

FINAL 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: **102000037599**

Product name(s): (Active substance(s)) **Prohexadione-Ca OD 75 (75 g/L)**

Central Zone

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT

(Authorisation)

Applicant: **Bayer Crop Science Division**

MS Finalisation date: 29/04/2022

Version history

When	What
April 2021	Original Bayer submission
July 2021	Dossier sent for evaluation
January 2022	zRMS finalised evaluation
April 2022	Final version prepared by zRMS after Commenting period

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

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:

- No information of the effectiveness of the cleaning procedure was provided (as requested by reg 284/2013)
- The two-year study is ongoing. It has to be assessed in the post-registration

The product Prohexadione-Ca OD 75 (75 g/L) (PRL OD 75 / Product Code 102000037599) has not been previously evaluated at zonal level. It was not the representative formulation during the renewal of approval of Prohexadione-Ca. All data and information assessed during the EU re-evaluation of Prohexadione-Ca is considered EU peer-reviewed data.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

This section of the draft registration report is a core document and as such will be submitted in all countries where the product will be registered. Since the legal name of the applicant may vary depending on the country this information is provided in the National document (Part A, point 1.1, Application background). The registration holder will be either Bayer or one of its' legal entities in the countries.

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

1.2.1 Producer(s) of the preparation

Name: Bayer S.A.S.
Address: 16, rue Jean-Marie Leclair
CS 90106
69266 Lyon Cedex 09
France
Contact: XXXXX
Telephone number: + 33 4 72 85 41 93
E-mail: sophie.lautraite@bayer.com

Location of the production site

CONFIDENTIAL information - data provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Please send all correspondence to:

Fine Agrochemicals Limited	Person to contact:	XXXXX
Hill End House, Whittington	Position:	Process R&D Manager
Worcester WR5 2RQ	Telephone No.:	+44 1905 361800
United Kingdom	E-mail:	grahams@fine.eu

Location of the production site

CONFIDENTIAL information - please refer to Fine's confidential data

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

substance(s)

Prohexadione-Ca min. 920 g/kg
There is no relevant impurity

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

Trade name: Please refer to Registration Report Part A for the relevant country

Company code number: Prohexadione-Ca OD 75 (75 g/L)
PRL OD 75
specification102000037599; UVP 86702428

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)

The formulation PRL OD 75 was not the representative formulation for the Annex I Renewal of the active substance(s) Prohexadione-Ca.

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) (g/L)	Technical content* (g/L)	Technical content** (%w/w)
Prohexadione-Ca	75	67.5 -82.5	81.5	7.91

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

** Based on the density of the formulation = 1.03 g/mL

Table 1.4-2: Safener and synergists

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max) (g/L or g/kg)	Technical content (g/L or g/kg)	Technical content (%w/w)
Not relevant	-	-	-	-

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Not relevant	-

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

Table 1.4-4: Information on active substances

Type	Prohexadione-Ca	
ISO common name	Prohexadione	Variant : Prohexadione-calcium
CAS No.	88805-35-0	127277-53-6
EC/List No.	618-212-2	603-193-5

Type	Prohexadione-Ca	
CIPAC No.	567	567.020

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

Table 1.4-5: Information on safeners/ synergists / co-formulant

Type	Name/Code Number	
Safener /synergist	not relevant	-
ISO common name	-	-
CAS No.	-	-
EC No.	-	-

Co-formulants:

CONFIDENTIAL information is provided separately (Part C).

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

Type: Oil -based suspension concentrates [Code: OD]

1.6 Function (KCP 1.6)

Plant growth regulator

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 light-yellow opaque liquid, without odour. It is not explosive and has no oxidising properties. The product has a flash point of 154 °C. It has a self-ignition temperature of 359 °C. In aqueous solution, it has a pH value around 4.3 at 25°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 based on the accelerated study results. Its technical characteristics are acceptable for an oil -based suspension concentrate formulation.

The intended concentration of use is 0.2% to 1.5% (according to the GAP table it is 0.3%-1.2% range per application).

