

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: HCV07

Product names: Vivendi 300 SL, Auksendy 300 SL, Cliophar Super

Chemical active substance:

Clopyralid-olamine, 395 g/l (300 g ae/l)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Renewal of Authorization under Art.43)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: 22/12/2021

MS Finalisation date: July 2023 (initial Core Assessment)

March 2024 (final Core Assessment)

Version history

When	What
December 2021	Article 43 submission for re-registration of HCV07 following Clopyralid Renewal of approval (Commission Implementing Regulation (EU) 2021/1191)
July 2023	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.
March 2024	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

Table of Contents

8	Fate and behaviour in the environment (KCP 9)	4
8.1	Critical GAP and overall conclusions.....	4
8.2	Metabolites considered in the assessment	8
8.3	Rate of degradation in soil (KCP 9.1.1)	8
8.3.1	Aerobic degradation in soil (KCP 9.1.1.1)	8
8.3.2	Anaerobic degradation in soil (KCP 9.1.1.1)	9
8.4	Field studies (KCP 9.1.1.2)	10
8.4.1	Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1).....	10
8.4.2	Soil accumulation testing (KCP 9.1.1.2.2)	10
8.5	Mobility in soil (KCP 9.1.2).....	11
8.5.1	Clopyralid	11
8.5.2	Column leaching (KCP 9.1.2.1)	11
8.5.3	Lysimeter studies (KCP 9.1.2.2)	11
8.5.4	Field leaching studies (KCP 9.1.2.3)	12
8.6	Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3).....	12
8.7	Predicted Environmental Concentrations in soil (PEC _{soil}) (KCP 9.1.3)	13
8.7.1	Justification for new endpoints.....	13
8.7.2	Active substance	13
8.8	Predicted Environmental Concentrations in groundwater (PEC _{gw}) (KCP 9.2.4).....	16
8.8.1	Justification for new endpoints.....	16
8.8.2	Active substance (KCP 9.2.4.1).....	16
8.9	Predicted Environmental Concentrations in surface water (PEC _{sw}) and sediment PEC _{sed} (KCP 9.2.5)	26
8.9.1	Justification for new endpoints.....	26
8.9.2	Active substance and the formulation (KCP 9.2.5)	26
8.9.2.1	PEC _{sw/sed} of HCV07	31
8.10	Fate and behaviour in air (KCP 9.3, KCP 9.3.1)	32
Appendix 1	Lists of data considered in support of the evaluation.....	33
Appendix 2	Detailed evaluation of the new Annex II studies.....	34
Appendix 3	Additional information provided by the applicant (e.g. detailed modelling data)	35
A 3.1	Predicted Environmental Concentrations in soil (PEC _{soil}) (KCP 9.1.3)	35
Appendix 4	Justification for Plant Uptake Factor (PUF) refinement	37

8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the HCV07

Critical use pattern of the active substance														
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, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val be- tween ap- plications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g 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	Poland	Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: BEAVC, BEAVA, BEAVD	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arv- ense, Matricaria spp.)	Broadcast, Foliar Tractor mounted boom	BBCH 12- 39 (until July 1st)	a) 1 b) 1	NA	a) 0,3 to 0,4 b) 03 to 0,4	a) AS1: 118,578 to 158,104 (as/ha), 90 to 120 (ae/ha) b) AS1: 118,578 to 158,104 (as/ha), 90 to 120 (ae/ha)	100-400	42 days	One application every two years. Maximum total dose rate must not ex- ceed 120 g ae/ha per crop; maximum individual dose: 120 g ae/ha. For residue management in crop rota- tion: no mitigation measures are re- quired for Leafy and Brassica vegeta- bles or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see la- bel for recommendations.	R Biennial ap- plication (FOCUS PEARL 4.4.4)
2	Poland	Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: BEAVC, BEAVA, BEAVD	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arv- ense, Matricaria spp.)	Broadcast, Foliar Tractor mounted boom, split application	BBCH 12- 15 First appli- cation at BBCH 12- 15. Second application at BBCH 12-15.	a) 2 b) 2	7 day in- terval	a) 0,2 b) 0,4	a) AS1: 79,052 (as/ha), 60 (ae/ha) b) AS1: 158,104 (as/ha), 120 (ae/ha)	100-400	42 days	Only every two three years. Split ap- plication: First application at 60 gae/ha (0,2L/ha) at BBCH 12-15 followed 7- days later by a second application at BBCH 12-15 at 60 gae/ha (0,2 L/ha). Maximum total dose rate must not ex- ceed 120 g ae/ha per crop; maximum individual dose: 120 g ae/ha. For residue management in crop rota- tion: no mitigation measures are re- quired for Leafy and Brassica vegeta- bles or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is	R Biennial ap- plication (FOCUS PEARL 4.4.4)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
													recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations..	
3	Poland	Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: BEAVC, BEAVD, BEAVA,	F	Broad-leaved weeds (BBBBB) (including but not only <i>Cirsium arvense</i> , <i>Matricaria</i> spp.)	Broadcast, Foliar Tractor mounted boom, split application	BBCH 12-15 First application at BBCH 12-15. Second application at BBCH 12-15.	a) 2 b) 2	7 day interval	a) 0,175 b) 0,35	a) AS1: 69,17 (as/ha), 52,5 (ae/ha) b) AS1: 138,341 (as/ha), 105 (ae/ha)	100-400	42 days	Only every two <u>three</u> years. Split application: First application at 52,5 gae/ha (0,175L/ha) at BBCH 12-15 followed 7-days later by a second application at BBCH 12-15 at 52,5 gae clopyralid/ha (0,175 L/ha). Maximum total dose rate must not exceed 105 g ae/ha per crop; maximum individual dose: 105 g ae/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations..	R Biennial application (FOCUS PEARL 4.4.4)
4	Poland	Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: BEAVC, BEAVD, BEAVA,	F	Broad-leaved weeds (BBBBB) (including but not only <i>Cirsium arvense</i> , <i>Matricaria</i> spp.)	Broadcast, Foliar Tractor mounted boom, split application	BBCH 15-31 First application at BBCH 15. Second application at BBCH 31.	a) 2 b) 2	10-day interval	a) 0,175 b) 0,35	a) AS1: 69,17 (as/ha), 52,5 (ae/ha) b) AS1: 138,341 (as/ha), 105 (ae/ha)	100-400	42 days	Every two years. Split application: first application at 52,5 gae/ha (0,175L/ha) at BBCH 15 followed 10 days later by a second application (at BBCH 31) at 52,5 gae /ha (0,175 L/ha). Interval between applications depends on time needed between first application at BBCH 15 reaches phase BBCH 31 at the second application. Maximum total dose rate must not exceed 105 g ae/ha per crop; maximum individual dose: 105 g ae/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid.	R Biennial application (FOCUS PEARL 4.4.4))

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
													For crop rotation management, see label for recommendations..	
5	Poland	Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: BEAVC, BEAVA, BEAVD	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast, Foliar Tractor mounted boom, split application	BBCH 15-31 First application at BBCH 15. Second application at BBCH 31.	a) 2 b) 2	10-day interval	a) 0,2 b) 0,4	a) AS1: 79,05 (as/ha), 60 (ae/ha) b) AS1: 158,1 (as/ha), 120(ae/ha)	100-400	42 days	Every two years. Split application: first application at 60 gae/ha (0,2 L/ha) at BBCH 15 followed 10 days later by a second application (at BBCH 31) at 60 gae/ha (0,2 L/ha). Interval between applications depends on time needed between first application at BBCH 15 reaches phase BBCH 31 at the second application. Maximum total dose rate must not exceed 120 g ae/ha per crop; maximum individual dose: 120 g ae/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations..	R Biennial application (FOCUS PEARL 4.4.4)
6	Poland	Winter Oilseed rape, Spring Oilseed rape, Mustard, Linseed EPPO Code: BRSNW	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Centaurea cyanus, Matricaria spp)	Broadcast, Foliar Tractor mounted boom	BBCH 30-51	a) 1 b) 1	NA	a) 0,4 b) 0,4	a) AS1: 158,104 (g as/ha), 120 (g ae/ha) b) AS1: 158,104 (g as/ha), 120 (g ae/ha)	100-400	Not applicable*	For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	A
7	Poland	Onion from Seeds EPPO Code: ALLCE	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast Foliar Tractor mounted boom	BBCH 11-16	a) 1 b) 1	NA	a) 0,4 b) 0,4	a) AS1: 158,104 (as/ha), 120 (ae/ha) b) AS1: 158,104 (as/ha), 120 (ae/ha)	100-400	42-days	For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid.	R Biennial application (FOCUS PEARL 4.4.4)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
													For crop rotation management, see label for recommendations..	

* 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

Explanation for column 15 “Conclusion”

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

zRMS comments:

It the GAP table above following uncertainty were corrected by the zRMS:

- For uses number 2 and 3 following double application to Fodder beet, Sugar beet, Red Beet, Turnip, Swede at BBCH 12-15 at application rate 0,4 L product/ha and 0,35 L product/ha zRMS corrected the application frequency. According to groundwater assessment formulation HCV07 may be applied every second year and not as previously stated every third year. For more details please refer to the commenting box under the point 8.8.
- For uses number 4 and 5 following double application to Fodder beet, Sugar beet, Red Beet, Turnip, Swede at BBCH 15-31 at application rate 0,35 L product/ha and 0,4 L product/ha, information about 10 days interval between applications was considered as incorrect. Further in the document the assessment was made based on the assumption that first application is at BBCH 15 and the second application at BBCH 31. As the second application at BBCH 31 will be reached after around 30 days, the 10 days interval seems to be unreasoned. Thus, the zRMS correct the information in table above that the interval between applications depends on time needed between the first application at BBCH 15 reach phase BBCH 31 at the second application.
- Furthermore, it is noted that minor crops such as fodder beet, red beet, swede, turnip, spring oilseed rape, white mustard, red mustard and linseed, under the conditions of use proposed, may be registered on the grounds of Art. 51 of Regulation 1107/2009.

8.2 Metabolites considered in the assessment

No metabolites are considered relevant in this assessment.

zRMS comments:

No relevant metabolites of clopyralid are formed in soil or aquatic systems according to EFSA Journal 2018;16(7):5389.

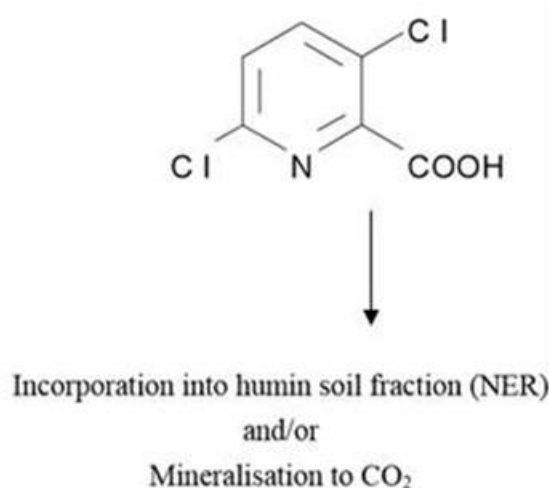
8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on the 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)

The rate of degradation of clopyralid in laboratory soil under aerobic conditions was evaluated during Annex I renewal (EFSA, 2018¹). No additional studies have been performed. Endpoints derived from laboratory degradation studies were not used in the evaluation of the formulation but are presented in Table 8.3-1 for completeness. A proposed degradation pathway in soil is presented in Figure 8.3-1.

