

REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: 19202

Product name: **KINVARA**

Chemical active substances:

MCPA, 233 g/L

Fluroxypyr, 50 g/L

Clopyralid, 28 g/L

Central Zone

Zonal Rapporteur Member State:

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	Initial RR
March 2025	Version modified by zRMS PL to take into account comments of cMSs and the applicant

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Sufficient data on identity, physical and chemical properties and other information are **not** available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are: **none**.

- **data-gap-1**
- **data-gap-2**
- **data-gap-3**

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: XXXX
Address: XXXX
XXXX

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substances

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 MCPA

MCPA	min. 950 g/kg
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MCPA does not contain any relevant impurities.

1.2.3.2 Fluroxypyr

Fluroxypyr Source 1	min. 987 g/kg
Fluroxypyr Source 2	min. 975 g/kg
Fluroxypyr Source 3	min. 980 g/kg
Fluroxypyr Source 4	min. 980 g/kg

N-methyl-2-pyrrolidone (NMP)	< 3 g/kg
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1.2.3.3 Clopyralid

Clopyralid Source 1	min. 970 g/kg
Clopyralid Source 2	min. 975 g/kg
Clopyralid Source 3	min. 970 g/kg

Clopyralid does not contain any relevant impurities.

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name:	Kinvara
Trade name:	Arrva
Company code number:	19202

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
MCPA	233	219 – 247	245.3	21.8
present as MCPA Potassium salt	277.3	260.7 – 294.0	N/A***	24.6
Fluroxypyr	50	45 – 55	Source 1: 50.7 Source 2: 51.3 Source 3: 51.0 Source 4: 51.0	4.5 4.6 4.5 4.5
Present as Fluroxypyr-meptyl	72	64.8 – 79.2	Source 1: 72.9 Source 2: 73.8 Source 3: 73.5 Source 4: 73.5	6.5 6.6 6.5 6.5
Clopyralid	28	25.2 – 30.8	Source 1: 28.9 Source 2: 28.7 Source 1: 28.9	2.6 2.6 2.6
Present as Clopyralid	36.9	33.2 – 40.6	N/A***	3.3

Active substance / variant	Declared content of the pure active substance / variant (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
ethanolamine salt				

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

** Based on the density of the formulation = 1.126g/mL (Note: only applies if a liquid formulation – delete this comment if not needed)

*** The content of active ingredient salts cannot be represented in terms of minimum purity of the active substance used

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (technical active g/L)	Maximum content (formulated product g/L)
N-methyl-2-pyrrolidone (NMP)	3g/kg	0.15 g/kg

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-3: Information on MCPA

Type	Name/Code Number	
ISO common name	MCPA	MCPA Potassium Salt
CAS No.	94-74-6	5221-16-9
EC No.	202-360-6	226-015-4
CIPAC No.	2	2

Table 1.4-4: Information on Fluroxypyr

Type	Name/Code Number	
ISO common name	Fluroxypyr	Fluroxypyr-meptyl
CAS No.	69377-81-7	81406-37-3
EC No.	none	279-752-9
CIPAC No.	431	431.214

Table 1.4-5: Information on Clopyralid

Type	Name/Code Number	
ISO common name	Clopyralid	Clopyralid ethanolamine salt
CAS No.	1702-17-6	57754-85-5
EC No.	216-935-4	N/A
CIPAC No.	455	455

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

Kinvara does not contain any safeners or synergists.

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Micro-emulsion	Code: ME
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1.6 Function (KCP 1.6)

Herbicide

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a uniform reddish-brown liquid with a hydrocarbon odour. It is not explosive and has no oxidising properties. The product is not flammable and has a flash point of >110°C. It has a self ignition temperature of >388°C. In aqueous solution, it has a pH value around 6 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging. Its technical characteristics are acceptable for a Micro-Emulsion (ME) formulation. The intended concentration of use is 0.55% to 1.5%.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

The product Kinvara is not classified from a physical chemical perspective.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Risk and safety phrase (or hazard or precautionary statements) are not applicable for the product Kinvara as this product is not classified from a physical chemical perspective.