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

Safety data sheets

Reference:	KCP Section 12/01
Title:	Prohexadione-Calcium OD 75 G
Report:	Anon.; 2021; M-766784-01-1
Authority registration No:	
Guideline(s):	--
Deviations:	--
GLP/GEP:	not applicable
Acceptability:	
Duplication (if vertebrate study):	

Reference:	KCP Section 12/02
Title:	Prohexadione calcium technical
Report:	Anon.; 2020; M-758837-01-1
Authority registration No:	
Guideline(s):	--
Deviations:	--
GLP/GEP:	not applicable
Acceptability:	
Duplication (if vertebrate study):	

Notifier Proposals for Risk and Safety Phrases (KCP 12)

There is no specific proposal linked to the physical chemical part.

Hazard pictograms:	
Signal word:	Warning

Hazard statements

H317	May cause an allergic skin reaction.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.
EUH401	To avoid risks to human health and the environment, comply with the instructions for use.

Precautionary statements

P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P308 + P311	IF exposed or concerned: Call a POISON CENTER/ doctor/ physician.
P391	Collect spillage.
P501	Dispose of contents/container in accordance with local regulation.

Compliance with FAO specifications:

The product Prohexadione-Ca OD 75 (75 g/L) complies with FAO specifications for an oil -based suspension concentrates formulation.

Formulation used for tests

The following batch has been used in the physico-chemical studies:
specification 102000037599-02, batch 2020-001264; 78.54 g/L active substance

