REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: 19202

Product name(s): **KINVARA**

Chemical active substances:

MCPA, 233 g/L

Fluroxypyr, 50 g/L

Clopyralid, 28 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Renewal of Authorization)

Applicant: XXXX

Submission date: 31/01/2024

Evaluation date: October 2024

MS Finalisation date: March 2025

Version history

When	What
January 2024	Article 43 of Regulation (EC) No. 1107/2009
October 2024	Conclusions of zRMS
March 2025	Version modified by zRMS PL to take into account comments of cMSs and the applicant
November 2025	zRMS correction following Applicant's comment

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013 and 545/2011.

This application is for the re-registration in the Central Zone of the product Kinvara, a micro-emulsion formulation containing the active substances MCPA (233g/L), Fluroxypyr (50g/L) and Clopyralid (28g/L) for use on cereals and grassland.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Northern zone	Finland: - Kinvara (3329) - Arrva (3533)	Estonia : - Kinvara (766/24.10.19) - Arrva (772/13.02.20) Latvia: - Kinvara (0672) - Arrva (0695) Lithuania: - Kinvara (AS2-84H(2019)) - Arrva (AS2-104H(2019)) Norway: - Kinvara (pending authorization) Sweden: - Kinvara (5530)
Central zone	Poland: - Kinvara (R - 231/2019) - Arrva (R-58/2020)	Ireland: - Kinvara (05381) - Brittas (06523) - Pradera (06524) Czech Republic: - Kinvara (5310-0) - Arrva (5310-1) Germany: - Kinvara (008450-00) - Arrva (008450-60) Hungary: - Kinvara (6300/19632-1/2019.NEBIH) - Arrva (6300/20753-2/2019.NEBIH) Romania: - Kinvara (560PC of 20.11.19) - Arrva (560PC of 20.11.2019)

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
		Austria: - Kinvara (4168-0) Belgium: - Kinvara (30980/B)
Southern zone	Spain: - Kinvara (ES-01143) - Cladda (ES-01143)	

0.1.3 Regulatory history of the active(s)

0.1.3.1 MCPA

Table 0.1-2: Summary of regulatory history of CAS No: 94-74-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No. 540/2011 Commission Implementing Regulation (EU) No.2023/1757
RMS	Italy
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/05/2006
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/01/2024
Date of final Commission (re-registration) deadline (Step 2)	31/01/2024
Current expiration of approval	~~31/10/2023~~ 15/08/2026
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

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

- to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions.
- the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones..

The SANTE review report for MCPA (SANCO/4062/2001; 11th July 2008) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An Review Report for MCPA made available in 2005.

Table 0.1-3: Information on minimum purity of MCPA

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
≥ 950 g/kg	MCPA Source: Refer to Letter of Access from Nufarm. Equivalence report available: N RMS: Unknown

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.3.2 Fluroxypyr

Table 0.1-4: Summary of regulatory history of CAS No: 69377-81-7

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No. 736/2011
RMS	Germany
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2012
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.03.2025
Date of final Commission (re-registration) deadline (Step 2)	31.03.2025
Current expiration of approval	31.12.2024
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

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 and/or with vulnerable climatic conditions;
- the risk to aquatic organisms.

The SANCO review report for fluroxypyr (SANCO/11019/2011; (revised) 23rd March 2017) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available in 2011.

Table 0.1-5: Information on minimum purity of Fluroxypyr

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
≥ 950 g/kg	Fluroxypyr Source 1: Shandong Luba Chemical Co. Ltd (Min. 987 g/kg) Equivalence report available: Y RMS: UK Fluroxypyr Source 2: Lier Chemical Co. Ltd. (Min. 975g/kg) Equivalence report available: Y RMS: NL Fluroxypyr Source 3: Hunan Bide Biochemical Technology Co., Ltd (Min. 980 g/kg) Equivalence report available: Y RMS: UK Fluroxypyr Source 4: Parijat Industries (India) Pvt. Ltd. (Min. 980 g/kg) Equivalence report available: Y RMS: UK

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.3.3 Clopyralid

Table 0.1-6: Summary of regulatory history of CAS No: 1702-17-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No. 540/2011
RMS	Finland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.10.2021
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.12.2036
Date of final Commission (re-registration) deadline (Step 2)	31.12.2036
Current expiration of approval	30.09.2036
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

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

- the specification of the technical material as commercially manufactured;
- the protection of operators, ensuring that conditions of use for operators include the application

of adequate personal protective equipment;
- possible presence of clopyralid residues in rotational crops;
- the possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops;
- the protection of groundwater under vulnerable conditions

The SANTE review report for Clopyralid (SANTE/10206/2021 Rev 1; 20 May 2021) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available in 2017.

