

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: **102000037599**

Product name(s): **Prohexadione-calcium OD 75 (75 g/L)**

Active substance(s):

Central Zone

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT

(Authorisation)

Applicant: **Bayer CropScience Division**

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Version history

When	What
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January 2022	zRMS finalised evaluation
April 2022	Final version prepared by zRMS after Commenting period

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8 Fate and behaviour in the environment (KCP 9)

Evaluator comments:

The text highlighted in grey was provided by the evaluator.

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, 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/ syner- gist per ha	Conclusion
					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			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	AUT	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400	-	PHI according to growth stage	
4	CZE	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400	-	PHI according to growth stage	
7	DEU	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400	-	PHI according to growth stage	
10	HUN	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400	-	PHI according to growth stage	
13	POL	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400	-	PHI according to growth stage	
16	ROU	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400	-	PHI according to growth stage	
19	SVK	Rape, winter (BRSNW)	F	winter solidness, growth regulation of crop	spraying (broadcast, overall)	12-18	a) 1 b) 1	-	a) 1.2 b) 1.2	a) PRL 90 b) PRL 90	100-400	-	PHI according to growth stage	
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
None														

Minor uses according to Article 51 (zonal uses)	
None	
Minor uses according to Article 51 (interzonal uses)	
None	

PRL: Prohexadione-Calcium

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

** 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

F: PHI determined by the growth stage of the application

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by eMS
N	No safe use

Table 8.1-2: Assessed (critical) uses during approval of Prohexadione-calcium concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No*	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
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg ai/hL product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.i/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU-N&S	Apples	F	Inhibition of vegetative growth and optimisation of fruit yield	SP overall	BBCH 31- 75	2	21-35 days	0.00625- 0.025	0.125	500-2000	55	-
2	EU-N&S	Cereals	F	Stem stabilization	SP	Before BBCH 39	1	Not applicable	0.025-0.05	0.075	150-300	(1) F	The use of immature crops for animal feed has not been assessed

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

** 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

8.2 Metabolites considered in the assessment

A metabolite, despropionyl prohexadione, was detected at 15.21% in a soil photolysis study under dry soil conditions. PEC values in soil were estimated for this metabolite in the EU review (EFSA Journal 2010; 8(3):1555), however it was noted in the EU review that the rapid rate of biodegradation under more realistic moist soil conditions would mean that it would not be expected to be formed under field conditions. No risk assessment was performed on this metabolite in the EU review; therefore this metabolite is not considered in this assessment.

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Prohexadione-calcium

The aerobic degradation of Prohexadione-calcium has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2010; 8(3):1555). No additional studies have been performed.

Table 8.3-1: Summary of aerobic degradation rates of Prohexadione-calcium in laboratory soils

Prohexadione-calcium, laboratory study, aerobic conditions							
Soil type	pH	Temperature (°C) / % MWHC	DT ₅₀ * / DT ₉₀ * (days)	DT ₅₀ (days) (20°C & pF2/10kPa)**	χ^2	Method of calculation	Evaluated on EU level y/n/ Reference
Loamy sand (USDA)	5.4 (CaCl ₂)	20°C / 40%	1.6 / 5.3	1.6	8.8	SFO	y/ EFSA Journal 2010; 8(3):1555
Sandy loam (USDA)	6.2 (CaCl ₂)	20°C / 40%	1.6 / 5.3	1.6	8.9	SFO	y/ EFSA Journal 2010; 8(3):1555
Sandy loam (USDA)	7.2 (CaCl ₂)	20°C / 40%	1.1 / 3.5	1.0	3.4	SFO	y/ EFSA Journal 2010; 8(3):1555
Clay (USDA)	7.2 (CaCl ₂)	20°C / 40%	4.1 / 14	2.9	6.4	SFO	y/ EFSA Journal 2010; 8(3):1555
Loamy sand (USDA)	5.6 (H ₂ O)	20°C / 40% 10°C / 40%	0.2 / 0.7 1.0 / 3.3	0.2	6.0 1.5	SFO SFO	y/ EFSA Journal 2010; 8(3):1555
Clay loam (USDA)	5.8 (H ₂ O)	20°C / 40% 10°C / 40%	1.1 / 3.5 1.0 / 4.4 6.8 / 23	0.6	10.2 10.1 4.3	SFO FOMC SFO	y/ EFSA Journal 2010; 8(3):1555
Sandy	5.3	20°C / 40%	0.4 / 1.4	0.3	6.2	SFO	y/ EFSA Journal 2010;