Compliance with FAO specifications:

The product Kinvara complies with FAO specifications.

Formulation used for tests

The formulation used in the tests has the same composition as the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Colour: Uniform Reddish-brown Odour: No strong odour Physical state: Translucent liquid	Y	Report OA02411 Campbell, N. (2014)	Accepted
Explosive properties (KCP 2.2.1)	Theoretical certificate by expert statement	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Does not present an explosive hazard	Y	Report OA02411 Campbell, N. (2014)	Accepted
Oxidizing properties (KCP 2.2.2)	Theoretical certificate by expert statement	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Does not present an oxidizing hazard	Y	Report OA02411 Campbell, N. (2014)	Accepted
Flash point (KCP 2.3.1)	EEC A9	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Flash point: >110°C	Y	Report OA02411 Campbell, N. (2014)	Accepted
Flammability (KCP 2.3.2)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Self-heating (KCP 2.3.3)	EEC A15	Sample: Kinvara Sample ID: 13-3600 Active Content:	No self-ignition observed up to 388 °C	Y	Report OA02411 Campbell, N. (2014)	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L				
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT31	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Not required as the pH of the sample was within the range 4-10	Y	Report OA02411 Campbell, N. (2014)	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT75.3	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Pre storage: pH (1%) = 5.87 Post storage at 54 °C for 14 days: pH (1%) = 6.46 Post 2 year storage: pH (1%) = 5.61	Y	Report OA02411 Campbell, N. (2014) Report OA02412 Campbell, N. (2016)	Accepted
Viscosity (KCP 2.5.1)	OEC 114	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Viscosity @ 20°C: 127.8 mPa.s Viscosity @ 40°C: 49.6 mPa.s	Y	Report OA02411 Campbell, N. (2014)	Accepted
Surface tension (KCP 2.5.2)	EEC A5	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Neat solution: 30.9mN/m 1% Dilution: 28.9mN/m	Y	Report OA02411 Campbell, N. (2014)	Accepted the product is surface active
Relative density (KCP 2.6.1)	EEC A3	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	1.1253 g/mL	Y	Report OA02411 Campbell, N. (2014)	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Bulk density (KCP 2.6.2)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Storage Stability after 14 days at 54° C (KCP 2.7.1)	AI content by validated HPLC method Ref: Study OA02413	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Pre storage: Colour: Uniform Reddish-brown Odour: No strong odour Physical state: Translucent liquid Appearance of packaging: samples were contained in white PE-HD plastic bottles with green screw caps. Samples displayed no evidence of any leaks. Active ingredient content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L Free Phenols (CIPAC MT69.2): 7.11g/kg of MCPA content. Post storage: Colour: Uniform Reddish-brown Odour: No strong odour Physical state: Translucent liquid Appearance of packaging: samples were contained in white PE-HD plastic bottles with green screw caps. Panelling of the bottles was noted after the accelerated storage period. Samples displayed no evidence of any leaks. Active ingredient content: MCPA: 238.6g/L Fluroxypyr-meptyl: 77.0g/L Clopyralid: 26.3g/L Free Phenols (CIPAC MT69.2): 6.52g/kg of MCPA content	Y	Report OA02411 Campbell, N. (2014)	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Minimum content after heat stability testing (KCP 2.7.3)	N/A	N/A	Not applicable	N/A	N/A	
Effect of low temperatures on stability (KCP 2.7.4)	CPIAC MT39.3	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	No separation observed. Sample remains homogeneous after 7 days at 0 °C.	Y	Report OA02411 Campbell, N. (2014)	Accepted