Figure 8.3-1: Proposed degradation pathway for clopyralid in soil



¹ EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance clopyralid. EFSA Journal 2018;16(7):5389, 28 pp. doi:10.2903/j.efsa.2018.5389

Table 8.3-1: Summary of aerobic degradation rates for clopyralid - laboratory studies

Clopyralid, Laboratory studies, dark aerobic conditions									
Soil name	Soil type	pH (H ₂ O)	t. (°C)	Moisture (% MWHC)	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2 / 10kPa ^a	Chi ² (%)	Ki- netic model	Evaluated on EU level / Reference
Parabraunerde	Silt loam	7.7	20	18.63 ^b	44.4 / 147.3	34.2	6.796	SFO	Yes / EFSA, 2018
Marcham	Sandy clay loam	8.3	20	20.19 ^b	34.5 / 114.7	32.4	5.478	SFO	Yes / EFSA, 2018
Castle Rising	Sandy loam	8.0	20	65.13 ^b	26.3 / 87.3	26.3	8.284	SFO	Yes / EFSA, 2018
Speyer 2.1	Sand	6.5	20	12.58 ^b	64.6 / 214.6	64.6	5.466	SFO	Yes / EFSA, 2018
Speyer 2.2	Sand	6.3	20	18.56 ^b	16.2 / 53.8	16.2	7.78	SFO	Yes / EFSA, 2018
Marshall county	Silt loam	6.0	25	23.42 ^c	8.6 / 28.5	11.6	6.49	SFO	Yes / EFSA, 2018
A	Sandy loam	6.2	20	24.28 ^d	16.5 / 54.8	16.5	4.856	SFO	Yes / EFSA, 2018
B	Clay loam	7.6	20	28.05 ^d	23.0 / 76.4	23.0	6.767	SFO	Yes / EFSA, 2018
C	Clay loam	5.6	20	48.17 ^d	4.9 / 16.2	4.9	12.73	SFO	Yes / EFSA, 2018
D	Loam	7.5	20	35.30 ^d	9.8 / 32.4	9.8	10.17	SFO	Yes / EFSA, 2018
Geometric mean (n = 10)						19.1			
pH-dependency					No				

^a normalised using a Q₁₀ of 2.58 and a Walker equation coefficient of 0.7

^b reported soil moisture 40 % of maximum WHC

^c reported soil moisture 75 % of 1/3 bar WHC

^d reported soil moisture 45 % WHC

Persistency is assessed for clopyralid, based on the triggering endpoints presented above. All DT₅₀ values << 180 days. Therefore it can be concluded that clopyralid is not classified as persistent.

zRMS comments:

Soil degradation data for clopyralid presented in Table 8.3-1 are in line with the EU agreed endpoint reported in EFSA Journal 2018;16(7):5389.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

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

The anaerobic degradation of clopyralid and its metabolites in soil was evaluated during Annex I renewal (EFSA, 2018)¹. No additional studies have been performed.

zRMS comments:

Anaerobic soil degradation data for clopyralid according to the EU agreed endpoints as reported in EFSA Journal 2018;16(7):5389 is longer than a year and no major metabolites were detected.

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)

The field dissipation rates of clopyralid were evaluated during Annex I renewal (EFSA, 2018)¹. No additional studies have been performed. Endpoints derived from field degradation studies were used in the evaluation of the formulation and are presented in Table 8.4-1.

Table 8.4-1: Summary of aerobic degradation rates for clopyralid - field studies

Clopyralid, Field studies									
Soil type	Location	pH (H ₂ O)	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	Chi ² (%)	DT ₅₀ (d) Norm ^a	Kinetic model	Evaluated on EU level / Reference
Loamy sand (bare)	Bargstedt, Germany	4.3	0-100	21.0	69.6	23.9	13.0	SFO	Yes / EFSA, 2018
Loam (bare)	Wilson, UK	6.2	0-100	16.7	55.6	22.6	13.5	SFO	Yes / EFSA, 2018
Silty clay loam (bare)	Sermaises, France	7.0	0-100	16.3	54	19.3	7.5	SFO	Yes / EFSA, 2018
Silty clay loam (bare)	Ansonville, France	8.2	0-20	0.16	12.1	5.36	2.07	DFOP / SFO Norm	Yes / EFSA, 2018
Clay loam (bare)	Mainbervilliers, France	7.1	0-20	6.04	28.3	7.22	2.7	DFOP / SFO Norm	Yes / EFSA, 2018
Silty clay loam (bare)	Oederquart, Germany	7.5	0-20	16.2	53.9	12.0	5.69	SFO	Yes / EFSA, 2018
Sandy clay loam (bare)	Middlefart, Denmark	7.5	0-20	23.7	78.7	13.1	8.46	SFO	Yes / EFSA, 2018
Clay loam (bare)	Canals, Spain	8.0	0-100	13.7	45.5	19.2	12.3	SFO	Yes / EFSA, 2018
Silty clay loam (bare)	B. Württemberg, Germany	7.4 ^b	0-100	10.2	33.9	7.94	9.34	SFO	Yes / EFSA, 2018
Silt loam (bare)	B. d'Islemade, France	7.3 ^b	0-100	9.11	30.3	17.6	7.41	SFO	Yes / EFSA, 2018
Geometric mean (n = 10)							7.05		
pH dependency				No					

^a normalised using a Q₁₀ of 2.58 and Walker coefficient of 0.7, values are DegT_{50, matrix}

^b 0-30 cm

Persistency is assessed for clopyralid, based on the triggering endpoints presented above. All DT₅₀ values << 180 days. Therefore it can be concluded that clopyralid is not classified as persistent.

zRMS comments:

Field degradation data for clopyralid presented in Table 8.4-1 are in line with EU agreed endpoints reported in EFSA Journal 2018;16(7):5389.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Soil accumulation testing is not required for clopyralid since DissT₉₀ in the field is not greater than the trigger value of 365 days.

zRMS comments:

According to EFSA Journal 2018;16(7):5389, studies on field degradation of clopyralid is not required.

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 Clopyralid

The mobility of clopyralid in laboratory soil was evaluated during Annex I renewal (EFSA, 2018)¹. No additional studies have been performed. Endpoints derived from laboratory adsorption/desorption studies are presented in Table 8.5-1.

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

Clopyralid							
Soil name	Soil type	OC (%)	pH (CaCl ₂)	K _r (L/kg)	K _{loc} (L/kg)	1/n (-)	Evaluated on EU level / Reference
Merzenhausen	Silt loam ^c	1.00	7.19	0.0057	0.57 ^a	0.9 ^b	Yes / EFSA, 2018
Kladenkirchen	Loamy sand ^c	0.98	5.34	0.0267	2.72 ^a	0.9 ^b	Yes / EFSA, 2018
Lanna	Clay loam ^c	2.06	6.62	0.0054	0.26 ^a	0.9 ^b	Yes / EFSA, 2018
Overhetfeld	Loamy sand ^c	0.93	6.49	0.0125	1.34 ^a	0.9 ^b	Yes / EFSA, 2018
Calke	Sandy loam ^d	3.15	5.7	0.01	0.5	0.489	Yes / EFSA, 2018
Longwoods	Sandy loam ^d	3.13	7.4	0.08	2.5	0.9 ^b	Yes / EFSA, 2018
LUFA 2.1	Loamy sand ^d	0.68	4.9	0.03	4.1	0.9 ^b	Yes / EFSA, 2018
Quilen	Loam ^d	4.02	6.9	0.16	3.9	0.804	Yes / EFSA, 2018
DU-L-PF	Clay loam ^d	6.47	6.3	0.14	2.1	0.829	Yes / EFSA, 2018
Geometric mean (n = 9)					1.41	-	
Arithmetic mean (n = 9)					-	0.836	
pH-dependency					No		

^a calculated and reported in M-CA, not in the study report

^b for modelling each soil was checked against OECD 106 reliability criterion ($K_d > 0.1$ for direct method and $K_d > 0.3$ for indirect method). Freundlich coefficient of soils not meeting the criterios was set to 0.9

^c BBA soil textural classification

^d USDA soil textural classification

zRMS comments:

Soil mobility data for clopyralid presented in Table 8.5-1 are in line with the EU agreed endpoints reported in EFSA Journal 2018;16(7):5389

8.5.2 Column leaching (KCP 9.1.2.1)

Column leaching studies for clopyralid were not conducted since reliable adsorption coefficient values were obtained in the laboratory soil mobility studies (see Section 8.5.1).

zRMS comments:

According to EFSA Journal 2018;16(7):5389 column leaching studies for clopyralid were not required.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

The mobility of clopyralid in soil was assessed with groundwater modelling tools (Section 8.8) using the degradation and adsorption data described under Section 8.4.1 and Section 8.5.1, respectively. However,

lysimeter studies for clopyralid were conducted as part of the original Annex I inclusion. The uses on oilseed rape and sugar beet studied in the lysimeter studies are no longer supported as representative for clopyralid in the AIR3 evaluation. However, the data were attached in the Annex I renewal dossier as additional information (EFSA, 2018)¹. No additional studies have been performed.

zRMS comments:

According to EFSA Journal 2018;16(7):5389 lysimeter studies for clopyralid were not required.

8.5.4 Field leaching studies (KCP 9.1.2.3)

Field leaching studies for clopyralid were not conducted since reliable adsorption coefficient data were obtained in laboratory soil mobility studies (Section 8.5.1) and leaching to groundwater was assessed with groundwater modelling tools (Section 8.8).

zRMS comments:

According to EFSA Journal 2018;16(7):5389 field leaching studies for clopyralid were 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.

Studies on the degradation of clopyralid in aquatic systems was evaluated during Annex I renewal (EFSA, 2018)¹. No additional studies have been performed. Endpoints derived from aquatic degradation studies are presented in Table 8.6-1.

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

Distribution: max in water 100.13 % at 0 d, max. sediment 19 % at 100 d (loamy sand) Distribution: max in water 99.0 % at 0 d, max sediment 26 % at 100 d (sandy silt loam)										
Water/ sed. system	pH water/ sed.	DegT ₅₀ whole sys. (d)	DegT ₉₀ whole sys. (d)	Kinetic model	DissT ₅₀ water (d)	DissT ₉₀ water (d)	Kinetic model	DissT ₅₀ sed. (d)	Kinetic model	Evaluated on EU level / Ref- erence
Loamy sand	6.5 / 5.5	>500	>500	First- order	128		First-order	>500	First-order	Yes / EFSA, 2018
Sandy silt loam	8.16 / 7.7	>500	>500	First- order	167		First-order	>500	First-order	Yes / EFSA, 2018
Geometric mean at 20 °C (n = 2) ^a					148					

^a normalised using a Q₁₀ of 2.58

zRMS comments:

Information on degradation of clopyralid in water/sediment systems presented in Tables 8.6-1 is in line with EU agreed endpoints reported in EFSA Journal 2018;16(7):5389.

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

8.7.1 Justification for new endpoints

EU agreed endpoints were used for the PEC_{soil} calculations of clopyralid (EFSA, 2018¹).

