REGISTRATION REPORT

Part A

Risk Management

Product code: -

Product name: KINVARA

Active substances:

MCPA, 223 g/L

fluroxypyr, 50 g/L

clopyralid, 28 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: BARCLAY CHEMICALS R&D Ltd

Date: 17/09/2018

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PART A – Risk Management

The company BARCLAY CHEMICALS R&D Ltd has requested marketing authorisation in France for the product KINVARA (no product code is stated), containing 223 g/L MCPA, 50 g/L fluroxypyr and 28 g/L clopyralid, 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 KINVARA where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of KINVARA have been made using endpoints agreed in the EU peer reviews of the active substances.

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

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 BARCLAY CHEMICALS R&D Ltd.'s application to market KINVARA 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 first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

MCPA

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 (EU) No 540/2011 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 MCPA, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2005 shall be taken into account Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate. Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones. Specific provisions of Regulation (EU) No 2017/1511 were to extend the approval's expiration date to 31 October 2018.

There is no EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance.

A Review Report is available (SANCO/4062/2001-final 11 July 2008).

Fluroxypyr

Commission Implementing Regulation (EU) 2017/856 of 18 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance fluroxypyr..

Specific provisions of Regulation (EU) No 736/2011 were as follows :

'PART A

Only uses as herbicide may be authorised.

PART B

For the implementation of the uniform principles referred to in Article 29(6) of Regulation

(EC) No 1107/2009, the conclusions of the review report on fluroxypyr, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 23 March 2017 shall be taken into account.

In this overall assessment, Member States must pay particular attention to:

— the potential contamination of groundwater by metabolite fluroxypyr pyridinol, when the active substance is applied in regions with alkaline or vulnerable soil or with vulnerable climatic conditions;

— the risk to aquatic organisms.

Conditions of authorisation shall include risk mitigation measures, where appropriate.'

An EFSA conclusion is available (EFSA Journal 2011;9(3):2091) and a Technical Report on the outcome of the consultation on confirmatory data used in risk assessment (31 July 2015).

A Review Report is available (SANCO/11019/2011 rev 5, 23 March 2017).

Clopyralid

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 (EU) No 540/2011 were as follows :

PART A

Only uses as herbicide may be authorised.

PART B

In assessing applications to authorise plant protection products containing clopyralid for uses other than spring applications, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.

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 clopyralid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— the protection of non target plants and groundwater under vulnerable conditions. Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate. The concerned Member States shall request the submission of further studies to confirm the results on animal metabolism. They shall ensure that the notifiers at whose request clopyralid has been included in this Annex provide such studies to the Commission within two years from the approval.
An EFSA conclusion is available (EFSA Scientific Report (2005) 50, 1–65, Conclusion on the peer review of clopyralid). A Review Report is available (SANCO/10012/2006 rev 3, 4 April 2006).

1.3 Regulatory approach

The present applications (2015-4878 for marketing authorisation and 2017-0874 for new packaging) were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] 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")[2] – 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[3] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight 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[4], implementing regulations, 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[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision

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

- the “reference” and “linked” 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 “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[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.

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 KINVARA, 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 letter(s) of access.

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

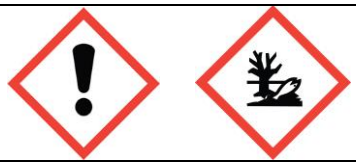
2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	KINVARA (no product code is stated)
Authorisation number	N/A : no marketing authorisation granted
Function	Herbicide
Applicant	BARCLAY CHEMICALS R&D Ltd
Composition	223 g/L MCPA 50 g/L fluroxypyr 28 g/L clopyralid
Formulation type (code)	Micro-emulsion (ME)
Packaging	HDPE bottles(1,and 2 L) HDPE containers (2.5, 5, 10, 15and 20 L)

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	Acute toxicity (oral), Hazard Category 4 Serious eye damage/eye irritation, Hazard Category 2	
Environmental hazards	Acute toxicity (oral), Hazard Category 4	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H302	Harmful if swallowed
	H319	Causes serious eye irritation
	H411	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.

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

N/A : no marketing authorisation granted

2.2.3 Other phrases linked to the preparation

N/A : no marketing authorisation granted

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). When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 17/09/2018

PPP (product name/code)	**KINVARA (no product code is stated)**	**Formulation type:**	**Micro-emulsion (ME)**
active substance 1	**MCPA**	**Conc. of a.s. 1:**	**223 g/L**
active substance 2	**fluroxypyr**	**Conc. of a.s. 2:**	**50 g/L**
active substance 3	**clopyralid**	**Conc. of a.s. 3:**	**28 g/L**
Applicant:	**BARCLAY CHEMICALS R&D Ltd**	**professional use**	☒
Zone(s):	**southern EU**	**non-professional use**	☐
Verified by MS:	**yes**		
Field of use:	herbicide		