Ambient temperature shelf life (KCP 2.7.5)	AI content by validated HPLC method Ref: Study OA02413	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Pre storage: Colour: Uniform Reddish-brown Odour: No strong odour Physical state: Translucent liquid Appearance of packaging: samples were contained in white PE-HD plastic bottles with green screw caps. Samples displayed no evidence of any leaks. Mass of packaging pre-storage (g): 1221.59 Active ingredient content: MCPA (Potassium salt): 238.8 (284.2)g/L Fluroxypyr (Meptyl ester): 52.6		Report OA02412 Campbell, N. (2016)	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>(75.8)g/L</p> <p>Clopyralid (ethanolamine salt): 26.2 (34.6))g/L</p> <p>Free Phenols (CIPAC MT69.2): 7.11g/kg of MCPA content</p> <p>Post storage: Colour: Unchanged from pre-storage</p> <p>Odour: Unchanged from pre-storage</p> <p>Physical state: Unchanged from pre-storage</p> <p>Appearance of packaging: samples were contained in white PE-HD plastic bottles with green screw caps. Panelling of the bottles was noted after the 2-year storage period. Samples displayed no evidence of any leaks.</p> <p>Mass of packaging post-storage (g): 1190.36</p> <p>Active ingredient content: MCPA (Potassium salt: 231.0 (274.9)g/L</p>			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Fluroxypyr (Meptyl Ester): 53.8 (77.4)g/L Clopyralid (ethanolamine salt): 28.3 (37.3)g/L Free Phenols (CIPAC MT69.2): 4.79g/kg of MCPA content			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	N/A	N/A	Not applicable	N/A	N/A	
Wettability (KCP 2.8.1)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Persistence of foaming (KCP 2.8.2)	CIPAC MT47.3	Sample: Kinvara Sample ID: F55574/2 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Time Foam <u>Minimum (1.8 L product in 400 L water D)</u> 2A: After 1 min 60ml 2B: After 1 min 60ml <u>Maximum (3 L product in 200 L water D)</u> 2A: After 1 min 50ml 2B: After 1 min 55ml	Y	Report OA03458 Chang. Ka Man (2021)	Accepted
Suspensibility (KCP 2.8.3.1)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Spontaneity of dispersion (KCP 2.8.3.2)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Dispersion stability (KCP 2.8.3.3)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Degree of dissolution and dilution stability	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.4)						
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Wet sieve test (KCP 2.8.5.1.2)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Dust content (KCP 2.8.5.2.1)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Particle size of dust (KCP 2.8.5.2.2)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Attrition (KCP 2.8.5.3)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Hardness and integrity (KCP 2.8.5.4)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Emulsifiability (KCP 2.8.6.1)	CIPAC MT36.3	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Pre-Storage: Uniform emulsion formed spontaneously at max (1.5%) and min (0.55%) use rates in CIPAC water A and D. No separation observed after 2 hours, therefore no further testing required. Post-Storage: Uniform emulsion formed spontaneously at max (1.5%) and min (0.55%) use rates in CIPAC water A and D. No separation observed after 2 hours, therefore no further testing required. that “post-storage” refers to post accelerated and post long term storage as well.	Y	Report OA02411 Campbell, N. (2014) Report OA02412 Campbell, N. (2016)	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Emulsion stability (KCP 2.8.6.2)	CIPAC MT36.3	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Pre-Storage: Uniform emulsion formed spontaneously at max (1.5%) and min (0.55%) use rates in CIPAC water A and D. Post-Storage: Uniform emulsion formed spontaneously at max (1.5%) and min (0.55%) use rates in CIPAC water A and D. that “post-storage” refers to post accelerated and post long term storage as well.	Y	Report OA02411 Campbell, N. (2014) Report OA02412 Campbell, N. (2016)	Accepted
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT36.3	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Pre-Storage: No separation observed after 2 hours, therefore no further testing required. Post-Storage: No separation observed after 2 hours, therefore no further testing required. that “post-storage” refers to post accelerated and post long term storage as well.	N/A	Report OA02411 Campbell, N. (2014) Report OA02412 Campbell, N. (2016)	Accepted The PPP remained stable uniform emulsion and unseparated after two hours. So, the study meets the requirements a
Flowability (KCP 2.8.7.1)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Pourability (KCP 2.8.7.2)	CIPAC MT148.1	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Poured residue Pre-Storage A: 1.41% Poured residue Pre Storage B: 1.53% Poured residue Pre-Storage mean: 1.47% Poured residue Post Storage A: 1.57%	Y	Report OA02411 Campbell, N. (2014) Report OA02412 Campbell, N. (2016)	Accepted Yet, it is not required for the ME formulation by SANCO/10473/2003 –rev.5