8.7.2 Active substance

The following PEC_{soil} calculations for clopyralid have not previously been reviewed and are provided in support of this assessment. For details please refer to Anagu and González Camarero, 2021 (Appendix 1). Further details are presented in Appendix 3 of this document (A 3.1).

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Crop	Sugar beets		Oil seed rape, winter	Onions
Application rate (g a.e./ha)	120	60	120	120
Number of applications (-) / interval (d)	1 / -	2 / 7	1 / -	1 / -
Crop interception (%) ^a	20		80	10

^a based on FOCUS (2014²)

Table 8.7-2: Input parameters for active substance for PEC_{soil} calculations

Compound	Molar mass (g/mol)	Max. occurrence (%)	DT ₅₀ (d)	Value in accordance with EU endpoint / Reference
Clopyralid	191.96	-	23.7 (maximum, n = 10)	Yes / EFSA, 2018

Table 8.7-3 PEC_{soil} for clopyralid following application to sugar beets (1 × 120 g a.e./ha, BBCH 12 – 39 interception = 20 %)

PEC _{soil} (mg/kg)		Sugar beets, 1 × 120 g a.e./ha	
		Actual	TWA
Initial		0.128	-
Short term	24 h	0.124	0.126
	2 d	0.121	0.124
	4 d	0.114	0.121
Long term	7 d	0.104	0.116
	14 d	0.085	0.105
	21 d	0.069	0.096
	28 d	0.056	0.087
	50 d	0.030	0.067
	100 d	0.007	0.041

² FOCUS (2014). Generic guidance for Tier 1 FOCUS ground water assessments, version 2.2. FOCUS groundwater scenarios working group.1.

Table 8.7-4 **PEC_{soil} for clopyralid following application to sugar beets (2 × 60 g a.e./ha, BBCH 12 – 15 interception = 20 %)**

PEC _{soil} (mg/kg)		Sugar beets, 2× 60 g a.e./ha	
		Actual	TWA
Initial		0.116	-
Short term	24 h	0.113	0.114
	2 d	0.110	0.113
	4 d	0.103	0.110
Long term	7 d	0.095	0.105
	14 d	0.077	0.095
	21 d	0.063	0.087
	28 d	0.051	0.079
	50 d	0.027	0.061
	100 d	0.006	0.038

Table 8.7-5 **PEC_{soil} for clopyralid following application to oil seed rape, winter (1 × 120 g a.e./ha, BBCH 30 – 50 interception = 80 %)**

PEC _{soil} (mg/kg)		Oil seed rape, winter, 1 × 120 g a.e./ha	
		Actual	TWA
Initial		0.032	-
Short term	24 h	0.031	0.032
	2 d	0.030	0.031
	4 d	0.028	0.030
Long term	7 d	0.026	0.029
	14 d	0.021	0.026
	21 d	0.017	0.024
	28 d	0.014	0.022
	50 d	0.007	0.017
	100 d	0.002	0.010

Table 8.7-6 **PEC_{soil} for clopyralid following application to onions (1 × 120 g a.e./ha, BBCH 11 – 16 interception = 10 %)**

PEC _{soil} (mg/kg)		Onions, 1 × 120 g a.e./ha	
		Actual	TWA
Initial		0.144	-
Short term	24 h	0.140	0.142
	2 d	0.136	0.140
	4 d	0.128	0.136
Long term	7 d	0.117	0.130
	14 d	0.096	0.118
	21 d	0.078	0.108
	28 d	0.063	0.098
	50 d	0.033	0.076
	100 d	0.008	0.047

zRMS comments:

Input parameters presented in Table 8.7-2 are in line with EU agreed parameters reported in EFSA Journal 2018;16(7):5389.

The soil exposure for clopyralid has been independently validated by the zRMS using FOCUS methods and EU agreed endpoints. The calculated PEC_{soil} values were in good agreement with these obtained by the Applicant. Therefore, results reported in tables above may be used for the soil risk assessment purposes.

PEC_{soil} of HCV07

Table 8.7-7: PEC_{soil} for HCV07 on various crops

Active substance / preparation ^a	Application rate (g/ha)	PEC_{act} (mg/kg)
HCV07	456	0.547

^a the formulation components are considered to dissipate rapidly after application, therefore only one application is taken into consideration. The PEC for the formulation was based on a density of 1.14 g/mL with an application of 0.4 L/ha and an interception rate of 10 % representing the maximum use and worst case interception rate in the GAP.

zRMS comments:

PEC_{soil} value for the formulated product is agreed by the zRMS and may be used in the risk assessment for soil organisms.

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

8.8.1 Justification for new endpoints

EU agreed endpoints were used for the PEC_{gw} calculations of clopyralid (EFSA, 2018¹). Justification for using a refined plant uptake factor of 0.5 is presented in Appendix 4.

8.8.2 Active substance (KCP 9.2.4.1)

The following PEC_{gw} modelling for clopyralid has not previously been reviewed and is provided in support of this assessment. For details please refer to Anagu and González Camarero, 2021 (Appendix 1). Only results most relevant to the current assessment are presented here.

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

Crop	Sugar beets		
Application rate (g a.e./ha)	120	100	60
Number of applications (-) / interval (d)	1 / -	2 / 7	2 / - ^c
BBCH growth stage	12 – 39 (July 1 st)	12 – 15	15 + 31 ^c
Modelling scenarios (timing, interception ^a)	BBCH 12 (AppDate), 20 % BBCH 31 (AppDate) 70 % BBCH 39 ^b (July 1 st) 70 %	BBCH 12 (AppDate) 20 %	BBCH 15 (AppDate), 20 % BBCH 31 (AppDate), 70 %
PHI (d)	42		
Frequency of application	Annual, biennial, triennial		
Models used for calculation	FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3, FOCUS MACRO 5.5.4		

Crop	Oil seed rape, winter	Onions / Vegetables, bulb
Application rate (g a.e./ha)	120	120
Number of applications (-) / interval (d)	1 / -	1 / -
BBCH growth stage	30 – 50	11 – 16
Modelling scenarios (timing, interception ^a)	BBCH 30 (AppDate), 80 % BBCH 50 (AppDate), 80 %	BBCH 11 (AppDate), 10 %
PHI (d)	-	42
Frequency of application	Annual, biennial, triennial	
Models used for calculation	FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3, FOCUS MACRO 5.5.4	

^a based on FOCUS (2014²)

^b according to the GAP, the latest application date should be the 1st of July. However, the AppDate recommended dates for some of the FOCUS scenarios (H, K, J and N) are later than the 1st of July. Therefore, simulations for BBCH 39 were performed with an application date of 1st July

^c 1st application at BBCH 15 and 2nd application at BBCH 31. For the Sevilla scenario, the AppDate recommended application dates for BBCH 15 and BBCH 31 are 20th December and 4th February, respectively. As this application sequence could not be implemented in PELMO, the second application date for the Sevilla scenario was set 27th December (7d interval).

Modelling was conducted in a tiered approach with the standard FOCUS scenarios. At Tier 1, the worst case plant uptake factor (PUF) of 0 was considered. A PUF value of 0.000271, resulting from Brigg's equation was assessed, however the resulting PEC_{gw} values were the same as the PEC_{gw} values obtained using a PUF of 0. Furthermore, since clopyralid acts systemically, it was considered appropriate to present higher tier (Tier 2) simulations conducted with a PUF of 0.5.

For sugar beets, the latest application date should be the 1st of July. However, the AppDate recommended dates for some of the FOCUS scenarios (H, K, J and N) are later than the 1st of July. Therefore, additional simulations were performed with an application date of 1st July as refinement for those scenarios.

In order to cover the wide range of BBCH growth stages represented in the GAP, more than one set of application dates were defined for some of the uses, to represent early and late BBCH growth stages. For some crops, a pre-harvest interval (PHI) is specified in the GAP. In cases where the AppDate v.3.06 recommended application date occurs later than the given PHI, the last application date was set to the harvest date minus the PHI.

Table 8.8-2 Application dates used for groundwater risk assessment

Crop (use)	Scenario	Application dates (absolute) ^a	
		First application	Second application
Sugar beets 1 × 120 g a.e./ha 1 × 100 g a.e./ha BBCH 12	Châteaudun	26-Apr (116)	-
	Hamburg	30-Apr	-
	Jokioinen	03-Jun	-
	Kremsmünster	30-Apr	-
	Okehampton	09-May	-
	Piacenza	02-Apr	-
	Porto	21-Mar	-
	Sevilla	27-Nov	-
	Thiva	08-May	-
Sugar beets 1 × 120 g a.e./ha 1 × 100 g a.e./ha BBCH 31	Châteaudun	05-Jun (156)	-
	Hamburg	30-Jun	-
	Jokioinen	07-Jul	-
	Kremsmünster	30-Jun	-
	Okehampton	04-Jul	-
	Piacenza	25-May	-
	Porto	10-Apr	-
	Sevilla	04-Feb	-
	Thiva	03-Jun	-
Sugar beets 1 × 120 g a.e./ha 1 × 100 g a.e./ha BBCH 39 (1-Jul)	Châteaudun	01-Jul (182)	-
	Hamburg	01-Jul	-
	Jokioinen	01-Jul	-
	Kremsmünster	01-Jul	-
	Okehampton	01-Jul	-
	Piacenza	01-Jul	-
	Porto ^b	20-Jun	-
	Sevilla ^b	20-May	-
	Thiva	01-Jul	-
Sugar beets 2 × 60 g a.e./ha BBCH 12 (7 d interval)	Châteaudun	26-Apr (116)	03-May (123)
	Hamburg	30-Apr	07-May
	Jokioinen	03-Jun	10-Jun
	Kremsmünster	30-Apr	07-May
	Okehampton	09-May	16-May
	Piacenza	02-Apr	09-Apr

Crop (use)	Scenario	Application dates (absolute) ^a	
		First application	Second application
	Porto	21-Mar	28-Mar
	Sevilla	27-Nov	04-Dec
	Thiva	08-May	15-May
Sugar beets 2 × 60 g a.e./ha BBCH 15 + 31 (1 st app. at BBCH 15 2 nd app. at BBCH 31)	Châteaudun	09-May (129)	05-Jun (156)
	Hamburg	20-May	30-Jun
	Jokioinen	14-Jun	07-Jul
	Kremsmünster	20-May	30-Jun
	Okehampton	28-May	04-Jul
	Piacenza	20-Apr	25-May
	Porto	27-Mar	10-Apr
	Sevilla	20-Dec	04-Feb
	Thiva	17-May	03-Jun
Oil seed rape, winter 1 × 120 g a.e./ha BBCH 30	Châteaudun	11-Mar (70)	-
	Hamburg	18-Apr	-
	Kremsmünster	15-Apr	-
	Okehampton	09-Apr	-
	Piacenza	07-Mar	-
	Porto	29-Dec	-
Oil seed rape, winter 1 × 120 g a.e./ha BBCH 50	Châteaudun	31-Mar (90)	-
	Hamburg	27-Apr	-
	Kremsmünster	25-Apr	-
	Okehampton	20-Apr	-
	Piacenza	27-Mar	-
	Porto	23-Feb	-
Onions / Vegetables, bulb 1 × 120 g a.e./ha BBCH 11	Châteaudun	03-May (123)	-
	Hamburg	03-May	-
	Jokioinen	25-May	-
	Kremsmünster	03-May	-
	Porto	09-Mar	-
	Thiva	18-Apr	-