silt loam (USDA)	(H ₂ O)	10°C / 40%	12 / 39		7.3	SFO	8(3):1555
Loamy sand (USDA)	6.9 (H ₂ O)	20°C / 40% 10°C / 40%	0.2 / 0.8 0.6 / 2.2	0.2	3.1 1.9	SFO SFO	y/ EFSA Journal 2010; 8(3):1555
Non normalised maximum			4.1				
Geometric mean (n=8)				0.66			
pH-dependency: y/n			n				
*: trigger endpoint; ** BBA classification system was used for normalisation procedure for all the soils							

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Prohexadione-calcium

The anaerobic degradation of Prohexadione-calcium has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2010; 8(3):1555). No additional studies have been performed.

Table 8.3-2: Summary of anaerobic degradation rates of Prohexadione-calcium in laboratory soils

Prohexadione-calcium, laboratory study, anaerobic condition				
Soil type	pH	Temperature (°C) / % MWHC	DT ₅₀ / DT ₉₀ (days)	Evaluated on EU level y/n/ Reference
Loamy sand	5.6 (H ₂ O)	20°C / 40% 10°C / 40%	<0.5 / - <2 / -	y/ EFSA Journal 2010; 8(3):1555
Clay loam	5.8 (H ₂ O)	20°C / 40% 10°C / 40%	<2 / - <32 / -	y/ EFSA Journal 2010; 8(3):1555
Sandy silt loam	5.3 (H ₂ O)	20°C / 40% 10°C / 40%	<4 / - <4 / -	y/ EFSA Journal 2010; 8(3):1555
Loamy sand	6.9 (H ₂ O)	20°C / 40% 10°C / 40%	<2 / - <2 / -	y/ EFSA Journal 2010; 8(3):1555

8.4 Field studies (KCP 9.1.1.2)

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

8.4.1.1 Prohexadione-calcium

Field studies for Prohexadione-calcium were not performed.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

It has been acknowledged in the EFSA Scientific Report (EFSA Journal 2010;8(3):1555), that soil accumulation studies are not requested for Prohexadione-calcium. No additional studies have been performed.

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.5.1 Laboratory studies (KCP 9.1.2.1)

8.5.1.1 Prohexadione-calcium

Table 8.5-1: Summary of soil adsorption/desorption for Prohexadione-calcium

Prohexadione-calcium							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Speyer 2.2	Loamy sand	2.2	5.6	3.72	166	1.02	y/ EFSA Journal 2010; 8(3):1555
Clay loam	Clay loam	3.3	5.8	10.12	307	1.04	
Sandy silt loam	Sandy silt loam	2.3	5.3	6.04	263	1.01	
Loamy sand	Loamy sand	0.6	6.9	0.49	82.17	0.93	
Arithmetic mean (n=4)					204.5	1.0	
Geometric mean (n=4)					182 ^a	-	
pH-dependency y/n					n		

^a The geometric mean was used in the PEC groundwater and surface water modelling in the EFSA Conclusion (EFSA Journal 2010, 8(3):1555)

8.5.2 Lysimeter studies (KCP 9.1.2.2)

No lysimeter studies had been submitted for Prohexadione-calcium. Based on properties of Prohexadione-calcium and the results of the groundwater modelling, lysimeter studies are not required.

8.5.3 Field leaching studies (KCP 9.1.2.3)

The field leaching studies have been not performed for Prohexadione-calcium. Based on properties of Prohexadione-calcium and the results of the groundwater modelling, field leaching studies are not required.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.6.1.1 Prohexadione-calcium

Table 8.6-1: Summary of degradation in water/sediment of Prohexadione-calcium

Prohexadione-calcium Distribution (max. water 103% after 0 days, max. sediment not detected)										
Water/sediment system	pH water/sed.	DegT ₅₀ whole syst. (d)	DegT ₉₀ whole syst. (d)	Kinetic, Fit	DissT ₅₀ water (d)	DissT ₉₀ water (d)	Kinetic, Fit	DissT ₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Silty clay loam	6.3/5.0	4.75 (persistence DegT ₅₀ 0.87)	15.78	HS	4.75	15.78	HS	-	-	y/ EFSA Journal 2010; 8(3):1555
Sandy loam	7.5/6.4	0.65	2.17	SFO	0.65	2.17	SFO	-	-	
Geometric mean (n=2)		1.8	5.9		1.8	5.9		-		

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

The PEC_{soil} are calculated for the use patterns of the product in the zone as presented in Table 8.1-1.