Composition of this batch is described 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)	OCSPP 830.6303 830.6302 830.6304	spec N° 102000037599-02 batch 2020-0012264	Physical state: liquid; opaque Colour: light yellow Odour: odorless	Y	Hoppe. M. 2020 M-753752-01-1	Accepted
Explosive properties (KCP 2.2.1)	UN-MTC Appendix 6, point 3 OCSPP 830.6316 DIN 51007	spec N° 102000037599-02 batch 2020-0012264	Not an explosive	Y	Gramm. V. 2020 M-753923-01-1	Accepted
Oxidizing properties (KCP 2.2.2)	UN O.2	spec N° 102000037599-02 batch 2020-0012264	No oxidising properties	Y	Gramm. V. 2020 M-753923-01-1	Accepted
Flash point (KCP 2.3.1)	EC A9 UN 32.4 DIN EN ISO 2719 OCSPP 830.6315	spec N° 102000037599-02 batch 2020-0012264	The flash point was determined to be 154°C	Y	Gramm. V. 2020 M-753923-01-1	Accepted
Flammability (KCP 2.3.2)			Not required as the formulation is not a solid nor a gas			
Self-heating (KCP 2.3.3)	EC A15 DIN EN 14522 ISO/IEC 80079-20-1	spec N° 102000037599-02 batch 2020-0012264	The self-ignition temperature has been found to be 359 °C.	Y	Gramm. V. 2020 M-753923-01-1	Accepted
Acidity or alkalinity (KCP 2.4.1)			Acidity/alkalinity not required as the preparation is neither strongly acidic (pH < 4) nor strongly alkaline (pH > 10).			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT75.3 OCSPP 830.7000	spec N° 102000037599-02 batch 2020-0012264	1% in deionized water pH = 4.3	Y	Hoppe. M. 2020 M-753752-01-1	Accepted
Viscosity (KCP 2.5.1)	CIPAC MT 192 OECD 114 OCSPP 830.7100	spec N° 102000037599-02 batch 2020-0012264	Kinematic viscosity: shear rate 20 s-1 $\nu = \eta / \rho = 217.4 \text{ mm}^2/\text{s}$ at 20 °C $\nu = \eta / \rho = 127.0 \text{ mm}^2/\text{s}$ at 40 °C shear rate 100 s-1 $\nu = \eta / \rho = 157.0 \text{ m}^2/\text{s}$ at 20 °C $\nu = \eta / \rho = 82.16 \text{ mm}^2/\text{s}$ at 40 °C Dynamic viscosity: shear rate 20 s-1 $\eta = 225.9 \text{ mPa s}$ at 20 °C $\eta = 130.2 \text{ mPa s}$ at 40 °C shear rate 100 s-1 $\eta = 163.2 \text{ mPa s}$ at 20 °C $\eta = 84.21 \text{ mPa s}$ at 40 °C	Y	Hoppe. M. 2020 M-753752-01-1	Accepted the PPP is a non-Newtonian fluid
Surface tension (KCP 2.5.2)	OECD115 EC A5	spec N° 102000037599-02 batch 2020-0012264	28 mN.m ⁻¹ at a dilution of 1 g/L (20°C) 26 mN.m ⁻¹ undiluted (25 °C)	Y	Hoppe. M. 2020 M-753752-01-1	Accepted It is a surface active
Relative density (KCP 2.6.1)	OECD 109 EC A3 OCSPP 830.7300	spec N° 102000037599-02 batch 2020-0012264	d ₄ ²⁰ = 1.039 d ₄ ⁴⁰ = 1.025	Y	Hoppe. M. 2020 M-753752-01-1	Accepted
Bulk density (KCP 2.6.2)			No study provided since this is only required for a solid formulation			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT46.3 OCSPP 830.6317	spec N° 102000037599-02 batch 2020-0012264	Stable throughout the test period of 14 days at 54 °C (a.s. content, colour, odour, physical status, pH, relative D ₄ ²⁰ density, persistent foaming, suspensibility, wet sieve test, particle size distribution, dispersion stability and pourability) Packaging material: COEX/PA bottles (= HDPE/PA). Please refer to Table below Table 2-1 for detailed results.	N	Hoppe. M. 2020 M-753752-01-1	Accepted Tested in COEX/PA packaging
Stability after storage for other periods and/or temperatures (KCP 2.7.2)			Not conducted as stable after 14 days at 54 °C			
Minimum content after heat stability testing (KCP 2.7.3)	Analytical method AM035319MF*	spec N° 102000037599-02 batch 2020-0012264	Packaging material: COEX/PA (= HDPE/PA) <u>a.s</u> Initial: 7.63% 14 Days 54 °C: 7.36% Degr. rate: 3.65%	N	Hoppe. M. 2020 M-753752-01-1	Accepted
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT39.3 Analytical method AM035319MF*	spec N° 102000037599-02 batch 2020-0012264	Stable throughout the test period of 7 days at 0 °C with respect to active substance content, visual separation, suspensibility, wet sieve test and dispersion stability. Please refer to Table below Table 2-1 for detailed results.	N	Hoppe. M. 2020 M-753752-01-1	Accepted
Ambient temperature shelf life (KCP 2.7.5)	CIPAC MT46.3 CLI No. 17		The formulation is expected to be stable for at least 2 years at ambient conditions based on the results of the accelerated study. The study is ongoing.	N		Ongoing