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
					Type (d-f)	Conc. of a.s. (i) (g/L)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hL min max	water L/ha min max	g a.s./ha min max	(l)	(m)
Agricultural uses															
Winter / Spring wheat Barley, Rye, Triticale, Oats	France	Kinvara	F	Annual + perennial broadleaf weeds	ME	233 MCPA 50 FXP 28 CPD	Foliar spray	GS **30** - 39	1	N/A	MAX: 0.4 MCPA, 0.08 FXP, 0.04 CPD	200 - 400	MAX: 700 MCPA, 150 FXP, 84 CPD	F	**Not acceptable:** risk to the consumers (non-compliance with fluroxypyr MRLs), risk of ground-water contamination and risk of adverse effects to terrestrial and aquatic organisms

Grassland – less than 1 year old	France	Kinvara	F	Annual + perennial broadleaf weeds	ME	233 MCPA 50 FXP 28 CPD	Foliar spray	March – June BBCH 30-39 for fodder/forage grass	1	N/A	MAX: 0.4 MCPA, 0.08 FXP, 0.04 CPD	200 - 400	MAX: 700 MCPA, 150 FXP, 84 CPD	F	**Not acceptable:** risk to the consumers (lack of animal feeding studies with MCPA), risk of ground-water contamin-ation and risk of adverse effects to terrestrial and aquatic organisms)
Grassland – more than 1 year old	France	Kinvara	F	Annual + perennial broadleaf weeds	ME	233 MCPA 50 FXP 28 CPD	Foliar spray	March – September BBCH 30-39 for fodder/forage grass	1	N/A	MAX: 0.4 MCPA, 0.08 FXP, 0.04 CPD	200 - 400	MAX: 700 MCPA, 150 FXP, 84 CPD	F	**Not acceptable:** risk to the consumers (lack of animal feeding studies with MCPA), risk of ground-water contamin-ation and risk of adverse effects to terrestrial and aquatic organisms)
Grass for seed – less than 1 year old	France	Kinvara	F	Annual + perennial broadleaf weeds	ME	233 MCPA 50 FXP 28 CPD	Foliar spray	March – June BBCH 30-39 for fodder/forage grass	1	N/A	MAX: 0.4 MCPA, 0.08 FXP, 0.04 CPD	200 - 400	MAX: 700 MCPA, 150 FXP, 84 CPD	F	**Not acceptable:** risk of ground-water contamination and risk of adverse effects to terrestrial and aquatic organisms)
Grass for seed – more than one year old	France	Kinvara	F	Annual + perennial broadleaf weeds	ME	233 MCPA 50 FXP 28 CPD	Foliar spray	March – September BBCH 30-39 for fodder/forage grass	1	N/A	MAX: 0.4 MCPA, 0.08 FXP, 0.04 CPD	200 - 400	MAX: 700 MCPA, 150 FXP, 84 CPD	F	**Not acceptable:** risk of ground-water contamination and risk of adverse effects to terrestrial and aquatic organisms)
Non-agricultural uses															

Amenity Grassland – less than 1 year old (river and port areas, road and motorway network, railway access, airport zones, industrial sites *etc*.)	France	Kinvara	F	Annual + perennial broadleaf weeds	ME	233 MCPA 50 FXP 28 CPD	Foliar spray	March - June	1	N/A	MAX: 0.4 MCPA, 0.08 FXP, 0.04 CPD	200 - 400	MAX: 700 MCPA, 150 FXP, 84 CPD	F	**Not acceptable:** risk of ground-water contamination and risk of adverse effects to terrestrial and aquatic organisms)
Amenity Grassland - more than 1 year old river and port areas, road and motorway network, railway access, airport zones, industrial sites *etc*.)	France	Kinvara	F	Annual + perennial broadleaf weeds	ME	233 MCPA 50 FXP 28 CPD	Foliar spray	March - September	1	N/A	MAX: 0.4 MCPA, 0.08 FXP, 0.04 CPD	200 - 400	MAX: 700 MCPA, 150 FXP, 84 CPD	F	**Not acceptable:** risk of ground-water contamination and risk of adverse effects to terrestrial and aquatic organisms)
Amenity turf (general purpose turf used on green spaces, business and science parks, commercial landscaping, golf courses, bowling greens, *etc*.)	France	Kinvara	F	Annual + perennial broadleaf weeds	ME	233 MCPA 50 FXP 28 CPD	Foliar spray	March - June	1	N/A	MAX: 0.4 MCPA, 0.08 FXP, 0.04 CPD	200 - 400	MAX: 700 MCPA, 150 FXP, 84 CPD	F	**Not acceptable:** risk of ground-water contamination and risk of adverse effects to terrestrial and aquatic organisms)

FXP = fluroxypyr CPD = clopyralid f.p. = formulated product

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 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

KINVARA is a micro-emulsion (ME) formulation. 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 translucent reddish-brown liquid, without strong odour. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature above 388 °C. In aqueous solution (1 %), it has a pH value of 5.87 at room temperature. There is 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 stability data indicate a provisional shelf life of two years at ambient temperature when stored in HDPE, as only an accelerated storage study has been provided. The technical characteristics are acceptable for a micro-emulsion (ME) formulation.

The formulation is not classified for the physico-chemical part.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methodology for the determination of the active substances is available and validated.