^a dates in brackets represents Julian days used in the MACRO simulations

Table 8.8-3 Input parameters related to active substance clopyralid for PEC_{gw} calculations

Compound	Clopyralid	Value in accordance with EU end-point / Reference
Molar mass (g/mol)	191.96	Y / EFSA, 2018
Water solubility (mg/L)	1.43 × 10 ⁵ (20 °C)	Y / EFSA, 2018
Saturated vapour pressure (Pa)	0 (worst case)	Y / EFSA, 2018
DT _{50,soil} (d)	7.05 (geometric mean, field, normalised, n = 10)	Y / EFSA, 2018
Transformation rate (1/d) ^a	0.098319 (to sink)	Y / EFSA, 2018
K _{foc} / K _{fom} ^b (L/kg)	1.41 / 0.818 (geometric mean, n = 9)	Y / EFSA, 2018
Freundlich Exponent 1/n (-)	0.836 (arithmetic mean, n = 9)	Y / EFSA, 2018
Plant uptake factor (-)	Tier 1: 0* Tier 2: 0.5 ^{***}	*Y / EFSA, 2018 ^{***} -Default value for systemic

Compound	Clopyralid	Value in accordance with EU end-point / Reference
		compounds (Gourlay, 2015 ³ and Hall, 2015 ⁴)
Limit for Freundlich (µg/L) ^c	0	Default ^c

^a for PELMO calculated as follows: $(\ln(2)/DT_{50})$

^b $K_{fom} = K_{foc}/1.724$

^c for PELMO based on the recommended default of 10^{-20} µg/L given in Jones et al. (2011) ⁵

FOCUS PEARL

Table 8.8-4 **PEC_{gw} for clopyralid following application to sugar beets (FOCUS PEARL 4.4.4)**

Crop (use)	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PUF 0			PUF 0.5		
		Annual	Biennial	Triennial	Annual	Biennial	Triennial
Sugar beets 1 × 120 g a.e./ha BBCH 12	Châteaudun	0.151	0.071	-	0.080	-	-
	Hamburg	0.114	0.064	-	0.048	-	-
	Jokioinen	0.257	0.134	0.105	0.130	0.068	-
	Kremsmünster	0.059	-	-	-	-	-
	Okehampton	0.065	-	-	-	-	-
	Piacenza	0.028	-	-	-	-	-
	Porto	0.040	-	-	-	-	-
	Sevilla	0.535	0.189	0.063	0.472	0.177	0.060
	Thiva	0.002	-	-	-	-	-
Sugar beets 1 × 120 g a.e./ha BBCH 31	Châteaudun	0.115	0.062	-	0.071	-	-
	Hamburg	0.201	0.083	-	0.127	0.053	-
	Jokioinen	0.239	0.101	0.076	0.161	0.067	-
	Kremsmünster	0.051	-	-	-	-	-
	Okehampton	0.045	-	-	-	-	-
	Piacenza	0.003	-	-	-	-	-
	Porto	0.009	-	-	-	-	-
	Sevilla	<0.001	-	-	-	-	-
	Thiva	0.001	-	-	-	-	-
Sugar beets 1 × 120 g a.e./ha BBCH 39 (1-Jul)	Châteaudun	0.136	0.065	-	0.096	-	-
	Hamburg	0.209	0.086	-	0.133	0.055	-
	Jokioinen	0.185	0.079	-	0.119	0.049	-
	Kremsmünster	0.054	-	-	-	-	-
	Okehampton	0.052	-	-	-	-	-
	Piacenza	0.004	-	-	-	-	-
	Porto	0.001	-	-	-	-	-
	Sevilla	<0.001	-	-	-	-	-
	Thiva	0.002	-	-	-	-	-
Sugar beets 1 × 100 g a.e./ha BBCH 12	Châteaudun	0.125	0.059	-	0.066	-	-
	Hamburg	0.094	-	-	-	-	-
	Jokioinen	0.209	0.109	0.085	0.107	0.056	-

³ Gourlay, V. (2015): Plant uptake of ¹⁴C labelled clopyralid in wheat and oilseed rape under greenhouse conditions; RLP Agro-Science GmbH, 67435 Neustadt a.d. Weinstraße, Germany; Lab Study No. AS421; DAS Study No. 150297; 25.06.2015; Unpublished

⁴ Hall, L. R. (2015): ¹⁴C Clopyralid: Metabolism in Confined Rotational Crops with a 30-Day Plant-back Interval; ABC Laboratories, Inc., Columbia, Missouri 65202, USA; Lab Study No. 69725; DAS Study No. 130733; 12 January 2015; Unpublished

⁵ Jones, R.R., Boesten, J.J.T.I., Klein, M. and van der Berg, E. (2011): Performance of the FOCUS 2010 Software Packages for Performing Tier 1 Ground Water Assessments in the EU.

Crop (use)	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PUF 0			PUF 0.5		
		Annual	Biennial	Triennial	Annual	Biennial	Triennial
	Kremsmünster	0.049	-	-	-	-	-
	Okehampton	0.054	-	-	-	-	-
	Piacenza	0.023	-	-	-	-	-
	Porto	0.033	-	-	-	-	-
	Sevilla	0.441	0.155	0.052	0.390	0.145	0.049
	Thiva	0.001	-	-	-	-	-
	Châteaudun	0.095	-	-	-	-	-
Sugar beets 1 × 100 g a.e./ha BBCH 31	Hamburg	0.165	0.068	-	0.105	0.043	-
	Jokioinen	0.193	0.082	-	0.130	0.055	-
	Kremsmünster	0.042	-	-	-	-	-
	Okehampton	0.037	-	-	-	-	-
	Piacenza	0.003	-	-	-	-	-
	Porto	0.008	-	-	-	-	-
	Sevilla	<0.001	-	-	-	-	-
	Thiva	0.001	-	-	-	-	-
Sugar beets 1 × 100 g a.e./ha BBCH 39 (1-Jul)	Châteaudun	0.112	0.054	-	0.079	-	-
	Hamburg	0.172	0.071	-	0.110	0.045	-
	Jokioinen	0.149	0.064	-	0.096	-	-
	Kremsmünster	0.045	-	-	-	-	-
	Okehampton	0.043	-	-	-	-	-
	Piacenza	0.003	-	-	-	-	-
	Porto	0.001	-	-	-	-	-
	Sevilla	<0.001	-	-	-	-	-
Sugar beets 2 × 60 g a.e./ha BBCH 12 (7 d interval)	Thiva	0.002	-	-	-	-	-
	Châteaudun	0.177	0.084	-	0.096	-	-
	Hamburg	0.126	0.070	-	0.055	-	-
	Jokioinen	0.290	0.153	0.120	0.158	0.082	-
	Kremsmünster	0.064	-	-	-	-	-
	Okehampton	0.074	-	-	-	-	-
	Piacenza	0.020	-	-	-	-	-
	Porto	0.047	-	-	-	-	-
Sugar beets 2 × 60 g a.e./ha BBCH 15 + 31 (1 st app. at BBCH 15 2 nd app. at BBCH 31)	Sevilla	0.578	0.185	0.056	0.543	0.176	0.053
	Thiva	0.002	-	-	-	-	-
	Châteaudun	0.136	0.072	-	0.079	-	-
	Hamburg	0.174	0.083	-	0.098	-	-
	Jokioinen	0.285	0.138	0.103	0.174	0.084	-
	Kremsmünster	0.049	-	-	-	-	-
	Okehampton	0.074	-	-	-	-	-
	Piacenza	0.008	-	-	-	-	-
	Porto	0.024	-	-	-	-	-
	Sevilla	0.119	0.023	-	0.110	0.018	-
	Thiva	0.002	-	-	-	-	-

Table 8.8-5 **PEC_{gw} of clopyralid following application to oil seed rape, winter (FOCUS PEARL 4.4.4)**

Crop (use)	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PUF 0			PUF 0.5		
		Annual	Biennial	Triennial	Annual	Biennial	Triennial
Oil seed rape, winter 1 × 120 g a.e./ha BBCH 30	Châteaudun	0.005	-	-	-	-	-
	Hamburg	0.054	-	-	-	-	-
	Kremsmünster	0.057	-	-	-	-	-
	Okehampton	0.046	-	-	-	-	-
	Piacenza	0.012	-	-	-	-	-
	Porto	0.482	0.227	0.164	0.465	0.220	0.158
Oil seed rape, winter 1 × 120 g a.e./ha BBCH 50	Châteaudun	0.005	-	-	-	-	-
	Hamburg	0.067	-	-	-	-	-
	Kremsmünster	0.045	-	-	-	-	-
	Okehampton	0.068	-	-	-	-	-
	Piacenza	0.012	-	-	-	-	-
	Porto	0.050	-	-	-	-	-

Table 8.8-6 **PEC_{gw} of clopyralid following application to onions (FOCUS PEARL 4.4.4)**

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PUF 0			PUF 0.5		
		Annual	Biennial	Triennial	Annual	Biennial	Triennial
Onions 1 × 120 g a.e./ha BBCH 11	Châteaudun	0.013	-	-	-	-	-
	Hamburg	0.113	0.064	-	0.061	-	-
	Jokioinen	0.164	0.092	-	0.077	-	-
	Kremsmünster	0.052	-	-	-	-	-
	Porto	0.046	-	-	-	-	-
	Thiva	<0.001	-	-	-	-	-

FOCUS PELMO

Table 8.8-7 **PEC_{gw} of clopyralid following application to sugar beets (FOCUS PELMO 5.5.3)**

Crop (use)	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PUF 0			PUF 0.5		
		Annual	Biennial	Triennial	Annual	Biennial	Triennial
Sugar beets 1 × 120 g a.e./ha BBCH 12	Châteaudun	0.031	-	-	-	-	-
	Hamburg	0.036	-	-	-	-	-
	Jokioinen	0.340	0.212	0.123	0.130	0.080	-
	Kremsmünster	0.070	-	-	-	-	-
	Okehampton	0.118	0.069	-	0.084	-	-
	Piacenza	0.180	0.096	0.072	0.132	0.069	-
	Porto	0.462	0.142	0.107	0.349	0.098	-
	Sevilla	0.993	0.443	0.171	0.879	0.383	0.142
	Thiva	<0.001	-	-	-	-	-
Sugar beets 1 × 120 g a.e./ha BBCH 31	Châteaudun	0.023	-	-	-	-	-
	Hamburg	0.076	-	-	-	-	-
	Jokioinen	0.164	0.092	-	0.086	-	-
	Kremsmünster	0.063	-	-	-	-	-
	Okehampton	0.074	-	-	-	-	-
	Piacenza	0.013	-	-	-	-	-
	Porto	0.042	-	-	-	-	-
	Sevilla	0.005	-	-	-	-	-