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Not required as shelf life at ambient temperature is expected to be stable at least 24 months.	N		
Wettability (KCP 2.8.1)			No study provided since this is only required for a solid formulation			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Persistence of foaming (KCP 2.8.2)	CIPAC MT47.3	spec N° 102000037599-02 batch 2020-0012264	After 1 min. in CIPAC D water. Conc.: 0.2 % 0 mL Conc.: 1.5 % 0 mL	N	Hoppe. M. 2020 M-753752-01-1	Accepted
Suspensibility (KCP 2.8.3.1)	CIPAC MT184 Analytical method AM035319MF*	spec N° 102000037599-02 batch 2020-0012264	In CIPAC D water. <u>prohexadione-calcium</u> Conc.: 0.2% 100 % Conc.: 1.5 % 100 %	N	Hoppe. M. 2020 M-753752-01-1	Accepted
Spontaneity of dispersion (KCP 2.8.3.2)			No study provided since this is only required for formulations forming suspension after dilution in water			
Dispersion stability (KCP 2.8.3.3)	CIPAC MT 180	spec N° 102000037599-02 batch 2020-0012264	<u>Conc.:0.2 % prep. in CIPAC D water.</u> Dispersion after: 0 min complete 30 min no sediment, no oil, no cream Re-dispersibility after 24 h complete 24.5 h no sediment, no oil, no cream <u>Conc. 0.2 % prep. in CIPAC A water.</u> Dispersion after: 0 min complete 30 min no sediment, no oil, no cream Re-dispersibility after 24 h complete 24.5 h no sediment, no oil, no cream <u>Conc. 1.5 % prep. in CIPAC D water.</u> Dispersion after: 0 min complete 30 min no sediment, no oil, < 0.05 ml cream Re-dispersibility after 24 h complete 24.5 h no sediment, no oil, < 0.05 ml cream <u>Conc. 1.5 % prep. in CIPAC A water.</u> Dispersion after: 0 min complete 30 min no sediment, no oil, 0.1 ml cream Re-dispersibility after 24 h complete 24.5 h no sediment, no oil, 0.05 ml cream	N	Hoppe. M. 2020 M-753752-01-1	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Degree of dissolution and dilution stability (KCP 2.8.4)			No study provided since this is only required for water soluble formulations			
Particle size distribution (KCP 2.8.5.1.1)	CIPAC MT187	spec N° 102000037599-02 batch 2020-0012264	Laser diffraction d(0.1) = 1.05 µm d (0.5) = 2.70 µm d (0.9) = 7.38 µm	Y	Hoppe. M. 2020 M-753752-01-1	Accepted
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT185	spec N° 102000037599-02 batch 2020-0012264	On a 75 µm sieve: < 0.01 %	N	Hoppe. M. 2020 M-753752-01-1	Accepted
Dust content (KCP 2.8.5.2.1)			No study provided since this is only required for granular formulations			
Particle size of dust (KCP 2.8.5.2.2)			No study provided since this is only required for granular formulations			
Attrition (KCP 2.8.5.3)			No study provided since this is only required for granular formulations			
Hardness and integrity (KCP 2.8.5.4)			No study provided since this is only required for tablet formulations			
Emulsifiability (KCP 2.8.6.1)			No study provided since this is only required for formulations forming emulsions			
Emulsion stability (KCP 2.8.6.2)			No study provided since this is only required for formulations forming emulsions			
Re-emulsifiability (KCP 2.8.6.3)			No study provided since this is only required for formulations forming emulsions			
Flowability (KCP 2.8.7.1)			No study provided since this is only required for granular formulations			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Pourability (KCP 2.8.7.2)	CIPAC MT148	spec N° 102000037599-02 batch 2020-0012264	Residue: 2.10 % Rinsed residue: 0.0.17 %	N	Hoppe. M. 2020 M-753752-01-1	Accepted
Dustability following accelerated storage (KCP 2.8.7.3)			Only for dustable powders			
Physical compatibility of tank mixes (KCP 2.9.1)			Where relevant please refer to local recommendations.			
Chemical compatibility of tank mixes (KCP 2.9.2)			Where relevant, please refer to local recommendations.			
Adhesion to seeds (KCP 2.10.1)			No study provided since this is only required for seed treatment formulations			
Distribution to seed (KCP 2.10.2)			No study provided since this is only required for seed treatment formulations			
Other/special studies (KCP 2.11)			There is no other / special study			