8.7.1 Justification for new endpoints

No deviations from EU agreed endpoints.

8.7.2 Active substance(s) and relevant metabolite(s)

Evaluator's Comments:	<p>Calculations of PECs for active substance were accepted. Calculations of PEC_s for metabolite Despropionyl-prohexadione were calculated by the evaluator.</p> <p>The interception of 40% was accepted.</p> <p>The maximum PEC_s values for active substance and its metabolite are presented in following table:</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Crop</th> <th>Oil seed rape (winter)</th> </tr> </thead> <tbody> <tr> <td>Application rate g a.s./ha</td> <td>90.0</td> </tr> <tr> <td>Compound</td> <td>PECs ini mg/kg soil</td> </tr> <tr> <td>Prohexadione calcium</td> <td>0.072</td> </tr> <tr> <td>Despropionyl-prohexadione</td> <td>0.0068</td> </tr> </tbody> </table> <p>PEC_s = 0.996 mg/kg for formulation was accepted.</p> <p>These values will be used in further risk assessment.</p>	Crop	Oil seed rape (winter)	Application rate g a.s./ha	90.0	Compound	PECs ini mg/kg soil	Prohexadione calcium	0.072	Despropionyl-prohexadione	0.0068
Crop	Oil seed rape (winter)										
Application rate g a.s./ha	90.0										
Compound	PECs ini mg/kg soil										
Prohexadione calcium	0.072										
Despropionyl-prohexadione	0.0068										

PEC_{soil} reports provided by the applicant are listed in Appendix 3.1.

Table 8.7-1: Input parameter related to application for PECsoil calculations

Use No.	1
Crop	Oil seed rape (winter)
Application rate (g.as/ha)	90
Number of applications/interval	1/-
Crop interception %	40
Depth of layer (relevant for plateau concentration) (cm)	20 (tilage)

Table 8.7-2: Input parameters for Prohexadione-calcium for PECsoil calculation

Compound	Molar mass (g/mol)	Max. occur. in soil (%)	DT ₅₀ (days)	Kinetics	Molar mass corr. factor (-)	Value in accordance to EU endpoint y/n Reference
Prohexadione-calcium	250.26	100	4.1	SFO	1	y/ EFSA Journal 2010; 8(3):1555
Despropionyl-prohexadione	156.0	15.21	6.0 d		0.623	y/ EFSA Journal 2010; 8(3):1555

8.7.2.1 Prohexadione-calcium

Table 8.7-3: PECsoil for Prohexadione-calcium on oil seed rape (winter), 1×90 g a.s./ha, 40% interception

PEC _{soil} (mg/kg)		Oil Seed Rape (winter)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.072	-	-	-
Short term	24h	0.061	0.066	-	-
	2d	0.051	0.061	-	-
	4d	0.037	0.052	-	-
Long term	7d	0.022	0.042	-	-
	14d	0.007	0.028	-	-
	21d	0.002	0.020	-	-
	28d	<0.001	0.015	-	-
	42d	<0.001	0.010	-	-
	50d	<0.001	0.009	-	-
	100d	<0.001	0.004	-	-
Plateau concentration (20 cm) after year 0		<0.001	-	-	-
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})		0.072	-	-	-

8.7.2.2 PEC_{soil} of PRL OD 75

Table 8.7-4: PEC_{soil} for PRL OD 75 on oil seed rape (winter) (BBCH 12-18)

Active substance	Application rate (g/ha)	PEC act (mg/kg)	PECTwa 21d (mg/kg)	Tillage depth (cm)	PEC _{soil,plateau} (mg/kg)	PEC _{accu} =PEC _{act} +PEC _{soil,plateau} (mg/kg)
PRL OD 75	1245.6	0.996*	-	5	-	-

* Formulation density 1038g/L and 40 % interception were taken into consideration in the calculations:-

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

Evaluator's Comments:	<p>Presented calculations PEC_{gw} for the active substance Prohexadione calcium were accepted.</p> <p>Calculations of PEC_{GW} for active substance were provided in with PUF = 0.0. Modelling was conducted using PEARL and PELMO models for a single maximum application rate for winter oil seed rape in all relevant scenarios.</p> <p>All used endpoints were agreed at the EU level.</p> <p>The maximum PEC_{GW} values for active substance is below the trigger value of 0.1 µg/L.</p>
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The PEC_{gw} are calculated for the use patterns of the product as presented in Table 8.1-1. When relevant and necessary, additional calculations adapted to country-specific data requirements are provided in the national addenda.