Crop (use)	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PUF 0			PUF 0.5		
		Annual	Biennial	Triennial	Annual	Biennial	Triennial
	Thiva	<0.001	-	-	-	-	-
Sugar beets 1 × 120 g a.e./ha BBCH 39 (1-Jul)	Châteaudun	0.031	-	-	-	-	-
	Hamburg	0.073	-	-	-	-	-
	Jokioinen	0.128	0.067	-	0.063	-	-
	Kremsmünster	0.066	-	-	-	-	-
	Okehampton	0.074	-	-	-	-	-
	Piacenza	0.004	-	-	-	-	-
	Porto	0.002	-	-	-	-	-
	Sevilla	<0.001	-	-	-	-	-
	Thiva	0.001	-	-	-	-	-
Sugar beets 1 × 100 g a.e./ha BBCH 12	Châteaudun	0.025	-	-	-	-	-
	Hamburg	0.030	-	-	-	-	-
	Jokioinen	0.278	0.173	0.100	0.108	0.066	-
	Kremsmünster	0.058	-	-	-	-	-
	Okehampton	0.097	-	-	-	-	-
	Piacenza	0.148	0.078	-	0.109	0.057	-
	Porto	0.377	0.116	0.088	0.285	0.080	-
	Sevilla	0.821	0.365	0.141	0.726	0.317	0.117
	Thiva	<0.001	-	-	-	-	-
Sugar beets 1 × 100 g a.e./ha BBCH 31	Châteaudun	0.019	-	-	-	-	-
	Hamburg	0.062	-	-	-	-	-
	Jokioinen	0.133	0.075	-	0.071	-	-
	Kremsmünster	0.052	-	-	-	-	-
	Okehampton	0.061	-	-	-	-	-
	Piacenza	0.010	-	-	-	-	-
	Porto	0.034	-	-	-	-	-
	Sevilla	0.004	-	-	-	-	-
	Thiva	<0.001	-	-	-	-	-
Sugar beets 1 × 100 g a.e./ha BBCH 39 (1-Jul)	Châteaudun	0.025	-	-	-	-	-
	Hamburg	0.060	-	-	-	-	-
	Jokioinen	0.103	0.055	-	0.052	-	-
	Kremsmünster	0.054	-	-	-	-	-
	Okehampton	0.061	-	-	-	-	-
	Piacenza	0.004	-	-	-	-	-
	Porto	0.001	-	-	-	-	-
	Sevilla	<0.001	-	-	-	-	-
	Thiva	0.001	-	-	-	-	-
Sugar beets 2 × 60 g a.e./ha (7 d interval) BBCH 12	Châteaudun	0.034	-	-	-	-	-
	Hamburg	0.037	-	-	-	-	-
	Jokioinen	0.379	0.237	0.137	0.169	0.104	0.060
	Kremsmünster	0.075	-	-	-	-	-
	Okehampton	0.134	0.069	-	0.056	-	-
	Piacenza	0.197	0.092	-	0.130	0.064	-
	Porto	0.409	0.149	0.096	0.299	0.101	0.070
	Sevilla	0.984	0.440	0.182	0.875	0.394	0.165
	Thiva	<0.001	-	-	-	-	-
Sugar beets 2 × 60 g a.e./ha	Châteaudun	0.031	-	-	-	-	-
	Hamburg	0.061	-	-	-	-	-

Crop (use)	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PUF 0			PUF 0.5		
		Annual	Biennial	Triennial	Annual	Biennial	Triennial
BBCH 15 + 31 (1 st app. at BBCH 15 2 nd app. at BBCH 31)	Jokioinen	0.268	0.141	0.098	0.124	0.067	-
	Kremsmünster	0.051	-	-	-	-	-
	Okehampton	0.104	0.049	-	0.063	-	-
	Piacenza	0.051	-	-	-	-	-
	Porto	0.174	0.064	-	0.135	0.047	-
	Sevilla ^a	0.357	0.175	0.069	0.279	0.116	0.053
	Thiva	0.001	-	-	-	-	-

^a the AppDate v3.06 recommended application dates for BBCH 15 and BBCH 31 are 20th December and 4th February, respectively. As this application sequence could not be implemented in PELMO, the second application date for the Sevilla scenario was set 27th December (7d interval).

Table 8.8-8 **PEC_{gw} of clopyralid following application to oil seed rape, winter (FOCUS PELMO 5.5.3)**

Crop (use)	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PUF 0			PUF 0.5		
		Annual	Biennial	Triennial	Annual	Biennial	Triennial
Oil seed rape, winter 1 × 120 g a.e./ha BBCH 30	Châteaudun	0.005	-	-	-	-	-
	Hamburg	0.018	-	-	-	-	-
	Kremsmünster	0.052	-	-	-	-	-
	Okehampton	0.051	-	-	-	-	-
	Piacenza	0.028	-	-	-	-	-
	Porto	0.947	0.478	0.336	0.879	0.458	0.322
Oil seed rape, winter 1 × 120 g a.e./ha BBCH 50	Châteaudun	0.003	-	-	-	-	-
	Hamburg	0.017	-	-	-	-	-
	Kremsmünster	0.038	-	-	-	-	-
	Okehampton	0.067	-	-	-	-	-
	Piacenza	0.025	-	-	-	-	-
	Porto	0.173	0.121	0.087	0.154	0.108	0.078

Table 8.8-9 **PEC_{gw} of clopyralid following application to onions (FOCUS PELMO 5.5.3)**

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		PUF 0			PUF 0.5		
		Annual	Biennial	Triennial	Annual	Biennial	Triennial
Onions BBCH 11 1 × 120 g a.e./ha	Châteaudun	0.012	-	-	-	-	-
	Hamburg	0.039	-	-	-	-	-
	Jokioinen	0.220	0.113	0.073	0.092	-	-
	Kremsmünster	0.059	-	-	-	-	-
	Porto	0.147	0.060	-	0.123	0.048	-
	Thiva	<0.001	-	-	-	-	-

FOCUS MACRO

Table 8.8-10 PEC_{gw} of clopyralid following application to sugar beets (FOCUS MACRO 5.5.4)

Crop (use)	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)
		PUF 0
		Annual
Sugar beets 1 × 120 g a.e./ha BBCH 12	Châteaudun	0.032
Sugar beets 1 × 120 g a.e./ha BBCH 31	Châteaudun	0.014
Sugar beets 1 × 120 g a.e./ha BBCH 39 (1-Jul)	Châteaudun	0.023
Sugar beets 1 × 100 g a.e./ha BBCH 12	Châteaudun	0.027
Sugar beets 1 × 100 g a.e./ha BBCH 31	Châteaudun	0.012
Sugar beets 1 × 100 g a.e./ha BBCH 39 (1-Jul)	Châteaudun	0.019
Sugar beets 2 × 60 g a.e./ha BBCH 12 (7 d interval)	Châteaudun	0.036
Sugar beets 2 × 60 g a.e./ha BBCH 15 + 31 (1 st app. at BBCH 15 2 nd app. at BBCH 31)	Châteaudun	0.023

Table 8.8-11 PEC_{gw} of clopyralid following application to oil seed rape, winter (FOCUS MACRO 5.5.4)

Crop (use)	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)
		PUF 0
		Annual
Winter oil seed rape 1 × 120 g a.e./ha BBCH 30	Châteaudun	0.002
Winter oil seed rape 1 × 120 g a.e./ha BBCH 50	Châteaudun	<0.001

Table 8.8-12 PEC_{gw} of clopyralid following application to vegetables, bulb (FOCUS MACRO 5.5.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)
		PUF 0
		Annual
Vegetables, bulb 1 × 120 g a.e./ha BBCH 11	Châteaudun	0.009

zRMS comments:

The application pattern presented in Table 8.8-1 is in general in line with the critical Central Zone GAP. It is noted that applications to sugar beet at application rate of 100 g as/ha was considered by the Applicant, however this rate is not listed in the GAP Table 8.1-1, thus it was not further validated by the zRMS.
The selected application dates were in line with these suggested by the AppDate v. 3.06. Correct crop interception for the intended crops stages were selected for the modelling purposes.

The input parameters considered in Tier 1 groundwater modelling for clopyralid and presented in Table 8.8-3 are in line with EU agreed endpoints, presented in EFSA Journal 2018;16(7):5389 with exception of vapour pressure set to 0, which is agreed by the zRMS as representing worst case.

It is noted that in LoEP at Tier 2 the PUF value of 0.000271 calculated according to Briggs equation (Briggs *et al.*, 1982) with $\log(Kow) = -2.63$ $TSCF = 0.774 \exp - [(\log Kow - 1.78)/2.44]$ was used, but this is considered as having no impact on the results. However, the Applicant for Tier 2 modelling used refined PUF of 0.5, indicating that results of the study by Gourlay (2015) confirm that clopyralid is a systemic compound which is taken up by roots of wheat and barley. It should be, however, noted that this study was already evaluated at the EU level and several uncertainties were noted, one of which was that due to the conditions, hydroponic systems promote uptake of the substance by plants which would be lower if plants were cultivated in soil, since adsorption of the substance to soil particles would reduce its availability. Taking this into account, the PUF value should be refined based on results of experiments performed in plants cultivated in soil and not in the nutrient solutions. Detailed discussion on the study by Gourley (2015) may be found in clopyralid RAR (Vol. 3CP, B.8 of March 2018). It should be also noted that the uptake of the substance by plants would also depend on other factors, such as the size of soil particles (higher uptake would be expected in sandy soils comparing to clay soils), soil pH, temperature, humidity and the plant itself.

Taking into account all above, the PUF value of 0.5 used at Tier 2 is not applicable anymore and therefore only PUF of 0 should have been considered in performed modelling, as it is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance. Thus, results at Tier 2 modelling for clopyralid were not considered by the zRMS and only results of the Tier 1 simulations were taken into account in the overall conclusion regarding the groundwater exposure.

The performed calculations were independently validated by the zRMS in additional modelling using PELMO 5.5.3 and PEARL 4.4.4 and MACRO 5.5.4 models and input parameters indicated in Table 8.8.-3 and application dates as suggested by AppDate 3.06.

Since Poland is the only cMS indicated in the GAP table, only scenarios required in Poland were considered (i.e. Châteaudun, Hamburg and Kremsmünster). Obtained results at Tier 1 were in good agreement with these derived by the Applicant for clopyralid. Results at Tier 2 based on PUF value of 0.5 were struck through as not relevant.

No unacceptable leaching of clopyralid in scenarios relevant in Poland is expected following application of HCV07 to:

- sugar beet at the biennial application rate of 120 g/ha at BBCH 12-39
- sugar beet at the biennial application rate of 2 x 60 g/ha at BBCH 12-15
- sugar beet at the biennial application rate of 2x 60 g/ha at BBCH 15-31
- oil seed rape, winter at the annual application rate of 120g/ha at the BBCH 30-50,
- onions at the biennial application rate of 120g/ha at the BBCH 11-16

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

8.9.1 Justification for new endpoints

EU agreed endpoints were used for the PEC_{sw} and PEC_{sed} calculations of clopyralid (EFSA, 2018¹).

8.9.2 Active substance and the formulation (KCP 9.2.5)

The following PEC_{sw} and PEC_{sed} modelling for clopyralid is provided in support of this assessment. For details please refer to Anagu and González Camarero, 2021 (Appendix 1). Only results most relevant to the current assessment are presented here.