No analytical method has been submitted for the determination of the relevant impurity N-methylpyrrolidone of the active substance fluroxypyr-meptyl in the formulation; this is required for control requirements.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) or this dossier and validated for the determination of residues of MCPA in plants, soil, water (surface and drinking) and air. No analytical method is available for the determination of residues of MCPA in foodstuffs of animal origin.

Analytical methods are available in the DAR or this dossier and validated for the determination of residues of fluroxypyr in plants, foodstuffs of animal origin, soil, water (surface and drinking) and air.

Analytical methods are available in the DAR or this dossier and validated for the determination of residues of clopyralid in plants, soil, water (surface and drinking) and air. No analytical method is available for the determination of residues of clopyralid in foodstuffs of animal origin.

Validated analytical method with an ILV should be provided for the determination of clopyralid in foodstuff of animal origin at the re-approval of the active substance clopyralid.

The active substances are 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

Endpoints used in risk assessment

Active substance: **clopyralid**		
ADI	0.15 mg/kg bw/d	EU 2006
ARfD	Not applicable	

AOEL	1 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* human study performed on the formulation according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (tested) 27.9 g/L	Diluted formulation (tested) 0.21 g/L
	In vitro (human) %	12*	7**
		Concentrate (used in formulation) 28 g/L	Spray dilution (used in formulation) 0.2 g/L
	Dermal absorption endpoints %	**12**	**7**

* The applicant excludes some cells with the sole argument that the absorption profile is different from the others. The zRMS disagrees with this argument. Indeed, taking into account the high variability of this kind of study, the standard deviation is particularly high in this study and that the recovery is highly variable between cells. The zRMS is therefore of the opinion that the exclusion of cells proposed by the applicant should not be done. Consequently, all of the cells tested are considered to derive the dermal absorption value.

Nevertheless, the "stratum corneum sample" of cell 8 was lost during the assay. Consequently, this cell had been removed from the calculation.

** Applicant excludes some cells with the sole argument that the absorption profile is different from the others. zRMS disagree with this argument. Indeed, taking into account the high variability of this kind of study and the fact that in this study, standard deviation is particularly high and that the recovery is really variable between cells, zRMS is of the opinion that the exclusion of cells proposed by the applicant should not be done. Consequently, all of the cells tested are considered to derive the dermal absorption value.

Active substance: **fluroxypyr-meptyl**			
ADI	0.8 mg/kg bw/d		EU 2011
ARfD	Not applicable		
AOEL	0.8 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* human study performed on the formulation according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (tested) 73.7 g/L	Diluted formulation (tested) 0.554 g/L
	In vitro (human) %	14*	6*
		Concentrate (used in formulation) 72 g/L	Spray dilution (used in formulation) 0.375 g/L
	Dermal absorption endpoints %	**12**	**6**

* Applicant excludes some cells with the sole argument that the absorption profile is different from the others. zRMS disagrees with this argument. Indeed, taking into account the high variability of this kind of study and the fact that in this study, standard deviation is particularly high and that the recovery is really variable between cells, zRMS is of the opinion that the exclusion of cells proposed by the applicant should not be accepted. Consequently, all of the cells tested are considered to derive the dermal absorption value.

Because of the low recovery (< 95 %), a normalisation was made.

Taking into account the fact that more than 75 % of the dose had been absorbed at half of the study, all of the tape strips (stratum corneum) was removed from the calculation.

Active substance: **MCPA**			
ADI	0.05 mg/kg bw/d		EU 2011
ARfD	0.15 mg/kg bw		
AOEL	0.04 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* human study performed on the formulation according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (tested) 233.2 g/L	Diluted formulation (tested) 1.753 g/L
	In vitro (human) %	16*	14**
		Concentrate (used in formulation) 233 g/L	Spray dilution (used in formulation) 1.75 g/L
	Dermal absorption endpoints %	**16**	**14**

* Applicant excludes some cells with the sole argument that the absorption profile is different from the others. zRMS disagrees with this argument. Indeed, taking into account the high variability of this kind of study and the fact that in this study standard deviation is particularly high and that the recovery is really variable between cells, zRMS is of the opinion that the exclusion of cells proposed by the applicant should not be accepted. Consequently, all of the cells tested are considered to derive the dermal absorption value.

Nevertheless, “stratum corneum sample” of cell 8 had been lost during the assay. Consequently, this cell had been removed from calculation.

Because of the low recovery (< 95 %), a normalisation had been made.

** Applicant excludes some cells with the sole argument that the absorption profile is different from the others. zRMS disagrees with this argument. Indeed, taking into account the high variability of this kind of study and the fact that in this study standard deviation is particularly high and that the recovery is really variable between cells, zRMS is of the opinion that the exclusion of cells proposed by the applicant should not be accepted. Consequently, all of the cells tested are considered to derive the dermal absorption value.

Taking into account the fact that more than 75 % of the dose had been absorbed at half of the study, all of the tape strips (stratum corneum) had been removed from calculation.

