traitement avec une herse légère (deux passages croisés). Les outils trop énergiques (disque canadien, vibroculteur) sont à proscrire car ils enfouiraient le napropamide trop profondément (diminution d'efficacité).

NAPROPAMIDE 450 SC s'utilise en pré-semis du colza sur un sol finement préparé.
* Sol à moins de 25% d'argile : 2,2 à 2,5 L/ha.
* Sol à plus de 25 % d'argile : 2,8 L/ha.

Une utilisation en post-semis prélevée du colza peut également être envisageable dans certaines situations. Cependant, l'efficacité sera alors plus aléatoire.

ROTATION

Cultures suivantes dans la rotation
Dans le cas où une céréale succéderait au colza d'hiver l'année suivante, il est obligatoire d'effectuer un labour de retournement à 20 cm précédant le semis.

Cultures de remplacement
Si le colza d'hiver doit être retourné, il est possible d'implanter au printemps:
- directement : choux, pomme de terre de consommation, colza de printemps, blé, radis, oignon.
- après un labour de 20 cm: pois de printemps, trèfle, tournesol, soja, (maïs : labour en mars, semis en mai).

COMPATIBILITE

Respecter la réglementation en vigueur. En cas d'utilisation en mélange avec un autre produit, il est obligatoire de réaliser un test préalable pour vérifier la compatibilité physique et biologique selon les conditions particulières de l'exploitation. Notre société décline toute responsabilité sur les conséquences résultant du mélange de différents produits.

NAPROPAMIDE 450 SC: Etiquette → 12/02/2013 → P. 2

Globachem

PREPARATION DE LA BOUILLIE

Remplir la cuve aux 3/4 du volume d'eau nécessaire. Mettre l'agitation en marche et bien agiter le bidon de NAPROPAMIDE 450 SC avant de verser la quantité nécessaire, puis compléter avec de l'eau jusqu'au volume final. Dans le cadre des bonnes pratiques agricoles, rincer 3 fois les emballages et verser l'eau de rinçage dans la cuve du pulvérisateur.

Laisser l'agitateur en fonctionnement pendant le trajet et jusqu'à la fin de la pulvérisation.

EMBALLAGE ET SURPLUS DE TRAITEMENT

Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Eliminer les emballages vides via une collecte organisée par un service de collecte spécifique (ADIVALOR). Diluer suffisamment les surplus de traitement et les pulvériser, en mélange avec les eaux de rinçage, sur le terrain (la culture) traité(e). Le brûlage ou l'enfouissement des emballages est interdit par la réglementation.

Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de fermes ou des routes.

IMPORTANT

Respectez les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage qui 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 en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces, la pression parasitaire,... . Compte-tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. Le fabricant garantit la qualité du produit vendu dans son emballage d'origine, ainsi que sa conformité à l'autorisation du Ministère de l'Agriculture. Globachem NV ne saurait être tenu en aucun cas responsable des conséquences inhérentes à toute copie de cette étiquette et la diffusion ou à l'utilisation non autorisée de cette dernière.

GARANTIE

Le fabricant garantit la qualité des produits. Vu qu'il n'a cependant aucun contrôle sur leur application, il décline toute responsabilité tant quant à une moins bonne action que quant à d'éventuels dégâts, résultant de l'application.

Appendix 3 – Letter(s) of Access

« The letters of access are available and have been removed for confidentiality reasons. »