Table 8.9-1: Input parameters related to application for PEC_{sw/sed} calculations

Crop	Sugar beets		Oil seed rape, winter	Vegetables, bulb
Application rate (g a.e./ha)	120	60	120	120
Number of applications (-) / interval (d)	1 / -	2 / 7	1 / -	1 / -
BBCH growth stage	12 – 39	12 – 15 ^b	30 – 50	11 – 16
Application window	BBCH 12 (Appdate) + 30 days ^a	BBCH 12 (Appdate) + 30 days ^a BBCH 12 (Appdate) + 37 days ^a	BBCH 30 (Appdate) + 30 days ^a	BBCH 11 (Appdate) + 30 days ^a
PHI (d)	42		-	42
Application period / region (relevant for STEP 1 and 2 only)	Northern Europe / Mar – May / Jun – Sep Southern Europe / Mar – May / Jun – Sep		Northern Europe / Oct – Feb / Mar – May / Jun – Sep Southern Europe / Oct – Feb / Mar – May / Jun – Sep	Northern Europe / Mar – May / Jun – Sep Southern Europe / Mar – May / Jun – Sep
Interception class (relevant for STEP 2)	Minimal crop cover		Average crop cover	Minimal crop cover
Application method	Ground spray			
CAM (Chemical application method)	2			1
Soil depth (cm)	4			4
Models used for calculation	STEPS 1-2 in FOCUS 3.2 FOCUS SPIN 2.2 FOCUS SWASH 5.3 (FOCUS PRZM 4.3.1, FOCUS MACRO 5.5.4, FOCUS TOXSWA 5.5.3)			

^a as recommended in FOCUS [30 + (application number-1)*interval] days]

^b also covers BBCH 15 + 31

Table 8.9-2: FOCUS Step 3 - Scenario related input parameters for PEC_{sw/sed} calculations for the application of HCV07

Crop (use)	Scenario	Application window used in modelling	
		Single application	Multiple application
Sugar beets 1 × 120 g a.e./ha BBCH 12 – 39	D3	05-May (125) – 04-Jun (155)	-
	D4	13-May (133) – 12-Jun (163)	-
	R1	26-Apr (116) – 26-May (146)	-
	R3	31-Mar (90) – 30-Apr (120)	-
Sugar beets 2 × 60 g a.e./ha BBCH 12 – 39 (7 d interval)	D3	05-May (125) – 04-Jun (155)	05-May (125) – 11-Jun (162)
	D4	13-May (133) – 12-Jun (163)	13-May (133) – 19-Jun (170)
	R1	26-Apr (116) – 26-May (146)	26-Apr (116) – 02-Jun (153)
	R3	31-Mar (90) – 30-Apr (120)	31-Mar (90) – 07-May (127)
Oil seed rape, winter 1 × 120 g a.e./ha BBCH 30 – 50	D3	21-Feb (52) – 23-Mar (82)	-
	D4	01-Mar (60) – 31-Mar (90)	-
	D5	01-Mar (60) – 31-Mar (90)	-
	R1	15-Apr (105) – 15-May (135)	-
	R3	07-Mar (66) – 06-Apr (96)	-
Vegetables, bulb 1 × 120 g a.e./ha BBCH 11-19	D3	03-May (123) – 02-Jun (153)	-
	D4	02-May (122) – 01-Jun (152)	-
	R1	28-Apr (118) – 28-May (148)	-
	R3	09-Mar (68) – 08-Apr (98)	-
	R4	09-Mar (68) – 08-Apr (98)	-

Values in brackets specify 'Julian Day'

Table 8.9-3: Input parameters related to active substance clopyralid for PEC_{sw/sed} calculations at Steps 1, 2 and 3

Compound	Clopyralid	Value in accordance with EU end-point / Reference
Molar mass (g/mol)	191.96	Y / EFSA, 2018
Water solubility (mg/L)	1.43×10^5 (20 °C)	Y / EFSA, 2018
Saturated vapour pressure (Pa)	1.36×10^{-3} (25 °C)	Y / EFSA, 2018
Diffusion coefficient in water (m ² /d)	4.3×10^{-5}	Default
Diffusion coefficient in air (m ² /d)	0.43	Default
K _{foc} / K _{fom} (L/kg)	1.41 / 0.818 (geometric mean, n = 9)	Y / EFSA, 2018
Freundlich Exponent 1/n (-)	0.836 (arithmetic mean, n = 9)	Y / EFSA, 2018
Plant uptake factor (-)	0 (worst case assumption)	Y / EFSA, 2018
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	Default
DT _{50,soil} (d)	7.05 (geometric mean, field, normalised, n = 10)	Y / EFSA, 2018
DT _{50,water} (d)	1000 (FOCUS default)	Y / EFSA, 2018
DT _{50,sed} (d)	1000 (FOCUS default)	Y / EFSA, 2018
DT _{50,whole system} (d)	1000 (FOCUS default)	Y / EFSA, 2018

PEC_{sw/sed}

Step 1-2

Table 8.9-4: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for clopyralid following application to sugar beets, BBCH 12 – 39^a, 1 × 120 g a.e. /ha

Scenario FOCUS	Period / Waterbody	Single Application		
		Max PEC _{sw} (µg/L)	21 d - PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1				
-	-	41.0	40.7	0.578
Step 2				
Northern Europe	Mar-May	5.41	5.37	0.076
Northern Europe	Jun-Sep	5.41	5.37	0.076
Southern Europe	Mar-May	9.72	9.65	0.137
Southern Europe	Jun-Sep	7.57	7.51	0.107

^a minimal crop cover used as worst case

Table 8.9-5: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for clopyralid following application to sugar beets, BBCH 12 – 15^{a, b}, 2 × 60 g a.e. /ha, 7 d interval

Scenario FOCUS	Period / Waterbody	Single Application			Multiple Application		
		Max PEC _{sw} (µg/L)	21 d - PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)	Max PEC _{sw} (µg/L)	21 d - PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1							
-	-	20.5	20.4	0.289	41.0	40.7	0.578
Step 2							
Northern Europe	Mar-May	2.71	2.69	0.038	4.21	4.18	0.059
Northern Europe	Jun-Sep	2.71	2.69	0.038	4.21	4.18	0.059
Southern Europe	Mar-May	4.86	4.82	0.069	7.45	7.39	0.105
Southern Europe	Jun-Sep	3.78	3.76	0.053	5.83	5.78	0.082

^a minimal crop cover used as worst case

^b also covers BBCH 15 + 31

Table 8.9-6: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for clopyralid following application to oil seed rape, winter, BBCH 30 – 50, 1 × 120 g a.e. /ha

Scenario FOCUS	Period / Waterbody	Single Application		
		Max PEC _{sw} (µg/L)	21 d - PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1				
-	-	41.0	40.7	0.578
Step 2				
Northern Europe	Mar-May	2.72	2.70	0.038
Northern Europe	Jun-Sep	2.72	2.70	0.038
Northern Europe	Oct-Feb	5.14	5.10	0.072
Southern Europe	Mar-May	4.33	4.30	0.061
Southern Europe	Jun-Sep	3.52	3.50	0.050
Southern Europe	Oct-Feb	4.33	4.30	0.061

Table 8.9-7: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for clopyralid following application to vegetables, bulb, BBCH 11 – 16, 1 × 120 g a.e. /ha

Scenario FOCUS	Period / Waterbody	Single Application		
		Max PEC _{sw} (µg/L)	21 d - PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1				
-	-	41.0	40.7	0.578
Step 2				
Northern Europe	Mar-May	5.95	5.91	0.084
Northern Europe	Jun-Sep	5.95	5.91	0.084
Southern Europe	Mar-May	10.8	10.7	0.152
Southern Europe	Jun-Sep	8.37	8.31	0.118

Step 3

Table 8.9-8: FOCUS Step 3 PEC_{sw} and PEC_{sed} of clopyralid following application to sugar beets

Use	Scenario	Water body	Max. PEC _{sw} (µg/L)	Dominant entry route	21d - PEC _{sw, twa} (µg/L)	Max. PEC _{sed} (µg/kg)
Sugar beets 1 × 120 g a.e./ha BBCH 12 – 39	D3	Ditch	0.643	drift	0.050	0.060
	D4	Pond	0.045	drift	0.043	0.033
	D4	Stream	0.525	drift	0.020	0.019
	R1	Pond	0.025	drift	0.024	0.014
	R1	Stream	0.435	drift	0.011	0.024
	R3	Stream	0.614	drift	0.036	0.051
Sugar beets 1 × 60 g a.e./ha BBCH 12 – 15 ^a	D3	Ditch	0.321	drift	0.024	0.030
	D4	Pond	0.022	drift	0.021	0.017
	D4	Stream	0.262	drift	0.009	0.009
	R1	Pond	0.013	drift	0.012	0.007
	R1	Stream	0.218	drift	0.006	0.012
	R3	Stream	0.307	drift	0.018	0.026
Sugar beets 2 × 60 g a.e./ha BBCH 12 – 15 ^a 7d interval	D3	Ditch	0.284	drift	0.042	0.036
	D4	Pond	0.041	drift	0.040	0.033
	D4	Stream	0.239	drift	0.022	0.017
	R1	Pond	0.021	runoff	0.020	0.012
	R1	Stream	0.466	runoff	0.012	0.027
	R3	Stream	1.98	runoff	0.101	0.170

^a also covers 2 × 60 g.a.e./ha, BBCH 15 + 31

Table 8.9-9: FOCUS Step 3 PEC_{sw} and PEC_{sed} of clopyralid following application to oil seed rape, winter

Use	Scenario	Water body	Max. PEC _{sw} (µg/L)	Dominant entry route	21d - PEC _{sw, twa} (µg/L)	Max. PEC _{sed} (µg/kg)
Oil seed rape, winter 1 × 120 g a.e./ha BBCH 30 – 50	D3	Ditch	0.76	drift	0.032	0.049
	D4	Pond	0.028	drift	0.026	0.015
	D4	Stream	0.604	drift	0.004	0.012
	D5	Pond	0.026	drift	0.025	0.015
	D5	Stream	0.606	drift	0.001	0.008
	R1	Pond	0.037	runoff	0.034	0.021
	R1	Stream	1.76	runoff	0.047	0.103
	R3	Stream	1.13	runoff	0.039	0.071

Table 8.9-10: FOCUS Step 3 PEC_{sw} and PEC_{sed} of clopyralid following application to vegetables, bulb

Use	Scenario	Water body	Max. PEC _{sw} (µg/L)	Dominant entry route	21d - PEC _{sw, twa} (µg/L)	Max. PEC _{sed} (µg/kg)
Vegetables, bulb 1 × 120 g a.e./ha BBCH 11 – 16	D3	Ditch	0.776	drift	0.057	0.069
	D4	Pond	0.106	drainage	0.104	0.072
	D4	Stream	0.591	drift	0.064	0.038
	R1	Pond	0.03	runoff	0.028	0.016
	R1	Stream	1.22	runoff	0.03	0.072
	R3	Stream	0.704	drift	0.015	0.028
	R4	Stream	5.61	runoff	0.199	0.427

zRMS comments:

The application pattern assumed in surface water exposure assessment presented in Table 8.9-1 is in line with Central Zone GAP; the worst case use pattern with risk envelope was assessed for use in sugar beet which is agreed by the zRMS.