3.1.3.1 Acute Toxicity

KINVARA, containing 233 g/L MCPA, 72 g/L fluroxypyr-meptyl and 28 g/L clopyralid, has a low inhalational and dermal toxicity but is irritating to eyes, and harmful if swallowed.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[8]	Equipment	Application rate kg/L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Cereals (agricultural uses)	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	3 L/ha (0.7 g MCPA/ha 0.15 g fluroxypyr/ha 0.08 g clopyralid/ha)	200-400	BBA
Amenity grassland, grass for seed (non-agricultural uses)	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	3 L/ha (0.7 g MCPA/ha 0.15 g fluroxypyr/ha 0.08 g clopyralid/ha)	200-400	BBA
Cereals, amenity grassland, grass for seed (non-agricultural uses)	F	Hand-held sprayer, hydraulic nozzles, low-level target	3 L/ha (0.7 g MCPA/ha 0.15 g fluroxypyr/ha 0.08 g clopyralid/ha)	200-400	UK POEM

Considering the proposed uses, operator systemic exposure was estimated using the German BBA and UK-POEM models.

Crop	Equipment	PPE and/or working coverall	% AOEL MCPA	% AOEL fluroxypyr	% AOEL clopyralid
Cereals (agricultural uses)	Tractor-mounted/ trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	38	0.3	0.1
Amenity grassland, grass for seed (non-agricultural uses)	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	8	0.1	<0.1
Cereals, amenity grassland, grass for seed (non-agricultural uses)	Hand-held sprayer, hydraulic nozzles, low-level target	Working coverall and gloves during mixing/loading and application	456	2	1

According to the model calculations, it may be concluded that the risk for the operator using KINVARA is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application when a tractor-mounted sprayer is used.

[8] Open field or glasshouse

According to the model calculations, it may be concluded that the risk for the operator using KINVARA is unacceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application when a hand-held sprayer is used.

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 2 % of the AOEL of MCPA and less than 0.1 % of the AOEL of fluroxypyr and clopyralid.

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to KINVARA.

3.1.3.4 Worker Exposure

KINVARA is used as herbicidal treatment on crops where there is no need to re-enter the treated area after application. Worker exposure is considered to be not relevant.

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

3.1.3.5 Resident Exposure

Residential exposure was assessed according to Martin *et al*. Exposure is estimated to be 0.9 % of the AOEL of MCPA for adults and 2 % of the AOEL for children. Regarding fluroxypyr and clopyralid, residential exposure (for adults and children) is less than 1 % of the AOEL.

It may be concluded that there is no unacceptable risk to the resident exposed to KINVARA.

3.1.3.6 Relevance of metabolites

-

3.1.4 Residues and Consumer Exposure

Overall conclusion

For the proposed use on cereals, the data available are considered sufficient for risk assessment. An exceedance of the current MRL of cereals for MCPA, clopyralid as laid down in Reg. (EU) 396/2005 is not expected. **However for fluroxypyr an exceedance of the current MRL of cereals cannot be excluded**.
Moreover for the proposed use on grassland, in the absence of ruminant feeding study for the active substance MCPA, the risk assessment for livestock cannot be finalised. Indeed, the calculated dietary burdens for ruminants exceed the trigger value of 0.1 mg/kg DM and based on the contribution of grass/hay in the ruminant diet, further investigation of residues is therefore required for this group of livestock. **Data on livestock feeding studies were not reviewed during the Annex I inclusion process and no studies were provided by the applicant**.

The chronic and the short-term intakes of MCPA, fluroxypyr and clopyralid residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France does not agree with the authorization of the intended use on cereals and grassland.

According to available data, the following specific mitigation measures are recommended:
In order to prevent occurrence of residues in succeeding crops:

- wait for 125 days after application to grow a new crop on which clopyralid is not registered. Crops grown less than 125 days after application will not be treated with clopyralid.
- root and tuber crops should not be grown as rotational crops after an application of fluroxypyr before a laps time interval of 10 months.

Data gaps

Noticed data gaps are:

- MCPA:
  - Feeding study on ruminants
  - Storage stability in animal matrices
- Fluroxypyr (noticed data gaps at EU level):
  - Information about the storage conditions of the samples from the fluroxypyr livestock feeding study is required in order to confirm the validity of the results of the reported ruminant feeding study. According to the Regulation CE n°2015/1040, this confirmatory data has to be submitted by 1st July of 2017.

Data on the toxicity of fluroxypyr-methoxypyridine is required as this metabolite is susceptible to accumulate in soil) and therefore, data on its plateau concentration and the transfer to plants.

Summary of the evaluation

The preparation KINVARA contains MCPA, fluroxypyr and clopyralid.

Summary for MCPA

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) No 491/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Cereals	Yes	Yes	Yes	Yes	Yes	No	No	-
/	Grassland	Yes	Yes	Yes	Yes	N/A	Not finalised	Not finalised	Feeding study on ruminants and storage stability in animal matrices required.
/	Grass for seed	Not evaluated in Section 4. This uses are not intended to be fed to animals or for human consumption.							
/	Amenity grassland								
/	Amenity turf								

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

As residues of MCPA do not exceed the trigger values defined in Reg. (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

When only the use on cereals is considered in the dietary burden calculations, no residue above 0.01 mg/kg is expected in animal commodities. Therefore, no feeding study is required for the intended use of MCPA on cereals and this use is considered fully supported by available data.