8.8.1 Justification for new endpoints

No deviations from EU agreed endpoints.

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

PEC_{gw} reports provided by the applicant are listed in Appendix 3.2.

Table 8.8-1: Input parameter related to application for PEC_{gw} calculations

Use No.	1
Crop	Oil seed rape (winter)
Application rate (g as/ha)	90
Number of applications/interval	1/-
Relative application date	Absolute dates are given in below table
Crop interception %	40
Frequency of application	Annual
Models used for calculation	FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3, FOCUS MACRO 5.5.4

Table 8.8-2: Application dates used for groundwater risk assessment

Scenario	Application dates (absolute)
	Oil seed rape (winter)
Châteaudun	11-Sep
Hamburg	06-Sep
Jokioinen	-
Kremsmünster	06-Sep
Okehampton	18-Aug
Piacenza	09-Oct
Porto	19-Sep
Sevilla	-
Thiva	-

8.8.2.1 Prohexadione-calcium

Table 8.8-3: Input parameter related to active substance for PEC_{gw} calculations

Compound	Prohexadione-calcium	Evaluated on EU level y/n/ Reference
Molecular weight (g/mol)	250.26	y/ EFSA Journal 2010; 8(3):1555
Water solubility (mg/L)	174.2 (20° C)	y/ EFSA Journal 2010; 8(3):1555
Saturated vapour pressure (Pa)	1.335 x 10 ⁻⁵ (20° C)	y/ EFSA Journal 2010; 8(3):1555
DT ₅₀ in soil (d)	0.66 (lab, normalised to pF2, 20 °C with Q10 of 2.58, geometric mean, n=8)	y/ EFSA Journal 2010; 8(3):1555
Transformation rate (d ⁻¹)	1.050223	Calculated from DT ₅₀
K _{foc} (mL/g) / K _{fom} (mL/g)	182/106 (geometric mean, n=4)	y/ EFSA Journal 2010; 8(3):1555
Freundlich exponent (1/n) (-)	1.0 (arithmetic mean, n=4)	y/ EFSA Journal 2010; 8(3):1555
Plant uptake factor (TSCF) (-)	0.0	y/ EFSA Journal 2010; 8(3):1555
Q10	2.58	y/ EFSA Journal 2010; 8(3):1555

Table 8.8-4: PEC_{gw} for Prohexadione-calcium on oil seed rape (winter) (with FOCUS PEARL/PELMO/MACRO) – 1×90 g a.s./ha, 40% interception

Crop	Scenario	80 th percentile PEC _{gw} at 1 m soil depth (µg/L)	
		Prohexadione-calcium	
		PEARL	PELMO
Oil Seed Rape (winter)	Chateaudun	<0.001	<0.001
Oil Seed Rape (winter)	Hamburg	<0.001	<0.001
Oil Seed Rape (winter)	Kremsmuenster	<0.001	<0.001
Oil Seed Rape (winter)	Okehampton	<0.001	<0.001
Oil Seed Rape (winter)	Piacenza	<0.001	<0.001