The crop interception for Step 1-2 is in line with FOCUS recommendations, simulations were performed for calculations for sugar beet and oil seed rape with assumption a worst case crop interception, which covers all intended uses of HCV07 and is agreed by the zRMS.

The input parameters considered by the Applicant in surface water modelling for clopyralid presented in Table 8.9-3 are in line with EU agreed endpoints reported in EFSA Journal 2018;16(7):5389.

In Step 3 simulations for clopyralid PUF value of 0 was assumed, in line with current recommendations.

The Step 1-3 surface water exposure was independently validated by the zRMS in additional simulations using the same input parameters. Results obtained by the zRMS were in good agreement with values obtained by the Applicant and results reported in Tables 8.9-4 to 8.9-10 may be used in the risk assessment.

8.9.2.1 PEC_{sw/sed} of HCV07

For foliar-applied crop protection products, spray drift is the most important route of contamination of surface waters. As formulations consist of a mixture of components, the spray drift PEC cannot be estimated by the FOCUS models, therefore it is considered using the FOCUS SWASH Drift calculator. The water body stream was corrected for additional input with a factor of 1.2.

Table 8.9-11: PEC_{sw} of HCV07 following the single application to various crops

Formulation	No. of applications	Maximum use rate (g/ha) ^a	Crop	PEC _{sw} ^b (µg/L)				
				Spray drift buffer (m)	Drift-reducing nozzles (%)			
HCV07	1	456	Onion		0	50	75	90
				FOCUS default	2.93	1.46	0.732	0.293
				5	0.794	0.397	0.199	0.079
				10	0.421	0.211	0.105	0.042
				15	0.307	0.154	0.077	0.031
				20	0.219	0.109	0.055	0.022

^a the formulation components are considered to dissipate rapidly after application, therefore only one application is taken into consideration. The PEC for the formulation was based on a specific density of 1.14 g/mL with an application of 0.4 L/ha representing the maximum application rate in the GAP.

^b PEC_{sw} values represent the maximum over ditch, pond and stream

zRMS comments:

The surface water exposure to formulation was validated by the zRMS using Spray Drift Calculator. Obtained results were in agreement with these reported in Tables 8.9-20 and may be used in the aquatic risk assessment.

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

Studies on the fate and behaviour in air with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

The fate and behaviour in air of clopyralid was evaluated during Annex I renewal (EFSA, 2018¹). No additional studies have been performed.

Table 8.10-1 Summary of atmospheric degradation and behaviour of clopyralid

Compound	Clopyralid
Direct photolysis in air	Not studied - no data requested
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air	DT ₅₀ (d): 19.5 derived by the Atkinson model using AOPWIN (v1.90)
Volatilisation	Vapour pressure (Pa): 1.36×10^{-3} at 25 °C Henry's Law Constant (Pa m ³ /mol): 3.28×10^{-10} From plant surfaces: ≤4 % after 24 hours From soil: <2 % after 24 hours

The vapour pressure at 20 °C of the active substance clopyralid is estimated to be $> 10^{-4}$ Pa (7.07×10^{-4} ; calculated with EVA 3). Hence the active substance clopyralid is regarded as semi-volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the clopyralid due to volatilisation with subsequent deposition should be considered. The low Henry's Law Constant indicates that partitioning into air is negligible. Therefore the risk of long range transport of clopyralid is acceptable.

zRMS comments:

Information regarding fate and behaviour of clopyralid in the air presented in Table 8.10-1 is in line with EU agreed data reported in EFSA Journal 2018;16(7):5389.

Due to the vapour pressure above trigger of 10^{-5} Pa, clopyralid may be considered as slightly volatile. The volatilisation from soil and plant surfaces was investigated in the course of the renewal process and indicated low volatilisation potential of this compound (<2% and <4% from soil and plant surfaces, respectively). Taking this into account, the contamination of the atmosphere from the intended uses of HCV07 is considered to be negligible.

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 9.1.3 KCP 9.2.4 KCP 9.2.5	Anagu, I. & González Camarero, P	2021	Predicted environmental concentrations of clopyralid in soil, groundwater, surface water and sediment following application to various crops – a modelling assessment for Europe Dr Knoell consult Report No. 109738-1 non GLP Unpublished	N	CAS

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
There were no studies submitted by the Applicant and not relied on					

List of data relied on 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	Vertebrate study Y/N	Owner
There were no studies relied on and not submitted by the Applicant.					

Appendix 2 Detailed evaluation of the new Annex II studies

No studies provided.

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

A 3.1 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

Initial PEC_{soil} values

The initial PEC_{soil} of the active substance is calculated according to Equation 1:

$$\text{Equation 1} \quad PEC_{soil,ini,1} = \frac{(A_1 - (A_1 \times p_1)) \times 10}{d \times bd}$$

where

PEC _{soil,ini,1}	= initial concentration in soil after single application (mg/kg)
A	= application rate of the active substance (g/ha)
p ₁	= fraction intercepted by the crop canopy (-)
d	= mixing depth, i.e. 5 (cm)
bd	= soil bulk density, i.e. 1.5 (g/cm ³)

The initial PEC_{soil} of the active substance after n applications is calculated according to Equation 2 considering degradation between the applications:

$$\text{Equation 2} \quad PEC_{soil,ini,n} = PEC_{soil,ini,n-1} \times e^{-k \times (t_n - t_{n-1})} + \frac{(A_n - (A_n \times p_n)) \times 10}{d \times bd}$$

The maximum PEC_{soil} of the metabolite is calculated with the same equation but considering a pseudo-application rate, taking into account the molar mass difference between parent and metabolite and the maximum occurrence of the metabolite in soil.

The actual and time-weighted average concentrations of the compounds are calculated according to Equation 3 and Equation 4, respectively:

$$\text{Equation 3} \quad PEC_{soil,act,t} = PEC_{soil,ini,n} \times e^{-k \times t}$$

where

PEC _{soil,act,t}	= actual PEC _{soil} at time t after initial/maximum PEC _{soil} (mg/kg)
PEC _{soil,ini,n}	= initial/maximum PEC _{soil} after n applications (mg/kg)
k	= first order degradation/dissipation rate constant in soil (ln(2)/DT ₅₀) (1/d)
t	= time after initial/maximum PEC _{soil} (d)

$$\text{Equation 4} \quad PEC_{soil,twa,t} = \frac{PEC_{soil,ini,n} \times (1 - e^{-k \times t})}{k \times t}$$

where

PEC _{soil,twa,t}	= time-weighted average PEC _{soil} over t days (mg/kg)
PEC _{soil,ini,n}	= initial/maximum PEC _{soil} after n applications (mg/kg)
k	= first order degradation/dissipation rate constant in soil (ln(2)/DT ₅₀) (1/d)
t	= time after initial/maximum PEC _{soil} (d)

Plateau Concentration

In addition to the seasonal PEC_{soil} calculations, the potential accumulation in soil following repeated annual

applications of the formulation was calculated. The accumulation potential can be described with the $PEC_{accumulation}$, which is the sum of the $PEC_{soil,ini,n}$ and the plateau concentration directly before the application in the next season ($PEC_{soil\ plateau}$). The calculation of $PEC_{soil\ plateau}$ and $PEC_{accumulation}$ is described in Equation 5 and Equation 6.

Equation 5
$$PEC_{soil\ plateau} = \frac{PEC_{soil,ini,d}}{(1 - e^{-k \times 365})} \times e^{-k \times (365 - (n_a - 1) \times i_a)}$$

where

$PEC_{soil\ plateau}$ = plateau concentration directly before the application in the next season (mg/kg)
 $PEC_{soil,ini,d}$ = $PEC_{soil,ini}$ on last application day with soil parameters for accumulation (i.e. 20 cm/5 cm soil depth; ploughing considered/not considered between seasons) (mg/kg)
 k = degradation rate (1/d)
 n_a = number of applications (-)
 i_a = interval between applications (d)

Equation 6
$$PEC_{accumulation} = PEC_{soil\ plateau} + PEC_{soil,ini,n}$$

where

$PEC_{accumulation}$ = accumulation PEC_{soil} (mg/kg)
 $PEC_{soil,ini,n}$ = initial PEC_{soil} in one season considering a soil depth of 5 cm (mg/kg)
 $PEC_{soil\ plateau}$ = plateau PEC_{soil} (concentration directly before the first application in the next season) considering a soil depth of 20 cm/5 cm (ploughing considered/not considered between seasons) (mg/kg)

Appendix 4 Justification for Plant Uptake Factor (PUF) refinement

Comments of zRMS:	<p>The information below were used by the Applicant to confirm that clopyralid is taken up by the plant roots and translocated to the upper parts of the plant.</p> <p>However as discussed above in the commenting box under the point 8.8 the performed experiments to refine PUF value are highly uncertain and may lead to overestimation of PUF and in consequence - underestimation of the groundwater exposure.</p> <p>Thus, information below is struck through as being not validated by the zRMS.</p>
-------------------	---

~~Translocation in plants was demonstrated in a dedicated PUF study (Gourlay, 2015³), and underpinned by comparing the PUF study to the 30 days plant back interval confined rotational study by Hall (2015⁴)~~

~~The dedicated PUF study by Gourlay (2015) is fully in agreement with the study test design that has been developed by German UBA and the German industry association IVA since October 2018. The study design has been shared for commenting with other Member States by UBA.~~

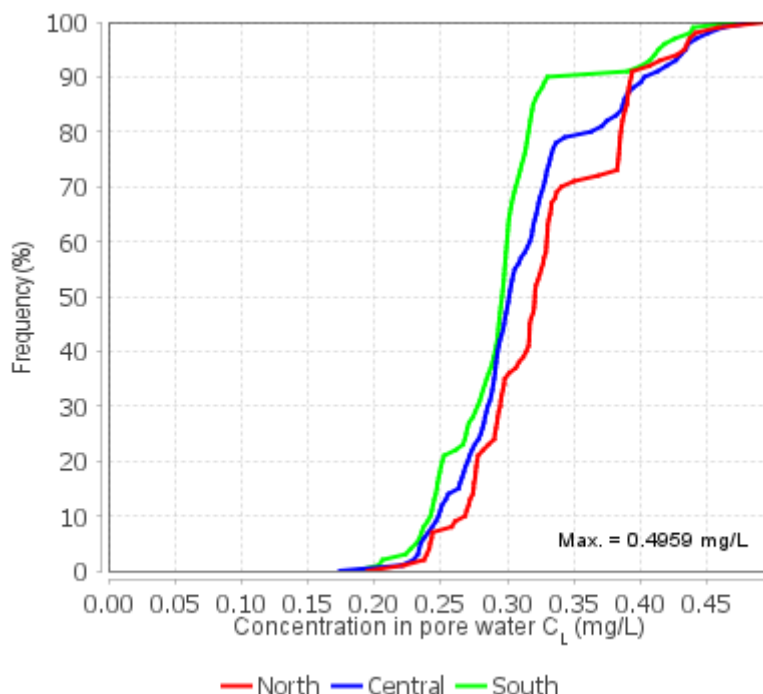
~~The applicant proposes that Tier 2 calculations with a $PUF = 0.5$ should be considered as a refinement. The dedicated PUF study Gourlay (2015) is compared to the 30 days plant back interval confined rotational crop study by Hall (2015) which was run with soil. The applicant also wants to draw the attention to previous EFSA conclusion on Succeeding and Rotational Crops (**EFSA Scientific Report, 2005 (50), Conclusion on the peer review of clopyralid**):~~