However, considering that the dietary burden for ruminants exceed the trigger value of 0.1 mg/kg dry matter (DM) when the use of MCPA on grassland is also considered and that residue can be found in livestock (ruminant) commodities, further investigation of residues in ruminants is therefore necessary. Data on livestock feeding studies were not reviewed during the Annex I inclusion process and no studies were provided by the applicant. In the

absence of ruminant feeding studies, the risk assessment for this group of livestock cannot be finalised for the intended use on grassland.

Summary for fluroxypyr

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) No 2015/1040	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Cereals	Yes	Yes	Yes	Yes	**No**	No	No	-
/	Grassland	Yes	Yes	Yes	Yes	N/A		No	-
/	Grass for seed	Not evaluated in Section 4. This uses are not intended to be fed to animals or for human consumption.							
/	Amenity grassland								
/	Amenity turf								

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

For fluroxypyr an exceedance of the current MRL of cereals cannot be excluded.
As residues of fluroxypyr do not exceed the trigger values defined in Reg. (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been investigated and the following mitigation measures are proposed:

- Root and tuber crops should not be grown as rotational crops following use of fluroxypyr before an elapsed time interval of 10 months.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin are therefore not necessary.

Summary for clopyralid

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) N° 322/2012	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Cereals	Yes	Yes	Yes	Yes	Yes	No	No	-
/	Grassland	Yes	Yes	Yes	Yes	N/A		No	-
/	Grass for seed	Not evaluated in Section 4. This uses are not intended to be fed to animals or for human consumption.							
/	Amenity grassland								
/	Amenity								

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) N° 322/2012	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
	turf								

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

According to clopyralid residue levels found in cereals and the contribution of these commodities in the diet (TMDI > 10 % ADI), processing studies on cereals are required. No data were submitted by the applicant. Therefore, the magnitude of clopyralid residues is not considered sufficiently investigated in cereals.

Residues in succeeding crops have been investigated and the following mitigation measures are proposed: It will be recommended to wait for 125 days after application to grow a new crop on which clopyralid is not authorised. Crops grown less than 125 days after application must not be treated with clopyralid.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin are therefore not necessary.

Summary for KINVARA

Crop	PHI for KINVARA proposed by applicant	PHI/withholding period* sufficiently supported for			PHI for KINVARA proposed by zRMS	zRMS Comments (if different PHI proposed)
		MCPA	Fluroxypyr	Clopyralid		
Cereals	F (BBCH 24-39)	Yes	Yes	Yes	F	-
Grassland	56 days	Risk assessment cannot be finalised.				

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 EF-1498
	Crop group	Led by MCPA	Led by fluroxypyr	Led by clopyralid	
Crops on which clopyralid is authorised	Root vegetables	-	10 months	-	For root crops a waiting period of 180 days after treatment with fluroxypyr before planting or sowing is required.
Crops on which clopyralid is not	Root vegetables	-	10 months	4 months	Do not grow other crops in the treated
	Other crops	-	-	4 months	

authorised					field less than 4 months (10 months for root and tuber crops) after application of clopyralid)

NR: not relevant

3.1.5 Environmental fate and behaviour

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 fluroxypyr, MCPA, clopyralid 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 were derived for the active substances and their metabolites but were not used for the ecotoxicological risk assessment because exposure calculations did not follow the recommendations of EFSA guidance (2014), especially regarding crop interception and geometric mean adsorption coefficients.

PECgw values for fluroxypyr as well as MCPA and their metabolites do not occur at levels exceeding those mentioned in Regulation (EC) 1107/2009 and guidance document SANCO 221/2000 on the relevance of groundwater metabolites according to the conditions of uses proposed.

PECgw values for clopyralid were not calculated according to the recommendations of EFSA guidance (2014), especially regarding crop interception and geometric mean adsorption coefficients. **Therefore, no reliable PECgw values are available for clopyralid and the risk assessment for groundwater cannot be finalised**.

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.

3.1.6 Ecotoxicology

The risk assessment of the formulation KINVARA was not performed according to the requirements of Regulation (EC) No 1107/2009. **It was not possible to conclude on acceptable risk following the use of KINVARA for many organisms, as none of the requirements were fulfilled either in terms of appropriate endpoints used or for the right application rate assessed**.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy level of KINVARA is considered satisfactory for all the requested uses, for post-emergence applications on dicotyledonous weeds.
- the selectivity level of KINVARA is considered acceptable for all the requested uses.
- the risks of negative impact on yield, quality, transformation processes and propagation are considered acceptable, as is the risk of negative impact on succeeding crops. However, special attention should be paid to the conditions when planting/sowing succeeding and replacement crops. The risk of negative impact on adjacent crops is considered acceptable. However, special attention should be paid to the conditions of application close to adjacent crops.

- There is a risk of resistance developing or appearing to MCPA, fluroxypyr and clopyralid, in particular for *Papaver rhoeas* which requires monitoring on straw-based cereals.