Oil Seed Rape (winter)	Porto	<0.001	<0.001
	MACRO		
	Châteaudun	<0.001	

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

Evaluator's Comments:	<p>The submitted PEC_{sw} and PEC_{sed} calculations were accepted. The used endpoints were agreed at the EU level.</p> <p>The recommended FOCUS models were used: FOCUS Step 1 & 2.</p> <p>Prohexadione calcium. The max PEC_{sw} are presented in the table below:</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Crop</th> <th>Application rate g a.s./ha</th> <th>Max PEC_{sw} (µg/L)</th> <th>Max PEC_{sed} (µg/kg)</th> </tr> </thead> <tbody> <tr> <td>Oil seed rape (winter)</td> <td>90.0</td> <td>0.828</td> <td>0.808</td> </tr> </tbody> </table> <p>In accordance with EFSA, 2010, no metabolite was taken into consideration.</p> <p>The PEC_{sw} for the formulation PRL OD 75 used in winter oil seed rape was corrected by the evaluator. Using the Drift Calculator in SWASH model the following mitigation measures were proposed.</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Formulation</th> <th>Application rate kg form/ha</th> <th>Distance (m)</th> <th>PEC_{sw} (µg PRL OD 75/L)</th> </tr> </thead> <tbody> <tr> <td rowspan="5">PRL OD 75</td> <td rowspan="5">1 x 1245.6</td> <td>1</td> <td>8.003</td> </tr> <tr> <td>5</td> <td>2.169</td> </tr> <tr> <td>10</td> <td>1.150</td> </tr> <tr> <td>15</td> <td>0.739</td> </tr> <tr> <td>20</td> <td>0.598</td> </tr> </tbody> </table> <p>The relevant mitigation measure will be recommended in ecotoxicological section.</p>	Crop	Application rate g a.s./ha	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)	Oil seed rape (winter)	90.0	0.828	0.808	Formulation	Application rate kg form/ha	Distance (m)	PEC _{sw} (µg PRL OD 75/L)	PRL OD 75	1 x 1245.6	1	8.003	5	2.169	10	1.150	15	0.739	20	0.598
Crop	Application rate g a.s./ha	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)																						
Oil seed rape (winter)	90.0	0.828	0.808																						
Formulation	Application rate kg form/ha	Distance (m)	PEC _{sw} (µg PRL OD 75/L)																						
PRL OD 75	1 x 1245.6	1	8.003																						
		5	2.169																						
		10	1.150																						
		15	0.739																						
		20	0.598																						

The PEC_{sw} are calculated for the use patterns of the product as presented in Table 8.1-1. When relevant and necessary, additional calculations adapted to country-specific data requirements in terms of relevant models, scenarios and risk mitigation measures, are provided.

8.9.1 Justification for new endpoints

No deviations from EU agreed endpoints.

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

PEC_{sw} reports provided by the applicant are listed in Appendix 3.3.

Table 8.9-1: Input parameter related to application for PECsw calculations

Plant protection product	PRL OD 75
Use No.	1
Crop	Oil seed rape (winter)
Application rate (g as/ha)	90
Number of applications / interval (d)	1/-
Application window (relevant for STEP 1-2 only)	Summer (June-September) Autumn (October-February)
Application method	Ground spray
CAM (Chemical application method)	CAM-2
Soil depth (cm)	4
Models used for calculation	STEPS 1-2 in FOCUS v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SPIN v3.3

Table 8.9-2: Input parameter related to active substance for PECsw calculations STEP 1/2

Compound	Prohexadione-calcium	Reference
Molecular weight (g/mol)	250.26	y/ EFSA Journal 2010; 8(3):1555
Water solubility (mg/L)	174 (20° C)	y/ EFSA Journal 2010; 8(3):1555
Saturated vapour pressure (Pa)	1.335 x 10 ⁻⁵ (20° C)	y/ EFSA Journal 2010; 8(3):1555
Diffusion coefficient in the water (m ² /d)	4.3 x 10 ⁻⁵	FOCUS default
Diffusion coefficient in the air (m ² /d)	0.43	FOCUS default
DT ₅₀ in soil (d)	0.66 (lab, normalised to pF2, 20 °C with Q10 of 2.58, geometric mean, n=8)	y/ EFSA Journal 2010; 8(3):1555
DT ₅₀ in water (d)	1.8 (lab, geometric mean n=4)	y/ EFSA Journal 2010; 8(3):1555
DT ₅₀ in sediment (d)	1000	FOCUS default, worst case
DT ₅₀ total water/sediment (d)	1.8 (lab, geometric mean n=4)	y/ EFSA Journal 2010; 8(3):1555
K _{foc} (mL/g) / K _{fom} (mL/g)	182/106 (geometric mean, n=4)	y/ EFSA Journal 2010; 8(3):1555
Freundlich exponent (1/n) (-)	1.0 (arithmetic mean, n=4)	y/ EFSA Journal 2010; 8(3):1555
Plant uptake factor (TSCF) (-)	0.0	FOCUS default, worst case
Wash off factor for from crop (1/mm)	0.05	FOCUS default
Maximum occurrence in soil (%)	100	y/ EFSA Journal 2010; 8(3):1555
Maximum occurrence in water/sediment (%)	100	y/ EFSA Journal 2010; 8(3):1555