~~*“Furthermore, metabolism studies indicated that clopyralid is systemically taken into plants and readily translocated in plants. Soil – plant transition factors to estimate the residue situation in rotational crops have been calculated by RMS and presented in the evaluation meeting. The values indicate that there might be good uptake from soil or even accumulation in the plants, and soil residues above 0.001 mg/kg might be present at the time of harvesting rotational crops.”*~~

~~The primary intention for conducting the study Gourlay (2015) was not to derive a measured PUF value for use in modelling but to demonstrate under controlled conditions that clopyralid will be taken up by roots and transported to the shoots. The observed PUF values were higher than the default $PUF = 0.5$ for root systemic substances. The experimentally derived PUF value should represent the potential of a crop to take up a substance. Actual uptake is downregulated in the simulation models. In the groundwater simulation models plant uptake is regulated by a) availability of substance in the pore water, and b) transpiration. This is similar to $DegT_{50}$, which enters the models determined at (or normalized to) 20°C. Actual degradation rates are adjusted for actual temperature conditions (ignoring soil moisture for the sake of simplicity).~~

~~With regards to a potential overestimation of substance availability in hydroponic systems the applicant would like to add that clopyralid test solution concentration had been selected to mirror what could be expected in soil pore water in the field. The magnitude of concentration had been estimated with EFSA model PERSAM whose mathematical equations are described in the EFSA Scientific Opinion on the assessment of exposure of organisms to substances in soil (**EFSA Journal 2012;10(2):2562**). Considering the common wheat scenario, a $DegT_{50} = 7.05$ days (geometric mean field), $K_{OC} = 1.41$ L/kg (geometric mean), and an application of 80 g clopyralid/ha (20% crop interception) the Tier 2 CDF of soil pore water concentrations across Europe can be predicted.~~

~~Below, the $PEC_{pore, water}$ shown is the 7 day TWA which is considered as more relevant to a study with an exposure duration of similar length. Furthermore, a 20 cm soil depth is considered because the root system will be found predominantly in this layer.~~



Predicted 7 day pore water concentrations of clopyralid over 20 cm following an application of 80 g clopyralid/ha at BBCH 20-29 to cereals yields a range from 150 to 500 $\mu\text{g/L}$. The average clopyralid test solution concentration was 70 $\mu\text{g/L}$ in Gourlay (2015). The reason for selecting a lower concentration than predicted was that pre-tests on plant tolerance had shown that higher concentrations would impair plant health in the test system.

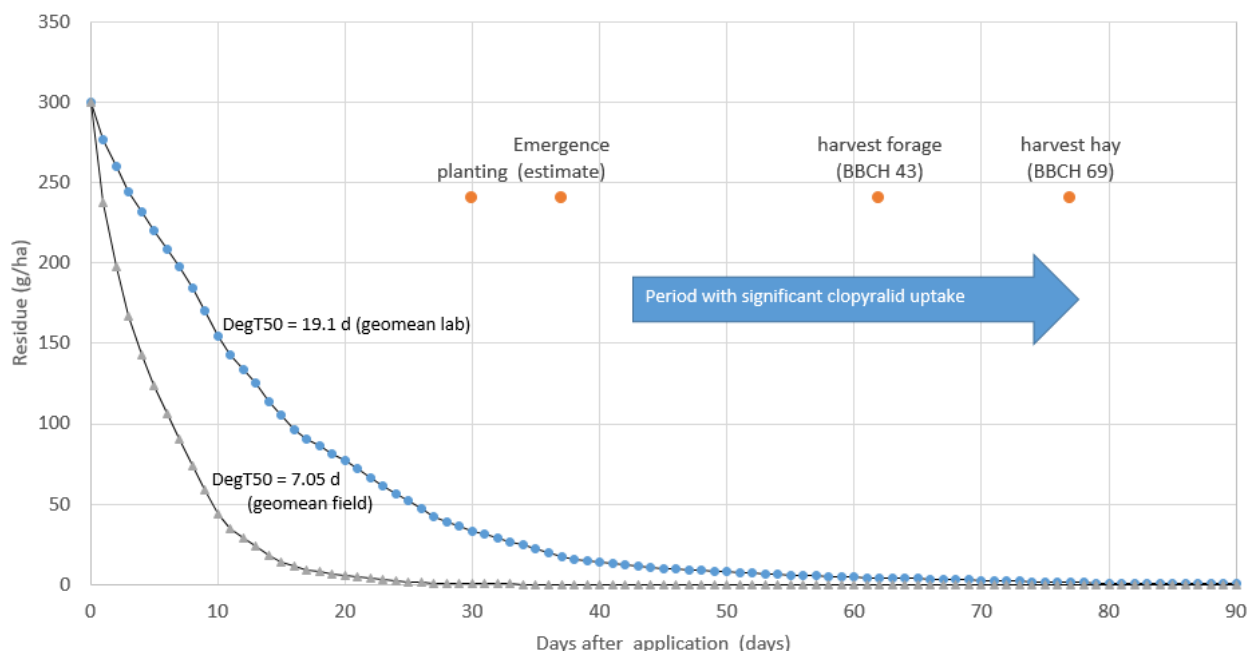
Additionally, the applicant would like to point to study Hall (2015), a 30-day plant back interval confined rotational study. One of the primary objectives was to provide an estimate of the total radioactive residues in three rotational crops (wheat, cabbage and radish) following an application of 300 g clopyralid/ha to bare soil 30 days prior to planting. Crops were grown in test plots containing a Missouri sandy loam. Wheat samples were harvested 62 days after treatment (DAT) at BBCH 43, as well as later. The first sampling is closest to the growth stage considered in Gourlay (2015), e.g. BBCH 21-31 at application of test item.

At 62 DAT clopyralid residue in wheat shoots amounted to 0.367 mg/kg. At 78 DAT to 0.729 mg/kg. These values are about one magnitude of order lower than observed by Gourlay (2015):

Replicate	Clopyralid in stem & leaves observed by Gourlay (2015) (mg/kg)
a	8.19
b	7.84
c	6.75
d	6.96
Average	7.43

Dry-matter content of clopyralid had not been reported in the study report but is recorded in the raw data.

The lower contents found by Hall (2015) may be explained by a lower exposure to clopyralid in soil. While soil concentrations had not been measured directly, an estimate can be provided. Below clopyralid residue decline is modelled with the geometric mean laboratory DegT_{50} (19.1 d) and the geometric mean field DegT_{50} (7.05 d). Considering both DegT_{50} values should show the range of soil residue that could be expected. The decline has been adjusted for observed daily soil temperature, which was always well above 20°C. Furthermore, the plots had been irrigated often. Soil moisture should not have affected degradation greatly.



No date is given for emergence of wheat in the trial. However, given the fairly high temperatures one week after planting can be assumed. With regards to clopyralid uptake it can be assumed that seedlings will not take up significant amounts since their canopy is still too small for higher transpiration rates.

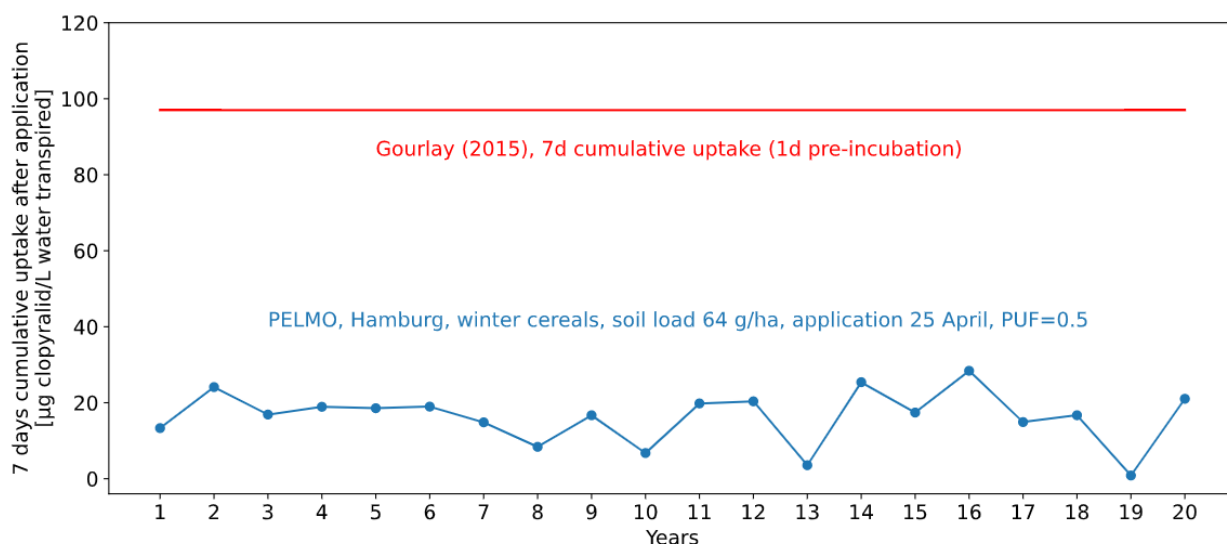
Taking this crop development into account it can be excluded that plants took up significant amounts of clopyralid before 44 DAT. Looking at the modelled residue decline curves 44 DAT corresponds to 0 to 10 g/ha clopyralid residue, depending on the DegT₅₀. This is a very low level and may explain why wheat dry matter residue contents of clopyralid were lower than in Gourlay (2015). Especially when considering that real uptake would not have taken place before BBCH 20, which would correspond to even lower soil residue contents.

Finally, the uptake observed by Gourlay (2015) is put into context with FOCUS PELMO modelling. A comparison is made between the uptake observed and the uptake modelled by FOCUS PELMO for a soil load of 64 g/ha in the Hamburg winter cereals scenario with an application date of 25 April and a refined PUF of 0.5.

FOCUS models do not simulate crop biomass. Therefore, a comparison is made by normalizing substance uptake by water transpired, e.g. for the 7-day period after application the uptake of clopyralid is divided by water transpired in the same period.

FOCUS PELMO output file PLOT.PLM reports variables TETD (water transpired; cm/d) and TUPF (substance taken up by crop; kg/ha.d). For each application year these two variables had been extracted for the 7-day period after application.

Below substance taken up in the 7 days after application is shown for each application year. For comparison the red line shows the uptake in winter wheat observed by Gourlay (2015).



Gourlay (2015) observed a normalized uptake of $97 \mu\text{g/L}$ ⁶ which is well above the amounts simulated by FOCUS PELMO (range 1 to $28 \mu\text{g/L}$). As alluded to above the hydroponic laboratory study can be considered as a best case similar to DegT_{50} soil degradation studies. Actual uptake is scaled down by environmental conditions in the modelling scenarios. Therefore, even with a consideration of a $\text{PUF} = 0.5$ the risk assessment is still conservative.

⁶Calculated from data presented in Table A 11 in Gourlay (2015): cumulative uptake with 1-d pre-incubation (mass uptake $26.33 \mu\text{g}$, water uptake 271.8 mL)