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Poured residue Post Storage B: 1.63% Poured residue Post Storage mean: 1.60%			
Dustability following accelerated storage (KCP 2.8.7.3)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Physical compatibility of tank mixes (KCP 2.9.1)	CRD Efficacy Guideline 305	Sample: Kinvara Sample ID: 13-3600 Active Content: MCPA: 238.9g/L Fluroxypyr-meptyl: 75.8g/L Clopyralid: 26.2g/L	Effectiveness of cleaning: Residual AI after specified cleaning procedure: MCPA: 0.037% Fluroxypyr-meptyl: 0.047% Clopyralid: 0.0319%	Y	Report OA02411 Campbell, N. (2014) Report OA02413 Campbell, N. (2014)	Accepted
Chemical compatibility of tank mixes (KCP 2.9.2)	N/A	N/A	Not applicable	N/A	N/A	
Adhesion to seeds (KCP 2.10.1)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Distribution to seed (KCP 2.10.2)	N/A	N/A	Not applicable to this formulation type.	N/A	N/A	
Other/special studies (KCP 2.11)	N/A	N/A	Not applicable.	N/A	N/A	

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

The plant protection product will be packaged in HDPE bottles. The HDPE bottles are manufactured to UN approved standards and are suitable for the hazards presented by the preparation. Each bottle has a foil seal when manufactured and a replaceable plastic screw cap to allow re-closure.

After storage at 54°C for 14 days and for 24 months at ambient temperature in the HDPE containers, no leaks in the packaging were noted confirming that the packaging is compatible with the preparation.

Table 4.1-1: Packaging information for 1L HDPE bottle

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	cylindrical / approx. 88.5 mm diameter x 233 mm
Opening:	50 mm standard 50mm tamper evident 63mm tamper evident
Closure:	Standard, tamper evident, child resistant
Seal:	Compression and I.H.S wad types
Manner of construction	Not detailed
UN/ADR	compliant

Table 4.1-2: Packaging information for 2L HDPE

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	cylindrical / approx. 189 x 155 x 106mm
Opening:	42mm tamper evident 42mm tamper evident
Closure:	Standard, tamper evident, child resistant
Seal:	Not detailed
Manner of construction	Not detailed
UN/ADR	compliant

Table 4.1-3: Packaging information for 2.5L HDPE

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	rectangular / approx. 225 x 155 x 106mm
Opening:	38 mm multi neck 42mm tamper evident 45mm standard
Closure:	Standard, tamper evident, child resistant
Seal:	Compression and I.H.S wad types

Type	Description
Manner of construction	Not detailed
UN/ADR	compliant

Table 4.1-4: Packaging information for 5L HDPE

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	cylindrical / approx. 305 x 126 x 193mm
Opening:	63mm with or without tamper evidence
Closure:	Not detailed
Seal:	Not detailed
Manner of construction	Not detailed
UN/ADR	compliant

Table 4.1-5: Packaging information for 10L HDPE

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	Rectangular / approx. 240mm x 179mm x 375mm
Opening:	54.75 mm inner diameter
Closure:	63mm polyethylene screw cap
Seal:	Not detailed
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-6: Packaging information for 20L HDPE

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	Rectangular / approx. 286mm x 220mm x 430mm
Opening:	Not detailed
Closure:	Polypropylene/Polyethylene cap/EPE cap liner
Seal:	Not detailed
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-7: Packaging information for 1L Fluorinated HDPE

Type	Description
Material:	Fluorinated High Density Polyethylene (FHDPE)
Shape/size:	cylindrical / approx. 88.5 mm diameter x 233 mm
Opening:	50 mm inner diameter
Closure:	polyethylene tamper evident screw cap
Seal:	HF-seal

Type	Description
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-8: Packaging information for 2L Fluorinated HDPE

Type	Description
Material:	Fluorinated High Density Polyethylene (FHDPE)
Shape/size:	Rectangular / approx. 155mm x 106mm x 189mm
Opening:	Approx. 42 mm inner diameter
Closure:	42mm polyethylene screw cap with or without tamper evidence
Seal:	HF-seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-9: Packaging information for 2.5L Fluorinated HDPE