8.9.2.1 Prohexadione-Calcium

FOCUS STEP 1/2

Table 8.9-3: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for Prohexadione-calcium following single application of PRL OD 75 to oil seed rape (winter) (modelling use oil seed rape (winter) -- summer -- 1×90g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21d-PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	-	25.0	RunOff	3.08	43.9
Step 2					
Northern Europe	Jun. - Sep. (Summer)	0.828 *	Drift	0.111	0.808 *
Southern Europe	Jun. - Sep. (Summer)	0.828 *	Drift	0.115	0.808 *

* Single applications are marked.

** TWA interval as required by ecotox

Table 8.9-4: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for prohexadione-calcium following single application of PRL OD 75 to oil seed rape (winter) (modelling use oil seed rape (winter) -- autumn -- 1×90g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21d-PEC _{sw,twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	-	25.0	RunOff	3.08	43.9
Step 2					
Northern Europe	Oct. - Feb. (Autumn)	0.828 *	Drift	0.122	0.808 *
Southern Europe	Oct. - Feb. (Autumn)	0.828 *	Drift	0.118	0.808 *

* Single applications are marked.

** TWA interval as required by ecotox

8.9.2.2 PEC_{sw} of PRL OD 75

PEC_{sw} for formulations are based on Ganzelmeier data covering the respective crop (arable crops) and the number of applications. All loadings are considered to occur in a single pseudo-application reaching the standard static ditch (width 1 m, depth 30 cm). Since no degradation data is available for the product, no TWA concentrations can be calculated.

Table 8.9-5: Initial PEC_{sw} via spray drift for PRL OD 75 following single application to oil seed rape

Formulation	No. of applications	Maximum-use rate (kg PRL OD 75/ha)	Distance (m)	PEC _{sw} (µg PRL OD 75/L)
PRL OD 75	1	1.2	1	11.501
			5	2.367
			10	1.204
			15	0.830
			20	0.623

* Formulation density 1038g/L and 40 % interception were taken into consideration in the calculations.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

The fate and behaviour in air of Prohexadione-calcium has been evaluated, full details of these studies are provided in the respective EU reference and related documents and summarised in the EFSA conclusion (EFSA Journal 2010; 8(3):1555). No additional studies have been performed.

Table 8.10-1: Summary of atmospheric degradation and behaviour

Direct photolysis in air	Not studied - no data requested (no absorbance above 290 nm)
Quantum yield of direct phototransformation	Not relevant
Photochemical oxidative degradation in air	DT ₅₀ of 31 hours derived by the Atkinson model; OH concentration (average) assumed to be 5 x 10 ⁵ cm ⁻³
Volatilisation	from plant surfaces: No information submitted
	from soil: No information submitted

The vapour pressure at 20° C of the active substance is $\geq 10^{-5}$ Pa (1.335 x 10⁻⁵). Hence, the active substance Prohexadione-calcium is regarded as semi volatile. Significant volatilisation of Prohexadione-calcium is not to be expected.

Appendix 1 Lists of data considered in support of the evaluation

All the general data and EU agreed endpoints mentioned for Prohexadione-calcium assessed in this Section 8 can be found in the following Assessment report and EFSA Conclusions published for the EU review of the active substance:

Assessment report – public version - June 2009– Initial risk assessment provided by the rapporteur Member State France for the existing active substance prohexadione-calcium, Vol. 3 – B.8. Available online: <https://www.efsa.europa.eu/en/consultations/call/public-consultation-active-substance-prohexadione-calcium>

EFSA Journal 2010;8(3):1555 - Conclusion on the peer review of the pesticide risk assessment of the active substance prohexadione (considered variant prohexadione-calcium)