Restrictions: None

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted**. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

N/A : not authorised

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

N/A : not authorised

3.4.2 Post-authorisation data requirements

N/A : not authorised

3.4.3 Label amendments

N/A : not authorised

Appendix 1 – Copy of the French Decision

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agence nationale de sécurité sanitaire alimentation, environnement, travail

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 règlementaire,

Vu la demande d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique ***KINVARA***

de la société	*BARCLAY CHEMICALS R&D LTD*
enregistrées sous les	*n°2015-4878, 2017-0874*

Vu les conclusions de l'évaluation de l'Anses du 25 mai 2018,

Considérant le risque de dépassement de la limite maximale de résidus en fluroxypyr sur les cultures destinées à l'alimentation,

Considérant également qu'en l'absence de données suffisantes, l'absence de risque d'effet nocif pour les organismes aquatiques et terrestres et l'absence de risque de contamination des eaux souterraines par le clopyralid ne peuvent être démontrées,

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.

KINVARA
AMM n°-

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Informations générales sur le produit	
Nom du produit	KINVARA
Type de produit	Produit de référence
Titulaire	BARCLAY CHEMICALS R&D LTD Damastown Way, Damastown Industrial Park, Mulhuddart, 15 DUBLIN, Irlande
Formulation	Micro-émulsion (ME)
Contenant	233 g/L de MCPA (sous forme de MCPA sel de potassium) 50 g/L de fluroxypyr (sous forme de fluroxypyr-meptyl) 28 g/L de clopyralid (sous forme de clopyralid sel d'éthanolamine)
Numéro d'intrant	534-2015.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le 17 SEP. 2018

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 : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15105911 Avoine*Désherbage	3 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus du fluroxypyr. L'usage est également refusé au motif que les risques inacceptables de contamination des eaux souterraines par le clopyralid et les risques d'effets nocifs pour les organismes aquatiques et terrestres ne peuvent pas être exclus.		
15105912 Blé*Désherbage	3 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus du fluroxypyr. L'usage est également refusé au motif que les risques inacceptables de contaminations des eaux souterraines par le clopyralid et les risques d'effets nocifs pour les organismes aquatiques et terrestres ne peuvent pas être exclus.		
18505901 Gazons de graminées* Désherbage	3 L/ha	1/an	-
	Motivation du refus : L'usage est refusé au motif que les risques inacceptables de contaminations des eaux souterraines par le clopyralid et les risques d'effets nocifs pour les organismes aquatiques et terrestres ne peuvent pas être exclus.		
15305905 Graminées fourragères* Désherbage	3 L/ha	1/an	-
	Motivation du refus : L'usage est refusé au motif que les risques inacceptables de contaminations des eaux souterraines par le clopyralid et les risques d'effets nocifs pour les organismes aquatiques et terrestres ne peuvent pas être exclus. L'usage est également refusé en raison de l'absence d'étude d'alimentation animale pour le MCPA permettant d'exclure des risques pour le consommateur.		

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Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
15105913 Orge*Désherbage	3 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus du fluroxypyr. L'usage est également refusé au motif que les risques inacceptables de contaminations des eaux souterraines par le clopyralid les risques d'effets nocifs et pour les organismes aquatiques et terrestres ne peuvent pas être exclus.		
00610005 Porte graine - Graminées fourragères et à gazons* Désherbage	3 L/ha	1/an	-
	Motivation du refus : L'usage est refusé au motif que les risques inacceptables de contaminations des eaux souterraines par le clopyralid et les risques d'effets nocifs pour les organismes aquatiques et terrestres ne peuvent pas être exclus.		
15705914 Prairies*Désherbage	3 L/ha	1/an	-
	Motivation du refus : L'usage est refusé au motif que les risques inacceptables de contaminations des eaux souterraines par le clopyralid et les risques d'effets nocifs pour les organismes aquatiques et terrestres ne peuvent pas être exclus. L'usage est également refusé en raison de l'absence d'étude d'alimentation animale pour le MCPA permettant d'exclure des risques pour le consommateur.		
15105915 Seigle*Désherbage	3 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus du fluroxypyr. L'usage est également refusé au motif que les risques inacceptables de contaminations des eaux souterraines par le clopyralid et les risques d'effets nocifs pour les organismes aquatiques et terrestres ne peuvent pas être exclus.		
01001026 Usages non agricoles*Désherbage* Zones herbeuses	3 L/ha	1/an	-
	Motivation du refus : L'usage est refusé au motif que les risques inacceptables de contaminations des eaux souterraines par le clopyralid et les risques d'effets nocifs pour les organismes aquatiques et terrestres ne peuvent pas être exclus.		

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

MESURES DE SÉCURITÉ

PROTECTION DE L'OPÉRATEUR :

L'opérateur doit porter :
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
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

En cas de contact du concentré avec la peau ou les yeux, RINCER IMMÉDIATEMENT.
NE PAS INHALER LES VAPEURS DE PULVÉRISATION.
LAVER SCRUPULEUSEMENT TOUS LES VÊTEMENTS DE PROTECTION après usage, surtout l'intérieur des gants.
SE LAVER SOIGNEUSEMENT LES MAINS ET TOUTE AUTRE PARTIE DU CORPS EXPOSÉE avant les repas et après le travail.