Type	Description
Material:	Fluorinated High Density Polyethylene (FHDPE)
Shape/size:	cylindrical / approx. 155mm x 106mm x 225mm (L x W x H)
Opening:	38 mm multi neck 42 mm tamper evident 45 mm standard
Closure:	polyethylene tamper evident screw cap
Seal:	Compression and I.H.S seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-10: Packaging information for 5L Fluorinated HDPE

Type	Description
Material:	Fluorinated High Density Polyethylene (FHDPE)
Shape/size:	Rectangular / approx. 193mm x 142mm x 305mm (L x W x H)
Opening:	Approx. 53 mm inner diameter
Closure:	63mm polyethylene screw cap with tamper evidence and foil cutter
Seal:	HF-seal
Manner of construction	Extruded
UN/ADR	Compliant

Table 4.1-11: Packaging information for 10L Fluorinated HDPE

Type	Description
Material:	Fluorinated High Density Polyethylene (FHDPE)
Shape/size:	Rectangular / approx. 240mm x 179mm x 378mm
Opening:	63 mm tamper evident
Closure:	Standard, tamper evident

Type	Description
Seal:	Not detailed
Manner of construction	Not detailed
UN/ADR	Compliant

Table 4.1-12: Packaging information for 20L Fluorinated HDPE

Type	Description
Material:	Fluorinated High Density Polyethylene (FHDPE)
Shape/size:	Rectangular / approx. 285mm x 228mm x 431mm
Opening:	60mm tamper evident
Closure:	Standard, tamper evident
Seal:	Not detailed
Manner of construction	Not detailed
UN/ADR	Compliant

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 1.4.1	Pomeroy, D.	2017	Analysis of 10 batches of Fluroxypyr-meptyl technical material to determine the content of a specified impurity, in compliance with Good Laboratory Practice (Relates Fluroxypyr-meptyl to Source 1) David Norris Analytical Laboratories Ltd, DNA4069 GLP Unpublished	N	XXXX
KCP 1.4.1	Pomeroy, D.	2017	Analysis of 10 batches of Fluroxypyr-meptyl technical material to determine the content of a specified impurity, in compliance with Good Laboratory Practice (Relates to Fluroxypyr-meptyl Source 2) David Norris Analytical Laboratories Ltd, DNA4070 GLP Unpublished	N	XXXX
KCP 2.1	Campbell, N.	2014	Determination of physical-chemical properties before and after accelerated storage procedure for 14 days at 54°C ± 2°C of Kinvara, a micro-emulsion (ME) formulation containing MCPA, Clopyralid and Fluroxypyr. Oxford Analytical Ltd, OA02411 GLP Unpublished	N	XXXX
KCP 2.1	Campbell, N.	2016	Determination of physical-chemical properties after 2 years storage under ambient (average warehouse) conditions of Kinvara, a micro-emulsion (ME) formulation containing MCPA, Clopyralid and Fluroxypyr. Oxford Analytical Ltd, OA02412	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 2.8.2	Chang, Ka Man	2021	Kinvara – Analysis of the impurity content for 1-Methyl-2-Pyrrolidinone (NMP) and Persistent Foam including method validation for NMP. Oxford Analytical Ltd, OA03458 GLP Unpublished	N	XXXX
KCP 2.2.2	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.3.1	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.3.3	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.4.1	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.4.2	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.5.1	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.5.2	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.6.1	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.7.1	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.7.4	-	-	⇒ KCP 2.1	N	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.8.2	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.8.6.1	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.8.6.2	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.8.6.3	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.8.7.2	-	-	⇒ KCP 2.1	N	XXXX
KCP 2.7.5	Campbell, N.	2016	Determination of physical-chemical properties after 2 years storage under ambient (average warehouse) conditions of Kinvara, a micro-emulsion (ME) formulation containing MCPA, Clopyralid and Fluroxypyr Oxford Analytical Ltd, OA02412 GLP Unpublished	N	XXXX

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source	Y/N	Owner

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP/non GLP/GEP/non GEP Published/Unpublished		

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte- brate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

No new data submitted