Results referring to the point KCP 2.7.1: Storage stability after 14 days at 54 °C ([M-753752-01-1](#))

Test	Initial	14 days at 54°C in COEX/PA bottles
Content of a.s. AM035319MF* HPLC/ESTD	7.63 % (79.3 g/L)	7.36% (76.4 g/L)
Packaging stability OCSPP 830.6320 COEX/PA	no negative effects observed	no negative effects observed
weight change	not necessary	< 0.1% no significant change
deformation of packaging	no panelling no ballooning	panelling (approx. 10 mm retracted on the side)
leakage	no leakage	no leakage
effect on closure	leak proof	leak proof
packaging/preparation interaction	no seepage, no claying, no sedimentation	no seepage no claying no sedimentation ~4 % brown supernatant on the top, can be easily re-homogenized.
Colour OCSPP 830.6302	light yellow	light yellow
Odour OCSPP 830.6304	odourless	odourless
Physical state OCSPP 830.6303	opaque liquid	opaque liquid
Acidity/alkalinity CIPAC MT 191	The determination was not required as the pH-value was between 4.0 and 10.0.	
pH-value CIPAC MT 75.3 OCSPP 830.7000	1% in deionised water	
	4.3	4.4
Relative density (EC) 440/2008 A.3 OECD 109 OCSPP 830.73003	D ₄ ²⁰ 1.039	D ₄ ²⁰ 1.038
Persistent foaming CIPAC MT 47.3	0.2% in CIPAC Standard Water D	
	13 mL foam after 10 s	10 mL foam after 10 s
	0 mL foam after 1 min	0 mL foam after 1 min
	0 mL foam after 3 min	0 mL foam after 3 min
	0 mL foam after 12 min	0 mL foam after 12 min
	1.5 % in CIPAC Standard Water D	
	20 mL foam after 10 s	32 mL foam after 10 s
	0 mL foam after 1 min	0 mL foam after 1 min
	0 mL foam after 3 min	0 mL foam after 3 min
	0 mL foam after 12 min	0 mL foam after 12 min
	in CIPAC Standard Water D	

Test	Initial	14 days at 54°C in COEX/PA bottles
Suspensibility CIPAC MT 184 method AM035319MF*	conc. 0.2% prohexadione-calcium: 100% conc. 1.5% prohexadione-calcium: 100%	conc. 0.2% prohexadione-calcium: 100% conc. 1.5% prohexadione-calcium: 101%
Wet sieve test CIPAC MT 185	residue on a 75 micron sieve < 0.01 %	0.02 %
Particle size distribution CIPAC MT187	d(0.1) : 1.05 µm d(0.5): 2.70 µm d*0.9): 7.38 µm	d(0.1) : 1.07 µm d(0.5): 2.79 µm d*0.9): 7.67 µm
Dispersion stability CIPAC MT 180	0.2% in CIPAC standard water A	
	initial: complete dispersibility after 30 min: no separation after 24 h: complete re-dispersibility after further 30 min: no separation	initial: complete dispersibility after 30 min: no sediment, no oil trace of cream after 24 h: complete re-dispersibility after further 30 min: no sediment, no oil trace of cream
	0.2% in CIPAC standard water D	
	initial: complete dispersibility after 30 min: no separation after 24 h: complete re-dispersibility after further 30 min: no separation	initial: complete dispersibility after 30 min: no separation after 24 h: complete re-dispersibility after further 30 min: no sediment, no oil 0.05 mL of cream
	1.5 % in CIPAC standard water A	
	initial: complete dispersibility after 30 min: no sediment, no oil, 0.1 mL cream after 24 h: complete re-dispersibility after further 30 min: no sediment, no oil, 0.05 mL cream	initial: complete dispersibility after 30 min: no sediment, no oil, 0.3 mL cream after 24 h: complete re-dispersibility after further 30 min: no sediment, no oil, 0.08 mL cream
	1.5 % in CIPAC standard water D	
	initial: complete dispersibility after 30 min: no sediment, no oil, < 0.05 mL cream after 24 h: complete re-dispersibility after further 30 min: no sediment, no oil, < 0.05 mL cream	initial: complete dispersibility after 30 min: no sediment, no oil, 0.09 mL cream after 24 h: complete re-dispersibility after further 30 min: no sediment, no oil, 0.08 mL cream
Pourability CIPAC MT 148	residue: 2.10 % rinsed residue:0.17%	residue: 2.34 % rinsed residue:0.20%

RMS conclusion on the accelerated study

The study is accepted. All physicochemical parameter are adequate.