Table 0.1-7: Information on minimum purity of Clopyralid

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
≥ 950 g/kg	~~Clopyralid Source 1: Zhejiang Yongnong Chem. Ind. Co. Ltd. (Min. 970 g/kg)~~ ~~Equivalence report available: Y~~ ~~RMS: UK~~ Clopyralid Source 2: Zhejiang Avilive Chemical Co., Ltd. (Min. 975 g/kg) Equivalence report available: Y RMS: ~~UK~~ Latwia Clopyralid Source 3: Lier Chemical Co., Ltd (for purity refer to Letter of Access from Lier) Equivalence report available: Y RMS: ~~NL~~ CZ

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.4 Regulatory history of the product

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-8: Summary of regulatory history of the product Kinvara

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
N/A	Kinvara	Germany	008450-00	21/02/2019	N/A
N/A	Arrva	Germany	008450-60	07/06/2019	N/A
N/A	Kinvara	Hungary	6300/19632-1/2019.NEBIH	01/10/2029	N/A
N/A	Arrva	Hungary	6300/20753-2/2019.NEBIH	09/12/2019	N/A
N/A	Kinvara	Czech Republic	5310-0	26/10/2018	N/A

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
N/A	Arrva	Czech Republic	5310-1	19/02/2019	N/A
N/A	Kinvara	Romania	560PC of 20.11.19	06/03/2020	N/A
N/A	Arrva	Romania	560PC of 20.11.2019	24/08/2020	N/A
N/A	Kinvara	Poland	R - 231/2019	18/12/2019	N/A
N/A	Arrva	Poland	R-58/2020 of 18.05.20	18/05/2020	N/A
N/A	Kinvara	Austria	4168-0	27/04/2020	N/A
N/A	Kinvara	NI	18436	24/05/2023	N/A
N/A	Brittas	NI	18587	20/06/2018	N/A
N/A	Kinvara	Ireland	05381	25/10/2018	N/A
N/A	Brittas	Ireland	06523	10/09/2019	N/A
N/A	Pradera	Ireland	06524	10/09/2019	N/A
N/A	Kinvara	Belgium	30980	05/07/2023	N/A

0.2 zRMS conclusion

Physicochemical properties:

The data submitted, which were previously accepted at the registration stage of the measure, are still acceptable after the renewal of clopyralid (Article 43). The previous outcome concerning a physicochemical section remains unchanged.

Efficacy:

The evaluation of the application for Kinvara herbicide resulted in the decision to grant the authorization. Registration renewal for Kinvara covers the same uses as the currently applicable label. No changes in the GAP and dose rates have been made for this renewal, compared to the currently approved GAP.

Toxicology:

The application of product Kinvara does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice providing that operator is wearing work wear covering arms, body and legs during mixing/loading and application and protective gloves and eye protection/face protection during mixing and loading.

The application of product Kinvara does not pose an unacceptable risk to the health of worker for its intended use within good agricultural practice providing that the worker is wearing a work clothing (long sleeved shirt, long trousers) during 2hrs inspection. No unacceptable risk for residents and bystanders is identified when the product is used as intended

Residues:

The data available for Kinvara is considered sufficient for risk assessment. An exceedance of the relevant current MRLs for MCPA, fluroxypyr and clopyralid in the intended crops is not expected. The chronic and the short-term intakes of MCPA, fluroxypyr and clopyralid residues are unlikely to present a public health concern. PL agrees with the authorization of the intended uses.