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 9.1.3 / 01	Koenig, N.; Ganbaatar, N.	2020	Prohexadione-calcium (PRL): Core PECsoil EUR - Modelling core info document for soil risk assessment in Europe Report No.: EnSa-20-0835, Edition Number: M-757890-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.1.3 / 02	Koenig, N.; Ganbaatar, N.	2020	Prohexadione-calcium (PRL): PECsoil EUR - Use in oil seed rape (winter) in Europe Report No.: EnSa-20-0838, Edition Number: M-762086-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.4.1 / 01	Koenig, N.; Ganbaatar, N.	2020	Prohexadione-calcium (PRL): Core PECgw EUR - Modelling core info document for groundwater risk assessment in Europe Report No.: EnSa-20-0836, Edition Number: M-757892-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer

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 9.2.4.1 / 02	Koenig, N.; Ganbaatar, N.	2020	Prohexadione-calcium (PRL): PECgw FOCUS PEARL, PELMO, MACRO - Use in oil seed rape (winter) in Europe Report No.: EnSa-20-0839, Edition Number: M-762085-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.5 / 01	Koenig, N.; Ganbaatar, N.	2020	Prohexadione-calcium (PRL): Core PECsw EUR - Modelling core info document for surface water risk assessment in Europe Report No.: EnSa-20-0837, Edition Number: M-757981-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 9.2.5 / 02	Koenig, N.; Ganbaatar, N.	2020	Prohexadione-calcium (PRL): PECsw, sed FOCUS EUR - Use in oil seed rape (winter) in Europe Report No.: EnSa-20-0840, Edition Number: M-762087-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer

Appendix 2 Detailed evaluation of the new Annex II studies

No new/additional study have been considered for this submission.

A 2.1	KCA 7.1 Fate and behaviour in soil
A 2.1.1	KCA 7.1.1 Route of degradation in soil
A 2.1.1.1	KCA 7.1.1.1 Aerobic degradation
A 2.1.1.2	KCA 7.1.1.2 Anaerobic degradation
A 2.1.1.3	KCA 7.1.1.3 Soil photolysis
A 2.1.2	KCA 7.1.2 Rate of degradation in soil
A 2.1.2.1	KCA 7.1.2.1 Laboratory studies
A 2.1.2.1.1	KCA 7.1.2.1.1 Aerobic degradation of the active substance
A 2.1.2.1.2	KCA 7.1.2.1.2 Aerobic degradation of metabolites, breakdown and reaction products
A 2.1.2.1.3	KCA 7.1.2.1.3 Anaerobic degradation of the active substance
A 2.1.2.1.4	KCA 7.1.2.1.4 Anaerobic degradation of metabolites, breakdown and reaction products
A 2.1.2.2	KCA 7.1.2.2 Field studies
A 2.1.2.2.1	KCA 7.1.2.2.1 Soil dissipation studies
A 2.1.2.2.2	KCA 7.1.2.2.2 Soil accumulation studies
A 2.1.3	KCA 7.1.3 Adsorption and desorption in soil
A 2.1.3.1	KCA 7.1.3.1 Adsorption and desorption
A 2.1.3.1.1	KCA 7.1.3.1.1 Adsorption and desorption of the active substance
A 2.1.3.1.2	KCA 7.1.3.1.2 Adsorption and desorption of metabolites, breakdown and reaction products
A 2.1.3.2	KCA 7.1.3.2 Aged sorption
A 2.1.4	KCA 7.1.4 Mobility in soil
A 2.1.4.1	KCA 7.1.4.1 Column leaching studies
A 2.1.4.1.1	KCA 7.1.4.1.1 Column leaching of the active substance
A 2.1.4.1.2	KCA 7.1.4.1.2 Column leaching of metabolites, breakdown and reaction products
A 2.1.4.2	KCA 7.1.4.2 Lysimeter studies
A 2.1.4.3	KCA 7.1.4.3 Field leaching studies
A 2.2	KCA 7.2 Fate and behaviour in water and sediment
A 2.2.1	KCA 7.2.1 Route and rate of degradation in aquatic systems (chemical and photochemical degradation)
A 2.2.1.1	KCA 7.2.1.1 Hydrolytic degradation
A 2.2.1.2	KCA 7.2.1.2 Direct photochemical degradation

- A 2.2.1.3 KCA 7.2.1.3 Indirect photochemical degradation**
- A 2.2.2 KCA 7.2.2 Route and rate of biological degradation in aquatic systems**
- A 2.2.2.1 KCA 7.2.2.1 "Ready biodegradability"**
- A 2.2.2.2 KCA 7.2.2.2 Aerobic mineralisation in surface water**