PROTECTION DE L'ENVIRONNEMENT

Ne pas contaminer l'eau en y déversant le produit ou son emballage* (Ne pas nettoyer l'équipement d'application à proximité d'eaux de surface/Éviter de répandre accidentellement toute trace de produit sur les exploitations agricoles et les routes).
* hormis utilisation selon les consignes.

ENTREPOSAGE/ÉLIMINATION

CONSERVER LE PRODUIT DANS SON EMBALLAGE D'ORIGINE, hermétiquement fermé, en lieu sûr.
RINCER ABONDAMMENT L'EMBALLAGE, vider les eaux de nettoyage dans le réservoir du pulvérisateur et l'appliquer selon la réglementation en vigueur.

RESPECTEZ LES CONSIGNES D'UTILISATION POUR ÉVITER LES RISQUES POUR L'HOMME ET POUR L'ENVIRONNEMENT

Fiche de données de sécurité disponible pour les professionnels sur simple demande.
Ce produit est autorisé en vertu du Règlement relatif aux produits phytopharmaceutiques (tel que modifié).

MODE D'EMPLOI

IMPORTANT : Ces informations sont autorisées à figurer sur l'étiquette du produit. Il conviendra de lire attentivement toutes les consignes suivantes afin d'assurer la sécurité et l'efficacité de l'emploi de ce produit.

INFORMATIONS IMPORTANTES		
HERBICIDE UNIQUEMENT A USAGE AGRICOLE		
Cultures/situations	**Dose totale maximale**	**Période d'application**
Blé d'hiver et de printemps, orge d'hiver et de printemps, avoine, seigle et triticale	3 L/ha par an, par culture	Au printemps – Du stade 4 talles jusqu'à la dernière feuille étalée, ligule visible
Prairie établie	3 L/ha par an	Mars à septembre
Prairie nouvellement semée	3 L/ha par an	Mars à juin
Pelouse d'agrément (- de 1 an)	3 L/ha par an	Mars à juin
Pelouse d'agrément (+ de 1 an)	3 L/ha par an	Mars à septembre
Gazons d'agrément	3 L/ha par an	Mars à juin
Cultures porte-graines : Graminées fourragères et Gazon de graminées (- de 1 an)	3 L/ha par an	Mars à juin
Cultures porte-graines : Graminées fourragères et Gazon de graminées (+ de 1 an)	3 L/ha par an	Mars à septembre

Restrictions

Ne pas appliquer KINVARA sur les cultures souffrant de stress dû à la sécheresse, à l'excès d'eau, aux basses températures, à une attaque de parasites ou de maladie, à une carence en éléments nutritifs ou en chaux ou à tout autre facteur ralentissant la croissance des cultures.
Ne pas appliquer KINVARA sur les prairies contenant du trèfle ou une autre légumineuse ou autre culture dicotylédone.
Lors de l'application de KINVARA, respecter une distance de 5 mètres avec les plantes non ciblées.

Contrôle des adventices

KINVARA est un herbicide employé pour lutter contre la pousse de mauvaises herbes dicotylédones annuelles et vivaces dicotylédones dans les cultures de céréales, les prairies agricoles, les pelouses et les gazons d'agrément, et les graminées porte-graines. Ce produit se compose d'un mélange de trois substances actives, chacune imitant l'action de l'auxine - acideindole-3-acétique (IAA), mais présentant aussi un spectre d'activité légèrement différent, c'est la raison pour laquelle cette association offre un éventail herbicide plus important que chacune des substances actives utilisées individuellement.
Une application au stade plantule des adventices, en conditions poussantes renforcera l'efficacité de KINVARA.

Préparation

Verser la quantité requise de KINVARA dans la cuve du pulvérisateur que l'on aura déjà pris soin de remplir à moitié d'eau et mis sous agitation. Compléter avec de l'eau jusqu'au niveau requis. Maintenir l'agitation de la substance obtenue pendant la pulvérisation et jusqu'à la vidange de la cuve.

Application

Appliquer sur feuillage sec. Ne pas pulvériser en cas de prévisions de pluies. Éviter toute dérive de pulvérisation sur les cultures et zones voisines.
Éviter les recroisements de pulvérisation.

Cultures

Ne pas rouler ou herser les cultures dans les sept jours qui suivent une application de KINVARA.

Sensibilité des mauvaises herbes

Le classement des mauvaises herbes dans le tableau suivant implique une bonne couverture de pulvérisation et de bonnes conditions de croissance.