Fate and behaviour:

The submitted exposure assessment in soil, groundwater and surface water was sufficient. Predicted environmental concentration in particular compartments were performed in accordance with EU requirements and FOCUS guidance may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

Ecotoxicology:

All relevant data and risk assessment are considered as adequate and sufficient. The risk assessment for all groups of organisms was performed in accordance with relevant guidance. An acceptable risk is expected if product is used in accordance with proposed pattern use in cereals. In case of use in grasslands, the risk is not acceptable for voles in mixture toxicity risk assessment for application rate of 3.0 L formulation/ha. For lower application rate of 2.5 L formulation/ha the risk is acceptable for voles in mixture toxicity risk assessment.

To protect arthropods and non-target terrestrial plants a 20m no-spray strip or 10 m with 50% drift reducing nozzle or 5 m with 75% drift reducing nozzle is required.

Uses to be considered safe on the basis of EU methodology:

Section B8-B9: 1

Others: 1-3

Uses to be considered non-safe on the basis of EU methodology:

Section B8-B9: 2-3

Others: None

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

None, but risk mitigation measures are required as outlined on part B6.

The following text is to be shortened or to be amended as necessary.

All uses/ GAPs are covered by established MRLs except for use in crop. An application for amending the MRL has been submitted by MS to EFSA EFSA Project Number (if applicable).

zRMS may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

Appendix 1 ALL intended uses

GAP rev. 1, date: 2023-02-14

PPP (product name/code):	Kinvara	Formulation type:	ME
Active substance 1:	MCPA	Conc. of as 1:	233 g/L
Active substance 2:	Fluroxypyr	Conc. of as 2:	50 g/L
Active substance 3:	Clopyralid	Conc. of as ….:	28 g/L[)]
Safener:	See Document C	Conc. of safener:	See Document C
Synergist:	See Document C	Conc. of synergist:	See Document C
Applicant:	XXXX	Professional use:	☒
Zone(s):	Central[(d)]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [(f)]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	AT, NI, IE, BE, RO, CZ, DE, HU, PL	Wheat, Barley, Oats, Rye, Triticale	F	Annual and perennial broadleaf weeds	Foliar spray	BBCH 24-39	a) 1 b) 1	N/A	a) 3 b) 3	a) 0.699MCPA, 0.15	200-400	N/A	BBCH 25-39 (AT) BE- 3L/ha RO- 2-3L/ha CZ -2-3L/ha HU – 2-3L/ha PL – 2-3L/ha -winter wheat, spring wheat, winter triticale, spring barley, rye, winter oats

										b) 0Flur,0.084CLP0.699MCPA,0.150Flur,0.084CLP			
~~2~~	~~AT, IE, BE, CZ,DE~~	~~Established Grassland~~	~~F~~	~~Annual and perennial broadleaf weeds~~	~~Foliar spray~~	~~March- Sept~~	~~a) 1 b) 1~~	~~N/A~~	~~a) 3 b) 3~~	~~a) 0.699MCP~~	~~200-400~~	~~AT, IE, CZ, DE, BE (PHI 7d)~~	~~IE (1st March-31st Aug) BE – 2.25 or 2.5L/ha AT (broad leaf dock & dandelion only)~~

										A, 0.150 F1 ur, 0.084 CLP b) 0.6999 MCPA, 0.150 F1 ur, 0.084 CLP			
3	BE	New grassland	F	Annual and perennial broadleaf weeds	Foliar spray	March – End Sept	a) 1 b) 1	N/A	a) 3 b) 3	a) 0.	200-400		BE – 2.25/2.5L/ha

										b) 0.699MCPA, 0.150F1ur, 0.084CLP 0.699MCPA, 0.150F1ur, 0.08			

										4 € L P			
2	AT, IE, BE, CZ, DE	Established Grassland (> 1 yr)	F	Annual and perennial broadleaf weeds	Foliar spray	March - Sept	1	N/A	2.5	0.699 (MCPA) 0.150 (Fluroxypyr) 0.084 (Clopyralid)	200 – 400	AT, IE, CZ, DE, BE (PHI 7d)	IE (1st March-31st Aug) BE – 2.25 or 2.5L/ha
3	BE	New Grassland (< 1 year)	F	Annual and perennial broadleaf weeds	Foliar spray	March – End Sept	1	N/A	2.5	0.699 (MCPA) 0.15 0(Fluroxypyr) 0.084 (Clopyralid)	200 – 400		BE – 2.25/2.5L/ha