Results referring to the point KCP 2.7.4: cold storage stability 7 days at 0 °C ([M-753752-01-1](#))

Test	Initial	7 days at 0°C in COEX/PA bottles
Content of a.s. AM035319MF* HPLC/ESTD	7.63 % (79.3 g/L)	7.36% (76.4 g/L)
Separation visual inspection	no visible separation	
Suspensibility CIPAC MT 184 method AM035319MF*	in CIPAC Standard Water D	
	conc. 0.2% prohexadione-calcium: 100% conc. 1.5% prohexadione-calcium: 100%	conc. 0.2% prohexadione-calcium: 100% conc. 1.5% prohexadione-calcium: 100%
Wet sieve test CIPAC MT 185	residue on a sieve	
	< 0.01 %	< 0.01 %
Dispersion stability CIPAC MT 180	0.2% in CIPAC standard water A	
	initial: complete dispersibility after 30 min: no separation after 24 h: complete re-dispersibility after further 30 min: no separation	initial: complete dispersibility after 30 min: no sediment, no oil, 0.05 mL cream after 24 h: complete re-dispersibility after further 30 min: no sediment, no oil, trace of cream
	0.2% in CIPAC standard water D	
	initial: complete dispersibility after 30 min: no separation after 24 h: complete re-dispersibility after further 30 min: no separation	initial: complete dispersibility after 30 min: no sediment, no oil, trace of cream after 24 h: complete re-dispersibility after further 30 min: no sediment, no oil, 0.05 mL of cream
	1.5 % in CIPAC standard water A	
	initial: complete dispersibility after 30 min: no sediment, no oil, 0.1 mL cream after 24 h: complete re-dispersibility after further 30 min: no sediment, no oil, 0.05 mL cream	initial: complete dispersibility after 30 min: no sediment, no oil, 0.3 mL cream after 24 h: complete re-dispersibility after further 30 min: no sediment, no oil, 0.2 mL cream
	1.5 % in CIPAC standard water D	
	initial: complete dispersibility after 30 min: no sediment, no oil, < 0.05 mL cream after 24 h: complete re-dispersibility after further 30 min: no sediment, no oil, < 0.05 mL cream	initial: complete dispersibility after 30 min: no sediment, no oil, 0.09 mL cream after 24 h: complete re-dispersibility after further 30 min: no sediment, no oil, 0.08 mL cream

RMS conclusion on the cold storage stability 7 days at 0 °C study

The study is accepted. All physicochemical parameter are adequate

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 nature and characteristics of the packaging: information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport and handling, resistance to and compatibility with the contents of the packaging, have been submitted, evaluated and are considered to be acceptable.

Table 4.1-1: Packaging information for 50 mL to 15 L bottles

Type	Description
Material:	COEX/PA Coextruded high density polyethylene (HDPE) with an internal barrier layer made of polyamide (PA) (HDPE/PA) COEX/EV Coextruded high density polyethylene (HDPE) with an internal barrier layer made of ethylene vinyl alcohol copolymer (EV) (HDPE/EV) EV can also be noted as EVOH
Shape/size:	cylindrical / rectangular – see below for sizes
Opening:	screw cap 32mm, 50 mm and 63 mm
Closure:	polyethylene screw cap
Seal:	HF seal, Foam Disc
Manner of construction	co-extruded (HDPE/PA, HDPE/EV)
UN/ADR	compliant

Volume	50 ml	100 ml	250 ml
Material I	-	-	HDPE/PA
Material II	HDPE/EV	HDPE/EV	HDPE/EV
Shape size [mm]	cylindrical 44x 82.6 mm	cylindrical 44 x 114.5 mm	cylindrical 62.5 x 137 mm
Opening	27.8 mm	27.8 mm	45 mm
Closure	Screw cap 32 mm	Screw cap 32 mm	Screw cap 50 mm
Seal	HF seal, foam disc	HF seal, foam disc	HF seal, foam disc
Manner of Construction	extruded, blow moulded	extruded, blow moulded	extruded, blow moulded
UN/ADR	compliant	compliant	compliant