Spectre d'activité sur les céréales :

Adventice		**Sensibilité[1]**
Arroche hastée	*Atriplex prostrata*	TS
Bleuet des champs	*Cyanus segetum*	TS

Spectre d'activité sur les céréales :

Adventice		Sensibilité[1]
Arroche hastée	*Atriplex prostrata*	TS
Bleuet des champs	*Cyanus segetum*	TS
Bouton d'or	*Ranunculus repens*	S
Capselle bourse-à-pasteur	*Capsella bursa-pastoris*	TS
Chardon des champs	*Cirsium arvense*	S
Chénopode blanc	*Chenopodium album*	S
Chénopode hybride	*Chenopodium hybridum*	TS
Coquelicot	*Papaver rhoeas*	MS
Datura officinale	*Datura stramonium*	MS
Delphinium ajacis L. Pied d'alouette	*Delphinium cossonianum*	S
Fumeterre des champs	*Fumaria agraria*	MS
Fumeterre officinal	*Fumaria officinalis*	S
Gaillet gratteron	*Galium aparine*	S
Galeopsis des champs	*Galeopsis intermedia*	TS
Galinsoga cilié	*Galinsoga quadriradiata*	MS
Géranium découpé	*Geranium dissectum*	TS
Sisymbrium sophia	Descurainia sophia	TS
Laiteron des champs	*Sonchus arvensis*	TS
Lamier amplexicaule	*Lamium amplexicaule*	MS
Lamier pourpre	*Lamium purpureum*	MS
Liseron des champs	*Convolvulus arvensis*	S
Matricaires	*Matricaria spp*	S
Morelle noire	*Solanum nigrum*	TS
Mouron des oiseaux	*Stellaria media*	S
Moutarde des champs	*Brassica sinapistrum*	TS
Myosotis des champs	*Myosotis arvensis*	S
Petite ciguë	*Aethusa cynapium*	TS
Petite ortie	*Urtica urens*	TS
Ravenelle	*Raphanus raphanistrum*	TS
Renoncule des marais	*Ranunculus philonotis*	S
Renouée des buissons	*Polygonum dumetorum*	MS
Renouées	*Polygonum spp*	S
Repousses de colza	-	TS
Séneçon commun	*Senecio vulgaris*	S
Spergule des champs	*Spergula arvensis*	TS
Véronique de Perse	*Veronica persica*	S
Violette des champs	*Viola arvensis*	MS

[1]TS = très sensible (>95 %) ; S = sensible (85-94 %) ; MS = modérément sensible (70-84 %)

Spectre d'activité sur les prairies :

Adventice		Sensibilité[1]
Mouron des oiseaux	*Stellaria media*	TS

Spectre d'activité sur les prairies :

Adventice		Sensibilité[1]
Mouron des oiseaux	*Stellaria media*	TS
Chardon des champs	*Cirsium arvense*	S
Lamier pourpre	*Lamium purpureum*	S
Bouton d'or	*Ranunculus repens*	MS
Patience sauvage	*Rumex obtusifolius*	S
Séneçon de Jacob	*Senecio jacobaea*	S
Pissenlit	*Taraxacum vulgare*	TS
Orties	*Urtica spp*	TS
Vesce à feuilles étroites	*Vicia sativa* subsp. *nigra*	TS

[1]TS = très sensible (>95 %) ; S = sensible (85-94 %) ; MS = modérément sensible (70-84 %)

Cultures de céréales : Utiliser un automoteur ou un pulvérisateur tracté. Pulvériser à moyen débit à 2-2,5 bars (30-35 psi), à raison de 200-400 L d'eau/ha pour couvrir entièrement les adventices ciblées. Augmenter le volume de bouillie sur les cultures denses ou si les adventices ont déjà bien poussé. Appliquer sur feuilles sèches.

Prairies, pelouses, gazons : Utiliser un automoteur ou un pulvérisateur tracté. Pulvériser à moyen débit à 2-2,5 bars (30-35 psi), à raison de 200-400 L d'eau/ha, le minimum étant de 300 L/ha sur les prairies établies pour s'assurer de couvrir l'intégralité des adventices ciblées. Augmenter le volume de bouillie sur les cultures denses ou si les mauvaises herbes ont déjà bien poussé. S'il n'y a pas lieu de pulvériser toute la surface, traiter seulement les zones infestées par les mauvaises herbes, voire chaque mauvaise herbe, au pulvérisateur à dos ou à la lance à main reliée à un pulvérisateur à pression hydraulique classique. De préférence, utiliser une buse à jet plat pour éviter les dérives de pulvérisation. Pulvériser uniformément, tout en évitant la formation de gouttes.

Mélanges
Pour s'informer sur les détails des mélanges compatibles, veuillez vous contacter : Barclay Chemicals Ltd., Damastown Way, Damastown Industrial Park, Mulhuddart, Dublin 15, Irlande.
Tél. : +353 1 8112900 Fax: +353 1 8224678 E-mail: info@barclay.ie

Cultures suivantes/résidus
Respecter un délai de 4 mois entre l'application de KINVARA et le semis d'une nouvelle culture. De surcroît, mettre en œuvre les mesures nécessaires d'atténuation des risques, en l'occurrence s'assurer du bon compostage de la paille et de l'herbe coupée, afin d'éviter la présence de résidus de clopyralid dans les cultures alternées et/ou suivantes.

Entretien du pulvérisateur
Les traces de substances résiduelles telles que le fluroxypyr dans la cuve peuvent abîmer les cultures sensibles. Après chaque jour d'utilisation de KINVARA, rincer abondamment le pulvérisateur à l'eau claire additionnée d'agent mouillant recommandé pour le nettoyage des pulvérisateurs. Veiller au rinçage complet de toutes les rampes et tuyaux.

Appendix 3 – Letter(s) of Access

Provided upon request.