- A 2.2.2.3 KCA 7.2.2.3 Water/sediment study**
- A 2.2.2.4 KCA 7.2.2.4 Irradiated water/sediment study**
- A 2.2.3 KCA 7.2.3 Degradation in the saturated zone**
- A 2.3 KCA 7.3 Fate and behaviour in air**
- A 2.3.1 KCA 7.3.1 Route and rate of degradation in air**
- A 2.3.2 KCA 7.3.2 Transport via air**
- A 2.3.3 KCA 7.3.3 Local and global effects**
- A 2.4 KCA 7.4 Definition of the residue**
- A 2.4.1 KCA 7.4.1 Definition of the residue for risk assessment**
- A 2.4.2 KCA 7.4.2 Definition of the residue for monitoring**
- A 2.5 KCA 7.5 Monitoring data**

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

A 3.1 8.7 Predicted Environmental Concentrations in soil (PECsoil) (KCP 9.1.3)

Comments of zRMS:	The submitted reports were evaluated and accepted. Calculations of PEC _s for active substance submitted by the Applicant were accepted. Applicant didn't submit calculations of PEC _s for metabolite Despropionyl-prohexadione and these were calculated by the evaluator.
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Reference:	KCP 9.1.3/01
Title:	Prohexadione-calcium (PRL): Core PECsoil EUR - Modelling core info document for soil risk assessment in Europe
Report:	Koenig, N.; Ganbaatar, N.; 2020; EnSa-20-0835; M-757890-01-1
Authority registration No:	
Guideline(s):	none
Deviations:	None
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Reference:	KCP 9.1.3/02
Title:	Prohexadione-calcium (PRL): PECsoil EUR - Use in oil seed rape (winter) in Europe
Report:	Koenig, N.; Ganbaatar, N.; 2020; EnSa-20-0838; M-762086-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	None
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

**A 3.2 8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw})
 (KCP 9.2.4.1)**

Comments of zRMS:	<p>The submitted reports were evaluated and accepted. In modelling the used endpoints were agreed at the EU level. The PUF = 0 was used in modelling.</p> <p>The application dates were accepted.</p> <p>The recommended models were used: FOCUS PELMO, FOCUS PEARL and FOCUS MACRO.</p> <p>The PEC_{gw} values were below the trigger value of 0.1 µg/L.</p>
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Reference:	KCP 9.2.4.1/01
Title:	Prohexadione-calcium (PRL): Core PEC _{gw} EUR - Modelling core info document for groundwater risk assessment in Europe
Report:	Koenig, N.; Ganbaatar, N.; 2020; EnSa-20-0836; M-757892-01-1
Authority registration No:	
Guideline(s):	none
Deviations:	None
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Reference:	KCP 9.2.4.1/02
Title:	Prohexadione-calcium (PRL): PEC _{gw} FOCUS PEARL, PELMO, MACRO - Use in oil seed rape (winter) in Europe
Report:	Koenig, N.; Ganbaatar, N.; 2020; EnSa-20-0839; M-762085-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	None
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

**A 3.3 8.9 Predicted Environmental Concentrations in surface water (PEC_{sw})
 (KCP 9.2.5)**

Comments of zRMS:	The submitted reports were evaluated and accepted. In modelling the used endpoints were agreed at the EU level. The Step 1 & 2 and Step 3 were used in PEC _{sw} and PEC _{sed} assessment. The application dates were accepted.
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Reference:	KCP 9.2.5/01
Title:	Prohexadione-calcium (PRL): Core PEC _{sw} EUR - Modelling core info document for surface water risk assessment in Europe
Report:	Koenig, N.; Ganbaatar, N.; 2020; EnSa-20-0837; M-757981-01-1
Authority registration No:	
Guideline(s):	none
Deviations:	None
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	

Reference:	KCP 9.2.5/02
Title:	Prohexadione-calcium (PRL): PEC _{sw, sed} FOCUS EUR - Use in oil seed rape (winter) in Europe
Report:	Koenig, N.; Ganbaatar, N.; 2020; EnSa-20-0840; M-762087-01-1
Authority registration No:	
Guideline(s):	not applicable
Deviations:	None
GLP/GEP:	no
Acceptability:	
Duplication (if vertebrate study):	