Volume	500 ml	1 L	3 L
Material I	HDPE/PA	HDPE/PA	HDPE/PA
Material II	HDPE/EV	HDPE/EV	-
Shape size [mm]	cylindrical 69 x 193 mm	cylindrical 88.5 x 244.5 mm	rectangular 190 x 140 x 236 mm
Opening	45 mm	45 mm	57.8 mm
Closure	Screw cap 50 mm	Screw cap	Screw cap
Seal	HF seal, foam disc	HF seal, foam disc	HF seal, foam disc
Manner of Construction	extruded, blow moulded	extruded, blow moulded	extruded, blow moulded
UN/ADR	compliant	compliant	compliant

Volume	5 L	10 L	15 L + cardboard
Material I	HDPE/PA	HDPE/PA	HDPE/PA
Material II	-	-	-
Shape / size [mm]	rectangular / 190 x 140 x 309 mm	rectangular / 226 x 186 x 370 mm	rectangular / 245 x 225 x 404 mm
Opening	57.8 mm	57.8 mm	57.8 mm
Closure	Screw cap	Screw cap	Screw cap
Seal	HF seal, foam disc	HF seal, foam disc	HF seal, foam disc
Manner of Construction	extruded, blow moulded	extruded, blow moulded	extruded, blow moulded
UN/ADR	compliant	compliant	compliant

Complying with CropLife International recommendation for one-way agrochemical packaging design criteria for liquids and solids [Guidelines for the safe formulation and packaging of crop protection products (Guideline 6)].

Resistance of the packaging material:

The material proposed for use (High Density Polyethylene Coextruded: HDPE/PA, HDPE/EV) are known from experience to be compatible with solvent based formulations and are resistant to the influences of chemicals. However, the resistance of the packaging material to its contents has been tested in the accelerated storage stability in accordance with CropLife International Technical Monograph No 17 (June 2009). The results show that no detrimental effects were noted thus demonstrating the acceptability of the packaging material.

RMS conclusion on proposed packaging information.

Based on the accelerated study all mentioned above packs are accepted for the PPP.

RMS conclusion on missing effectiveness of the cleaning procedure data.

According the reg. 284/2013 effectiveness of the cleaning procedure shall be tested by applicant and adequate information is required. No data were provided for evaluation in Poland. It is considered as DATA GAP

Appendix 1 Lists of data considered in support of the evaluation

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 2.1 / 01 ... also filed: KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.7 / 01 KCP 2.8.2 / 01 KCP 2.8.3 / 01 KCP 2.8.5.1 / 01 KCP 2.8.7 / 01	Hoppe, M.	2020	Storage stability at elevated temperature and cold stability of prohexadione-calcium OD 75 (75 g/L) - Packaging material: COEX/PA - Final report (14 days) Report No.: FM0408(PKF02)G01, Edition Number: M-753752-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.2 / 01 ... also filed: KCP 2.3 / 01	Gramm, V.	2020	Safety-relevant data of prohexadione-calcium OD 75 (75 g/L) Report No.: 2020/00182, Edition Number: M-753923-01-1 Bayer AG, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP Section 12 / 01	Anon.	2021	Prohexadione-Calcium OD 75 G Report No.: M-766784-01-1 Bayer AG, Leverkusen, Germany GLP/GEP: n.a. unpublished	No	-public data-
KCP Section 12 / 02	Anon.	2020	Prohexadione calcium technical Report No.: M-758837-01-1 Fine Agrochemicals Limited, Whittington, Worcester, United Kingdom GLP/GEP: n.a. unpublished	No	-public data-

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

List of data submitted or referred to by the applicant and relied on are available via the Letter of Access from Fine Ltd. All data mentioned as part of DAR, RAR, or EFSA journals are considered as relied on.

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

A 2.1 Prohexadione-Ca

No new data.